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Cryoport, Inc.

Second Quarter 2018 Earnings Conference Call

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CONFERENCE CALL PARTICIPANTS

Todd Fromer, *KCSA Strategic Communications.*

Paul Knight, *Janney*

Richard Baldry, *ROTH Capital*

Jason Seidl, *Cowen & Company*

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PRESENTATION

Operator:

Greetings. Welcome to the Cryoport second quarter 2018 Results Conference Call. At this time, all participants are in a listen-only mode. A brief 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. It is now my pleasure to introduce your host, Todd Fromer of KCSA Strategic Communications. Please go ahead.

Todd Fromer:

Good afternoon. 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 1-A, 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, and 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 during this call, Dr. Sawicki will provide you with his comments on our sales and marketing activities, and Mr. Stefanovich will detail our financial results for the quarter.

Our performance continues to be strong. As of the end of the second quarter of 2018, Cryoport is responsible for supporting 258 clinical trials, and the first two, FDA-approved commercial CAR-T therapies from Novartis and Gilead's Kite. The ongoing ramp of new clinical trials and reported revenue from our commercial agreements drove a 59% revenue increase in the second quarter for our Company, compared to the same period in the prior year, and a 54% increase over the first six months of 2017.

The Novartis and Gilead's commercial ramps are progressing in an increasing but measured pace. Both companies are supremely focused on certifying points-of-care centers to ensure that these novel and critical therapies are administered properly, and that all protocols and procedures are understood and adhered to. Additionally, both companies mentioned in their recent and respective second quarter earnings calls that they are expecting European approval this current quarter. We're working diligently with both of these companies as they make ready for their respective European commercial launches. I will provide more detail on our progress in the Biopharma market as well as in the reproductive medicine, and animal health markets shortly.

First, I would like to talk about some of the investments that we're making in our infrastructure to ensure that we're well positioned to scale our operations throughout the remainder of 2018 and beyond. As many of you know, the regenerative medicine market, which is a core driver of our growth and our focus, is undergoing rapid advancements as the ongoing research, development, investment, and more recently, global expansion of transformational treatments and cures gain space. This year alone, global financings and regenerative medicine totaled over $7.9 billion, up over 79% year-over-year. Cryoport’s advanced temperature-controlled logistics solutions are critical to ensure these delicate therapies maintain their efficacy and reach patient safely. By trusting Cryoport with their invaluable commodities, our clients are demonstrating an extremely high level of confidence in the effectiveness and reliability of our industry-leading logistics solutions, which as you might expect, results in high (inaudiblr) client relationships and a very high client retention rate.

As Cryoport becomes more integrated into its clients’ drug development and delivery processes, we're no longer viewed by many of our clients as simply a logistics company, but instead as an integrated piece of

the manufacturing and commercialization process, and a valued distribution partner. This influences our clients to position us in their business workflow and is creating new and different expectations for the type of partner they expect us to be.

Now, more than ever, we have a clear visibility of Cryoport's exciting near and long-term growth pathway, and it is therefore becoming increasingly important for us to invest in building out the Company's infrastructure to support the integrated role in anticipated growth. This has been a major focus for us during the first half of 2018, and I'm pleased to report that we are making significant progress in expanding and improving our competencies along our business, including our quality assurance system, sourcing, engineering, cost accounting, logistic solutions, and information technology to name a few. We're also bolstering our personnel, not just in our headquarters in Irvine, California, but also in our two newly-opened logistics centers in anticipation of a higher level of global logistics demand.

We moved quickly to open these two new state-of-the-art global logistics centers, one of which is located in Livingston, New Jersey and the other in Amsterdam, Netherlands. Both facilities are operational and supporting customers, with official opening schedule for the month of October. The processes for opening new facilities is not trivial. Besides the build-out, staffing, training, and permitting, very rigorous client certifications and audits have been passed and completed. This additional infrastructure is the beginning of further planned development that will drive our global expansion and position us to ramp our client agreements, as additional anticipated therapy approvals in the European Union and the United States take place.

It should also be noted that the demand we're experiencing from existing customers reaches beyond the United States and Europe to the Asia-Pacific region where we also are currently in various stages of planning to further expand our global footprint. We're always focusing on improving our technology and expertise at every opportunity and ensuring that Cryoport maintains its competitive edge and reputation for best-in-class service, whether that is through the quality, experience, technology, or the dedicated customer service that Cyroport delivers. Although we distinguish our services primarily, there are trade secrets and unrivalled know-how, we have four patent-pendings on new products that will be launched later this year or next.

As our credentials grow, so do our partnerships with other industry-leading companies. As an example World Courier, which is a part of AmerisourceBergen, has partnered with Cryoport to integrate our full suite of temperature control solutions into its global network. This integrated platform includes Cryoport's complete chain of compliance solutions to biopharmaceutical companies, ensuring full traceability of equipment processes and handling of cells and gene therapies while in transit.

While we've been working with World Courier for several years now, this expansion of our relationship is another indication of the need for the quality systems and solutions that only Cryoport can provide for commercialized therapies. The partnership means that Cryoport's complete suite of temperature-controlled logistics solutions will now be offered through World Courier's global network of more than 140 company-owned offices, operating across 50 countries. Partnering with World Courier will enable a greater number of pharmaceutical companies to easily access our logistic solutions plus the must-have information we provide through our advanced information technology.

