



Cryoport, Inc.

Second Quarter 2017 Earnings Conference Call

August 08, 2017

C O R P O R A T E P A R T I C I P A N T S

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Brian Marckx, *Zacks Investment Research*

Sean Hannan, *Needham & Co.*

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P R E S E N T A T I O N

Operator:

Good afternoon, ladies and gentlemen. Welcome to the CryoPort Second Quarter Earnings Conference Call. Today's conference is being recorded and will be available on the Company's website.

Now, I will turn the conference over to Mr. Todd Fromer, Managing Partner of KCSA. Thank you. You may begin.

Todd Fromer:

Thank you, Operator. Good afternoon, everyone, and thank you for joining us today for CryoPort's second quarter ended June 30, 2017 earnings conference call. For those of you that have dialed in by phone, there is a webcast slide to accompany these comments which can be found on the events page of the Investor Relations section of the Company's website at cryoport.com.

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

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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 W. Shelton:

Thank you, Todd. Good afternoon, ladies and gentlemen. Thank you for joining us today. With me this afternoon is our Chief Commercial Officer, Dr. Mark Sawicki, who, later during this call, will provide you with an update on the progress we're experiencing across all of our markets, and Robert Stefanovich, our Chief Financial Officer, who will go into the details of our financial results for the second quarter.

As reported this afternoon, our results for this quarter continued to demonstrate strong top line performance with revenue growth up 52% year-over-year as we once again provided consistent growth across all three of our markets in the life sciences: biopharma, reproductive medicine and animal health. Our strongest performance was in the biopharma market which now accounts for 76% of our total revenue and is our largest growth market. For that reason, the focus on this call will be on some of the top profile and recent developments in the biopharma market which we expect will have a significant and positive impact on Cryoport's revenue, operations and profitability. Biopharma revenues is up 69% year-over-year and 10% sequentially as we continue to make steady progress expanding our client roster with the addition of 19 new biopharma clients for the second quarter. We are now supporting 172 clinical trials in this space.

For several years, we have witnessed increasing levels of activity in the clinical trials of regenerative therapies in the United States. According to the research published in May of this year, the global regenerative medicine market was valued at \$18.9 billion in 2016 and is expected to grow to over \$54 billion by 2021 representing a compound annual growth rate of 23% during that timeframe. We identified this trend several years ago when it was still in its infancy and we were diligent to establish Cryoport as the gold standard temperature control logistics provider serving the emerging regenerative medicine market by providing the most dependable, most advanced temperature control logistics solutions in the world.

We have done this by our ever continuing development and implementation of advanced technologies and by implementing an aggressive marketing and sales strategy focused on securing comprehensive speciality logistic support agreements for clinical trials with an emphasis on regenerative medicines.

This strategy is working and continues to pave the way for our provision and agile development of comprehensive temperature control logistic solutions, increasing revenue streams, incredible positioning for contracts supporting the commercialization of therapies as they apply for and are granted FDA approval. These successful acquisitions of our strategic to-date has Cryoport to be the preferred provider to support clinical trials of the leading players in the developing regenerative medicines including

Novartis, bluebird bio, Juno, Bellicum, Celgene, (inaudible), Johson, Kite Pharma and many others. This is an impressive feat for an emerging company such as Cryoport and we are proud of the foundation we have built for the Company, which as we see it has put us on the cusp of significantly accelerating revenue growth over the next several years.

Strengthened by our progress, we remain committed to adding services for existing client relationships and establishing new service agreements with new clients supported by our growing reputation for advanced technology, services and solutions. The regenerative medicine market is based on the concept that a patient's all immune cells or anti-bodies can be genetically engineered to fight disease. It can be used to address a wide variety or a wide array of health issues and is revolutionizing treatment options for cancer, congenital diseases and traumas. The field of Immuno-Oncology attracted billions of dollars in regenerative medicine investment and there are now approximately 300 CAR-T clinical trials running throughout the world. For many companies engaged in the development of regenerative medicines depending of the science, the specific science, cryogenic logistics is an essential element in the design and implementation of the clinical trials, and even more so when it comes to the delivery of the commercial product and the surety of delivering efficacy.

We are increasingly seeing biopharma companies in the regenerative medicine space recognize the need for expert temperature control and cold-chain logistics management solutions and Cryoport is of course at the forefront of this process. While the success of a treatment cannot be guaranteed when in clinical trial phases by working with many of the leading players we believe the Cryoport is expertly positioned to leverage this industries growth and continue to build a sustainable business generating steady cash flow as the industry evolves and more and more treatments are developed and commercialized.

Two thousand seventeen appears to be the year for the introduction of the first CAR-T therapies as Novartis and Kite Pharma are the news of the day. Last month Novartis announced that the FDA oncologic drugs advisory committee unanimously recommended approval of its CTL019 investigational CAR-T therapy for the treatment of relapse or refractory paediatric and young adult patients with B-cell acute lymphoblastic leukaemia, sometimes known as ALL, A-L-L. A final decision is expected later this year. A small part of what was submitted to the committee last November was that the Company's results from a Phase 2 trial in B-cell acute lymphoblastic leukemia demonstrated that 83% of patients achieve complete remission or complete remission with incomplete blood count recovery in three months. Also overall survival of the patients was 89% at six months; very, very impressive.

