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Cryoport, Inc.

First Quarter 2017 Earnings Conference Call

May 4, 2017

CORPORATE PARTICIPANTS

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PRESENTATION

Operator:

Good afternoon, ladies and gentlemen. Welcome to the CryoPort First Quarter Ended March 31, 2017 Earnings Conference Call. Today's conference is being recorded and will be available on the Company's website. Now, I will—want to turn the conference over to Mr. Todd Fromer, Managing Partner of KCSA. Mr. Fromer.

Todd Fromer:

Thank you, Operator. Good afternoon, everyone, and thank you for joining us today for CryoPort's calendar quarter ended March 31, 2017, earnings conference call. For those of you that have dialed in by phone, there is a slide deck to accompany these comments which can be found on the events page of the Investor Relations section of the Company's website at cryoport.com.

Before we begin today, I would like to remind everyone that this conference call contains certain forward-looking statements. All statements that address our operating performance, events or developments that we expect or anticipate occurring in the future, are forward-looking statements. These forward-looking statements are based on Management's beliefs and assumptions and not on information currently available to our Management Team. Our Management Team believes these forward-looking statements are reasonable, as, and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not

undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experiences and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in Item 1A, Risk Factors, and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission and those described from time to time in other reports which we file with the Securities and Exchange Commission.

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

Jerrell W. Shelton:

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

We had solid topline performance for our first quarter ended March 31, reporting year-over-year revenue growth of 74%. All of our markets, Biopharma, Reproductive Medicine, and Animal Health, experienced significant growth, demonstrating both the strength of our life sciences logistics technology platform and our excellent marketing position as we continue to leverage our reputation as the leading provider of the most dependable advanced temperature-control logistics solutions for the life sciences.

In my following remarks, I will briefly recap our progress in our Animal Health and Reproductive Medicine markets, before addressing our significant achievements in the Biopharma market, which is both the largest portion of our business by revenue and our greatest growth opportunity by market.

We reported our second consecutive quarter of growth in the Animal Health market with revenue up 28% year-over-year. We are pleased with this market—that this market has rebounded and expect this to continue throughout 2017 as we secure new clients and grow our existing business. During the first three months of 2017, we added VetStem Biopharma to our Animal Health client roster. VetStem Biopharma is a pioneer in the use of regenerative stem cells in veterinary medicine and we're proud to be supporting their clinical (phon) logistics requirements. Furthermore, as disclosed in January 2017, Cryoport was chosen by Jackson Laboratory to support its Cryopreservation Group. While the initial revenue impact of Jackson Lab was minor during the quarter, once fully on board, we expect significant annual volumes to be completed from its sites located in Bar Harbor, Maine, and Sacramento, California.

Reproductive Medicine revenue increased by 26% for the first quarter compared to the same quarter last year, led by a 52% increase in the US market which continues to remain a strong growth market for Cryoport. This quarter saw the launch of CryoStork Next Flight Out cryogenic logistics solutions for the Reproductive Medicine market which we introduced during our yearend 2016 conference call. We're happy to report that it's showing market acceptance and momentum.

The big news for the quarter, however, was Biopharma. We reported record revenue and a growth rate of 100% year-over-year for the first quarter of 2017. This was driven by the signing of 27 new Biopharma clients and by new clinical trial agreements with both new and existing clients. Biopharma revenue now accounts for 75% of our total revenue compared to 69% of total revenue for the preceding quarter ended December 31, 2016. We believe this increase further validates our strategy of focusing on Biopharma.

Our sales and marketing strategy for the Biopharma market is currently focused on securing clinical trial agreements in the Regenerative Medicine space, which can develop into multiyear agreements and scale

as our clients progress through the clinical trial Phases, one, two, and three, and thereby unlocking revenue growth.

During the quarter, we secured 14 new clinical trials with biopharma companies bringing the total number at clinical trials supported by Cryoport to 139 compared to 78 this time last year. These trials are a strong foundation on which to grow our business in the Biopharma market, and we're excited to be on the cusp of realizing significantly higher levels of activity.

As a reminder, annualized revenue to Cryoport for Phase 1 trials typically ranges from $15,000 to $75,000 annually; Phase 2 $75,000 to $125,000; and for Phase 3 $200,000 to $1 million, and when commercialized and fully ramped up, we anticipate $2 million to $20 million annually. Today, we support 64 Phase 1 clinical trials, 58 Phase 2, 17 Phase 3. Of course, all these trials will not progress to commercialization. But this is a very strong pipeline which includes some of the foremost innovators in the biopharma industry. Most of these trials are pioneering the regenerative medicine industry where we're positioned as the leading cold chain logistics provider and where there is tremendous opportunity for relatively near-term growth.