Now I will go into detail about our specific achievements in the Biopharma market during the second quarter 2018 and how we are positioning for longer term growth. Biopharma revenue rose 73% year-over-year and contributed 83% of our total revenue for the second quarter, which was over $3.8 million. Revenue from our commercial agreements with Yescarta and Kymriah accounted for approximately $446,000 of this. When these products are fully rolled out and patient numbers have reach capacity, we expect to generate significantly higher revenue from these therapies. As stated by the companies, this ramp will be ongoing for the next several years as they continue to expand their indications and

geographic availability. We are already seeing positive updates from both Novartis and Gilead as to their partners.

We're also pleased with the continued growth of the number of clinical trials we support, driven by new clients and expanded relationships within our existing client base. In the second quarter of 2018, we increased the total number of clinical trials we support by a net of 22, bringing the total number of clinical trials supported to 258, up from 172 this time last year and from 236 at the end of the first quarter of this year. Of the trials we currently support, 34 are in phase three. In addition, five BLA or EMA filings have occurred thus far in 2018 and we expect another four BLA or EMA filings to occur before year's end based on internal information and the forecast from the Alliance for Regenerative Medicine. This is complemented by 20 regenerative medicine advanced therapy designations, known as RMAT, that have been granted so far this year with Cryoport supporting the majority of them.

An RMAT designation is a special designation given to sponsors of cell and gene therapies if their product is intended to treat serious or life-threatening diseases and there is preliminary clinical evidence that it can address unmet medical needs as defined in the 21st Century Cures Act. An RMAT is an award by the United States Food and Drug Administration that allows for faster, more streamlined approvals of regenerative medicine products within the United States.

Now, turning to animal health, our revenue increased 7% year-over-year. Animal health is a good market for Cryoport. But our core focus has been primarily on the Biopharma market, where there is a transformational growth with enormous opportunity. We know that the animal health market will continue to benefit from our solutions and we will more vigorously pursue growth in that market as our priorities permit.

Similarly, we see substantial upside in the reproductive medicine market. In the second quarter of 2018, we reported a 17% revenue growth year-over-year as demand for assisted reproductive technology within the United States continues to drive demand for our solutions, where we're continually on the lookout for ways in which to innovate, expand our markets, and grow revenue.

As announced earlier this week, we are planning to launch our new CryoStork Insurance program shortly. We believe that this is a great complement to our industry-leading logistic solutions, which provide express transportation across the United States for the full spectrum of reproductive health commodities such as embryos, sperm, eggs and reproductive tissue. With many couples struggling with infertility and approximately 6.7 million women in the United States unable to bear a child, for the American Society of Reproductive Medicine, we're proud to expand our range of solutions to the reproductive health market. We expect increasing clinic adoption of our services which will drive further growth.

Now for more detail and information on our sales and marketing activities, initiatives, successes, and outlook, I will turn the call over to Dr. Mark Sawicki, our Chief Commercial Officer. Mark?

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 support of regenerative medicine distribution on a global scale. The emergence of regenerative medicine as a viable therapy class has amplified the focus on current clinical product distribution standards and the need to enhance requirements. To that end, both the Alliance for Regenerative Medicine and the Foundation for the Accreditation of Cellular Therapy have instituted review bodies reviewing all aspects of the collection, manufacture, transportation, and administration of regenerative medicines. Cryoport has played an instrumental role in the development

and implementation of safer, more controlled systems, which are currently being adopted as standard practice in the industry.

The latest of these is our emerging chain of compliance process requirements for regenerative medicine distribution, which are rapidly becoming a 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. Enhanced compliance standards are now being employed by an increasing number of Cryoport clients and we anticipate this trend to accelerate in the coming months.

Given the rapid development of the regenerative therapy market, as discussed on the last earnings call, we have been preparing for a substantial increase in the number of clinical trials as well as commercial products we can support within our infrastructure. As Jerry mentioned earlier, in support of this increase in demand from developers of the next era in medicine, we are launching two new state-of-the-art logistics centers, one in Livingston, New Jersey in the United States, and the other one in Amsterdam, Netherlands. Moreover, our entire service portfolio will be offered out of these facilities including our cryogenic and Cryoport Express C3 or Cryoport Certified Cool Platform for (inaudible) degrees Celsius.

For several years now, one of our key biopharma strategies has been focused on securing agreements to support clinical stage therapies so that when these products move through the clinical stages towards commercialization and the logistics requirements rise, we are the first choice logistics provider. Of the trials we currently support, the net number of phase threes jumped to 44 in the most recent quarter. On their recent second quarter 2018 earnings call, Norvatis reported $16 million of sales for Kymriah compared with $12 million in the first quarter, and stated that, while it is early, the launch for children and young adults with B-cell ALL is going well.