I hope many of you have seen from our recent announcements that Novartis has chosen Cryoport, its industry leading advance technology suite of cryogenic logistic solutions support its future commercial launch of CTL019. Our role is to support Novartis by providing cryogenic logistics including distribution and real time monitoring to ensure the environments in which our logistic services are provided are satisfactory to support the delivery of the efficacy of these therapies and if those logistics environments are not compromised during transportation. The quality of our solutions which include engineered proactive reliable monitoring and communications to safeguard potential temperate excursions that could affect the efficacy of a therapy is unmatched in the market.

At Cryoport, our message is science, logistics, certainty, and we're proud that Novartis is a trusted partner for this important and crucial task. Our contract to support this single Novartis commercialized therapy has the potential to generate \$8 million to \$10 million of revenue per year through Cryoport once it is fully launched and reaches its potential. Novartis CTL019 therapy has the potential to be one of the great successes of regenerative medicine and we're honoured to be playing one of the critical supporting roles of ensuring patient access.

Of course winning the support agreement for Novartis as a lead therapy is a true validation of Cryoport's value to the life sciences market. By market cap, Novartis is one of the largest healthcare companies in

the world. Our relationships, the demonstration at Cryoport is truly the gold standard for temperature controlled logistics in the biopharma industry.

Just days later after the Novartis filing, Kite Pharma completed its VLA submission to the FDA for approval of its CAR-T Axi-Cel previously known as ZUMA-1. It also applied for priority review the same status the FDA awarded to Novartis CTL019, the FDA set an action date of November 29, 2017. Kite Pharma also submitted a marketing authorization application to the European medicines agency for Axi-Cel, as a treatment for patients with relapsed refractory diffused large B-cell lymphoma. This application represents the first CAR-T cell therapy submitted to the European medicines agency. Yesterday, Kite announced that it had initiated a clinical program at the European Union with its first patient now be treated with Axi-Cel. Cryoport is managing the cold-chain logistics for this clinical program and we expect patient enrolment to ramp throughout 2017. Kite has a market cap of \$6.4 billion and is a very hot profile Company in the regenerative medicine space. In fact, Cryoport currently supports the entire Kite pipeline of clinical stage therapies and we're excited to see them approaching commercialization with the first of their therapies in the very near term.

According to the alliance for regenerative medicine, we can expect three more BLAs to be filed during 2017. As more and more immunotherapy products move through trials and approach commercialisation, we intend to be in full support of each of them with our advanced technologies, agile deployment capabilities, know-how and standard setting solutions. As I mentioned earlier, we currently support 172 clinical trials having added 33 new clinical trial programs during the second quarter of 2017. My comments on Novartis and Kite are an excellent example of how our clinical trial agreements with biopharma companies can drive substantial revenue growth for Cryoport's therapies developed and move through clinical trial phases and approach commercialisation.

Now, Dr. Mark Sawicki, our Chief Commercial Officer will recap our progress in animal health and reproductive medicine, both of which continued to perform well and provide steady cash flow to our Company. In addition, he will augment by comments regarding biopharma and provide further details on the trends in our biopharma market. As a reminder, please hold your questions for Mark until the question-and-answer period. Mark, the floor is yours.

Mark W. Sawicki:

Thank you, Jerry. It's pleasure to speak with all of you today. Jerry has highlighted our biopharma market so I will begin with my comments on animal health and reproductive medicine followed by an overview of the biopharmaceutical market, specifically within the regenerative therapy space. Jerry has provided some details surrounding the business impact of recent client announcements and how they fit into our strategy as we engage the market and drive revenue in the current fiscal year which I will augment.

First, I will briefly recap our progress in the animal health and reproductive medicine markets, both of which continue to perform well. In the animal health space, we support two key healthcare needs. One is logistic support of key vaccines and reproductive materials for food stock, and the other is logistics support for stem cell and clinical trial materials for companion animal treatments. Animal Health revenues were up approximately 15% year-over-year largely driven by our long term agreement with (inaudible) with whom we have been working with for over four years, in addition to a number of recently added clinical trials in the animal health space. The animal health market is a solid market for Cryoport and we are pleased to see it continue to perform well and generate steady returns from our client base.

Our solutions in this area are considered the best in the industry and we are confident we will continue to make inroads in this market. With a number of clinical trials in this space accelerating, we anticipate additional demand in the coming quarters. Reproductive Medicine revenue also increased approximately

15% for the second quarter compared to the same quarter last year. We continue to feel the adverse impacts of increased restrictions on reproductive tourism on international revenue but this was more than offset by the growing domestic market which saw revenues rising an impressive 57%.

To maximize this opportunity in the domestic market, we have both deployed additional shippers and have optimized our go to market strategy for our solutions. We are pleased with our performance in the reproductive medicine market as it becomes increasingly clear that there is a long term sustainable demand for these solutions. We are making investments in our reproductive business to ensure we maintain our competitive edge with the highest quality products on the market. Additionally we believe our new Cryo store (phon) offering will enhance our domestic growth in the coming quarters.

