CryoPort, Inc.

Third Quarter 2018 Earnings Conference Call

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PRESENTATION

Operator:

Greetings and welcome to CryoPort, Inc. Third Quarter 2018 Earnings Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

I would now like to turn the conference over to Todd Fromer, Managing Partner at KCSA Strategic Communications. Thank you. You may begin.

Todd Fromer:

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

available to our Management Team. Our Management Team believes these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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

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

Jerry 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, and our Chief Financial Officer, Mr. Robert Stefanovich. Later on this call, Dr. Sawicki will provide you with his comments on our business development activities and Mr. Stefanovich will detail our financial results for the quarter.

The third quarter was a very strong quarter for our Company as we made meaningful progress in securing new clients, forming strategic partnerships, investing in long-term growth strategy, and growing revenue. Revenue increased 76% year-over-year to $5.3 million for the quarter. This growth was driven by a record 37 new clinical trial agreements we secured during the quarter in addition to approximately $555,000 in commercial revenue as we scaled our global agreements, supporting Novartis Kymriah and Gilead's Yescarta, the first two FDA approved CAR-T cell therapies.

Our progress at CryoPort reflects broad achievements as the global regenerative medicine market continues its climb to an inflection point. In total, four Market Authorization Applications or MAAs had been filed in the European Union so far this year, and one Biologic License Application or BLA that's been filed in the United States. Moreover, 27 Regenerative Medicine Advanced Therapy designations or ARMAT designations, 17 Breakthrough designations, and 43 Fast Track designations had been granted by the FDA. As anticipated, the European Commission granted market authorization for both Gilead's Yescarta and Novartis' Kymriah approving these treatments for use in the 28 countries of the European Union, Norway, Iceland, and Lichtenstein. Moreover, Yescarta and Kymriah also received National Health Service approval for the United Kingdom.

As a reminder, CryoPort's agreements with Gilead and Novartis cover all these expansions of services. On Gilead's recent earnings call, its management team stated that it expects Yescarta to be authorized at approximately 20 E.U. sites by the end of 2018, and we're working diligently to enable and assure the delivery of this therapy to new patient populations at all these sites. Likewise, Novartis's sales strategy is also progressing and we're working closely alongside them to prepare for commercial launches in Europe and beyond.

In September, Novartis received approval by Health Canada for the treatment of relapsed, refractory, pediatric and young adult, Acute Lymphoblastic Leukemia or ALL patients, and Relapsed Refractory Adult Diffuse Large B-cell lymphoma or DLBCL patients, and announced its plans to invest in the production of cell and gene therapies at its site in Switzerland, as well as entering into a strategic collaboration with

cellular biomedicine group to manufacture and supply Kymriah in China. We view all these investments as indicative of the expected reach of Kymriah and we're committed to supporting Novartis as it manages its global commercialization process.

As we become more entrenched in the regenerative medicine market, as a core part of the manufacturing and commercialization process, the pace at which we are securing new business continues to accelerate. Over the last 12 months, we have added a net total of 100 clinical programs bringing the grand total of clinical trials supported by CryoPort to just under 300, 295 to be exact. This rapidly increasing number of clinical stage therapies and the diverse range of therapies we support, illustrates the need for the high-quality systems and solutions that only CryoPort can provide.

Our business is rapidly gaining momentum as advances in the regenerative medicine market propel these therapies toward commercialization. In fact, 38 clinical programs that we support are already in Phase 3 trials, the final phase before commercialization. Now, with the industry approaching an inflection point and as we move into year two of approval processes, we are expecting at least one BLA filing to occur before year's end, bringing the 2018 BLA/MAA total to six and we anticipate at least another six to be filed in 2019. These numbers are based on internal information and the public forecast from the Alliance for Regenerative Medicine.

To expand our reach even further within the regenerative medicine industry, we're forming strategic partnerships that will enable us to deliver our recently launched chain of compliance solution, which offers full traceability of equipment, processes, and handling of cells in gene therapies while in transit to biopharmaceutical companies globally.