Furthermore, as we already mentioned on our last earnings call, Kymriah has been approved by the FDA for its second indication, the treatment of adult patients with a relapsed or refractory large B-cell lymphoma was inelligible, or relapsed after autologous stem cell transplant. On June 29, Novartis announced that it has received a positive opinion from the Committee for Medicinal Products for Human Use, also known as CHMP in Europe, for both indications of Kymriah that already had U.S. approval. The CHMP is the European Medicines Agency Committee responsible for human medicines and this marks the first CHMP opinion for a CAR T-cell therapy in two distinct indications: DLBCL in adults and B-cell ALL in children, bringing Novartis closer to making Kymriah available to the EU, to patients who are critically in need of the new treatment options. Additionally, Novartis has filed for Kymriah's commercial approval of Japan, Australia and Canada. As a reminder, our current agreement with Novartis covers any expansion of services for Kymriah, as well as any other future additional indications including global approvals.

Now moving on to Gilead. Gilead reported second quarter sales of Yescarta of $68 million compared with $40 million in the first quarter of 2018. It also reported that it has completed the authorization of more than 60 cancer centers, which cover approximately 80% of the Yescarta available, eligible patients in the United States. It is continuing to work on authorizing additional centers, while also working with centers to enhance patient flows and educating community oncologists about cell therapy, and helping them to connect their patients to cancer centers for appropriate treatment. Last month, Gilead also announced that the CHMP adopted a positive opinion for Yescarta approval in the EU for relapsed or refractory DLBCL. Gilead expects the European Commission to grant marketing authorization in the current quarter. It is already preparing for the European launch, with plans to complete the authorization of more than 20 centers in the EU by the end of 2018. Additionally, Gilead is opening a 117,000-square foot manufacturing facility in Amsterdam, that is proximal to our new Amsterdam facility. As with Novartis, our current commercial agreement covers this potential expansion of services.

As you can see, we are still in the very early stages of the ramp of these first two commercial CAR T-cell therapies, and there is a very clear path to accelerated revenue growth ahead of us. We are very proud of our role supporting Gilead and Novartis as they bring their cell therapies to a wider range of patients around the world, and we are encouraged by their early progress with the rollouts.

Beyond Gilead and Novartis, Bluebird Bio announced on July 26 that their LentiGlobin gene therapy was granted accelerated status by the European Medicines Agency for the treatment of transfusion-dependent beta thalassemia or TDT. The EMA previously granted priority medicines or prime eligibility in orphan medicinal product designation to LentiGlobin for the treatment of TDT. LentiGlobin is also part of the EMA's adaptive pathways pilot program, which is part of the EMA's effort to improve timely access for patients to new medicines. The U.S. Food and Drug Administration also granted LentiGlobin orphan drug status and breakthrough therapy designation for the treatment of TDT. Bluebird Bio announced that they intend to file an NAA for LentiGlobin in TDT with the EMA later in 2018.

Turning to Animal Health, as mentioned previously, we have recently unveiled a number of new companion animal clinical trials that tend to have lumpy revenues early in their clinical development, as well as a number of larger laboratory moves supporting another large animal health entity. We anticipate that a number of these will start to ramp in the coming two quarters, which will positively impact our revenues in these areas.

Finally, within our reproductive medicine markets, we are excited to announce the launch of our CryoStork insurance product. Cryostork insurance will enable expecting parents to insure their reproductive materials against the risk of damage and loss when being moved between clinics. Our sales strategy for this insurance product will be aimed at both the intended parents and the fertility clinics. We currently have relationships with approximately 400 clinics. These clinics will recommend, and in some cases require, expectant parents to utilize our solutions as part of the IVF process. For clinics, the Cryostork insurance product helps them to minimize risks. For expecting parents, they can have the added financial security during their IVF treatment. For Cryoport, this represents an additional revenue stream that we can bring to market relatively quickly. We anticipate rapid adoption of this service throughout our clinic network and client base as it is unique to the marketplace.

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

Jerrell (Jerry) Shelton:

Thank you, Mark. Now for a detailed financial report on our second quarter, I'll 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 the financial results for the three and six months' periods ended June 30, 2018, provide some additional comments, then turn the call back to Jerry.

For the six-month period, net revenues increased by $3 million or 54% to $8.7 million, compared to $5.6 million for the same period in the prior year. Biopharma, our largest market, increased by 68% over the prior-year period to $7.1 million from $4.3 million in the first half of 2017 as a result of the continuing increase in the number of biopharmaceutical clients utilizing our services, increase in clinical trials supported for these clients and the commencement of commercial launches of Yescarta and Kymriah. Our revenue from animal health decreased 3% to $518,000 for the first half of 2018 compared with the same period of 2017, primarily a result of the temporary pause in the trial conducted by one of our animal health customers in the first quarter, which has since resumed.

Revenue in the Reproductive Medicine market increased by 19% over the prior-year period to $1 million. This increase was driven by the 26% increase in revenues in the U.S. market and partially offset by a 1% decrease in revenues in the international market. We continue to see growing demand for comprehensive and reliable solutions in this market and intend to build out our leadership position.

Gross margin for the six-month period ended June 30, 2018 was 54% or $4.7 million, compared to 47% or$ 2.6 million for the prior year. This increase in gross margin by over seven percentage points is primarily due to the economies of scale from the increase of business volume, allowing us to leverage our technology-based business model.

