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# Cryoport, Inc.

## Third Quarter 2017 Earnings Call

## November 2, 2017

## CORPORATE PARTICIPANTS

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**Jerrell Shelton,** *Chief Executive Officer*

**Mark Sawicki,** *Chief Commercial Officer*

**Robert Stefanovich,** *Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

**Matthew Frankel,** *Cowen & Company*

**Sean Hannan,** *Needham & Company*

**Paul Knight,** *Janney Montgomery*

**Leonard Yaffe,** *Stocdoc Partners*

## PRESENTATION

**Operator:**

Good afternoon, ladies and gentlemen. Welcome to the Cryoport Third 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.

**Todd Fromer:**

Thank you, Operator. Good afternoon everyone and thank you for joining us today for Cryoport's Third Quarter Ended September 30, 2017 Earnings Conference Call. For those of you that have dialed in by phone, there is a webcast with slides 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 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 and projections. These risks and uncertainties include but are not limited to those described in item 1A, Risk Factors, and elsewhere in our annual report on Form 10-K filed with the Securities and Exchange Commission, and those described from time to time in other reports which we file with the Securities and Exchange Commission.

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

**Jerrell Shelton:**

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 who, later during this call, will provide you with an update on the progress we are experiencing across our markets; and Robert Stefanovich, our Chief Financial Officer, who will explain the driving forces behind our financial results.

We are pleased with the revenue growth we achieved in the third quarter of 2017. Higher shipping volumes from clinical trials combined with new agreements across our biopharma, animal health and reproductive medicine markets, led to a 52% revenue increase for our ompany compared with the same period in the prior year.

During the quarter, we also announced that Gilead's Kite Pharma selected Cryoport to support the commercial launch of its FDA-approved CAR-T therapy Yescarta. This is the second agreement of its kind for Cryoport, following the signing of a long-term agreement with Novartis to support the commercial launch of its CAR-T therapy Kymriah, which we announced in July. Kymriah already has FDA approval to treat children and young adults with relapsed refractory acute lymphoblastic leukemia, known as ALL. Earlier this week, Novartis filed a supplemental biologics license application with the FDA for expanded use of Kymriah to treat adults with relapsed refractory diffuse large B cell lymphoma, known as DLBCL. Our current agreement with Novartis covers this expansion of services if Kymriah is approved for its second indication.

Cryoport's agreements with Kite and Novartis represent major revenue growth opportunities for the Company, and I will provide more details on these exciting developments later in this call. We see both of them as validation events supporting our biopharma strategy. But first, I'd like to give you a broader recap of events from the quarter.

Our biopharma revenue now accounts for 78% of total revenue, and it is clearly the market where we see the greatest potential. For the third quarter, biopharma revenue increased 65% year over year, driven by service agreements that provide our advanced cold chain logistic solutions to support ground-breaking clinical trials, predominantly in the regenerative medicine space.

We were also pleased to secure an additional 20 new clinical trial programs during the third quarter. This represents an increased pace for new trials won by Cryoport and brings the number of clinical trials we currently support to a record 195, up from 172 in the second quarter of this year and up from 88 in the third quarter of last year.

While we are very proud of the significant traction we have made with clinical trial clients, this activity is just the tip of the iceberg. Where it gets really exciting, and where our biopharma market revenues will

start to significantly increase, is the point at which our clients' regenerative therapies reach commercial viability. Commercial distribution of cellular therapies require a step up in the robustness of cold chain logistics management, and of course much higher shipping volumes. For Cryoport this means longer-term contracts with our clients, as well as additional services, which means significantly higher revenue potential.

Our sales and marketing strategy has therefore focused on securing clinical trial agreements in the biopharma market and scaling these agreements as our clients' therapies progress through the clinical trial phases and reach commercialization.

Looking at the current breakdown of clinical programs supported by Cryoport, we can clearly see clinical progression in our existing client base as programs progress from Phase 1 to Phase 2 to Phase 3. Of the 195 clinical programs supported by Cryoport, 20 are in Phase 3, up from 17 at the end of the second quarter this year, and 82 are in Phase 2, up from 73 in the second quarter.

Cryoport is very well positioned to accelerate its growth as the regenerative medicine market continues to develop as patients begin to realize the benefits of these marvelous cellular therapies. The early stages of this trajectory are clearly under way. To support the industry's development, we've heavily invested and continue to heavily invest in developing the most advanced cold chain technologies in the world, including our Cryoport Express Shippers, our SmartPak II condition monitoring system, and our Cryoportal management platform. The introduction of Cryoport Certified Cool and supporting technologies along with consulting to help our clients successfully embrace reliable temperature-controlled solutions to get their products to market with efficacy. Our years of work in strategic planning have uniquely prepared us to support major commercial launches like no other company on the planet.

On our last call, we disclosed that we had signed a long-term contract with Novartis to support Kymriah, a CAR-T therapy for children and young adults with B cell acute lymphoblastic leukemia that is refractory or has relapsed at least twice. At that time, this was the first and only CAR-T therapy to have been approved by the FDA. Since then, another of our clients, Gilead's Kite Pharma, has been granted FDA approval for its CAR-T therapy, Yescarta, previously known as Axi-cel, for the treatment of aggressive non-Hodgkins lymphoma. We are pleased to have these two long-term contracts in place to provide these industry leaders with comprehensive end-to-end cold chain logistic solutions to support a ramp in shipping volumes for these revolutionary CAR-T therapies as patient adoptation accelerates. When commercial sales have fully ramped up, these agreements are expected to bring in $8 million to $10 million each in annual revenue to Cryoport.