Last quarter, we discussed while World Courier, which is part of AmerisourceBergen, chose to partner with Cryoport to integrate our full suite of temperature-controlled solutions into its global network, this expansion means that CryoPort's complete suite of temperature-controlled logistic solutions for life sciences industry is now offered through World Courier's global network of more than 140 Company-owned offices operating in 50 countries. This quarter, we signed a strategic partnership with Be The Match BioTherapies to deliver end-to-end supply chain services to the cell and gene therapy industry. Be The Match offers integrated systems and software to manage the collection and delivery of cellular therapies. It is leading the charge to develop a more efficient and standardized cell therapy supply chain, and with more than 30 years of experience, its expertise includes management of 22,000 cell and blood shipments annually.

Our collaboration supports efforts by both Be The Match and CryoPort to standardize critical elements of the cell therapy supply chain, as well as processes, and apheresis, and transplant center networks. By pairing CryoPort's expertise in temperature-controlled logistics with Be The Match Biotherapies' expertise in apheresis center and onboarding management, case management and logistics, clinical research, and outcomes data collection and analysis, we will offer full end-to-end supply chain and outcome support for companies developing and delivering autologous and allogeneic cell and gene therapies.

The enabling operating platform that we provide manages more cell therapy products than any other solution in the marketplace, enabling cell and gene therapy companies to more rapidly discover, develop, and deliver next generation therapies. Building out our systems, solutions, and infrastructure, whether through strategic partnerships such as those with Be The Match BioTherapies and World Courier, or investments in businesses such as our state-of-the-art global logistic centers in New Jersey and the Netherlands, ensures that we can achieve deeper integration into our clients' systems and processes, scale operations, and retain our market-leading position as the best-in-class specialty logistic solutions provider for the life sciences industry. To advance these objectives, we're also looking at diversifying our portfolio solutions through M&A activity.

For several months, we have diligently been identifying potential acquisition targets and we're currently in discussions with several companies. Any acquisition target that we pursue will have solutions and systems that deepen and/or are complementary to our existing offering for our life sciences market. While the aforementioned initiatives, among others, continue to advance our strategy in the biopharma market, we're also focused on executing on our growth strategies in both reproductive medicine and animal health. Revenue from our reproductive medicine market was strengthened 43% year-over-year driven by both domestic and international demand.

The launch of CryoStork Insurance, which is designed to better serve intended parents, as disclosed in our last earnings call, further contributed to our growth in this market. Revenue to our animal health market, representing approximately 5% of our total revenue, declined by 8% compared to the third quarter of 2017. The biopharma market continues to be our primary focus; however, we will also continue to pursue growth opportunities in both reproductive medicine and animal health.

Now, for more detailed information on our sales and marketing activity initiatives, successes, and outlook, I'll turn the call over to Dr. Mark Sawicki, our Chief Commercial Officer.

Dr. Mark Sawicki:

Thank you, Jerry. It's a pleasure to have the opportunity to speak with you today.

CryoPort operates at the cutting edge of the life sciences industry, and in many cases, facilitates future directionality of systems, processes, and regulatory requirements in supportive regenerative medicine distribution on a global scale. The regenerative medicines sector is approaching a noteworthy inflection point. Four transformative products are now on the market and accessible to greater numbers of patients every day through label expansion and additional geographic approvals. Dozens of additional therapies are in late stage studies with four Marketing Authorization Applications or MAAs having been filed in the European Union so far this year, and one Biologics License Application or BLA filed in the United States. Moreover, as Jerry mentioned earlier on the call, 27 RMAT designations, 17 breakthrough designations, and 43 Fast Track Designations have been granted. No less impressive is the financing activity in this space.

Year-to-date, the regenerative medicine industry has raised $10.3 billion in financing, with IPOs and venture capital raises this year already being much higher than previous year totals. All of this activity in the space has led to multiple notable clinical milestones in 2018, including the following: Novartis released data in June from its JULIET trial of Kymriah, which demonstrated more than one year durability of response in adults with relapsed or refractory DLBCL; Mesoblast released data on Remestemcel-L for the treatment of acute graft versus host disease showing an 87% 28-day survival rate, and a 75% overall survival rate for the often fatal condition; Bluebird Bio presented positive data from its Phase 3 trial of its LentiGlobin gene therapy for patients with transfusion-dependent beta thalassemia and non-Beta0/Beta0 genome types; Kiadis Pharma received RMAT status in the U.S. for ATIR101, and anticipates MAA approval in early 2019 for ATIR101, and adjunctive immunotherapeutic administered in combination with hematopoietic stem cell transplantation; Novartis and Gilead-Kite have received marketing approvals for their respective CAR-T products in Europe and the U.K.; and Enzyvant initiated a rolling Biologics Licensing Application or BLA for RVT-802 for the treatment of complete DiGeorge anomaly.

