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CDNA - Q1 2015 CareDx Inc Earnings Call

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PRESENTATION

Operator

Good day, ladies and gentlemen. Welcome to the CareDx 2015 Q1 Financial Results Conference Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session and instructions will be given at that time.

(Operator Instructions).

As a reminder, this conference call is being recorded. I would now like to turn the conference over to your host, Leigh Salvo with Investor Relations, you may begin.

Leigh Salvo - ***Westwicke Partners - IR***

Thank you for participating in today's call. Joining me from CareDx are Peter Maag, President and Chief Executive Officer; and Ken Ludlum, Chief Financial Officer.

Earlier today, CareDx released financial results for the quarter ended March 31, 2015. The release is currently available on the company's Web site at www.caredx.com.

Before we begin, I would like to remind you that management will make statements during this call that includes forward-looking statements within the meaning of federal securities laws, which are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

Any statements contained in this call that are not statements of historical facts should be deemed to be forward-looking statements. All forward-looking statements, including without limitation, our examination of historical operating trends, and our future financial expectations are based upon our current estimates and various assumptions. These statements involve material risks and uncertainties that could cause actual results or events to differ materially from those anticipated or implied by these forward-looking statements. Accordingly, you should not place undue reliance on these statements.

For a list and description of the risks and uncertainties associated with our business, please see our filings with the SEC. CareDx disclaims any intention or obligation except as required by law to update or revise any financial projections or forward-looking statements, whether because of new information, future events, or otherwise. The conference call contains time sensitive information and is accurate only as of the live broadcast today, May 12, 2015.

I will now turn the call over to Peter Maag. Peter?

Peter Maag - ***CareDX - President, CEO***

Thanks Leigh. Good afternoon, everyone. Last week we spent with Alli, a heart transplant patient who has been short of breath throughout her childhood and was diagnosed with congenital heart disease at the age of 19 when someone finally checked her heart beat and realized that her heart rate was somewhere between 20 and 30.

She was put on the waiting list, and it took another seven years until she got a heart transplant. Five years later, Alli is full of life and continues to inspire people around her, including CareDx and many donor awareness campaigns in which she is active. Ally has benefited from AlloMap in her surveillance management.

I would like to start this call with a summary of our first quarter highlights and talk about our growth drivers and then our performance towards our strategic goals. I will then ask Ken to dive deeper into the financials for the first quarter and our guidance for 2015. And then we look forward to your questions.

Now, starting with our first quarter financial highlights, revenue was $7.2 million in the first quarter of 2015, a 22% increase over the first quarter of 2014. We also increased our cash balance by $2.6 million to $39 million through refinancing our term loan, which puts the company in a solid financial position.

To recap our three primary strategic objectives, and they are number one, increase the utilization of AlloMap; two, develop cell-free DNA test in transplantation; and three, add momentum through realizing inorganic growth opportunities. I'll spend the next few minutes providing some of the highlights we achieve towards meeting each of these objectives during the quarter.

Now starting with AlloMap, we saw continued increase in adoption of AlloMap, a blood-based test used to monitor heart transplant patient recipients for the risk of cellular rejection. In the first quarter, AlloMap was used for heart transplantations approximately 3,100 times, representing an increase of 11% versus the first quarter of 2014.

Given that we have a concentrated customer base, changes in a few centers make a difference, and the weather conditions in Q1, might not have been favorable for routine surveillance visits. Our team's continuous focus is on driving volume growth. I'd like to highlight for you how we are doing that. We continue to grow the number of centers adopting our technology through formal protocol development.

Out of the 129 transplant hospitals in the U.S., AlloMap was used in 115 during the last 12 month. As of the end of the first quarter, there were 58 centers with established AlloMap protocols, up from 48 in the previous quarter, which means that almost half of the heart transplant centers in the U.S. now have a formal AlloMap protocol.

In order to further penetrate the market, we will continue to focus as -- we will continue to follow a center by center approach and develop specific programs that allow us to further demonstrate the benefits of increasing AlloMap usage in monitoring the health of heart transplant recipients, thereby helping clinicians make personalized treatment decisions for their patient’s long-term care.

Commercial excellence in execution is critical for the success of CareDx. We have appointed Josh DeFonzo to the CareDx leadership team as our Chief Commercial Officer driving our AlloMap patient access and customer engagement strategies by providing an integrated solution.

Driving fully coordinated stakeholder engagement, managing the establishment of and adherence to protocols, as well as supporting transplant centers and optimizing their workflow will be the focus for Josh and the team in 2015. Josh brings more than a decade of specific sales and marketing experience in the life sciences. He joined us last fall from Endogastric Solutions where he led the execution of their commercial strategy. We look forward to his contribution to our organization.

Now let me update you on reimbursement and coverage. On the reimbursement front we continue to have positive coverage decisions from all the major carriers and accomplishments that few other diagnostic companies can claim.