Our long-term engagement with Kite Pharma is structured to support Yescarta throughout its life cycle. Our advanced cryogenic logistic solutions are designed to meet all Gilead's expanding requirements, including the use of Cryoport Express Shipper, SmartPak II condition monitoring system, and the Cryoportal logistics management platform. We not only monitor shipments with our 24-7 logistic support, we provide an intervention capability and record vital information which always includes the chain of custody and the chain of condition.

I'd like to emphasize that working with Gilead's Kite Pharma to support its commercialization of Yescarta is a milestone for Cryoport. Not only does it present a major new revenue growth opportunity, it also adds to the confirmation of our reputation as the logistics partner of choice to the life sciences industry's efforts in the development of immunotherapies.

In addition to this commercial agreement, Cryoport provides cryogenic logistic support for 12 other clinical stage therapies being developed by Gilead's Kite Pharma.

Our growth is closely tied to and broadly reflects the growth in the regenerative medicine space. According to the Alliance for Regenerative Medicine at the end of third quarter, there were 934 clinical trials under way in cell and gene therapies and other regenerative medicine technologies across numerous indications.

We have established ourselves as the gold standard for cold chain logistics, with an impressive client roster to support this reputation. Furthermore, we are still seeing considerable industry-wide investment in the development of regenerative medicine which we expect to spur growth, and by extension Cryoport's growth as well, for many years to come.

Analysts' forecasts indicate that the global regenerative medicine market will grow to $54 billion by 2021, as research and development continues to capture the potential for regenerative therapies to treat heretofore untreatable maladies. This paradigm shift in the practice of medicine due to recent advances in cellular therapies is just at the beginning of gaining traction globally.

Cryoport is at the right place, at the right time, with significant revenue opportunities embedded in our clinical trial client base, our strong pipeline of potential new clients, and our two high-profile long-term commercial agreements to support the first two FDA-approved CAR-T therapies.

Cryoport's position as a critical solution provider supporting temperature control logistics for the biopharma sector portends a phenomenal global opportunity for our company.

Logistics encompasses an increasingly technical and broad spectrum of services. As a first in class company, operating in a revolutionary market, we are committed to ensuring that the Company remains at the forefront of innovation and retains its exceptional reputation in the life sciences sector.

This was recently demonstrated by the expansion of our solutions and the launch of our new state of the art C3 logistic solution to support high-value regenerative therapies that require temperature-controlled transportation within the 2° to 8° Celsius temperature range. Cryoport's C3 shipper offers the first 2° to 8° logistics solution designed for synergistic integration into its comprehensive Cryoportal logistics management platform. This introduction means that Cryoport can support the entire logistics continuum for regenerative medicine clinical and commercial programs.

The C3 solution, Cryoport Certified Cool, was developed in response to recurring requests from our clients who wanted to be able to leverage our trusted SmartPak II condition monitoring system and our Cryoportal logistics management platform to manage their shipments, not only for the cryogenic temperature range but also for other temperature bands. We are excited to leverage our technology platform to expand our solutions and to gain market share.

Prior to turning this call over to Dr. Mark Sawicki, I would like to briefly touch on our progress in the animal health market, where revenue increased 33% year over year. The increase was primarily driven by an international relocation of material for a new client in Europe, Boehringer Ingelheim, increased revenue from a regenerative medicine client that we onboarded in 2016, and higher volume from our largest client in this market, Zoetis.

Looking forward, there are substantial opportunities to grow our animal health revenue, coupled with the fact that we are starting to see an acceleration of clinical development in this space. We are supporting a number of programs that we think will ultimately lead to commercial products and we expect to see additional programs commence over this next year.

Strong revenue was also seen in the reproductive medicine market, where our revenue growth was driven by a strong domestic demand for assisted reproductive technologies. We are the leading provider

of cryogenic logistic solutions in the United States reproductive medicine market and we're certainly one of the leading players in the world.

Animal health and reproductive medicine sales and marketing activities emphasizing our highly effective solutions and growing reputation across the life sciences industry continue to drive new client agreements and strong revenue in both these markets.

As a result, we are confident that there is more room for Cryoport to grow market share and increase revenue from both animal health and reproductive medicine.

Now, Dr. Mark Sawicki, our Chief Commercial Officer, will 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 Sawicki:**

Thank you Jerry.

It's a pleasure to have the opportunity to speak with you today. Jerry has highlighted our three markets: biopharma, animal health, and reproductive medicine. My objective for this call is to provide you a synopsis of Cryoport's strategies and drivers within these key markets, focusing my comments primarily on the biopharmaceutical market, specifically within regenerative therapy, as well as provide more detail surrounding the business impact of recent announcements and how they fit into our strategy to engage the market and drive revenue in the current and next fiscal year.

First, I would like to provide a short overview of the animal health space. As mentioned previously, Cryoport supports two key health care needs within the space: one in the transport of key vaccines and reproductive materials for food stock, and the other in the movement of stem cell and clinical trial materials for companion animal treatments. The market is expected to grow at an anticipated 5.4% compound annual growth rate over the next seven years, driven by vaccines and companion animal therapies, both of which are core to our animal health business.

Our efforts have results in a revenue increase of 33% from the animal health market for the third quarter compared to the same quarter last year.

With the number of clinical trials in this space accelerating, we are onboarding new vaccine and clinical trial programs anticipated to start in the coming quarters, and anticipate growth to notably accelerate in 2018 within the animal health space.

Within the reproductive medicine space, Cryoport has recently launched its mycryostork.com website to support and market our CryoStork service offering in support of the increasing demand within the $2.2 billion space.

CryoStork is a unique service offering providing intended parents the most reliable solution for moving the reproductive materials by incorporating our SmartPak II condition monitoring system and the Cryoportal management platform in support of their shipments. Cryoport has observed continued growth in the domestic demands for IVF transportation as observed by an increase of 62% in the U.S. market as compared to the same quarter last year.