Operating expenses increased by $2.7 million for the six-month period ended June 30, 2018, or 33% as compared to the prior year. This increase is primarily a result of building out our organization's support of the expected increase in business logging, recruiting fees, non-cash stock-based compensation expense, and startup costs for the new logistics centers in Livingston, New Jersey and Amsterdam, Netherlands. We reported no interest expense for the six months ended June 30, 2018, compared to interest expense in the prior-year quarter of $16,000.

Net loss for the six months ended June 30, 2018, was $5.2 million or $0.19 per share, compared to a net loss of $3.6 million or $0.18 per share for the same period of 2017. The net loss for the six-month period ended June 30, 2018 includes 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 earnings before interest tax, depreciation and amortization, EBITDA, for the six-month period ended June 30, 2018 continued to improve by approximately $400,000 to a negative $1.4 million compared to the same six-month period in the prior year, even with the ongoing investments we are making to build out our organization and enhance our global footprint through our new logistics standards.

Now moving to our quarterly result. For the second quarter, net revenue increased by $1.7 million or 59% to $4.6 million, compared to $2.9 million for the prior-year second quarter. This quarter was driven by our success in the biopharma market where revenues increased by 73% over the prior-year quarter from $2.2 million to over $3.8 million.

The increase in the number of clinical trials and ramp in revenues from the two commercial therapies who we are currently supporting are the growth drivers for this quarter. I expect it to drive future revenue acceleration as clinical trials advance and are commercialized, and commercial therapies ramp and are launched in new geographies or for additional indications.

Our revenue from MFF increased 7% to $279,000 for the quarter compared to the same period of 2017. Novartis continues to be our largest client in this market and we are currently in the process of renewing our agreement with them. Revenue in the Reproductive Medicine market increased by 17% over the prior-year second quarter to $499,000. This increase was primarily due to an increase in the U.S. market of 23% driven by our continued success of our marketing campaigns as well as the expansion of our suite of logistics solutions such as CryoStork. Revenues in the international market increased by 2%.

Gross margin from second quarter 2018 was 54% or $2.5 million, compared to 48% or $1.4 million for the prior-year quarter. This increase in gross margin by over six percentage points is primarily due to the economies of scale from the increase of our business volume. As we have mentioned in previous calls, our target margin is 60%. Having said that, bringing new logistics centers online, such as our logistics centers in Livingstone, New Jersey and Amsterdam, Netherlands, may impact margins temporarily as logistics operations fully ramp.

Operating expenses increased by $1.7 million for the three-month period ended June 30, 2018, or 53% as compared to the prior year. This is primarily due to the result of building out our organization in support for the expected increase in business volume, startup costs for the new logistics centers in New Jersey and Netherlands, and non-cash stock-based compensation expense.

We continue to invest in building out our organization and expertise to meet the growing demand of our solutions and expected ramp in business. Net loss for the second quarter of 2018 was $2.5 million or $0.09 per share, compared to a net loss of $1.9 million or $0.08 per share for the second quarter of 2017.

Adjusted EBITDA for the three-month period ended June 30, 2018 continued to improve to a negative $0.8 million compared to a negative $0.9 million for the same three-month period in the prior year. We ended our quarter with a strong cash position and are debt-free, reporting $20 million in cash and cash equivalents as of June 30, 2018, compared to $15 million as of December 31, 2017. The increase in cash and cash equivalents was primarily a result of the aforementioned warrant tender offer with net proceeds of $4.6 million and regular row of exercises further bolstering our cash balance and allowing us to execute on our plans for 2018 and beyond.

Overall, we are very well-positioned and funded to continue to execute our strategy and drive organic growth. Lastly, we file our quarterly report on form 10-Q with the SEC today.

With that, I'll turn the call back to Jerry. Jerry?

Jerrell (Jerry) Shelton:

Thank you for your financial report, Robert. We appreciate the support of our loyal and long-term shareholders. At all times, our priority is to build a successful, sustainable business that will bring value to all our stakeholders.

In June, we were pleased that Cryoport was added to the Russell Indexes. We consider that recognition an acknowledgment of the progress we have made executing on our mission and the strong support we have received from the investment community, some of whom are on the call today. Being included in the Russell Indexes provides additional liquidity for our stock and broadens shareholder base.

Approximately $9 trillion in assets under Management are benchmarked as invested in products based on the Russell Indexes which underscores the importance of these indexes to the financial markets. We also continue to work to further increase our exposure to institutional investors. To that end, we will be attending investment conferences held by both Cowen and Janney during the third quarter, in addition to regularly conducting non-deal road shows.

We have an excellent investment story to tell. Cryoport Solutions are mission-critical to our biopharma customers. Our demand is stronger than it has ever been. We have multiple new commercial agreements on the near-term horizon and opportunities to expand existing relationships globally. We have also established a pipeline of clinical trials in various stages that will fuel our long-term growth for many years to come. The Cryoport Team has established an industry-leading brand, erected high barriers to entry in terms of infrastructure technology and know-how, and built a strong balance sheet upon which to continue growing our Company organically and through acquisitions when possible. It's an honor to lead our capable team of people, and it is an exciting time to be an investor in Cryoport.