We are supporting a rapid development in the regenerative therapy market as discussed. We are now supporting 295 clinical trials of which 38 are in Phase 3. Our momentum has caused us to develop and open two new state-of-the-art logistics centers located in Livingston, New Jersey, and Amsterdam, Netherlands in the most recent quarter. These facilities complement our logistics centers in Irvine, California and Singapore, and provide CryoPort the ability to effectively scale in support of our existing

portfolio of clinical and commercial clients, as well as enabling our client base to have flexibility and redundancy in support of their groundbreaking, life-saving therapies.

In addition to global capacity enhancements being implemented in the most recent fiscal quarter, CryoPort continues to drive standards and support of the various standards coordinating bodies, working to define appropriate controls in regenerative therapy distribution in support of emerging standards such as ISO TC276.

The latest of these endeavors is our emerging chain of compliance initiative for regenerative medicine distribution, which is rapidly becoming the standard for ensuring product integrity. Chain of compliance provides complete traceability of the equipment, processes, and logistics handling used in managing the environmental control of the therapy while it is in transit.

Turning to animal health. We have recently on-boarded a number of new companion animal clinical trials that tend to produce lumpy revenue recognition early in their clinical development. We anticipate that these will start to ramp in the coming quarters.

Finally, within our reproductive medicine market, we experienced a 43% year-over-year increase in demand for our services. We attribute this increase to our expanded partnerships with a growing number of clinics within the United States and abroad that are now referring increasing volumes through our Cryostore service offering. In addition, the launch of our CryoStork insurance product is now being offered to intended parents as additional protection for their reproductive materials against the unlikely risk of damage and loss when being transported between fertility clinics or healthcare centers. This is a sensitive area for our clients. We are seeing increasing adoption of this service throughout our clinic network and direct client base as it is unique to the marketplace.

Thank you. I will now turn the call back over to Jerry.

Jerry Shelton:

Thank you, Mark. Now for a detailed financial report of our third quarter, I will turn the call over to our Chief Financial Officer, Mr. Robert Stefanovich. Robert, the floor is yours.

Robert Stefanovich:

Thank you, Jerry. Good afternoon everyone. I will review results for the three and nine-month periods ended September 30th, 2018, provide some additional comments, and then turn the call back to Jerry.

For the nine-month period, net revenue increased by 61% or $5.3 million to $13.9 million compared to $8.6 million for the same period in the prior year. Biopharma, our largest market, representing 83% of our total net revenue for the nine-month period, increased by 76% over the prior year from $6.6 million to $11.6 million. This was a result of the continued increase of the number of biopharmaceutical clients utilizing our services, the increase in clinical trial supported for these clients and the scaling of the commercial launches of Yescarta and Kymriah.

Our revenue from animal health decreased by 4% to $748,000 for the nine-month of 2018 compared to the same period in 2017. Revenue from our largest animal health client, Zoetis, increased by 13%. However, this increase was more than offset by the effect of a larger laboratory move that was carried out during the second and third quarter of 2017 as well as one of our animal health clients discontinuing trial activity towards the end of 2017.

Revenue in our reproductive medicine market increased by 27% over the prior-year period to $1.6 million. This increase was driven primarily by an increase in revenues in the U.S. market. The recent introduction of CryoStork Insurance, which is designed to better serve intended parents, was launched in response to the rise in demand for assisted reproductive medicine and was well received. We continue to see a growing demand for comprehensive and reliable solutions in this market and intend to build out our leadership position.

Gross margin for the nine-month period ended September 30th, 2018 was 53% or $7.4 million compared to 49% or $4.3 million for the prior-year period. This increase in gross margin by approximately four percentage points was primarily due to the economies of scale resulting from the increased business volume and pricing adjustments, combined with a reduction in freight as a percentage of revenues, which was partially offset by the running cost of our new logistics centers in Livingston, New Jersey and Amsterdam, The Netherlands that both commenced operations during the third quarter of 2018.