As of March 31, 2015 we had been reimbursed for approximately 80% of all AlloMap results delivered in the 12 month ended September 30, 2014. This notched up slightly this quarter from previously 79%. AlloMap is broadly reimbursed in comparison to other high value molecular diagnostic offerings. We continue to expect reimbursement to remain in this range going forward.

In following the progress of our pipeline activities, it is most important to follow the progress of our clinical trial. We have two studies in heart underway. Our outcomes AlloMap Registry Study or OAR and our Cell-free DNA Outcomes AlloMap Registry or D-OAR, and now we have the DART study, cell-free DNA in kidney which I will highlight in a minute.

Starting with OAR, we continue to see growing enrollment. Almost 1,300 samples from 436 patients enrolled in the study were received from 16 centers as of March 31st. The long term outcome data collected will continue to build clinical evidence for the use of AlloMap as a surveillance solution in heart transplant recipients.

The cell-free DNA component of the study has been launched in eight centers with 64 patients enrolled, and we have collected 118 samples as of March 31st. You will note that we have added five centers in this quarter which is terrific progress given all the other things that were going on this quarter. With increasing awareness in the heart transplant community and large centers entering the trial, we expect to see patient and sample numbers continue to increase.

Awareness of cell-free DNA and the reputation of CareDx in this area continues to grow. The relevant scientific congress for the heart transplant community is the International Society of Heart and Lung Transplantation, ISHLT.

In early April, we had a significant presence at the annual meeting. CareDx had nine abstracts accepted, including three abstracts on our OAR registry study, three on cell-free DNA, and three investigator initiated abstracts on long-term outcomes and immunosuppressant optimization with AlloMap.

I should note that the three cell-free DNA abstracts were selected as oral presentations, a measure of the interest in this area by ISHLT. Our company sponsored lunch symposium had stellar attendance with tremendous audience participation.

Since the meeting was held in Europe, we had two leading heart transplant cardiologist covering the two continents as our Chairs: Dr Kobashigawa from Cedars Sinai. LA and Dr. Schulz from Bad Oynhausen in Germany.

The presentation highlighted several key updates including surveillance that AlloMap continues to attract clinical interest in early use after transplantation. We had previously reported on the publication in the medical journal circulation. We were also interested to see the reports on AlloMap used in the context of CMV infection as well as its utility in immunosuppression optimization.

As AlloMap has been widely adopted, it is great to see clinicians discussing the clinical utility of the test in a high profile transplant study. The emerging utility of cell-free DNA as a biomark in transplantation which was studied using CareDx's CARGO II blood samples showed correlation with organ rejection.

This data is important as the data reconfirms cell-free DNA as the biomarker for rejection. Following the single center work from Dr. Vlaminck, Quake, and Khush from Stanford. The described multicenter study is a confirmation of the relevance of the approach and extends our understanding of this clinically relevant biomarker.

We also demonstrated in this study that there is significant added value in the combination of AlloMap and cell-free DNA. Since the test focused on the two different underlying pathophysiologies of the transplant. One, AlloMap serving as a marker for the immune system of the patient and two, cell-free DNA serving at the marker for sell injury of the donated organ.

The test compliments each other. This is not always the case with biomarkers, but our data demonstrates this benefit. In addition, clinicians appreciated the value of not having to separately genotype the donor and the recipient, greatly simplifying the implementation of the test in the future.

We continue to make cell-free DNA available for heart clinicians as a research use, only test in combination with AlloMap through our D'OAR Registry Study program. Following quickly on the heels of ISHLT was the American Transplant Congress in Philadelphia last week, we were delighted to have three key opinion leaders highlighting the emerging impact of CareDx Technology on the future of clinical practice. Our presence at the Congress marks our entry into a billion dollar kidney market surveillance opportunity with 300,000 patients waiting for better personalized treatment option.

I can't tell you how excited we are that we are up and running on our DART study which uses circulating donor derived cell-free DNA for diagnosing rejection in kidney transplant recipients. The Cleveland Clinic with Dr. Poggio recently enrolled the first patients in this study. DART, as an observational study is designed to demonstrate the clinical performance characteristics of circulating cell-free DNA, detecting clinical and sub-clinical rejection in kidney allograft recipient.

The study is also designed to demonstrate the correlation of circulating cell-free DNA to renal function using both serum creatinine levels and estimated glomerular filtration rate. In the first phase of the DART study we expect to enroll 200 patients and at least six centers and collect blood samples from patients over a period of 18 months.

We anticipate an interim readout in the first half of next year. The timing is mainly driven by the number of blood samples that are associated with clinical events especially rejection. The team is laser sharp focused on engaging centers and recruiting patients into the draft.

Now let me turn to an update on our partnerships. In collaboration with Diaxonhit, our European commercial partner we continue to make good progress with the University of Strasbourg in France to establish it as our promotional AlloMap lab in Europe. In addition, the French Ministry of Health has approved funding for a multi-million dollar initiative that will allow 15 transplant centers in France to use AlloMap to monitor their transplant patients.