In the most recent quarter, just a month after unanimously approving the first CAR-T cancer therapy, Novartis's Kymriah that uses a patient's own genetically engineered immune cells, the FDA approved a second such therapy developed by Gilead's Kite Pharmas, Yescarta, developed for patients with large B

cell lymphomas, both programs which are being supported commercially by Cryoport. Then, on Tuesday of this week, Novartis further announced that it has filed a supplemental biologics license application with the FDA to expand the use of Kymriah to adult patients with relapsed refractory diffuse large B cell lymphoma, known as DLBCL, for those who do not qualify for a stem cell transplant. Cryoport's existing agreement with Novartis covers this anticipated expansion in commercial activity, and, if approved by the FDA, would represent an expansion in the current revenue opportunity for Cryoport. Novartis also plans to submit an additional application for marketing authorization for Kymriah with the European Medicine Agency in both diffuse large B cell lymphoma and pediatric acute lymphoblastic leukemia later in 2017. The company plans additional regulatory filings for Kymriah outside of the U.S. and E.U. in 2018.

This accelerated pace of FDA filings and approvals are a validation of the strategy Cryoport has been focused on in the biopharma space over the last 33 months. As previously mentioned on this call, Cryoport is now supporting 195 clinical trials, including 20 Phase 3 programs. I would like to remind everyone that these are net numbers. As programs are halted, fail, or are approved, they are removed from this count.

In accordance with the ARM forecast, which is the Alliance for Regenerative Medicine, we are anticipating at least another two to four additional BLA filings and a commercial agreement in the coming year, as these programs and others continue to mature and approach commercialization. In fact, we are currently in discussion with several companies about their commercial launch strategies.

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 launched its C3 product offering in the most recent quarter. This provides our client the opportunity to leverage our SmartPak II condition monitoring system and the Cryoportal management platform in support of their 2°C to 8°C shipping requirements. Receptivity of our C3 product has been positive, with multiple companies already adopting our newest logistic solution in support of their clinical pipelines and existing late phase partners evaluating the benefit of revalidating their current late clinical and commercial distribution strategies in adopting our C3 solution.

Finally, as mentioned previously, in addition to the regenerative therapy space, Cryoport has been successful in landing large pharma support projects supporting their global biologics manufacturing. Although the transition of these types of projects has been complex and slower than anticipated, we are approaching completion on the contractual and quality-related aspects for full onboarding to be finalized. Once fully converted, these will ramp throughout the next fiscal year. Cryoport anticipates additional program adds in this space in the coming quarters as our market awareness in this space develops.

I will now turn the call back to Jerry. Jerry?

**Jerrell Shelton:**

Thank you Mark.

Now for a detail financial report for the third quarter, I'd 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 Stefanovich:**

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

Net revenue for the nine-month period ended September 30, 2017, was $8.6 million, an increase of 58.4% or $3.2 million as compared to $5.4 million reported for the same period last year. As Jerry and Mark already mentioned, the biopharma market continues to be the leading driver behind our revenue growth.

Revenue in the biopharma market increased by 76% over the prior year to $6.6 million for the nine months ended September 30, 2017, driven by an overall increase in the number of clients utilizing our solutions, complemented by growth in frequency from our current client base. We added 68 new bio-pharma accounts during the first nine months of the year, further expanding our platform for future revenue growth.

Revenue in the reproductive medicine market increased by 17.5% to $1.3 million for the nine-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 56.9%, and partially offset by a decline in international markets of 34.6%, which continues to be impacted by the restriction of medical and reproductive tourism and change in regulations in certain countries.

Our revenue for the animal health market was $782,000 for the nine-month period ended September 30, 2017, representing a 24.6% increase over the same period in the prior year, reflecting the addition of a new client and growth from current clients.

Gross margin for the nine-month period was 49.3% or $4.3 million compared to 39.6% or $2.2 million for the same period last year. This is an improvement of 10 percentage points and reflects 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 $950,000 or 10.6% to $9.9 million for the nine-month period ended September 30, 2017, as compared to $8.9 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 non-cash compensation expense.

Net loss attributable to common stockholders for the nine-month period ended September 30, 2017, was $5.6 million or $0.25 per share compared to a net loss of $8.9 million or $0.67 per share.

Adjusted EBITDA for the nine-month period ended September 30, 2017, was a negative $2.6 million, an improvement of 37.8% compared to a negative $4.2 million for the same nine-month period of the prior year.

Now moving to our quarterly results, for the quarter net revenues increased by $1 million or 51.9% to $3 million for the three months ended September 30, as compared to $2 million for the prior year quarter. This growth was driven by our success in the biopharma market, where revenues increased by 64.7% over the prior year quarter to $2.3 million from $1.4 million. This reflects an increase of 20 new clients during the quarter as well as revenue growth within our existing client base.

Revenue in the reproductive medicine market increased by 11.9% over the prior year quarter to $409,000 for the three months ended September 30. This increase was primarily driven by revenue growth in the U.S. market of 62.1%, partially offset by a decrease of 55% internationally.

Our revenue in the animal health increased by 32.6% to $248,000 for the quarter compared to the same period in the prior year, due to recent client addition and growth from existing clients.

Gross margin for the three months ended September 30 was 53.5% or $1.6 million compared to 40.3% or $797,000 for the prior year quarter. This increase in gross margin by 13 percentage points is primarily due to the economies of scale from the increase of our business volume coupled with pricing adjustments.

Operating expenses increased by $637,000 for the three months ended September 30, 2017, or 21.5% as compared to the prior year.