For example, many of you are familiar with the emergence of CAR-T gene therapy, an exceptionally promising field of immune therapeutic alternatives which is revolutionizing treatment options for a multitude of health issues including cancers, congenital diseases, and traumas. Much of the ground-breaking research and development taking place in personalized medicine now dictates strict temperature and timeline compliance for biologic materials transported around the globe. These therapies rely on state of the art cryogenic logistics solutions as the only effective method of maintaining efficacy when they are transported and stored, making temperature-controlled logistics a strategic concern in the design and implementation of clinical trials and the delivery of commercial products.

Two thousand seventeen is shaping up to be a breakthrough year for the regenerative medicine industry, the potential embedded gains in each of Cryoport's clinical trial agreements being more and more apparent as we witness significant progress from our clients. A notable example was Kite Pharma, the first company in the regenerative medicine space who have filed a Biologic License Application with the Federal Food and Drug Administration. Kite's BLA is a request or permission to commercialize its biologic products and if granted, will lead the way for Kite to launch its lead product, ZUMA-1, for the treatment of aggressive non-Hodgkin's Lymphoma. ZUMA-1 is the first of its kind in cell therapy and is intended to produce a rapid and durable complete response in patients by using the patient's own cells to threat his or her cancer. In addition to ZUMA-1, Cryoport supports six additional Kite trials for clinical stage therapies. Needless to say, we're proud to be a trusted partner to Kite and have the privilege to support its progress toward advancing novel immunotherapy treatments.

Another of our clients, Novartis, has been granted Priority Review by the FDA and is moving closer to its potential launch of CTL019, its treatment for Leukemia. By market cap, Novartis is one of the largest pharmaceutical companies in the world and we're honored to be playing one of its critical roles of ensuring patient access to its clinical trials and now potential commercialization. Kite and Novartis demonstrate our success at forming strong relationships with key players in the regenerative medicine market. The personalized medicine market is forecast to change the face of medicine as more and more therapies move toward commercialization, creating a multi-million-dollar industry.

With the first two CAR-T cell therapies expected to receive FDA approval this year, Cryoport is in a position to play a significant enabling role and thereby begin to build substantial value for Cryoport shareholders who have put their investment dollars to work. In addition to these two exciting companies, the market forecast is for at least three, possibly four, more BLAs to be filed during 2017. Commercial launch opportunities' approach is important for Cryoport to be in a position to scale with solutions so that we are ready to support upcoming commercial launches without delay. The potential revenue for Cryoport in supporting a commercial launch is significantly higher when compared with revenue from

clinical trials. For that reason, it is imperative that our clients see a strong balance sheet that enables us to finance the investments associated with our logistics solutions supporting commercialized products.

I would now like to comment on the recently completed capital raise of $11.4 million during the first quarter which provides us with the resources we need to support upcoming commercial launches and further build out our business infrastructure. As your CEO and a fellow shareholder, I'm confident that this much-needed capital raise was the best way to build long-term value for Shareholders, especially considering we had only approximately $3 million in cash near the end of March 2017. This financing was spearheaded by two renowned investment banking firms with strong reputations and networks needed to raise the capital we sought.

We looked at a myriad of options to raise capital, a debt financing would've come with ominous interest rates and possibly even an equity conversion component. We also explored another warrant exchange but the capital it would have potentially raised would have been insufficient. So, we chose to go with a straight common stock public offering. As a common stock only, equity financing, this financing contained no warrant coverage. As you know, warrants add to dilution and, depending on their terms, can often hurt Shareholder interest over the longer term.

The financing closed on March 31 and its major benefits are as follows: first, it was important to our larger clients that we had a healthy cash balance, giving them comfort in our ability to handle their business. When entrusting us with their valuable biologic commodities, these biopharma companies cannot take known and extraordinary risk and that includes not only assessing the quality of our logistics solutions which, of course, are the best on the market, but also ensuring that Cryoport has sufficient cash on hand to deploy its solutions in a timely and efficient manner and finance working capital needs. As a result of this capital raise, we are confident we have the flexibility and resources to support the ramp up of the upcoming commercial launches.

Secondly, it enabled us to attract quality institutional investors. This has significantly improved our liquidity and our trading—the trading volume in our stock. Third, it provided us with additional analysts' research coverage. Today, Needham and Company has supported us with a report and we feel certain Cowen and others will follow, providing investors and prospective investors with broader independent research.