Operator, please open the floor for questions.

Operator:

Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate 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 comes from Paul Knight with Janney. Please go ahead. Mr. Knight, your line is live.

Paul Knight:

Okay, can you hear me now? Can you hear me?

Jerrell (Jerry) Shelton:

We can hear you now, Paul.

Paul Knight:

You hear me now?

Jerrell (Jerry) Shelton:

We can.

Paul Knight:

Very much. Hey, Jerry. Congratulations on the growth in the quarter. Is this coming from increments of the customer or is it multiple trials from the same client?

Jerrell (Jerry) Shelton:

I'll let Dr. Sawicki answer that question.

Mark Sawicki:

It's a combination of both. We do have strong new client acquisitions which are contributing new trials to that total portfolio volume, as well as existing clients contributing to that 258 trials.

Paul Knight:

Great. Then, if I think about the operating loss, I guess it was really attributable to the facility expansions in New Jersey and Amsterdam? Would that be the right way to think about it?

Jerrell (Jerry) Shelton:

Yes. I'm going to turn that one to Robert Stefanovich.

Robert Stefanovich:

Yes, Paul. You're absolutely right. It's a combination. If you look at the operating expenses that we have, part of that is the startup costs for the Netherlands and to some extent, for our facility in New Jersey.

Then, we also had the additional stock-based compensation expense as outlined in the Q that is embedded into the operating expenses. That's a non-cash item.

Paul Knight:

Then, last, Jerry. If you could talk about where do you think you are in a competitive position in the marketplace, are you increasing your 120,000 data points? Is that like building a bigger moat? Where do you think you are with potential competition that might be out there?

Jerrell (Jerry) Shelton:

Well, Paul, I think we're in the strongest position ever. As I mentioned, for example, in terms of momentum, we've filed for five new patents. One of those is new product demand, two of them are effectiveness, and two of them are revolutionary to the industry. In terms of competitive positioning in the marketplace, we're reconfirmed every day, and we work very, very hard to maintain that. We never have an arrogance about our competitive advantage. We're always working to make sure that we're sensitive to the market, and especially sensitive to our individual clients and their needs and that we're moving ahead on every front.

If you look at our packaging, our information technology, and our logistics expertise, we do nothing but improve that on a daily basis, certainly on a quarterly basis. I think we're in an excellent position. We don't see any new competition on the front. We don't see any strengthening competition. As you saw recently, we signed a strategic agreement with World Courier, where about World Courier took on all the cloud port solutions, giving them the strength of our chain of compliance story, our chain of compliance methodology that wouldn't be available to them otherwise. That's an Amerisource Bergen company. That's a company that has infinite assets that they could put to work, but they chose Cryoport as opposed to trying to build it themselves. They chose it for a reason, because of the competitive advantages that we have.

Paul Knight:

Okay. Thank you very much.

Operator:

Our next question comes from Richard Baldry with ROTH Capital. Please go ahead.

Richard Baldry:

Thanks.

Jerrell (Jerry) Shelton:

Hi, Rich.

Richard Baldry:

How are you?

Jerrell (Jerry) Shelton:

Good.

Richard Baldry:

Good. The two new facilities are up and launched, I assume the European one is probably not throughputting yet because we haven't had approvals there. But is the New Jersey facility actually throughputting actual services as we talk right now?

Jerrell (Jerry) Shelton:

Actually, the New Jersey facility was approved officially today. Both facilities are throughputting. We will have a measured ramp-up, making sure that everything is working the way we know that it's designed to work and that we confirm that everything is working the right way. They both are working. They both are approved by our clients and by our quality assurance team here at Cryoport.

Richard Baldry:

In terms of the cost to get those launched, they fold into the cogs line, I guess, and maybe somewhere in the T&A as well. Are there any one-time things that got them up and launched in the quarter that would fall away? Or is it more of a steady state, now that they're up and running, this is the new level for those?

Jerrell (Jerry) Shelton:

I'll turn that to Robert Stefanovich.

Robert Stefanovich:

Yes. Just a few comments on that, Rich. In terms of the facilities being up and running, this is really just now happening. It's really not reflected in the second quarter. We did have, obviously, startup costs associated with that. One hard cost, just $300,000 that are embedded in our operating expenses startup costs, as well as capitalized assets in the range of $200,000 to $250,000, plus bringing in now the additional Cryport Express Shippers that include our Smartpak Condition Monitoring System. But if you really look at those two operating centers, it's really now starting, and we'll see ramps that's not included in the second quarter.

Richard Baldry:

Maybe, could you talk about any sort of intermediate term plans for additional facilities, maybe in Asia or somewhere else to support the clinical trials that you're working with now, or the future approvals being sought by clients you've got commercially?

Jerrell (Jerry) Shelton:

Rich, that's a very good question. Certainly, that's in our planning purview. But our answers right now has to be on getting these two new logistics centers up and running appropriately and satisfactorily. But, your question is absolutely in our purview and in our planning horizon.