Now for our third market biopharma, activity in the transformative regenerative medicine market, especially gene and cell therapy has continued to be robust with a Novartis CAR-T cell therapy CTL019 being unanimously recommended for approval by the FDA Advisory Committee to treat paediatric relapsed and refractory acute lymphoblastic leukemia known as ALL. Additionally, Kite Oharma just announced that it submitted a marketing authorization application to the European Medicines Agency for Axi-Cel as a treatment for patients with relapsed and refractory diffused large B-cell lymphoma known and DLBCL transform cellular lymphoma and primary mediastinal B-cell lymphoma. As has been disclosed previously, both of these companies are active clients of Cryoport. As Jerry mentioned, we have been selected to support a commercial launch of CTL019 for Novartis which is the first commercial CAR-T cell contract to be awarded in the immunotherapy space.

For Cryoport, this is a validation of the strategy was built which has been intensely focused on the space over the last 30 months. We anticipate additional commercial agreements in the coming months as immuno-oncology programs along with others continue to mature and approach commercialization. We continue to see our technically advanced logistic solutions becoming more entrenched within our clients clinical and commercial process as the complexity of supporting these programs increases.

We also work diligently to ensure we are ready and prepared to leverage the huge emerging opportunity that is presenting itself within the market today. Our relationships in the life sciences continue to mature and involve ever greater number of collaborations and partnerships which has led some requirement for additional support in seizing the revenue opportunity and managing and fully developing these commercial opportunities.

With these elements in mind it has led us to the appointment of two additional business development executives with strong credentials and performance track records: Mr. Colin Coffua as Vice President of Strategic Accounts; and Mr. John Phillips as Executive Director of Consulting Services. As Vice President of Strategic Accounts, Mr. Coffua will focus on growing our revenue by winning and/or diversifying larger strategic accounts predominantly within biopharma as well as clinical research organizations. Colin is a highly qualified and accomplished sales and marketing executive who joined Cryoport Board because he sees the enormous value required for service offerings supporting the regenerative medicine space.

Additionally, Mr. Philips joined Cryoport to build and meet our growth and our temperature controlled logistics consulting services. John possesses the requisite skills required to meet the request we received for developmental and/or consulting work supporting logistics needs for forthcoming clinical and commercial launches which are becoming commonplace. We continue to grow our presence in the clinical trial space regenerative medicine. One of the results of this successful execution of our biopharma strategy continues to be the expansion of the number of clinical programs we support. That number is now up to 172 which represents a sequential increase of 21% over the last quarter and a 91% increase over the same quarter last year. These numbers closely correlate to 30% increase observed in the second quarter of our corporate index. I would like to point out that eight trials were halted or stopped

during the second quarter with the 172 clinical trials number that I stated earlier is the net increase in number.

The regenerative therapy clinical market is a dynamic space as evidenced by the overall growth in the number of clinical trials. While not all of the trials will succeed, they represent key targets for future growth. Cryoport has established a leading position in support of clinical trials and we intend to keep our dominance in this space. Our unique temperature controlled logistics competencies in the cryogenics space have also caused us to be selected to support scenario in the design, development and implementation of a tailored cryogenic cold-chain logistics solution for Sanaria malaria vaccines. Sanaria's current work in vaccine development is being supported by grants from the National Institute of Allergy and Infectious Diseases and National Institute of Health and the U.S. Department of Defense.

Cryoport's temperature control solutions will be applied to Sanaria's distribution of its vaccine to travel clinics and the U.S. military as well as assist in the implementation of Phase 3 clinical trials for the vaccine.

With that, I will now turn the call back to Jerry. Jerry?

Jerrell W. Shelton:

Thank you for a terrific report Mark. Now for a detailed financial report for the quarter I would like to call on our Chief Financial Officer, Robert Stefanovich. Again please hold your questions for Robert until the question-and-answer period. Robert the floor is yours.

Robert S. Stefanovich:

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

Net revenue for the six month period ended June 30, 2017 was \$5.6 million, an increase of 62.1% or 2.2 million as compared to \$3.5 million reported for the same period last year. 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 82.3% over the prior year to \$4.3 million for the six months ended June 30, 2017 driven by an overall increase in the number of clients utilizing the Company solutions, complement by growth and frequency from current client. We added 46 new biopharma accounts during the first six months of the year further expanding our platform for future revenue growth. Revenue in the reproductive medicine market increased by 20.5% to \$844,000 for the six month period compared to the same period of the prior year. This increase was primarily driven by revenue growth in the U.S. market of 54.2% and partially offset by a decline in international markets of 24% which continues to be impacted by the restriction of medical and reproductive tourism and changing regulations in certain countries.

Our revenue for the animal health market was \$534,000 for the six month period ended June 30, 2017 representing a 21.2% increase over the same period in the prior year reflecting the addition of a new client and growth from current client. Gross margin for the six month period was 47% or \$2.6 million compared to 39.3% or \$1.4 million for the same period last year. This is an improvement of 8 percentage points and reflect several management initiatives to drive margin growth towards our target of 60%, as we grow the business and benefit from economies of scale.