Since completing the offering, we have received some questions about why our raise entailed a significant discount to the then-market price of Cryoport. Here are some of the reasons: we embarked on the offering with great anticipation with the internal knowledge of our progress, momentum, and future prospects. However, we knew that we had to prove—we had to improve our balance sheet to support our future. The bankers, Cowen and Needham, set up very good meetings that were a huge step up in quality and well received.

Although the investor prospects liked our story, they had the following issues: there were no comparable companies to measure our value against; Cryoport is unique. Our liquidity was poor as our average daily trading volume is low. Our valuation was below $100 million so their view was we were on the more speculative side. The prospective commercialization of the two products for which we have contracts were still in Phase 3. Other public offerings that were being priced around us included warrants, and the investors knew we needed the cash on our balance sheet.

For these reasons, the investor indications and firm bids were for a large discount, not unusual but painful. After careful consideration, we agreed to sell 5.5 million shares of common stock at $2 per share with a 15% over-allotment option which was exercised. On the one hand, it was a bitter pill. On the other hand, to recapitulate, we accomplished the following: assurance for our commercial clients that we would have the capital to deliver our services without fail or interruption, institutional Shareholders, independent research from several sources, and liquidity in our stock and additional retail market makers.

As a result of the offering, Cryoport is now in a position to continue to build its infrastructure, finance its working capital needs, and take advantage of a large opportunity it has in its immediate future. Our trading volume has picked up significantly since the offering closed and our stock price has begun to recover. In addition to the Wall Street analysts covering our stock currently, we think a few more will be covering us shortly, and finally, we have several long-term institutional Shareholders and we work to add more. This offering, despite being done at a steep discount to market, paves the way for Cryoport to move forward and I believe we can move beyond our previous share price in the not too distant future.

Now, I would like to turn the call over to Dr. Mark Sawicki, our Chief Commercial Officer, to give you a market overview and an update of the trends in the regenerative medicine industry and how these may affect Cryoport. As a reminder, please hold your questions for Mark until the question-and-answer session period. Mark, the floor is yours.

Mark W. Sawicki:

Thank you, Jerry. It's a pleasure to speak with all of you today. My objective for the call is to provide you with a synopsis of Cryoport's strategies and drivers within our key markets which include Animal Health, Reproductive Medicine, as well as the Biopharmaceutical market, specifically within regenerative therapy, as well as provide more details surrounding the business impact of recent announcements and how they fit into our strategy to engage the market and drive revenue in the current year.

First, I'd like to provide a short overview of the Animal Health space. Cryoport supports two key healthcare needs within this space; one in the transport of key vaccines and the reproductive materials for food stock in the livestock and poultry space, and the other in the movement of stem cell and clinical trial materials for companion animal treatments. The animal vaccine market is anticipated to be one of the strongest growth areas in the coming years within Animal Health, with an anticipated compound annual growth rate of between 5.8% and 9.3% depending on the report (phon). The growth of the veterinary vaccines market is propelled by the increase in livestock population and repeated breakouts of livestock diseases, increasing incidents of zoonotic diseases, initiatives by various government agencies, and the introduction of new vaccine types, many of which now require cryogenic temperatures.

Additionally, Cryoport has seen a significant increase in the manufacture and distribution of stem cell for companion animal use. In the veterinary field, the mesenchymal stem cells isolated from bone marrow or adipose tissue through minimal manipulation have been applied for treating tendon, ligament, and joint diseases with significant clinical relevance in horses and dogs, in orthopedic conditions. In fact, Cryoport is currently supporting multiple new vaccines and treatments in the clinical space, such as VetStem's programs, that may lead to commercialization in the coming years.

In the Reproductive Medicine space, space Cryoport has observed continued maturation of the domestic demands for IVF transportation, as observed by an increase of 52% in our US revenues from this market. We believe that much of this increase is due to our evolving relationships with many of the fertility clinics within the United States, new service offerings such as our new CryoStork Next Flight Out options, and effective marketing outreach. The name Cryoport is becoming synonymous with reproductive transportation with many of our clients requesting a Cryoport for transport, not a cryo shipper.

Internationally, the reproductive tourism and surrogacy markets are still complex and create risks such that many individuals are refraining from utilizing them. Until governmental regulations are well understood in key reproductive tourism markets, we anticipate the international markets to remain soft.