Richard Baldry:

You sort of talked a little bit about the fact that your partners are viewing you differently as things evolve, maybe as you move into the commercialization phase. Maybe, could you talk about what specifically that means? Is it that they're understanding more, how important this is to the process, or there's something about the volume, as you retire volume that's changing, that makes them come back to you and have some different needs over time? Thanks.

Jerrell (Jerry) Shelton:

Yes, Rich. That's a very good question and it's certainly an evolving arena. I'm going to turn that to Dr. Sawicki who is right on the front line with these people all the time.

Mark Sawicki:

Yes, hi. What we're seeing is our clients are increasingly coming to us for guidance from a regulatory standpoint. This chain of compliance competency that we've been working on is a perfect example of that. What it is, is it's us starting to dictate within the marketplace what that standard should be. This is largely predicated on client requests and observations in conjunction with their clinical activity, in their commercial launches, and feedback from both the FDA and the European Medicines Agency. It all comes back to a higher threshold from a quality standpoint for commercial products versus clinical products in this space. There's a much lower tolerance for the traditional status quo logistics distribution competencies that have been in the market for this period of time. Yes. We're absolutely becoming an indispensable aspect when it comes to helping them from a guidance standpoint and dealing with the FDA and European Medicines Agency in conjunction with commercial activity.

Richard Baldry:

Thanks. Just last sort of check, a question on the stock-based comp stepped up. Was there any one-time-milestone types things in there or is this a new level we should think about as a steady state forward? Thanks.

Jerrell (Jerry) Shelton:

Yes. For your planning purposes and modeling purposes, assume we're kind of a steady state with the amounts that we have. There weren't any milestone type of vesting features in Q. Generally, our stock options are pretty plain vanilla in terms of the vesting schedule.

Richard Baldry:

Right. Congrats on the great quarter.

Jerrell (Jerry) Shelton:

Thank you.

Operator:

Our next question comes from Jason Seidl with Cowen and Company. Please go ahead.

Jason Seidl:

Thank you, Operator. Hey, Jerry and team. I want to go back to the facilities and maybe ask the question a different way. In terms of a revenue standpoint, Jerry, what's the scalability of these facilities for the Cryoport network?

Jerrell (Jerry) Shelton:

Jason, are you saying what's the potential scalability of these facilities?

Jason Seidl:

Yes, in terms of a revenue basis. Ballpark.

Jerrell (Jerry) Shelton:

Okay. We build these facilities on the modular basis, and we build them on a scalable basis, I should say. A scalable basis in that we build them out of a footprint of about 7,500 square feet, give or take a couple of hundred square feet. Then, we also negotiate for leases of the first right of refusal and leases of the adjacent properties so that we have the room to expand as we need to expand. While we don't give out specifics for each individual in terms of the actual revenue because, of course, part of that depends on what we're supporting in the mix, we're scalable. We did build them out for supporting these, to begin with, these first two commercial therapies, both in Europe and United States, Yescarta and Kymriah, and other indications that those therapies might be approved for. They're scalable and we feel that they can support, for example, Kite is building a 100,000-square foot plant within a mile of our Amsterdam operation. That's why we placed it in the position that it's placed in. They are scalable, but we don't give out specific numbers for it. I think it'd probably be a mistake, for each of our logistics centers.

Jason Seidl:

Well, then it's clear that there's some room to grow. I didn't think your placement of the Amsterdam facility was a happy accident. But, that sounds like there's some good growth to come. I want to touch a little bit on the chain of command product because that intrigues me. Because somebody else brought up where you are in the competitive landscape (inaudible) even more of an advantage out there. Does anybody else have anything that's close to this product?

Jerrell (Jerry) Shelton:

Well, actually, Jason, we have the phrase trademarked and no, they don't. I'll let Mark go into more detail about what is included in our chain of compliance. Because it's an extremely important concept, and one that the industry is warming to very, very quickly.

Mark Sawicki:

As we started taking a look at this based on the feedback that was coming back from the regulatory authorities in particular, in conjunction with both the Novartis and the Gilead Kite launches, one of the—there was some commonality in regards to theme related to an enhanced regulatory footprint around this compliance competency. What the compliance competency is, is it's an enhanced traceability of all of the equipment and processes which are related to distribution of these therapies. What we're doing, in essence, is we're putting the same regulatory scrutiny on our equipment and processes as you would see in a G&P biologics manufacturing footprint. This has never been done in a logistics space. The reason that we have the ability to do it is we have a unique informatics platform, or Cryoportal, which we have been able to collect and cross-reference all the data that's coming into that system into a single unified database that is fully integrated. Most other parties have their track-and-trace from a scan code basis in database A, their data capture from their data loggers in database B, their incoming order management process may even be in a third database, and they have no way to cross-reference them, and they don't have any traceability competency down to the serial level on any equipment in their infrastructure.

We do all those things and we can integrate them together, and that's something very, very favorable from the FDA and European Medicines Agencies. They're the ones who are really, honestly starting to drive this competency, and it does put us in a very unique position. I hope that answers your question.

Jason Seidl:

It does. Very much so. It sounds like it's a big advantage for you guys. Well, listen, I'll turn it over to somebody else. I appreciate the time, as always, gentlemen.

Jerrell (Jerry) Shelton:

Thank you, Jason.