General and administrative expenses increased $389,000 or 25.8% for the quarter. This increase is primarily due to an increase in salaries and associated employee costs of $151,000; an increase of $132,000 for public company-related expenses including legal fees; an increase in stock-based compensation expense of $115,000; an increase of $22,000 for insurance premiums; and implementation and related costs for our new ERP system of $16,000. These increases were partially offset by a $50,000 decrease in allocated facility costs.

Sales and marketing expenses increased by $118,000 or 9.5% for the quarter. This increase was primarily due to a $167,000 increase in salaries and associated costs including recruiting fees incurred to expand our sales force; a $31,000 increase in allocated facility costs; an increase in travel and lodging expense of $18,000; an increase in implementations cost for our new ERP system of $17,000; and an increase in stock-based compensation expense of $17,000. This increase was partially offset by a reduction in outsourced marketing consulting of $150,000 as a result of bringing this function in house.

Engineering expenses increased by $130,000 for the quarter as compared to the prior year quarter. The increase was primarily due to an increase of $97,000 in wages and associated employee costs to add the software development products manager and reflect a new position of a chief technology officer; facility expenses of $76,000; testing and validation expenses of $29,000; and an increase of $23,000 in stock-based compensation expense. These increases were partially offset by a reduction of $111,000 in web portal development expenses.

We reported no interest for the quarter ended September 30, 2017, compared to interest expense in the prior quarter of $19,000 as a result of paying off all of the outstanding promissory notes in April of this year.

Net loss attributed to common stockholders for the three months ended September 30, 2017, was $2 million or $0.08 per share compared to $2.2 million or $0.14 per share for the last fiscal year quarter.

Adjusted EBITDA for the third quarter ended September 30 was a negative $831,000, an improvement of 34% compared to a negative $1.3 million for the same three-month period in the prior year.

The Company reported $15.4 million in cash and cash equivalents as of September 30 compared to $4.5 million for the fiscal year ended December 31, 2016. The increase in cash was a result of the underwritten public offering with net proceeds of $11.4 million earlier this year, and proceeds from the exercise of warrants and stock options of $3.8 million. 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, we received an additional $980,000 in proceeds from the exercise of warrants and stock options.

We filed our Form 10-Q with the SEC for the quarter ended September 30 today. With that, I would like to turn the call back to Jerry. Jerry?

**Jerrell Shelton:**

Thank you Robert. Now I'd like to turn the call back to the Operator for your questions.

**Operator:**

Thank you. We will now begin the question and answer session. To join the question queue, you may press star then one on your telephone keypad. You will hear a tone acknowledging your request. If you are using a speaker phone, please pick up your handset before pressing any keys. To withdraw your question, please press star then two. We will pause for a moment as callers join the queue.

Our first question comes from Jason Seidl of Cowen. Please go ahead.

**Matthew Frankel:**

Hi guys, it's Matt Frankel on for Jason. How are you doing?

**Jerrell Shelton:**

Hi Matt, how are you?

**Matthew Frankel:**

Fine, thank you. Thanks for taking the questions. First thing I wanted to ask you about was potential new facilities, either here in the U.S. or in Europe. I know that was something we talked about last time. I'm just wondering if you can give an update on that.

**Jerrell Shelton:**

We have a facility planned. It's in process now for the Eastern United States. We also will be making some additions in the E.U.

**Matthew Frankel:**

Okay, and will that growth be able to support, for instance, the Novartis opportunity that you referenced earlier in the call, or is that incremental to that type of growth? If you could just speak to that.

**Jerrell Shelton:**

No, the facility in the Eastern United States will be for helping, for assisting us in carrying out our mission and our responsibilities to Novartis, and then of course we will have the—there'll be other responsibilities as we move on, in other parts of the world, and we'll support those as well. But the Eastern facility will be supporting Novartis, for sure.

**Matthew Frankel:**

Okay. There's a report out in the marketplace that we got wind of, I'm assuming you guys have as well, about a company, Biolife Sciences, and what they're doing and how they compete with you guys. To some extent the report referenced how they're doing things in a more cost-effective way for customers. I was wondering, to the extent you know about it, I was wondering if you can please address it and help us better understand what you're doing versus what they're doing.

**Jerrell Shelton:**

Sure, sure, Matt. I appreciate your asking that question.

As a former publisher, it's easy to recognize a piece of fiction. So I'm happy to provide some true context relating to the analyst report. This so-called analyst report is flawed, it's incomplete, and it demonstrates a complete lack of knowledge as to the key considerations cellular therapy clients consider when they're shipping their valuable commodities.

First, the report is focused on Dewar vacuum flask performance using static testing methodology, which is not applicable to infield testing. Remember, Cryoport uses shippers, which are much more than a Dewar vacuum flask, for transport. So while Dewar vacuum flask hold time is important, real time risk assessment of the handling of the shipper is far more important in mitigating risk. Our shippers and systems track the infield performance of all carriers as well as the status of our shippers in real time, near real time, I mean they're polled every six seconds and then we download every (inaudible).

So if the alternative Dewar to which the article refer is placed—I'm not calling it a report because it's really more like an article—refers is placed into the cargo hold of an airplane upside-down or on its side, it'll be compromised significantly. Our systems have the ability to detect such activity and Cryoport personnel, who are monitoring every shipment, have the ability if necessary to intervene to address the improper handling or condition.

Cryoport Express shippers are not off the shelf. Significant additional components and modifications to manage the in-fleet handling effectively are part of each shipper. One example of this is our SLIDERITE shipper which prevents orientation issues with our shippers.

Second, the Dewar vacuum flasks have a life. This report doesn't address that at all. Their performance changes over time due to repeated use and mechanical wear. A Dewar validated to hold for 15 days at the time of manufacture will not perform to that standard over time and repeated uses.