Within Biopharma, Cryoport remains focused on maintaining its position as the cryogenic cold-chain logistics leader within the regenerative therapy space, one that continues to rapidly change and mature. Within the most recent quarter, Kite Pharma announced that it has completed its rolling submission of it's

BLA for Axi-Cel, previously known as ZUMA-1, as a treatment for patients with relapsed or refractory aggressive non-Hodgkin's Lymphoma, or NHL, or ineligible for autologous stem cell transplant, or ASCT. Novartis also announced that the FDA has accepted the Company's BLA and granted Priority Review for CPLO19, an investigational CAR-T therapy in relapsed and refractory pediatric and young adult patients with B-cell acute lymphoblastic leukemia, as well as FDA Breakthrough Therapy Designation for the treatment of adult patients with relapsed and refractory diffuse large B-cell lymphoma, or DLBCL.

Cryoport is very active in client engagement in this space and is recognized as a critical component to successful implementation of both clinical and commercial launch strategies. In the current quarter, we added 27 new biopharma clients as well as 14 new clinical programs, expanding the number of clinical trials we support to 139, which include 17 Phase 3 trials. I would like to make clear that 139 is a net number, as four programs failed or were suspended in the first quarter as well.

The growth in the regenerative medicine space continues. The Alliance for Regenerative Medicines recently reported that as of the end of the first quarter, there were a total of 855 clinical trials in the generative medicine space, up from 804 at the end of 2016. Another good sign is that $2.5 billion was invested in the space during the first quarter of 2017 alone, which is a significant amount when you consider that the entire amount invested in all of 2016 was $5.1 billion. Cryoport is now actively supporting multiple commercial programs, is the main primary cryogenic logistics partner for three late Phase 3 commercial track programs, all of which anticipate commercialization, if approved, within the current fiscal year and anticipates BLA filings for an additional two to four Phase 3 programs within our current portfolio over the next year.

As mentioned previously, in addition to the regenerative therapy space, Cryoport has been very successful in landing large pharma support projects for global biologics manufacturing. We have recently been awarded two global program support contracts from top-10 pharmas in addition to the projects already supported. Both projects wins entail the large pharma client dissolving their own cryogenic fleet and shifting all shipping over to Cryoport. These will ramp throughout the current fiscal year. Cryoport anticipates additional program adds in this space in the coming months and quarters as market awareness of Cryoport develops.

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

Jerrell W. Shelton:

Thank you, Mark. For our financial report for this quarter, I'd like to call on our Chief Financial Officer, Mr. Robert Stefanovich. Again, please hold your questions for Robert until the question-and-answer period. Robert?

Robert S. Stefanovich:

Thank you, Jerry. Good afternoon, everyone. I will now review our quarterly results and then turn the call back to Jerry. As a reminder, we recently changed our fiscal year-end to December 31, so we are now reporting on our first quarter of both fiscal and calendar year 2017. For the quarter, net revenues increased by $1.2 million or 74.4% to $2.7 million for the three months ended March 31, 2017, as compared to $1.6 million for the three months ended March 31, 2016. This increase was primarily driven by the continuing increase in the number of biopharmaceutical customers utilizing our services and frequency of shipments compared to the same period in the prior year.

Revenue in the Biopharma market increased by 100% over the prior year, to $2 million for the three months ended March 31, 2017, driven by an overall increase in the number of clients utilizing our solutions complemented by growth from our current clients. We added 14 new clinical trials during the first quarter. As I have emphasized on our last call, this increased activity in the clinical trial space is

building a pipeline of commercial candidates, and is expected to drive future revenue growth as these clinical trials advance and resulting therapies are commercialized.

Revenues in the Reproductive Medicine market was up by 26% over the prior year and increased to $418,000 for the three months ended March 31, 2017. This increase was driven by revenue growth in the US market by 52%, and was partially offset by a 12% revenue decrease in the international markets year-over-year.

Our revenue in Animal Health increased 28% to $272,000 for the quarter compared to the same period in 2016. This was driven by the on-boarding of several new clients in this market. While our primary sales and marketing focus is directed towards the Biopharma market, both Reproductive Medicine and the Animal Health markets are solid markets with good growth potential for Cryoport.

Gross margin for the three months ended March 31, 2017 was 46% or $1.3 million as compared to 37% or $582,000 for the same period in 2016. This increase in gross margin by almost 9 percentage points was primarily due to the economies of scale from the increased business volume coupled with pricing adjustments. Operating expenses decreased 6% or $183,000 for the three months ended March 31, 2017, as compared to the same period in 2016. Sales and marketing expenses decreased $107,000 or 14% primarily as a result of a reduction in outsourced marketing consulting and reduced recruiting and related fees compared to last year's first quarter.