Operator:

Next question comes from Sean Hannon with Needham & Company. Please go ahead.

Sean Hannon:

Thanks. Good afternoon. Thanks for taking the questions here. Let me see if I can start from the top line with some variables you had mentioned a little bit earlier. As you folks observe the revenue ramps at the two approved Biopharm clients of yours with (inaudible) and Jescarta, as you observe those ramps and as you observe then the trade specialized (inaudible) and hospitals, can you give us an update here that might be a little more specific in terms of how you're modifying your expectations of timelines, say, for Gilead or Novartis with those specific therapies to hit those targeted $8 million to $10 million in revenues? Because it seems like they're at a little bit of a different pace, albeit they're at different price points, but I think that an updated perspective would be useful particularly given that we're on the edge of EMA approval.

Jerrell (Jerry) Shelton:

Sean, I'm going to make a few comments and I'm going to turn it over to Mark Sawicki to give you a more detailed answer to your questions. I want to start off by saying, first of all, we're dealing with revolutionary therapies. These therapies have never before been done and these companies are taking great care to make sure that those points of care are qualified and that the inoculations take place and that the therapies are exactly right. They don't want any setbacks, they don't want any problems, and they're being very responsible. We're highly respective of that. Is the ramp a little bit off, where we expected? Yes, it is, but that's to be expected. This is biology that we're working with. It's data-driven, and data is being collected and care is being taken and a responsible approach is being taken as well. With that, I'll turn it to Mark for a more finite answer.

Mark Sawicki:

Thanks, Jerry. As we take a look at this and we look at the activity ongoing within our two commercial clients, they continue to take a very, very aggressive stance in the marketplace. I think publicly they disclosed enhanced manufacturing competencies. Jerry talked about the Kite facility in Amsterdam, Novartis has announced additional manufacturing capacity coming online in Europe as well. Very aggressive expansion plans, both of them have publicly acknowledged their launch profiles in Europe. I don't think that we're going to see a material difference in that ramp. I would still feel very confident that that topline is an appropriate number, it's just that as these things come online, we're going to see that ramp just aggressively modifying, maybe geographically more so than than anything on a significant delay or anything else along those lines.

Sean Hannon:

Okay, well, let me ask in a different way because I just feel I need a little bit more information. Because we're a few quarters into the experience, and albeit, yes, it's a new one and its a learning process for everybody but do we feel, from a Cryoport standpoint, as you guys are making your internal investments, either hard capital and facilities in this quarter whether it be in Livingston or Amsterdam or also in, say, personnel and other efforts, we clearly, within Cryoport, are going to have some views and adjustments around when do we think we can hit this type of numbers? Because that's going to support your investment path as well. At this point, are we talking about the ability that we should be able to get into the range in concept, in the year 2020 or 2021 or is it possible that it's a little further out than that?

Jerrell (Jerry) Shelton:

I think, first of all, there is a lot of data available on both the Kite and the Gilead Kite website and through their calls as well as through Novartis. As for our planning, we feel that our planning is on target. We didn't build facilities for them to be vacant or hire people for them to be idle. There is some orchestration to take place and there is a load to place on these facilities and ramp up times and so forth, as I mentioned earlier, but we feel that we're on schedule. We are coordinated with the manufacturers and we have dedicated program managers and we have fluid conversation lines going all of the time. We feel confident that we're on the right pathway and we made the right decisions in terms of building out our capacity and our planning. Mark, would you like to add anything to that?

Mark Sawicki:

No, I think that's accurate. While we can't provide specific guidance on what the ramp schedules look like because it's proprietary in nature, what Jerry had mentioned is true. We're working very, very closely with both parties and ensuring that we have the right assets in place at the right time. We haven't gone through an aggressive build-out of two new facilities with the expectation that that volume is distant in timeframe.

Sean Hannon:

Understood. Okay. All right, let me switch gears for a moment into talking a little bit around the OpEx. Sounds like what was addressed for an earlier question stock-comp level should be, I mean, the dollar point relatively static. Even as I hold that out and I look at the level of OpEx spent, should we continue to see incremental ramp-up from here, just in a general nature, you continue to grow your business as well as expand your efforts to bring on new clients? To what degree should we be seeing that or is there some element to the dollar spends you're able to maintain here? If you can help us to understand the path of this OpEx through the end of the year at least, I think that would be really helpful.

Jerrell (Jerry) Shelton:

Sean, let me turn this to Robert in just a moment, but again, I'm going to make a general comment or two. You can expect some lumpiness in our OpEx now and in the future, because we build facilities and they don't instantly have volume coming through them, revenues associated with them, so we have to build in advance, and so there will be some lumpiness there. The margins that we've talked about in the past are absolutely the margins that we believe—well, we know are in sight, that's 60% gross margin and 30% operating profit. But on the road to that, you'll see some lumpiness as we build out the infrastructure, the logistics network not only in the United States but around the world. Robert, would you like to add to that?