Operating expenses increased by $4 million for the nine-month period ended September 30th, 2018 or 40% as compared to the prior year. This increase was primarily a result of building out our organization in support of the increase in our business volume and expected growth, non-cash stock-based compensation expense and startup costs for the new logistics centers in Livingston, New Jersey and Amsterdam, Netherlands. In short, it was primarily driven by the continued buildout of our infrastructure.

We reported no interest expense for the nine months ended September 30th, 2018 compared to interest expense in the prior period of $16,000. Net loss for the nine months ended September 30th, 2018 was $7.3 million or $0.26 per share compared to a net loss of $5.6 million or $0.25 per share for the same period of 2017. The net loss for the nine-month period ended September 30th, 2018 included a one-time non-cash charge of $0.9 million as a result of the warrant tender offer completed in February of this year.

Adjusted EBITDA for the nine-month period ended September 30th, 2018 continued to improve to a negative $1.8 million compared to a negative $2.6 million for the same nine-month period in the prior year, even with the ongoing investments we are making to build out our organization, enhance our global footprint through our new logistics centers.

Now moving to our quarterly results. For the third-quarter, net revenue increased by $2.3 million or 76% to $5.3 million compared to $3 million for the prior-year third quarter. The quarterly performance was driven by our success in the biopharma market where revenue increased by 91% over the prior-year quarter from $2.3 million to $4.5 million. The increase in the number of clinical trials and ramp in revenues from the two commercial therapies we are currently supporting, were the growth drivers for this quarter and are expected to drive future revenue acceleration as clinical trials advance in a commercialized and commercial therapies ramp and are launched in new geographies or for additional indications.

Our Biopharma revenue represented 85% of revenue for the quarter. Our revenue from animal health decreased 8% to $230,000 for the quarter compared to the same period in 2017. Zoetis continues to be our largest client in this market and we are currently in the process of extending our agreement with Zoetis. Revenue in the reproductive medicine market increased by 43% over the prior-year third quarter to $584,000. This increase was due to an increase in the U.S. market of 30% and an increase in the international market of a 102% driven by the continued success of our marketing campaigns, maturing of commercial relationships with key fertility clinics, as well as expansion of our suite of logistic solutions including CryoStork.

Gross margin for the third quarter of 2018 was 52% or $2.7 million compared to 54% or $1.6 million for the prior-year quarter. Bringing our new logistic centers in Livingston, New Jersey and Amsterdam, Netherlands online impacts gross margin in the short-term, however, as business volume ramps and the

utilization of these logistics centers increases, gross margins will increase. As we have mentioned on previous calls, our target gross margin is 60%.

Operating expenses increased by $1.3 million for the three-month period ended September 30th, 2018 or 36% as compared to the prior year. This increase is primarily due as a result of building out organization in support of the expected increase in business volume, non-cash stock-based compensation expense, and start-up costs for the new logistics centers.

We continue to invest in building out our organization expertise and infrastructure to meet the growing demand of our solutions and expected ramp in business.

Net loss for the third quarter of 2018 was $2.1 million or $0.07 per share compared to a net loss of $2 million or $0.08 per share for the third quarter of 2017.

Adjusted EBITDA for the third quarter of 2018 improved to a negative $0.4 million compared to a negative $0.8 million for the prior-year third quarter.

We ended our third quarter with a strong cash position and are debt-free, reporting $23.7 million in cash, cash equivalents, and short-term investments compared to $15 million as of December 31st, 2017. Lastly, we filed our Form 10-Q for the three- and nine-month periods ended September 30th, 2018 with the SEC today.

Now, I will return the call back to Jerry. Jerry?

Jerry Shelton:

Thank you, Robert. Operator, please open the call for questions.

Operator:

Thank you. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Our first question is from Jason Toledo with Cowen and Company. Please proceed.

Adam:

Hey guys. This is Adam on for Jason. Thank you for taking my question. I guess first of all, just looking at the growing cash balance and your cash and short-term investment balance on your balance sheet, I know you guys talked a little bit about the M&A that you guys are looking at but maybe could you just touch a little bit more on that. What are you looking for in acquisition as you approach that and is this situations where you guys are approaching targets or targets are coming and approaching you about taking them over? Thanks.