General and administrative expenses decreased by $111,000 or 6% compared to the same period of 2016, primarily due to prior year charges resulting in our decision to co-develop and outsource certain manufacturing functions. Engineering and development expense increased by $105,000 or 73% for the three months ended March 31, 2017, as compared to the prior year quarter. Development efforts were focused on further enhancing the functionality of our SmartPak II Condition Monitoring System and designing and validating additional new primary and secondary packaging solutions and accessories in response to requests from our clients.

Interest expense decreased $66,000 for the three months ended March 31, 2017 as compared to the same period in 2016 due to a decrease in the amortization of debt discount from related party of (inaudible) signals. Net loss attributable to common stockholders for the three-month period ended March 31, 2017 was $1.8 million or $0.10 per share compared to $2.8 million or $0.26 per share for the quarter ended March 31, 2016.

Adjusted EBITDA for the first quarter ended March 31, 2017 was a negative $867,000, a reduction of 51% compared to a negative of $1.8 million for the same three-month period in the prior year. We've reported $14.5 million in cash and cash equivalents as of March 31, 2017, compared to $4.5 million for the fiscal year ended December 31, 2016. As Jerry mentioned earlier, on March 31, 2017 we completed an underwritten public offering for net proceeds of $11.4 million using the formal (inaudible) registration statement that we filed with SEC earlier this year. This strengthened our balance sheet and allowed us to remove the growing concern language included in our previous filings with the SEC.

Lastly, we filed our Form 10-Q for the three-month period ended March 31, 2017 with the SEC today.

With that, I'll turn it back to Jerry for questions.

Jerrell W. Shelton:

Thank you, Robert. Before my closing comments, I'd like to turn the call back to the Operator for questions.

Operator:

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

The first question comes from Sean Hannan with Needham & Company. Please go ahead.

Sean Hannan:

Yes, thanks very much for taking my questions here. Nice job in terms of the revenues through the quarter and overall results. It's nice to see the story emerging here. First question I have is really coming out of the equity offering. Can you elaborate a little bit on the use of the cash in terms of the timing of how you'd expect that to be used through the year, and then part B to that, any updated color in terms of the potential, say, for a staging facility versus perhaps establishing a beach-head at some of your clients, don't know what the current thoughts might be around that as well as how you're evaluating the economics of one versus the other? Thanks.

Jerrell W. Shelton:

Robert, you want to take that?

Robert S. Stefanovich:

Yes. So, just a few comments. In terms of the raise itself, as I think everyone listening is aware of, we've done a lot of work in bringing on clinical trials with 17 being in Phase 3. Two have filed the BLA so they're getting ready, if successful with the BLA, to launch commercially. With that, there's certain requirements for us to build up our fleet of shippers, of SmartPak Condition Monitoring Systems, and increase the overall infrastructure to handle the increases and need for our solutions going forward. So, that's really a main part of the use of proceeds.

The other part is really strengthening our balance sheet, eliminating the growing concern coming from our financial statements. We're working with multi-billion-dollar life science companies and they expect a company and a partner with a strong balance sheet.

To your second question, Sean, just related to setting up operation centers and co-locations, these are active discussions that are ongoing. We do have plans and setting up an Eastern operations center. We're looking at Europe as well, and in terms of discussing the needs of our clients as they get ready to commercially launch, certainly those include discussions of potentially having a facility or an operation center within their site or co-located next to their site.

Sean Hannan:

Okay, that's helpful, and then in terms of the programs that you're supporting today, for the trials that you're currently, say, in a Phase 2 or 3, to what degree are you getting insight or feedback from your clients in the progression of those therapies? For example, one of the sales, I think, coming out of a Phase 3, is that something that you had perhaps some inkling of in supporting that client? Just trying to understand, as you think about what's on the horizon for you particularly as we transition from one phase and graduate to the next, how much insight you actually have around that in close dialogue with your clients?

Jerrell W. Shelton:

It's a good question, John, and I am going to turn to Mark Sawicki to answer that question.