Robert Stefanovich:

Yes. Just a few comments, and then like you said, we already mentioned some of it. If you look at the operating expense excluding the stock-based compensation expense and also including the start-up

costs that we had during the second quarter, which, they were about $300,000 included in the operating expense, then you start really looking after through quarterly operating expense that we had outside of those two items. When you look at that and compare that, for instance, to even the second quarter of last year, it's only an increase of about $420,000 or $430,000. That's really the increase in organizational structure that we had. If you go and look at the second half of this year, we did already allow the build out of the organizational structure. We have the sales team in place, we have the quality organization in place, and the other supporting staff. Where you may see additional increases is really more strategic to support the growth and logistics management and the logistics centers. If you look at operating expenses going forward, I wouldn't expect a significant increase in operating expenses compared to the second quarter of this year.

Sean Hannon:

Okay. Thanks very much. Thanks for addressing the question, folks.

Jerrell (Jerry) Shelton:

Thanks, Sean.

Operator:

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

Brian Marckx:

Hi, guys. Congrats on the quarter. One on biopharma revenue. It looks like the dollar amount increased from Q1 and excluding the commercial revenue, it looks like it was the greatest increase on a quarter-over-quarter basis that you've ever had. Is there anything particularly unique in the Q2 biopharma number?

Jerrell (Jerry) Shelton:

I think there is, and I think it has to do with our Business Development Team. I'll let Mark answer that in more depth.

Mark Sawicki:

Yes, Brian. Our team has worked really, really hard on capturing as much market share as possible. We've been targeting acquisition of as many clinical trials as possible. We have a bonus of new programs that have been brought on, and new clients that have brought new trials in that are now starting a second and third trial. We feel very strongly that that's not a one-time event, that that's going to help contribute moving forward to, obviously, our revenue growth.

Brian Marckx:

Then in terms of just general pricing, have you been able to take some pricing increases as well?

Jerrell (Jerry) Shelton:

Mark, why don't you answer that?

Mark Sawicki:

Yes. Obviously, we're always driving towards improving margins through accretion in base pricing, but we're also significantly diversifying our revenue stream beyond just our traditional core assets. We put a large program management organization in place now which drives direct revenue on a headcount basis. We've instituted our Consulting business which is now starting to contribute notable revenue as well. Those are just the beginning. We do believe that will also contribute to an average enterprise value of a given client in the coming quarters.

Brian Marckx:

Relative to the World Courier arrangement, is your Cryoportal integrated with their system, similar to the way it was with FedEx and UPS?

Jerrell (Jerry) Shelton:

It will be. There's an integrative aspect to that. All of that's outlined in the announcement, so there's no new news here, but that is a part of it, yes. We made our entire suite of solutions available to World Courier, and we think that's going to bode well for both World Courier and certainly, for Cryoport.

Brian Marckx:

Jerry, in terms of timelines for full integration, do you have an idea of when you think that may be completed?

Jerrell (Jerry) Shelton:

Full integration with World Courier?

Brian Marckx:

Yes.

Jerrell (Jerry) Shelton:

Well, we've worked with World Courier for a number of years. We formalized and extended our relationship and that's what this is all about. That integration should be finished in this quarter.

Brian Marckx:

Okay. Great. Thank you.

Operator:

Our next question comes from Len Yaffe with Stocdoc Partners. Please go ahead.

Len Yaffe:

Thank you very much. I would like to add that I think another validation of what you're undertaking is the fact that Regeneron just announced this past weekend they were investing significantly in Bluebird Bio, including the purchase of $100 million in stock, way above the current market price of the stock in developing six targets with them. I think that they recognize that this is a long way to go. What I was wondering was two things. One is, as the Kymriah-Yescarta sales grow sequentially, what type of

proportionate increase, until other products get approved, should we expect in your revenue base given that it could depend on sales in the U.S. versus not the U.S.? Then, the second question for Rob would be, could you give us some sense, given the scaling out in anticipation of years/decades of significant new products coming to market, what this means to roughly, not exactly at all, would be a breakeven quarterly revenue level for Cryoport? Thank you.

Jerrell (Jerry) Shelton:

First of all, Len, thank you for your comments there in the beginning. I'm going to turn you to Mark to answer the first question, and then to Robert for the second.

Mark Sawicki:

Yes. Len, as much as I'd love to give you guidance in regards to what that looks like for both products, I'm going to have to steer you back to both the Novartis and the Gilead announcements for their earnings and projected ramps. It's not in our place to speculate and put that data out. I'm just going to reiterate that we built out two new facilities to support these and we still feel very bullish on their prospects but I'm not going to go beyond that at this point in time. Robert, you want to comment on the second?

Robert Stefanovich:

Yes, Len. Just a few comments to add. As Jerry mentioned earlier, we're building out our organizational structure to support and really to leverage our positioning in the market space. With that said, if you look at cash flow breakeven range, we're looking at currently about $24 million to $28 million in annualized revenue. As we further build our organization and as we see the ramps from these commercial launches, we'll probably have a more accurate picture as to when to expect breakeven. At some point, we'll also start giving forecast to the market space, but given the dynamics in the marketplace right now and our positioning, it's a little bit too early for us to do so.

Len Yaffe:

Great. Thanks so much.

Jerrell (Jerry) Shelton:

Thank you.

Operator:

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

Jerrell (Jerry) Shelton:

Thank you, everyone. Thanks for joining us.