Jerry Shelton:

Well, thank you for the question. It's both, targets are approaching us and we certainly are investigating and approaching targets, so it's the typical M&A, it's a mix of things. A lot of attention is being gained by the market and the activities in the market, so it's what you would expect these days. So, in terms of the kinds of acquisitions we're looking for, it's the same M&A activity that I've described before. It's filling out

our vision of our specialty logistics mandate for serving the life sciences. It's everything from the point of origin to the points of destination. So, that includes packaging information technology, logistics expertise, information, as I said earlier, information type companies, and software, and storage fulfillment. Those type of activities. Anything that's in that logistics chain is something that we're interested in.

Adam:

Got it. Thank you for that. Maybe just a second one here from me. In terms of the CryoStork Insurance product that you guys have, I guess kind of comparing that to some of your other product offerings, looks like this is more of a asset-light or financial services type of product. So I was wondering, are you guys going to look more at doing more kind of financial services types of products, or is this a one-off thing for you guys, and not something that you'll look to expand on or kind of diversify with going forward? Thanks.

Jerry Shelton:

I'm going to direct that question to Mark Sawicki, but the short answer is no, we're not looking for other financial type products. Mark will tell you more about the characteristics of that offering.

Dr. Mark Sawicki:

The short answer is I think we've talked about this before. Our focus is around risk management for our clients. Since IVF is a business to consumer product, the insurance product itself is a risk mitigation or risk management platform, our offering for them. So, it's kind of ties back to that compliance-related element that we've been talking about over the last few quarters.

Adam:

Got it. Well, that's it from me guys. Thank you so much. Appreciate it.

Jerry Shelton:

Thank you.

Dr. Mark Sawicki:

Thank you.

Operator:

Our next question is from Andrew D'Silva, with B. Riley FBR. Please proceed with your question.

Andrew D'Silva:

Hey, good afternoon. Congrats on the progress. Thanks for taking my questions. I was jumping between a couple of calls so I apologize if you already answered some of these questions. I'm just kind of a little bit curious as far as how you're viewing your position right now within the broader landscape. Are you seeing opportunities with partners when you start with one trial as they initiate a second or third clinical trial that you're getting up, put into more and more spots earlier in the process of getting a Phase 3 with somebody, and as a ramp-up of Phase 1 you're automatically implemented in there?

Jerry Shelton:

Yes, Andrew, thank you. That's a really interesting question and we're happy to address it. I'm going to address that to Mark to answer for you.

Andrew D'Silva:

Sure.

Dr. Mark Sawicki:

So our entire strategy over the last couple of years is to develop a first-mover advantage in this space, and we've really been focused on getting in early, and becoming very, very sticky with our clients. So, our entire service platform itself has been centered around customer experience, the ability to support an ever-increasing aspect of their portfolio itself, and cover all of their program. So, we have many, many relationships, where we start with one program and we're now supporting 10 to 15 programs or more. So yes, that's absolutely an objective of ours.

Andrew D'Silva:

Is there a substantial customer concentration when we start thinking about it at a Phase 3 or overall clinical trial level? I mean, I know you're working with some of the heavy hitters in this space, so I would imagine it's a little bit top heavy but just based on the sheer number, it's kind of hard to tell.

Dr. Mark Sawicki:

I think it's fairly easy to take. If you take a look at the Alliance for Regenerative Medicine quarterly reports that come out, you can extrapolate what our position is against that. We have by far the largest market share in this space throughout all the phases, and that's something that we fully intend on maintaining and expanding on.

Andrew D'Silva:

Okay. Now that you're starting to get a little bit more clarity from you're already existing commercialized partners and more BLAs are being filed, do you feel good about where you stand on that commercial $2 million to $20 million range once scale happens with these products, or do you want to expand it a little bit or narrow it? Just curious on how you view that.

Jerry Shelton:

You know Andrew, that's a good question and I think maybe both Mark and Robert have comments on that. So, let's start with Mark, and then, Robert will have some comments.

Dr. Mark Sawicki:

Obviously, being a year in from an experience base on commercial products, I think our expectations have—we maintain our confidence in that expectation. Robert, you want to add on that at all?