Mark W. Sawicki:

Sure, happy to answer it. So, one of the things we do as we develop our relationships with our clients is that we work with them very closely to understand, A, what the client enrollment schedules look like. We actually get full projections in regards to patient enrollments, what the timing of that patient enrollment is, and ultimately, launch projections of patient dosing and other things. That doesn't mean they're always exactly accurate but we do get that information regularly from our clients. In fact, it's something that we need from a planning standpoint because we have to ensure that we have the capital equipment in place to support the projected volumes, in particular on a global basis. So, it is something we look at very closely with all of our clients.

Sean Hannan:

Okay. That said, and as you think about your own internal planning, if we're expecting incrementally maybe another three to four BLAs filed this year based on progress relevant to those trials, is there insight or what color can you share in terms of working that into 2018, how that could be potentially set up?

Jerrell W. Shelton:

From which perspective? The number of commercial relationships we believe we'll have in a year?

Sean Hannan:

The ability to see your clients progress to BLA filings.

Jerrell W. Shelton:

Yes, I mean, all of—our expectation, as Robert had said on the call, that we're already in the process of supporting two BLA PAI launch programs and activities. We anticipate up to another between two and four through the end of this year. That's based on our clients projections at this point in time.

Sean Hannan:

Sure, and I had gotten all that. What I was asking about was '18.

Jerrell W. Shelton:

Oh, '18. I think, '18, ultimately we're going to see product line expansion, so the initial launches are in many cases for very narrow product—or indications, and so I think we'll see secondary and tertiary filings on a number of these and we do anticipate additional filings in the 2018 time frame as well.

Sean Hannan:

Okay.

Jerrell W. Shelton:

Can't give you a number at this point but, yes, our expectations will be additional filings.

Sean Hannan:

Sure, understood, and that's helpful, and then a question is posed for Robert. As we think about in context of the two trials that already have some filings in process, the expectation that we could see some special commercialization by the end of this year. As we think of that, any changes, nuances that would have an influence on your ability to reach an effective cash breakeven at some point there in the fourth quarter or how do we think about that from where we stand today? Thanks.

Jerrell W. Shelton:

Yes, I think our positioning really hasn't changed. We're working with clients in a very new market so in terms of the timing of these commercial launches, and this will obviously generate gradually an increase in revenues, but we don't have certainty on the timing. But we do have a significant pipeline and book of business with existing clients in Biopharma with Phase 3 clinical trials, so expect our base business to grow and then obviously as we have these commercial launches, if they're expedited and if they're as successful as some of them have articulated to their investors, then you'd see a faster ramping revenues and that would take us to a quicker pathway to cash flow breakeven.

Sean Hannan:

Okay, and then last question here, we obviously took an initial take at trying to think about how your business scales over the course of the next few years. There's clearly a lot that's going to be moving around and particularly our assumptions, even as we progress through 2017 here, but in a general conceptual manner, can you talk a little bit about how you'd to expect to scale your op ex as you grow your revenues? Ultimately this—you're going to start generating some decent profitability down the road, obviously the revenue side of the story is a huge chunk of the equation right now, but just trying to understand then a little bit more insight around the op ex around that. Thanks so much.

Robert S. Stefanovich:

Well, Sean, as we grow and our balance sheet gets stronger, we'll use all the tools available to us. We'll use—certainly, we'll use equity. We'll use our retained earnings. We'll use debt instruments. So, our—we'll be intelligent about that. We're not going to overextend ourselves and jeopardize the Company but we're also going to be prudent and we definitely will use leverage as it's appropriate in the future.

Jerrell W. Shelton:

Yes, and maybe just to add to that, as I've said before, this is a very technology-centric company and business model. So, as we grow and as our revenue streams grow, you'll see more efficiencies of scale. Having said that, there are some investments related to setting up operations centers and expanding from an operational perspective. You should also expect that we'll continue to be driving innovation within this industry. When you look primary and secondary packaging, you look at further enhancements of our SmartPak Condition Monitoring System in our software. So, there will be additional expenses related to really strengthening our position in this market space and continuing to be the leader in this market for cryogenic shipping solutions.

Sean Hannan:

Okay. Some of that sounds like spending that's going to be more of a cap ex spend. What I was trying to get a sense of is how are, say, SG&A costs, ramp and ultimately, if I have interpreted some thoughts correctly, you folks have a target model at some point in time down the road where you can get to certain op ex levels, whether that be 30% or some framework around that. Any color or commentary on how to think about that as a target model?

Jerrell W. Shelton:

Well, I think if you look at the operating expenses and, rightfully you noted, look at use of proceeds, we are building up our fleet and the infrastructure. If you look at the regular SG&A expenses you'll see some increase just in increasing our presence, also our sales and marketing presence outside of the US as well as further building our organizations here in the US, but it's not a substantial, immediate increase. This is over time and where you'll see some increase in sales and marketing expenses. On the general and administrative expenses, those should be fairly moderate.