The increase in gross margin over the prior year was a result of increased business volume coupled with pricing adjustments. Operating expenses increased by \$313,000 or 5.2% to \$6.3 million for the six month

ended June 30, 2017 as compared to \$6 million for the prior year period. This increase is primarily due to an increase in the number of employees', salaries and associated employee costs and higher noncash compensation expense. Net loss attributable to common stockholders for the six month period ended June 30, 2017 was \$3.6 million or \$0.18 per share compared to a net loss of \$6.7 million or \$0.54 per share. Adjusted EBITDA for the six months ended June 30, 2017 was a negative \$1.8 million, a reduction of 40% compared to a negative \$2.9 million for the same six months of the prior year.

Now, moving to our quarterly results, for the quarter net revenues increased by \$1 million or 52.1% to \$2.9 million for the three months ended June 30, 2017 as compared to \$1.9 million for the prior year quarter. This growth was driven by our success in the biopharma market where revenues increased by 69% over the prior year quarter to \$1.3 million to \$2.2 million. This reflects an increase of 19 new clients during the quarter as well as revenue growth within our existing client base.

Revenue in the reproductive medicine market increased by 15.2% over the prior year quarter to \$426,000 for the three months ended June 30, 2017. This increase was primarily driven by revenue growth in the U.S. market of 57% partially offset by a decrease of 33% internationally. Our revenue in the animal health increased by 14.6% to \$262,000 for the quarter compared to the same period in the prior year due to a recent client addition and growth from (inaudible). Gross margin for the three months ended June 30, 2017 was 47.8% or \$1.4 million compared to 40.8% or \$782,000 for the prior year quarter. This increase in gross margin by seven percentage points is primarily due to the economies of scale from the increase of business volume coupled with pricing adjustments.

Operating expenses increased by \$496,000 for the three months ended June 30, 2017 or 18% as compared to the prior year. General and administrative expenses increased \$356,000 or 25.2% for the quarter. This increase is primarily due to a one time employee practice settlement of \$136,000, an increase in salaries in associated employee cost of \$82,000, public Company related expenses in the amount of \$57,000 including legal fees and patent and trademark related fees of \$32,000. Sales and marketing expenses increased by \$41,000 or 3.4% for the quarter. This increase is primarily due to recruiting fees and related costs of \$85,000 incurred to expand our sales force and increase in stock based compensation expense of \$22,000, and an increase in marketing trade show expense of \$10,000. These increases were partially offset by a reduction in our outsourced marketing consulting of \$117,000 as a result of bringing this function in-house.

Research and Development expenses increased \$94,000 or 69.9% for the quarter as compared to the prior year second quarter. This increase was primarily due to \$50,000 in compensation recruiting and associated employee costs including the addition of a software development product manager, \$53,000 in testing and validation expenses related to various components of our solutions and new product development and an increase in facility related expenses of \$21,000. These increases were partially offset by a reduction of \$36,000 and web portal development expenses. We continually strive to improve and expand the features of our Cryoport express solutions. Our developments are directed to facilitating safe, reliable and efficient logistics of life science commodities through innovative and technology based solutions. These developments are also expected to further strengthen our position as the gold standard in the industry.

We reported no interest expense for the quarter ended June 30, 2017 compared to interest expense in the prior year quarter of \$21,000 as a result of paying off all outstanding promissory notes in April of this year. Net loss attributed to common stockholders for the three months ended June 30, 2017 was \$1.9 million or \$0.08 per share compared to \$3.9 million or \$0.28 per share for the last fiscal year quarter. Adjusted EBITDA for the second quarter ended June 30, 2017 was a negative \$884,000, a reduction of 22% compared to a negative of \$1.1 million for the same three month period in the prior year.

The Company reported \$12.9 million in cash and cash equivalents as of June 30, 2017 compared to \$4.5 million for the fiscal year ended December 31, 2016. The increase in cash is a result of the underwritten public offering of net proceeds of \$11.4 million earlier this year. Noteworthy also is that we are now debt free having repaid the remaining related party notes payable in April of this year. Subsequent to quarter end in July 2017, we received proceeds of \$1.8 million from the exercise of \$3 warrants that were originally issued in connection with the tender offer in 2016.

Lastly, we will file our Form 10-Q with the SEC for the three months and six month period ended June 30, 2017 tomorrow Wednesday August 09.

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

Jerrell W. Shelton:

Thank you, Robert. Now I would like to turn the call back to the Operator for your questions. Operator?

Operator:

Thank you. Ladies and gentlemen, we will now 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 that your line is in the question queue. You may press star two if you need to remove your question.

For participants using speaker equipment, it might be necessary to pick up your handset prior to pressing the star keys. One moment while we poll for questions.

Your first question comes from Jason Seidl with Cowen. Please proceed. Your line is live.