At Cryoport our systems re-qualify all components of our shippers, including the Dewars, after each use. The requalification process provides updated hold time performance after every use and assures its performance in the next. This process is consistently audited by our clients, quality teams, and has been found to be superior to any other process or system in the worldwide marketplace, and also provides a unique platform for partners and clients' quality systems from a regulatory perspective with the FDA as we have historical performance data on every functioning component of every one of our shippers, including the Dewars, in our fleet for every use. Our informatics platform, the Cryoportal management system, provides significant advantages in this area as well as in the in-field risk assessment required to mitigate risk throughout transport.

Third, the article touts a smaller footprint for the Savsu Dewar, as it does not use an outer enclosed package in order to save in shipping costs. All Cryoport shippers do include an outer shell for a multitude of reasons and we have significant data from more than 180,000 legs of shipments that show this is a significant and important feature.

Any Dewar subjected to drop or lateral forces of up to 50 Gs without a shock absorbency provision will sustain significant damage, potentially compromise the vacuum that maintains the hold time of that unit, and in some cases affect primary packaging of the commodity being shipped.

In addition, repeated exposure to outside contamination into a Dewar that may need to enter a regulated space is of significant concern as production of cellular therapies occurs in clean room environments. The outer packaging of units provide our clients with the cleanest, safest and most effective way to transport their therapies.

Matt, there just a few other facts regarding this fictitious article. Cryoport does not use Chart XC Dewars in its shipper fleet, and that was the subject of the article.

Secondly, the Savsu Dewar as described would not pass the following regulations: ISTA, that stands for the International Safe Transit Association; ISTA infectious substance, it would not pass ISTA 3A; and it would not pass ISTA 7E.

Thirdly, the size of the enclosure of the XC Dewar is vastly overstated, creating a false favorable skew in the shipping cost advantage of the Savsu Dewar.

Fourthly, and of course we think that outer package is important, but they overstate the size. According to our information from Chart, the XC Dewar model has a charge time of two hours, not 48 hours as stated in the article.

Fifthly, the article incites a fear factor that is false as it gives the impression that shipments on their side are the norm. This is simply not the case as it relates to Cryoport, and of course Cryoport has systems to mitigate this sort of thing if it does happen, as I stated earlier. On the other hand, from our considerable experience, if they were to ship their Dewar with the stated configuration, that is without packaging, their Dewar would be on its side 70% to 80% of its time. Consequently, their stated dynamic cold time would be much, much lower than stated.

Sixthly, on a final technical point in the article, the nitrogen evaporation rate—that is the NER—of their Dewars is horrible. Based on the information provided in the article, the Savsu Dewar burns nitrogen at an incredible rate of 0.85 kilograms per day, while Cryoport Dewars burn around 0.56 kilograms per day. It's clear from their own data that Savsu is making up for its inefficiencies by adding more LN2 to its Dewars, which can be observed in the wet waste they report.

So as I stated at the beginning of my answer, this article is fiction, and not very good fiction at that.

**Matthew Frankel:**

Appreciate that, Jerry. I appreciate the thorough response there. I mean, it sounds like an apples to oranges comparison. But appreciate all the color.

One final question and then I'll get back into the queue and give someone else some time. Just want to know if there's any way you feel comfortable quantifying the revenue potential, revenue opportunity from the BLAs you expect to be filed over the next year, the commercialization opportunity you expect over the next year. Any way to put some numbers around that, and what it means for you guys?

**Jerrell Shelton:**

Sure, I'll ask Mark Sawicki. Mark, would you like to comment on that?

**Mark Sawicki:**

Yes, I can give some color on it. You know, guys, so, as we have stated, we anticipate an additional two to four filings next year, which obviously would have a lead time in regards to commercialization, but I think, using the same measure, in particular for any of the autologous treatments as you would observe with either the Novartis or the Kite expectations which Jerry commented upon in the earnings call, its probably reasonable ramp rate and timing would be similar to any of these types of launches. But we also have a number of programs which are allogeneic in nature, and if those allogeneic therapies file and are approved, the volumes of these units will be an order of magnitude or two higher than that of a

autologous therapy. So we would anticipate seeing numbers that could easily drive into the $40 million to $60 million range at full absorption if they were approved and were approved for their broader application. So it depends on the nature of the therapy approved and the timing of it.

**Matthew Frankel:**

All right. Thank you for your time, guys.

**Mark Sawicki:**

Not a problem.

**Operator:**

The next question comes from Sean Hannan of Needham and Company. Please go ahead.

**Sean Hannan:**

Thanks folks. A number of questions here tonight. So first, wanted to see if I could just get a little bit more specificity on the impacts of the approvals here with Novartis and Kite. What's the activity look like now with them today versus a few months ago? What's being shared with you in terms of ramp-up and activity? How does this materialize timing-wise for cash outlays on your ends and investments? How that impact is for the investments and the support of the facilities, you'd referenced that a little bit earlier, and of course, how should the revenues be ramping here in the next few quarters? So, we have some key milestones that we've hit, and any more color that we can get around this and how it affects the model would be greatly appreciated.

**Jerrell Shelton:**

Sean, thank you for the question. I mean, everyone has those questions on their mind, and I appreciate your asking those questions. There is a ramp-up period, and I'm going to let Dr. Sawicki talk about that in just a moment, but there definitely is a ramp-up period and remember, these things are data-driven, number one; number two, these are revolutionary therapies, they've never been done before, so, no matter what your plan is, you know that the plan is going to have to be adjusted as it's implemented because things just simply don't go the way you expect them to go in anything, much less in revolutionary products. But to give a little more color on the ramp and what to expect, I'll turn it over to Mark.