Sean Hannan:

Thanks for taking my questions, folks.

Jerrell W. Shelton:

Thank you for the questions, Sean.

Robert S. Stefanovich:

Thank you.

Operator:

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

Brian Marckx:

Hi, guys. Congratulations on the quarter, pretty impressive. You guys have done a very good job of turning the business north. That Q1 certainly speaks to that, and my first question relates pretty much to that. So, you guys have had a lot of success in building a clinical trial support database over the last, say, 12 to 18 months, and prior to that, I guess it was a little bit longer of a slog, I guess. So, wondered if you could just provide a little bit of insight in terms of, what is the kind of the catalyst, do you think, do you see as—in accelerating the number of clients that you brought on recently, is that direct sales efforts? Is it just kind of fundamental to the regenerative medicine space in terms of growth? Is it something else, just sort of, I guess, a broad view of that. That would be great.

Jerrell W. Shelton:

Yes, Brian. I'm going to turn it over to Mark because Mark is an integral part of the leadership in that endeavor and as I mentioned a couple of earnings calls, we repositioned ourselves a couple of years ago and we finally gained enough strength that we could adjust our strategy to clinical trials and we made enormous progress and there's a long, long way to go ahead of us. Mark, do you want to take over?

Mark W. Sawicki:

Sure. Fundamentally, it's a very, very simple proposition. The Company has some very unique technology and informatics that lend itself to conveying scientific advantage, and what we did was we repositioned and reestablished our messaging to, in essence, sell against the scientific platform versus a transactional logistics approach, and at the end of the day, that resonated. We went, 2.5 years ago, from seven clinical programs to over 140 and it's largely due to being able to effectively educate our client base as to how we contribute to their scientific achievements and support them and minimize risk.

Brian Marckx:

Yes, that's helpful, Mark. Then, how much, if it all, is it somewhat of, I guess, a self-fulfilling prophecy, for lack of a better term, or kind of a snowball effect that you've built so many clients over such a period of time and can use that to market forward in terms of validation of what you do? Is it—do you see that kind of, sort of a momentum effect?

Jerrell W. Shelton:

Yes. I mean, it gives us inertia, right, so in the market place, we now have inertia based on our acceptance within a set demographic of the biotech community, but we're not resting on those laurels. If you listen to our earnings call, one of the statements I made is that we're starting a push into supporting a broader biologics footprint and that sits on the same message, fundamentally, which is our ability to manage risk from a scientific perspective. So, we expect to start to be able to continue to accelerate our progress in the marketplace but broaden our reach beyond regenerative therapy, significantly.

Brian Marckx:

Okay. If I could chip to the commercialized support and, I guess, what are the expectations in terms of when you would know more from your clients in terms of what their expectations are for your ability to support and what the—essentially, what the requirements would be to support their product and when those discussions would be finished I guess.

Jerrell W. Shelton:

Well, honestly those discussions have been ongoing for well over 18 months. We're working hand in hand with them through their processes of their filings and their regulatory approvals processes. So, it's kind of business as usual for us. There is no surprises here. We understand what is required of us. We're working kind of very carefully and closely with them to ensure that they are able to have a successful product launch. It's pretty straight forward.

Brian Marckx:

Okay. All right, guys. Thank you.

Jerrell W. Shelton:

Thank you.

Operator:

The next question is from Greg Kitt with Pinnacle Fund. Please go ahead.

Greg Kitt:

Hello. Thank you for taking my questions.

Brian Marckx:

It's no problem.

Greg Kitt:

Congratulations on a great quarter. I was excited to hear gross margins were extremely impressive and the progress that you made on cash used from operations was impressive as well. I was wondering if you could—I have a couple of questions. I was wondering if you could just talk to the gross margins in the quarter and if there is a multiple year trend you can point to, that would be very helpful. Thank you.

Jerrell W. Shelton:

Greg, that's a question we get a lot and as we stated before, our gross margin target is 60% and our operating margin target is 30%. So, to put a little color on that in terms of the build-up and how we get there and so forth, I'll turn it over to Robert Stefanovich.