Robert Stefanovich:

No, I just want to support that. As you know, there's a lot of activity going on not only in the U.S. and Europe but our clients in the commercialization is also moving into Asia, China, and Japan. So as that evolves, we'll get greater clarity as to the range of business that we can get through those commercial therapies in those regions as well.

Andrew D'Silva:

Got it. Perfect. Thank you. Last question from me. One of your, I guess, quasi competitors, possible supplier announced that they had a partnership, that's one of your partner subsidiaries, and I was curious if you had any plans of moving to different temperature ranges? I believe this one was closer to dry ice versus cryogenic storage capacity levels.

Jerry Shelton:

I'll direct that to Mark.

Dr. Mark Sawicki:

So there's definitive inherent liabilities in the distribution of live cell-based products on dry ice. The particular instance that you're referring to, they had a clinical history of using this and what we're seeing in most cases is folks that have been using dry ice for distribution, they can't change that mid-phase. So, what their goal and there are many times their strategy is to launch that product using that existing package, and then, optimize and manage risk after a commercial launch occurs. So our strategy with those folks is to allow them to get on market and then transition them to a lower risk, higher quality option which is the conversion of dry ice into the liquid nitrogen format, and that's what we stick by.

Andrew D'Silva:

Okay, perfect. Thank you. I'll take everything else offline but thanks for the time. Good luck going forward.

Jerry Shelton:

Thank you.

Operator:

Our next question is from Jason Kolbert, with H.C. Wainwright. Please proceed with your question.

Dr. Ed Morrison:

Hi, guys. This is Dr. Ed Morrison (phon) for Jason. Just wondering now that you have some of the new logistic centers open and available, how much do you think they contributed to this increase in trials that you've seen this quarter, especially, since they were only recently opened?

Jerry Shelton:

The contribution was minimal because they were only recently opened.

Dr. Ed Morrison:

Okay. So do you expect significantly more pull-through into the next quarters or do you think it's going to take a couple of more years to get them fully online?

Jerry Shelton:

That we think that the locality or location is important. The logistics centers generally take about six months or so to get fully up and operational. Both these new centers are operational now and servicing our clients. So, we feel confident with those centers and with their contribution for the future.

Dr. Ed Morrison:

Okay, thanks. And just switching gears a little bit. I'm just wondering what you're projecting as the ramp for Kymriah and Yescarta especially as they get some more new approvals in a lot of different geographies?

Jerry Shelton:

Mark's very close to that so I'll let him answer that question.

Dr. Mark Sawicki:

I mean, it's very simple. We rely on our client's projections. It's not something that we can disclose realistically. It's confidential.

Dr. Ed Morrison:

Okay, thanks, guys. I appreciate the time.

Dr. Mark Sawicki:

I may just add to that, in prior calls, we've given the range of $8 million to $10 million annualized revenue once those therapies are fully commercially launched.

Dr. Ed Morrison:

Right. Thank you for that clarification.

Operator:

Our next question is from Paul Knight with Janney. Please proceed with your question.

Paul Knight:

Hi there, Jerry. Congratulations on the quarter. Are you releasing the revenue for the approved therapies or is it inferred from the discussion on number of trials?

Jerry Shelton:

Paul, let's talk about that. Say, rephrase that, would you?

Paul Knight:

Are you releasing the revenue you're getting out of the commercial customers? Then really my question is, I think we can all back out that that was in line with, at least what I was thinking. But I'm trying to really get to the point of you had 295 trials, you've averaged $14,000 to $15,000 per trial customer historically. Is that average going up for these trial customers? Then, can you talk about the ramp of your commercial side.

Jerry Shelton:

Okay. So Paul, I think I understand your question. In my comments, I mentioned that we had $555,000 of revenue recognition in this quarter from commercial products, and of course, they're on a ramp. As Mark disclosed earlier, we take the company's forecast, we don't try to modify that in any way in terms of what the future looks like. In terms of our revenue per phase of trial, it's pretty much what we've talked about before in phase one. It's 15 to—what is the range, Robert? It's 15 to—what is the range? Do you remember?

Robert Stefanovich:

Fifteen to seventy five, and then we have Phase 2 at 75 to 250, and then we have Phase 3 that can be up to $1 million, really depends on what indication it is of the number of patients involved in the trial.

Jerry Shelton:

Then of course, commercialization, our range is wide but it depends on the indication. It's $2 million to $20 million once its commercialized.