Jason Seidl:

Thank you, Operator. Hey, gentlemen. Good afternoon here. A couple of quick questions, the Novartis announcement to me was not only important it's just a revenue opportunity but they are such a very respected name in the pharmaceutical industry, it would seem to me that this could help you market your services even more to the rest of the industry. Is that the way we should look at it like this is going to—not that you guys weren't one of the premier providers before, but this really puts you square on the map in front of everybody.

Jerrell W. Shelton:

I think that it does more than put us on the map in front of it. We are a transformative—we are supporting a transformation in the pharmaceutical industry. We are a transformative Company supporting a transformation in the biopharmaceuticals. This is quite challenging, and to have met all of the standards and to be where we are as I said in my comments is a true validation of what we're doing as Novartis has rigorous standards that we have to meet and have gone through for the commercialization of their therapy. It's much more from my point of view than a revenue opportunity. So it certainly puts us square on the map, I mean we're transformative Company and we are unique in the sense that there is no other Company in the world that provides a specialty logistic services that we provide, so we have validated this in a number of ways. Mark you may have some other comments to add to that?

Mark W. Sawicki:

Yes, Jerry, thank you. One of the biggest benefits to us of a Company such as the stature of Novartis approving us for a commercial launch, it ties into the regulatory side of things. Obviously a big challenge of becoming a commercial partner for a product such as this is going through the rigors of the auditing process itself, and now that we've successfully done this with the Novartis and honestly with a few dozen other entities, that in itself conveys a very important message in particular when you're an emerging Company. So, from that perspective absolutely.

Jason Seidl:

Okay. Great. Let me talk about your other two business lines which each grew about 15%, how should we think about the growth in those areas going forward? Granted, it might not be the transformational nature as the CAR-T cell therapy, but clearly they're providing you with some cash flow.

Jerrell W. Shelton:

Let me start and then Mark will have his point of view to add, but in animal health there are substantial opportunities and as matter of fact there are substantial opportunities and reproductive medicine of a different nature and our strategies would be very different in those two markets, but that hasn't been the priority. You know, those have not been, those markets are important markets to us. We are growing in those markets but they haven't been the primary priority for growing the Company. The growth is in—our target has been and as Mark suggested in his comments at clinical trials for the past 30 months or so, and that's starting to come to fruition. We put more and more power into the Company by winning those clinical trials. But, in animal health we definitely have a lot of upside potential, a lot of upside opportunity in supporting reproduction and supporting vaccine. In IBF (phon) it's more a geographic thing, a geographic expansion and we'll get to that at some point but it's a fragmented market. We are the dominant player in the United States and we're certainly one of the dominant players in the world, and there is room for growth in that market. Mark would you like to add to that?

Mark W. Sawicki:

Yes, I think the only thing I'd add at this point on the animal health space is we're starting to see an acceleration of true clinical development in the stem cell side of companion animals. In fact we're supporting a number of programs from, albeit they're not a traditional wonderful trial by the FDA standards, they are still a clinical program that will lead to a commercial product, and we expect to see additional programs of that nature over the next few quarters.

Jason Seidl:

Okay. Fantastic. Gentleman, thank you for your time.

Jerrell W. Shelton:

Thank you, Jason.

Mark W. Sawicki:

Thank you, Jason.

Operator:

Our next question comes from Paul Knight with Janney Montgomery Scott.

Paul Knight:

Hi, guys. Congratulations on the quarter.

Jerrell W. Shelton:

Thank you, Paul.

Paul Knight:

It was 122 active clinical trials at the end of the quarter and what, that's plus 42 on the gross ads, plus 33% on the net and then what, 19 new biopharma customers, are those the right data points?

Mark W. Sawicki:

No, it's actually, it was 139 clinical programs last quarter, which went up to 172 programs net which does not include the eight programs that were terminated during the quarter with 19 new clients, that's correct.

Paul Knight:

Okay, and then the make-up of that, you are seeing what? That's obviously 91% growth in trials, can you talk about those trial specifically? Are they earlier staged now? Is it a lot of growth in what area, CAR-T, immune-oncology? Could you talk about the make-up of these new wins?

Mark W. Sawicki:

Yes, I can give you a little bit of guidance around that. If you look at the breakdown of clinical programs themselves at this point, of those 172 programs, 82 are Phase 1 programs, 73 are Phase 2 programs and 17 are Phase 3 programs. Approximately—and I don't have the updated numbers, approximately 60% are immuno-oncology products and the remainder are a smattering of different other indications from cardio to ocular to C&S and others. Does that answer your question?

Paul Knight:

Yes it does. Are you—I guess if you could talk to the regenerative medicine is it—you see it accelerate—I think it's more specifically CAR-T, it seems a little slower, what are you seeing there?

Jerrell W. Shelton:

You know, if you look at the alliance regenerative medicine you know they're seeing continued growth in this space. In fact, they are now saying there's approximately 900 programs underway from a clinical perspective in the second quarter of this year. So, they're similar to the growth that we're seeing, they're seeing the same thing from their own internal data. I don't believe that anything is slowing down. We're still seeing considerable investment in this space.