Robert S. Stefanovich:

Yes, Greg. Just a few comments. We talk about the business model overall, we look at gross margin, we've already seen significant improvements year-over-year and it's really driven by a number of things; one, in terms of how we price our solutions and it's really a fee-for-service value-based pricing. The other part is we're continuously making changes in terms of our processes, in terms of the equipment we use and with that we continuously look for efficiencies of scale and so you'll continue to see that as we move forward and expand our solutions and expand the volume of transaction. But really, there is two parts that are driving the improvement in gross margins; one is really the pricing of our solutions and the expansion of our revenues streams; the second part is really when you look at how we deliver our solutions and how we integrate efficiencies in that process and materials we use.

Greg Kitt:

Great. Thank you. That's helpful. The other question I had was on BLA filings. You've talked about the two that you've already won and I believe that I heard on the call there's potentially three to four more BLA filings coming later this year. Could you—is there any reason that those additional BLA filings would be different in size from the two clients that you're currently working with, if those products are approved?

Jerrell W. Shelton:

There certainly is a variance. Mark, would you like to speak to that?

Mark W. Sawicki:

I think it's pretty straight forward. Yes, I mean, there is a variance. It all depends on the indication that these particular therapies are moving towards. If we look at the portfolio, some of them have broader applications than others. I would anticipate, of those you'll see a couple of small patient subsets and one or two of them probably even have larger subset than the two that we're currently moving forward to support. But I can't really elaborate more than that at this point.

Jerrell W. Shelton:

Greg, you can look at the websites of these companies and see patient populations in many cases and that sort of thing, but it is variances, as Mark just described, and we can't go too much farther in terms of speculating on what they might look like.

Greg Kitt:

Perfect. Okay, thank you, and to me, when I think about this story, I think this is a really exciting time for your Company. You've spent multiple years building up for this ramp and now you're kind of at the door

step with—you could—we shouldn't probably expect that those additional three to four BLA filings, that all those will have positive Phase 3 data and that those will all be approved because that's—but if we exit this year potentially with maybe four approved BLAs that could be commercial products, it just seems like it would be a really exciting time for your Company as we look forward the next two or three years.

Jerrell W. Shelton:

Well, that's certainly the way we see it, Greg.

Greg Kitt:

Thank you, and congratulations.

Jerrell W. Shelton:

Thank you.

Operator:

The next question comes from Len Yaffe with Stoc*Doc Partners. Please go ahead.

Leonard Yaffe:

Thank you very much, and I apologize, I was a little late to the call so if this has been already addressed, feel free to pass but I've just come from several immunotherapy conferences and what I've noticed is the incredible excitement by the part of physician community as well as Kite and Novartis for the introduction of what may be immunotherapies over by the end of this, early next year, and their recognition of the importance at the whole cryogenics logistics process and I was wondering a couple of things; one of the thinkings that was being proposed was that there's a set of patients that's a little bit like what we saw with Hep-C, that are going to be awaiting this therapy as docs become more aware of it and so initially following approval for (inaudible) company, whenever it happens, there may be significant bolus of patients to be treated. It could then quiet down as we see how it does and then maybe ramp up some more if the results are good. But I was wondering if you could discuss the capacity that you have in terms of supporting an initial launch of such a product and if you have any indications that suggest things could progress along that methodology. Thank you so very much.

Jerrell W. Shelton:

Yes, Len, being a doctor, you know these companies are going to be very careful in the introduction and the way they introduce these products and they have specific timelines and specific launch programs that we will be following. Mark, would you like to comment further on that?

Mark W. Sawicki:

Yes, I mean, if you look at their filings, most of them are launching against very narrow indications, so with small patients populations and so the data that we have is obviously in conjunction to support those launches but there is a lot of contingencies being made behind the scenes to support any sort of rapid adoption into some of the other indications that are being actively pursued so that if their rollout is stronger than anticipated, we'll easily be able to support any of those volumes. We've put a system in place, within our Company, from a scalability standpoint, that was built to be able to structurally support some of these allogeneic therapies which would have hundreds of thousands of doses a year distributed, not tens of thousands or thousands, so we feel very comfortable on our ability to scale in an expeditious manner to support any given product launch.

Leonard Yaffe:

Great. Thank you so very much.

Jerrell W. Shelton:

Thank you, Len.

Operator:

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

Jerrell W. Shelton:

Thank you, Operator, and I would like to extend my thanks to all of you for listening in today. We're happy you took the time to join us in our earnings call and we're pleased with our progress this quarter. We're looking forward to the prospects ahead of us in 2017 and beyond. Thank you very much.

Operator:

This concludes today's conference call. You may disconnect your lines. Thank you for participating and have a pleasant day.