**Mark Sawicki:**

Yes, sure, thanks Jerry. So we do get projections from our commercial clients in regards to patient enrolment, as well as manufacturing capacity. I think that our stipulated expectation of getting to that $8 million to $10 million revenue rate in three years is a reasonable expectation. They are dosing commercial patients at this point in time; I can't get more specificity beyond that, but we are aware of that. Much of the ramp is going to be dictated by their own commercial capacity to produce these therapies. We will be able to support the volumes regardless of how quickly they ramp, we are well positioned to do that, but I think we're going to hit saturation in that three-year time frame is a reasonable expectation as we have stated before. So I think that it'll be a fairly linear ramp up to that point in time, unless they bring additional manufacturing capacity on line, which may accelerate those numbers a bit.

**Jerrell Shelton:**

The other part of your question—thanks, Mark. The other part of your question, Sean, had to do with investment and support, and I'll make a couple of comments and turn it over to Robert Stefanovich to be more specific, but—or as specific as we can.

We've been building out our infrastructure to support these therapies and to support our growth. We continue to do that because this is a very exciting market that is unfolding here, and it's going to unfold—it is unfolding now and it's going to unfold even more rapidly as we move forward, so that we clearly will have to finance inventories and accounts receivable and infrastructure and so forth. We're on the pathway to doing that; as I mentioned, there are two facilities, two logistic centers, under planning right now, and we'll be implementing. But Robert, would you like to add anything to that?

**Robert Stefanovich:**

Well, maybe just briefly. We're really in the very unique position right now in a market that's really just now starting to ramp tremendously. With that, we want to make sure we leverage this opportunity that we have. Part of levering this opportunity is to make sure that we have the infrastructure to support our current commercial clients as well as those that we see in the pipeline. Certainly all of our clients that are moving from a Phase 2 to a Phase 3, or more importantly from a Phase 3 moving towards a BLA filing, are expecting us to have the right infrastructure within the U.S., as well as outside of the U.S. and Europe and some of the other countries, to support their expected growth. So those are things that we're carefully evaluating, to make sure that we have the infrastructure in place to do so.

**Sean Hannan:**

Okay. All right. So that's very helpful. Another question here in terms of looking at the number of trials you guys reported. So it's 195. I think there were the Phase 3 and 2 that were called out here. That 195, does that ultimately include the Novartis and Kite numbers, or do they move out of that aggregation? So that's actually kind of part one to the question, and I'll—once you clarify that I'll see if I can ask a little bit more.

**Jerrell Shelton:**

Sean, as the two commercial therapies move out of the trials, we are supporting other therapies that are in trials for both Novartis and Kite.

**Sean Hannan:**

Sure. Okay. So that 195, so that's trials, but in terms of total therapies really then, ultimately, that number would be like a 197. Is that accurate?

**Jerrell Shelton:**

That's right.

**Sean Hannan:**

Okay. So based on that, when I step back I look at the say typical dollar opportunities you'd have in support of different trials, or at least trial classifications, and think about where these dollars should be running on an annualized basis. Not necessarily that you'd be there today at the onset for all of them, but where they ultimately should be, what's represented. I'd suspect that this certainly should be in excess of $20 million, without necessarily any full run rate contributions from that Novartis or Kite, those approvals

there. So can you help provide some views on the logic of how you're currently set up with your revenue acceleration based on trials you already have in hand today?

**Jerrell Shelton:**

Well, I'll let Robert make a couple comments, but as you know we don't give guidance, and so I'm not going to give you guidance on revenue today. But we take a conservative approach in our revenue forecasting internally because it's important to us that we're fiscally responsible. With that, I'll let Robert make a few comments about that if he wishes. (Inaudible)

**Sean Hannan:**

Just to clarify, not asking for guidance; trying to understand the run rate representation of what you have in place, which isn't necessarily indicating that you'd have to guide toward that. So just trying to understand a profile of what we have here.

**Jerrell Shelton:**

Right.

**Robert Stefanovich:**

Yes, no, I understand. Yes, so yes, let me just add a few things. One reason why we focus on presenting the clinical trials of the phases in this market space is twofold. One, we mentioned in the past we have a very sticky solution so our client retention has been extremely high. As our clients progress from a Phase 1 to Phase 2 to a Phase 3, that revenue opportunity to us increases quite significantly. In the past we've mentioned, when the Phase 1 starts ramping, it can ramp up to $15,000 to $75,000 annualized revenues. Now a Phase 2 and a Phase 3 are significantly higher, so a Phase 2 could be between $75,000 and $150,000 and the Phase 3 could actually go up from $200,000 to $1 million. Now having said that, if you look at the totality of the clinical trials that we support, you'll obviously have ramp-ups of different trials, you have some trials that are suspended, on hold, or failed, and some trials that come in new. So you really have to look at a weighting of that revenue potential for each of those clinical trials, depending on which phase they're in. But this helps you and helps others get an indication as to what's in the pipeline, what is the revenue potential, and the other things we've talked about in the past as well is the success rate of clinical trials moving forward, ultimately culminating into a BLA filing and a commercial launch. So when you look at those two components, it allows you to also reflect the modeling and maybe come up with your own views as to what the revenue can look like over time over the next few years.

Obviously, a significant component to that are the BLA filings, are the commercial launches, especially if you look out in the next two-three years, in terms of the expectations for those commercial launches and what the ramp will be.

**Sean Hannan:**

Understood. Okay. Another question here and I'm going to hop back into the queue, so, just in terms of the opportunity for some label expansion here with Novartis, what types of dollars could we talk about around that? I'm not sure if I had caught that during the prepared remarks. Thanks so much, folks.

**Jerrell Shelton:**

Mark, you want to take that?