The other thing Paul is this is a transformative industry. I think that, you know, regulatory and especially are being conservative as they look at what's happening here, it's in looking at the data, so it is data driven and you do have to have an update and sometimes you can't forecast that specifically right on the point of when you're going to have all the data that you need for advancing. I agree with Mark, I don't see a slowdown at all; I see it progressing pretty much is as we have seen for the past couple of three years.

Paul Knight:

Okay.

Mark W. Sawicki:

Yes, and most of that growth is expansion of existing clients' portfolios, so they are diversifying and an expanding their clinical portfolio. That's where we see the majority of those increases came from existing relationships.

Paul Knight:

Okay. Thank you.

Operator:

Our next question comes from Brian Marckx with Zacks Investment Research.

Brian Marckx:

Hi, guys. Great quarter. Congratulations. Jerry, you mentioned that \$8 million to \$10 million, the revenue opportunity with CTL019, and I think the language you used was when it's fully launched and when it reaches its potential, correct me if I'm wrong please, but if you can just help us with I guess exactly what that means when it's fully launched?

Jerrell W. Shelton:

Well, these new therapies because they are—I'm sorry to use the word again, because they are transformational have a pretty exacting ramp up, and so Novartis has reported for example that they will open with I think it's 30 centers and they will have one of their representatives at each one of those points of care for overseeing the inoculation of the patients initially. That's just exercising care and medicine and so forth.

Our best guess right now and it's strictly guess so I can't do any better than that this point because again this is data driven, it's results driven and so forth, but the best guess is it takes about 18 months to get that therapy up and running based on the information that we've seen from Novartis. So, it's a ramp up, you don't just open the gate and let the therapies all out at one time.

Brian Marckx:

Right, yes. Absolutely understood. Assuming it does get FDA approval and let's just assume it's late Q3 early Q4, would you expect to see meaningful revenue and of course understood that it has a lot to do with the way the rollout looks like, I assume anyway, but with what you're modeling internally, would you expect to see meaningful revenue from that agreement in 2017?

Jerrell W. Shelton:

What do you consider meaningful revenue, Brian?

Brian Marckx:

Let's call it 10%.

Mark W. Sawicki:

Really, we don't give guidance at this point in time, you know, especially when it comes to the commercial relationships with Novartis and (inaudible) clients. You really have to look at what they give in terms of their own guidance and then translate that into what it means for Cryoport. We want to be very cautious in terms of what kinds of give on revenues related to those commercial drug roll outs.

Jerrell W. Shelton:

I want to add, I mean, you know obviously we have models that are built based on Novartis projections, but those are projections that we can't disclose. They would have to disclose those projections themselves in regards to enrollments you know additional filings and expansion into other therapeutic areas for their core product.

Mark W. Sawicki:

Brian, lot of things that we have said are you know Novartis has given a lot of information out so one could go to their site and see that data and interpret for themselves, and maybe you'll get to number, maybe not, we can't give the guidance but I was just curious what your view was.

Brian Marckx:

Okay. Yes, I appreciate that. How about in terms of margins? Would there be any expectation that margins would differ in any way lower or higher or be relatively in-line with what we've seen currently or recently mid to high-40s with this Novartis agreement?

Jerrell W. Shelton:

If you look at margin growth, we talked a little bit about that in our last earnings call, 2016 we ended with 40% for the year. We have since increased for the first half of 47% and for this quarter 48%. Our target blended margin is 60% gross margin, so we're working towards that target and that's done with a couple of things. One is in terms of our overall pricing and value based pricing of our solutions. The second part is the efficiencies with scale. As the volume increases you'll see efficiencies of scale and improvement with margin as well towards that target of 60%. When it comes specifically to the clients that we're working with that are getting ready to commercially launch, as you may expect there is greater revenue potential there because really the breadth of our support and our solutions that we're providing to those clients for the commercial launches is more significant. Certainly that will impact our margins as well.

Brian Marckx:

Impact your margins in a positive way I assume?

Jerrell W. Shelton:

Yes. That's in the positive way, yes.

Brian Marckx:

Okay, if we can just talk about Kite a little bit, and with the understanding that I know there's a probably only so much that you can talk about, but relative to the Novartis agreement, is the Kite agreement similar in potential revenue opportunity to Cryoport given that their initially indication is relatively close in size of patient population to Novartis'.

Robert S. Stefanovich:

Let me answer that Brian, so we haven't made any formal announcement yet around the Kite commercial agreement, but I can't comment on their commercial strategy and how it relates to our revenue at this point in time, but if we base it similar to what we see from the clinical side, we would expect an opportunity in-line with the Novartis relationship, possibly even a little bit higher potential.

Brian Marckx:

Okay. Then if we talk about Novartis, I guess it's probably a better example because they've got a few things in the hopper as well and they hope to expand the label pretty rapidly. So, if we talk about \$8 million a year as an example, if they expand the label, is that proportional to the revenue opportunity to Cryoport?

Jerrell W. Shelton:

Well obviously any increase in overall patient population that we support would relate to an increase in revenue, but it's not a direct linear relationship based on the fact there's other complexities within our contractual commitments that tie into non-shipment related revenue tied into program management and other facility related elements.