Paul Knight:

Okay. I missed that first two minutes so I missed that at 550, so that seems to be better than at least what I was expecting. Can you talk about the number of facilities globally, Jerry, that you ultimately see? Is it 15? Is it 12? Is it 20? Then could you talk about, what is the cost to develop a facility like Livingston or Amsterdam?

Jerry Shelton:

Paul, that's a difficult question for me to answer because the way we will build out our centers will be based on hotspots. We hot map all of our shipments throughout our network, and then secondarily, it'll be opportunistic based on client demand. So, it's very difficult for me to give any kind of an estimate about how many logistic centers will ultimately be in our network.

Paul Knight:

Then the cap ex, should we just refer to your cap ex on your cash flow to get a feel for that cost ramp over the last four quarters?

Jerry Shelton:

I think that's reasonable. Our logistic centers are not terribly expensive to open, and of course, we've been building inventory all along. So, I think that's a reasonable way to look at it.

Paul Knight:

Then lastly, market, this was a big number on the number of clinical trials customers. I guess there's still a lot of momentum you're seeing in the region space, or can you talk about tone of business as the quarter concluded, even though I know you don't release backlog.

Jerry Shelton:

Well, yes, and I'm going to turn that to Mark in just a moment, but I don't know whether you missed it or not. We do have 38 new clinical trials bringing us to just under 300 clinical trials supported in the regenerative medicine space. As far as tone goes, I think that speaks to it, but Mark can give you more color on that.

Dr. Mark Sawicki:

Yes. So, our trial onboards come from a couple of different sources, one is expansion of existing clients. One of the things you see in that area is, the market still has a lot of enthusiasm, in fact, increasing enthusiasm for this space. Some of these entities that we're working with have self ascribed that they may have as many as 80 to 90 clinical programs in this space within the next 24 months, and that's just one client alone. So, there's a lot of additional—you know we're very sticky, and so we're able to capture that existing share. But the nature of our platform is a very regulatory friendly platform. Our chain of compliance really ties into this traceability aspect that we've been talking a lot about, and it provides a lot of security in this space for our client base. So, we're still continuously adding new clients and new programs based on the fact that they view us as the most regulatory appropriate option in support of their portfolios.

Paul Knight:

Okay. Thank you and congratulations.

Jerry Shelton:

Thanks, Paul. Thanks very much.

Dr. Mark Sawicki:

Thanks.

Operator:

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

Richard Baldry:

Thanks. Can you talk about whether the new facilities impacted the full quarter for cost sort of a way for us to think about the gross margins in the fourth quarter, whether they'd be similar or if it wasn't in for a full quarter, maybe they'd be down a little bit?

Jerry Shelton:

Richard, Robert's going to answer that question.

Robert Stefanovich:

Yes. Hi, Richard, may I just to answer your question? So if you look at the two logistics centers we set up in Netherlands and in New Jersey, we brought them online towards the end of the third quarter. So, there were some costs directly associated to the gross margin. You'll see in our 10-Q filed with the SEC, that would provide some additional detail around the startup costs as well. So, it will have an impact temporarily as we see the logistic centers fully operational and fully covered with transactions. You'll see that gross margin is impacted somewhat for the next one or two quarters.

Richard Baldry:

Okay, and maybe we'll see this on the Q comments. But were any of those startup costs sort of one-time oriented or is it really just standard operating expenses kind of step-up on a run rate basis?

Robert Stefanovich:

Well, it's a combination of both. So you have onetime operating costs. They're actually included in the operating expenses, so below the line of gross margin, and then we have operating costs towards the end of the quarter, which are in the cost of sales that impacted gross margin once the facilities were live and operational. We still believe the target of 60% is very achievable. So, we're still moving towards that target of 60%.

Richard Baldry:

Okay. You've talked a bit more actively about acquisitions now. So, can you talk about the analysis of time-to-market maybe versus ROI on build versus buy? Maybe use a use case like storage. You could obviously buy a facility that's up and running or build one yourself. You've proven to be able to do that. So, how do you think about that? What do you think is more important, being able to go quickly into the market or sort of a longer ROI kind of focus? Thanks.