**Mark Sawicki:**

Yes. Happy to. I think the benefit in that for us is going to be a long term benefit. In the short term, most of the growth is going to be based on manufacturing capacity, and in the linear progression of that as companies like Novartis and Kite staff up and build out their commercial competency to manufacture these therapies at a much higher scale than they have. So that's going to be the bigger limiting factor in the short term. So I don't anticipate it having a significant upside on, I would say, the first three or four quarters; I think we'll start to see a benefit from that in the second and third fiscal year as they have—their restrictions on manufacturing capacity diminish and they can leverage the expanded label application to dose more patients that are unconstrained from that manufacturing capacity issue. So I think that's the way you should look at it at this point in time.

**Sean Hannan:**

Okay. Thanks, folks.

**Jerrell Shelton:**

Thank you.

**Operator:**

The next question comes from Paul Knight of Janney Montgomery. Please go ahead.

**Paul Knight:**

Thanks for your time this evening and congratulations on your growth rate.

**Jerrell Shelton:**

Thank you, Paul.

**Robert Stefanovich:**

Thank you.

**Paul Knight:**

The question I have is, when you look at the average dollar per clinical trial, it looks like the average revenue per trial goes down. Is this just really an indicator of a lot of Phase 1 tests and preclinical coming in the door? Then the second question is, your share relative to regenerative medicine, the Alliance for Regenerative Medicine trials seems to be very high. Is it fair to say that your share is that high, relative to your growth rate of 23 customers and their incremental increase it looks like it's about 35?

**Jerrell Shelton:**

The first part is—

**Robert Stefanovich:**

Yes, I mean I think that—

**Mark Sawicki:**

Sorry, go ahead, Robert.

**Jerrell Shelton:**

I'd like to direct the first part of that question to Robert, and the second part to Mark. So could you take the first part, Robert?

**Male Speaker:**

Robert? Did we lose you?

**Jerrell Shelton:**

Robert, are you there?

Okay. Mark?

**Mark Sawicki:**

We may have lost him, Jerry.

**Jerrell Shelton:**

Okay, Mark, go ahead and take the whole thing. Take the question.

**Mark Sawicki:**

Yes, not a problem. So, the way you can look at it is yes. We have a significant share in the regenerative therapy space. This is by design. This is an area that we very aggressively courted. Our platform is unique to this particular therapy space and conveys significant advantages in particular when they're looking at things from a regulatory filing standpoint, as alluded by some of the comments Jerry made around the means by which we manage our shipper fleet and the qualification processes and things along those lines.

One other aspect to consider here is, we have actually onboarded quite a few new programs over the last three or four months. There's a period of time in which these things take to fully ramp, so just because you see a net number of 195 doesn't mean all 195 trials are chugging along at full speed at this point in time. They will have a bigger impact as they ramp up, and we do see others that, as they transition from a Phase 2 to a Phase 3 or Phase 1 to Phase 2, there's a data reporting period in which they may stop shipping for four or five months as they evaluate their data to make a decision on moving forward from a clinical standpoint. So, just because there is 195 in process doesn't mean all 195 are actively shipping at any given time. Hopefully that gives you a little bit better picture.

**Paul Knight:**

Yes. Sure does.

**Mark Sawicki:**

Great.

**Jerrell Shelton:**

Thank you.

**Operator:**

The next question comes from Leonard Yaffe of Stocdoc Partners. Please go ahead.

**Leonard Yaffe:**

Hi. Can you hear me?

**Jerrell Shelton:**

We can, Len.

**Mark Sawicki:**

Yes we can, Len.

**Leonard Yaffe:**

Okay, great, thanks. I have two questions, one financial and one business.

On the financial side, I notice that your gross profit margin improved by about 550 basis points sequentially on about a 3% revenue increase sequentially, which seems probably to be much higher than what would have been expected a year ago. I would expect some of it is the product mix shift towards biopharms. But I was wondering if you could comment on that as well as if it gives you a greater comfort hitting that 60% gross profit at perhaps a lower revenue level.

My business question is, you were talking a little bit before about an article that was published on a competing product, and I was just wondering, unlike other cryogenic shipped products, you were talking about drug therapies that are costing $350,000 to $430,000 so far. In your discussions with the manufacturers, what have they reflected to you in terms of the importance of the company they use to the logistics, given the cost of the logistics relevant to the cost of the product, and how comfortable they would be with the person, the company that went through clinical trials with them, versus trying to save some money with another company? Thank you so very much.

**Jerrell Shelton:**

So, on the first question …

**Robert Stefanovich:**

I'm back on.

**Jerrell Shelton:**

Let's take the first one first. Mark, is—Robert, are you back?

**Robert Stefanovich:**

Yes, I'm—

**Mark Sawicki:**

Robert had some technical difficulties.

**Robert Stefanovich:**

Yes. Len, good question.

**Jerrell Shelton:**

Did you hear the question on the gross margin?

**Robert Stefanovich:**

Yes, I heard. I had jumped on at the end of Mark's comment. Yes, on the gross margin, if you go back, you can see, 2015 was a 30% and 2016 was 40% gross margin. We always emphasize that we're a very technology-centric company, leveraging software that we have and the systems that we've put in place. It's very important to understand that when you look at our gross margin. That does allow us, as we ramp our business, our transaction volume, to improve the gross margins further. We also, as we ramp now towards the support of commercial launches, we're looking at our systems continuously, trying to improve how we do things, make them more efficient and more cost-effective. So all these things are contributing to margin growth to where we are now, and looking at the current quarter that we just finished, being at 53.5% we're certainly on track to getting to our target of 60%.