Brian Marckx:

Okay. All right. Great. Thanks guys.

Jerrell W. Shelton:

Thank you, Brian.

Operator:

Once again ladies and gentlemen, star, one on your telephone keypad to ask a question. Our next question comes from Sean Hannan with Needham & Co. Please proceed with your question.

Sean Hannan:

Thanks. Good evening. Also nice job on the results folks. It seems that you're executing actually fairly well toward where some of these (inaudible) trajectories have been coming out at, so nice job on that front. I want to follow up first on a question that was a little bit earlier actually, a few of them and some earlier comments. First, the 900 programs that were cited from the—in terms of regenerative therapies, is that for the overall categorization or was that specifically with an oncology focus because I thought it was a broader set?

Jerrell W. Shelton:

It is a broader set. It's the entire market.

Sean Hannan:

Okay, all right. Great. Then in terms of the commentary, I think it was Jerry that may have provided this a little bit earlier, in terms of the 18 month runway, what is your start time effectively for that? Is that as of

day one let's say when we get that official FDA approval, what's the thought process in terms of that starting line?

Jerrell W. Shelton:

Those are yet to be determined, that's—the start line is not a hard thing. It's not—that's yet to be determined Sean, so the only way I can't tell you.

Sean Hannan:

Right. Okay, well I guess I'm just trying to frame the context that it probably—I'm assuming it probably doesn't mean that we're looking 18 months out now. Now, realizing that the FDA approval could be close, you have announced your official partnership with them is (inaudible) therapy but that start time or start line really is not effective yet, correct?

Mark W. Sawicki:

Sean, the 18 month timeframe that Jerry is talking about is the entire process. That process starts well before any commercial contract announcement. So no, I mean in essence it doesn't mean that you're not going to see a ramp for 18 months after an FDA approval, it means that the entire pipeline process from early commercial discussion through execution and then revenue ramp is approximately 18 months.

Sean Hannan:

Okay, so in theory...

Mark W. Sawicki:

I mean, we've been working with Novartis on their commercial strategy a lot longer than July 24 or whatever it was that we made that announcement.

Sean Hannan:

Yes. Okay, so then in theory that start line has already begun?

Mark W. Sawicki:

Yes.

Sean Hannan:

Okay. All right, that's really helpful. Okay, and then as you think about the level of activity that may then start to occur as they commercialize, you know, granted if they get approval from the FDA, what are some updated thoughts you might be able to provide for us in terms of how you execute, how well-positioned are you to support that right now, the nature and level of incremental investment that you might have to make as you prepare for that and move forward here through the end of '17?

Jerrell W. Shelton:

Do you want to take that Mark?

Mark W. Sawicki:

Yes, I'm happy to. We're prepared today to support a commercial launch and the real question is a short term launch strategy versus a long term absorption and support strategy. Most of the intermediate and longer term strategic goals tie around long term management of a commercial product, not around strategies to be able to support that product from a commercial launch standpoint. We're ready for that— if it came out tomorrow we'd be ready to support it tomorrow. Does that answer your question?

Sean Hannan:

Absolutely. That's fantastic, and then as an add-on to that, I'm sure that in the background there probably would be other conversations that you'd have with Novartis today or perhaps even some of your other clients such as Kite, in terms of exploring perhaps some other services that would attract only a little bit more of where your core competencies are and support of their overall efforts. Is that type of dialogue taking place? Should we think about some level of service expansion that could be born out of this effort over the next couple of months or quarters that might be worthwhile to consider here?

Jerrell W. Shelton:

Sean, we definitely would not want to be talking about anything specific in that arena, but you know, as I mentioned you know earlier, we are a transformative Company and we're growing in our services. I mean, Mark talked about you know two editions to our staff in the strategic area and also in the consulting area, but that's not the only places that we're growing in our Company. Logistics is a very broad spectrum, it's everything from the point—from our point of view it's everything from the point of let's say in an (inaudible) therapy, it's everything from the draw of the asperses all the way through into the inoculations. So, it's a lot of different areas and we're growing in all of those areas. Can we grow with our existing clients? That's the intention. A big part of this growth will take place with existing clients and then additional growth will take place with new clients, but to be more specific than that I think is not in our best interest to just start getting into the area of guidance and forecasting which we don't do. Does it makes sense?

Sean Hannan:

Yes, absolutely. Well, to be blunt, it sounds like there is probably some conversation of how do enhance this relationship and what more can we do? But then, you need to be sensitive around what you would say for that?

Jerrell W. Shelton:

Yes, always those conversations Sean, always.

Sean Hannan:

Sure. Okay, and then last one here in terms of operational efficiencies, any investments within the process that you folks are making—I believe if I remember correctly, there are some aspects of the overall process within your facility out there in California that might be a little bit more manual than you would prefer, how are some of the upgrades to that effort or in taking in some equipment, getting that installed and up and running, what is the progress there and any color around that would be very helpful.