Jerry Shelton:

Rich, we're about effectiveness over efficiency. We can always work on efficiency. So, going quick into the market is not something that's in the way we're going to—we don't approach the market that way. We approach the market to be the most effective in the marketplace and to be the best service to our clients and to support regenerative therapies and the other segments of the life sciences that we serve. So, there's no bias one way or the other as to how we go into—how we expand into the marketplace. The only bias we have is to be careful, to be effective, and to make sure that we're safe, secure, and that we're certain as we say on our logo. So, that's my view about your question.

Richard Baldry:

Great, thank you.

Operator:

As a reminder, it is star, one on your telephone keypad if you would like to ask the question.

Our next question is from Sean Hannan with Needham & Company. Please proceed.

Sean Hannan:

Yes. Thanks for taking my question here tonight. I wanted to ask you about the therapies that you're supporting as you look at what's already approved in terms of out there as a commercial product. Those that are in waiting in the filing or about to be in the filing process as well as then your Phase 3's that you are supporting? Can you give us some level of indication around the degree of overlap that we might be looking at for these various biopharma companies getting at similar, same, the overlap on the indication front? Clearly, I'm thinking about competitive dynamics, there's going to be some Influences, therefore, ultimately how we would assume each and every one of these individually could contribute to you in terms of shipments. So, just trying to get a better perspective around that.

Jerry Shelton:

That's a good question and we toil with that to some degree. We're not experts in that area but Mark has some views on it that we can share.

Dr. Mark Sawicki:

Yes. So if you take a look at the portfolio overall and if you guys haven't, I would recommend that you go to the Alliance for Regenerative Medicine website, they have a clinical progression database which in essence you can look at the progression of a lot of these different programs. If you look at the next tranche of programs that are targeting commercial launch over the next 24 months, in almost every instance, these are moving beyond the hematopoietic cancer space. You have moving into things like sickle cell and skeletal-related issues and other things. So, we think that that portfolio will diversify beyond the blood cancers in the near future.

Sean Hannan:

Okay, that's very helpful. Then coming back to some of the topics that you've hit on for M&A, just wanted to see if I can hear kind of an overarching set of thoughts as you speculate how this industry evolves, the need for cryogenic storage, where ultimately that resides particularly as uptake continues around some of these therapies. How much that might be on-site, whether it be some of the leading hospitals, where else it might be and to what degree it's of interest or could be a risk that you would take on as this whole space and models evolve from here? Can you talk about that, both sides of the coin? That would be helpful. Thanks.

Jerry Shelton:

Well, that's a broad question. I thought—I tried to answer that a little bit earlier, but our interest goes in anything that's in the value chain for delivering our specialty logistic services, all of those areas that we talked about earlier, the information technology. Information is very important to us. It's an overarching theme on everything we do and it's an overarching theme in the industry at large. So, information technology is an important area. Storage is definitely an important area, as is packaging. So, all of these things are important and acquisitions of course are opportunistic. We do look at make versus buy risk factors and opportunity in evaluating anything that we do in terms of expanding and growing and supporting our business.

Sean Hannan:

Thanks so much.

Operator:

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

Jerry Shelton:

Thank you, Operator. I wasn't prepared for you exactly at that moment. So, just give me one second to get back to my desk here and give you some comments. I do want to thank everyone for joining the call today. As we close, I would like to say that we're pleased with our progress this quarter. The number of biopharma clients on our books is an all-time high and we're supporting a record 38 Phase 3 clinical trials

in the regenerative therapy space. We think we have a growing and robust client base that will continue to drive steady revenue growth not only in the near term, but for many, many years to come. Despite our strong foundation, we're always looking for ways to invest in our business, to springboard our development, and achieve even higher growth rates. We have a clear opportunity to gain market share and increase the number of clients we support as reflected by our client pipeline and our potential for continued expansion in our markets.

Furthermore, as mentioned earlier in this call, by forming partnerships and exploring potential acquisitions, we're building a strong ecosystem and maneuvering ourselves to become embedded in even more areas of the temperature-control supply chain supporting the life sciences industry. Our market opportunity grows larger everyday and our position within it becomes even stronger.

So on behalf of our entire team, we appreciate your support and participation in our endeavor to build CryoPort to its full potential. Until our next earnings call, I bid you farewell and a good evening.

Operator:

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