The other part is, towards the end of last year, we really revisited our pricing model overall, which allowed us to get a higher revenue per client per transaction, which also further contributed to the increase in gross margin. So you're absolutely right, we have seen significant increase, at least compared to last year, and we expect that to continue. Having said that, as we build out our infrastructure, set up additional locations for logistics operation centers, obviously that will flow into our cost of sales partially as well, and so it really depends on how we ramp and in terms of sales as to how the gross margins develop, but our target continues to be 60% and certainly achievable.

**Jerrell Shelton:**

And the last part …

**Mark Sawicki:**

Let me address the second part. Yes, I'll address the second part, Len, for you. It's very very simple when you think about it from a contextual standpoint. One of the biggest telling elements to us is that, A, in a number of these commercial launches, Cryoport was written into their commercial filings from a regulatory standpoint, as well as written into any commercial offering they had for correlated services that weren't related to our services but were complementary, either before or after or in parallel, where they mandated that certain clients work with us on any given commercial launch. It all comes back to, at the end of the day, the uniqueness of our informatics platform because, in essence, what it does is it provides them for the first time in a logistics format the ability to be able to track equipment performance, very similar to how the FDA tracks equipment performance from a manufacturing, either biologics manufacture or small molecule manufacturing, competency. Every piece of equipment in those situations has to have a track

record of performance that the FDA can go back and look at, regardless of whether or not that given drug was manufactured in that piece of equipment. Similarly, we have the ability to trace that out on a logistics format so that all of our equipment they can correlate back to every given use, even if it wasn't used for distribution of that particular drug, and the FDA loves that. That's one of the biggest things here. If you think long term, equipment is one thing, but you have to think about where the regulatory bodies are going to go into the future here, and from our perspective this is going to become a mandated thing because it provides a much better level of understanding and control when you're shipping therapies that are irreplaceable.

**Leonard Yaffe:**

Thank you.

**Mark Sawicki:**

You're welcome.

**Operator:**

Our next question comes from Sean Hannan of Needham and Company. Please go ahead.

**Sean Hannan:**

Thanks for giving me an opportunity for a follow-up here. So, sorry if I had missed this. Is there a way if you folks can recite the specific third quarter numbers for each, biopharma, animal health and IVF?

**Robert Stefanovich:**

Yes, sure. You just want for the quarter?

**Sean Hannan:**

Yes. Yes.

**Robert Stefanovich:**

… or for the nine months as well? Yes so biopharma is $2.3 million, reproductive medicine is 409 and animal health is 248.

Our quarterly report with the SEC should be on the SEC website as well, which contains more detailed information.

**Sean Hannan:**

Okay, great. Then, also, coming to the opportunities in front of you for your clients in looking at another two to four BLA filings the course of the next 12 months and that there's another potential commercial agreement that could materialize here. Please be patient with the question around this. If I were to reverse course about nine months ago, and go through dialogue with you folks, I think the impression at say a few months or quarters ago was that we'd be through about probably four BLA filings by this point. So, if I aggregate the perception of the opportunities of '17 plus '18 and contrast that to what I feel we may be talking about and looking at right now, it seems like it's a little bit more tempered on that BLA filing and commercialization front, and it is not to go and throw water on what's been accomplished so far,

because what's been accomplished has been quite a bit. But just trying to better understand that tempering and what may have changed and any color you can impart around that as a reflection of where your clients stand today. Thanks.

**Jerrell Shelton:**

Mark, do you want to address that? You're closer to …

**Mark Sawicki:**

Happy to do so. Yes I mean, you're absolutely right. I mean what we do is when we put forth projections it's based on what our client base is looking at from a filing standpoint, and so if you technically look at it from the beginning of a year, there's actually two BLA filings that went commercial and we just had a third SBLA from Novartis that went through, so you have in essence three filings from a commercialization standpoint. So we're not too far off from that perspective, but there were a number of programs that we are supporting and as we talk about it's always a net number, and so some of them have been either cancelled, so we did have a Phase 3 that was planning a BLA filing, the company ran out of money and shelved their Phase 3 program. We have no control over that. So we do see things from that from time to time, but we just—we track these on a rolling basis, and we look at what these activities are, and every supplemental filing on some of these commercial launches, we're not going to—we could detail those out as separate independent events as well, but when we're talking two to four additional and we're really looking at either completely new indications or new companies from a filing standpoint. So, not sure if that answers your question or not, but that's kind of the reality of it.

**Operator:**

This concludes the question and answer session. I would like to turn the conference back over to Mr. Jerry Shelton for any closing remarks.

**Jerrell Shelton:**

Well, I think we've had a good session of questions. I really appreciate all of your questions.

We're incredibly excited about Cryoport's future, and consider us to be in a position to accelerate our 75% compounded annual growth rate due to our positioning as a vital supporting logistic service for the life sciences and all leading players in the revolutionary regenerative medicine market.

Advancement of regenerative medicine is a revolution in medicine, medical science, as it is changing the focus from treating symptoms of chronic and degenerative diseases to providing cures. It also directly addresses costs that constitute approximately 83% of the $2.5 trillion annual health care spend which is growing due to our aging population.

When we think about how to leverage this opportunity, our focus at all times is on innovation, effectiveness, and the quality of our supporting services. We believe that by developing unrivalled logistic support systems we become integrated and indispensable to our biopharma clients. So far, this strategy has been borne out by our ability to get in front of the right people and secure contracts, some of which are multibillion-dollar biopharma companies who had previously never heard of Cryoport. Now we're becoming a well known brand in the field and every day our credibility and client pipeline grows in reflection of this.

As long term shareholders, your support of Cryoport is invaluable and has helped us to get to where we are today. We thank you for taking the long view and for your ongoing support. I look forward to updating you again on our 2017 year-end call. Thank you.

**Operator:**

This concludes our conference call. You may disconnect your lines. Thank you for participating, and have a pleasant day.