Jerrell W. Shelton:

Yes, I can give you a lot of color around that Sean. First of all there, is nothing mangled in our operation nothing. That's a not a good word for describing any...

Sean Hannan:

(Inaudible) was manual.

Jerrell W. Shelton:

I'm sorry.

Sean Hannan:

The word was manual.

Jerrell W. Shelton:

Mangled is what you said?

Sean Hannan:

Manual.

Jerrell W. Shelton:

Okay, so I misunderstand the word, I thought it was mangled. So, in terms of efficiency, business is always working on two levels; one for efficiency and one for effectiveness, and the first thing we must do we must think about is effectiveness. We definitely have to think about efficiency, but effectiveness is the foremost thing in our mind. The second thing is to make processes more efficient and to earn more money, and so we work with those two variables all the time in our Company, and in terms of new process in the Company, or new procedures, or new equipment, we're working on that constantly. What you saw in our logistic center just last year is nothing like what you see in our logistic center today, and it was that way 24 months ago to last 12 months ago and it will continue to be that way because we are building an incredibly interesting and rich company. Yes, we are addressing those things but the most important thing to us, the number one thing is to make sure that we are effective in what we do and that we deliver on what we promise to our clients; after that we work on efficiency.

Sean Hannan:

Okay. Thanks very much. I appreciate Jerry and sorry that that came through mangled.

Jerrell W. Shelton:

Glad you didn't say that. Thank you very much Sean. Thank you.

Operator:

Our next question comes from Len Yaffe with Stockdoc Partners.

Len Yaffe:

Thank you so much. I had one financial and two business questions. The financial question for Rob, I noticed impressively that your incremental gross margin in the second quarter, so if you look at the extra \$600,000 in gross profit dollars on the extra \$1 million in revenues came out to 61%, and I know your

target gross margin as you get larger is 60%, I was just wondering if that could be a conservative number which is fine or if it could be higher than that ultimately that you could achieve as you get to a much larger revenue scale given that you effectively had that for incremental margin this quarter?

Robert S. Stefanovich:

That was a very good question, Len. Our modeling is based on that target of and I would say it's a blended marginal of 60%. As we are opening to different other offerings within our overall solution, you'll get additional margin contribution. There's certainly upside potential for us as a Company and we stayed with our target of 60% but you're very right, this may be a conservative number, but that's what we're working towards at this point in time.

Len Yaffe:

Great. Then on the business side, on the clinical trials, the 172 versus 139 last quarter, I noticed that you increased in Phase 2 by 15 from 73 to 58 and what I'm wondering is to what extent does that represent roughly if you know new clients coming in already in Phase 2 using your service versus what I would hope for would be some clients from the prior quarters having a Phase 1 project advancing into Phase 2 which show that there was some good progress and then you're adding more clients more at the Phase 1 level.

Mark W. Sawicki:

Yes, Len I don't have the numbers in front of me to be frank to look at the exact contribution, but suffice to say it's a combination. We do see progression of programs that are moving from Phase 1 to Phase 2 in our existing client base and we're also winning new clients. Like I said, I apologize for not having the exact ratios in front of me, but suffice to say it is both.

Len Yaffe:

Great. Then last question is Kite on their conference call stated that, you know, and you alluded to it in your remarks that they had on—market application for three indications, the primary one being deal DLBCL in the European Union, and what they said on their conference call today was that they would be, I believe initially collecting the samples in Amsterdam sending them to the U.S. in a Cryopreservation state for manufacturer and growth and all, and then having to send them back to the EU. So, I was just wondering if you have logistics capability over in the EU where the relationship becomes more formalized that you'd be able to support while they're still doing it in the EU to the U.S. until they set up something in the EU for manufacturing that you could support the Cryopreservation both incoming and on the return side which would be obviously 2x the amount of shippers that would be required.

Jerrell W. Shelton:

Len, let me give you a really direct answer before Mark speaks. I'm speaking to you from Amsterdam.

Len Yaffe:

Well, that's an odd coincidence because by golly that's where they mentioned today. So, I hope you're having a great time in a phenomenal city. I will take that as wonderful to hear.

Jerrell W. Shelton:

Yes. The short answer is yes, we're supporting their clinical programs worldwide. It's irrelevant of location.

Len Yaffe:

Great because they obviously sounded like they were gearing that up significantly. Thank you so very much.

Jerrell W. Shelton:

Thank you, Len.

Operator:

Thank you. I would now like to turn the floor back over to Jerrell Shelton for closing comments.

Jerrell W. Shelton:

Thank you all for your terrific questions. The question-and-answer period is the most fun part of giving an earnings call and we really appreciate you joining our call today, and we appreciate your interest in Cryoport immensely. As we continue to make more strategic investments in our business and grow our market share, our primary goal and our foremost priority is to provide superior service and that's the service and the effectiveness I was talking about earlier for all of our clients and to maximize the value for our long term shareholders. We look forward to updating you on our next quarterly call and until then we bid you all a good day. Thank you.

Operator:

Thank you. Ladies and gentlemen this concludes today's conference. You may disconnect your lines at this time. Thank you all for your participation.