We consider this an important milestone in our progress to introduce AlloMap in Europe. However, we continue to expect only a modest contribution of ex-U. S. sales in 2015. In summary, we are off to an exciting start to 2015. Our AlloMap continues to provide a solid base of revenue for business.

In addition, we are advancing kidney product developments using our cell-free DNA technology which has the potential to become a new diagnostic alternative for kidney transplant recipients.

I will now turn the call over to Ken to review our financial highlights and to provide guidance for the year.

Ken Ludlum - ***CareDX - CFO***

Thank you, Peter. Starting with revenue in the first quarter, revenue was $7.2 million, up 22% from the first quarter of 2014. Note that 98% of that revenue was from U.S. AlloMap usage. The cost of testing in the first quarter was $2.7 million compared to $2.2 million in the first quarter of 2014. This was also up 22%, so the increase was generally in line with a higher AlloMap revenue.

However, this quarter was affected by some write offs of some expired consumables used in AlloMap testing. This is a quarter specific event and I expect ongoing cost of testing to be in line with expectations going forward.

R&D expense is $1.4 million in the first quarter compared to $720,000 in the first quarter of 2014. As expected, higher R&D expenses reflect initiation of our cell-free DNA program as it moved beyond the initial development stage and into the enrollment in a cell-free DNA study in kidney.

Sales and marketing expenses for the first quarter were on plan at $2 million compared to $1.5 million in Q1 2014. This line item increased mainly due to increased overall marketing and also to a Congress presence in the first quarter of the year and the travel expenses associated with that.

G&A expenses were $2.7 million for the quarter, an increase of $900,000 over the $1.8 million we spent in Q1 of last year. This increase is entirely due to yearend audit and legal fees for a public company all recognized in the first quarter of this year and the increased expenses and personnel needed to run a public company.

Regarding our contingent payment line item in operating expenses, the change in our stock price over the quarter made the estimated value of the stock payment to ImmuMetrix shareholders a bit lower. This is the company we acquired in June of 2014, and this expense item dropped by roughly $250,000. This payment is payable all in stock and reflects the change in accounting estimate only. There is no cash involved in this expense item.

Interest expense of over $800,000 was higher this quarter due to the final payments and cost of terminating our previous loan. Interest expense should go back to a level of roughly $200,000 per quarter in future quarters. This payment this past quarter was a onetime termination payment and added about $0.05 per share to overall expenses.

The first quarter 2015 net loss was $2.2 million compared to a loss of $1.3 million for the same quarter in 2014. Our EPS was a loss of $0.19 per share in Q1 of this year versus a loss of a $1.29 in Q1 of 2014. The shares outstanding for the quarter were at $11.8 million versus only roughly $1 million in last year's first quarter.

Turning to the balance sheet, at the end of the first quarter we had $39 million in cash and cash equivalents versus $36.4 million at December 31, 2014. This difference reflects a modest operating cash burn of $1.4 million in the quarter, offset by net new proceeds of $4 million from the new loan facility put in place in January. This new loan lowered our interest cost from almost 10% to just over 5% per year, eliminated back-end termination and pre-payment penalties, had less covenants and can be increased in size in the future.

Now turning to guidance for the full year of 2015, we continue to expect revenue to be in the range of $28 million to $30 million. I will now turn the call back to Peter for a few closing remarks.

Peter Maag - ***CareDX - President, CEO***

Well, we had a busy Q1 at CareDx with AlloMap growth and major advances in our pipeline and addition of great talent to the organization. Thank you for your time and listening into this call. With that we'd now like to open the call up to question. Operator.

QUESTION AND ANSWER

Operator

(Operator Instructions).

Our first question comes from the line of Bill Quirk of Piper Jaffray. Your line is now open.

Alex Nowak - ***Piper Jaffray - Analyst***

Great, thanks. This is actually Alex Nowak in for Bill tonight. When do you expect to receive -- expect the OAR trials and the DOR trials to actually end and when do you expect the first data to read out for those?

Peter Maag - ***CareDX - President, CEO***

Alex, thank you very much for this good question. The OAR and the DOR trials are actually set up as registry trials. So we will have them ongoing as long as we provide AlloMap and cell-free DNA going forward.

Initial read-outs have actually been provided at the ISHLT last year and even at this year there were a number of great news following the OAR and DOR registry. So think of this as an ongoing wealth of information coming out of the observational studies that we are doing on this registry trial.

Alex Nowak - ***Piper Jaffray - Analyst***

Okay, now that makes sense. And then I know I am looking well into the future with this next question, but with the DART 2 - well, for the DART 2 study, when do you expect initial enrollment and maybe the initial data readout?

Peter Maag - ***CareDX - President, CEO***

The initial data readout of the DART 1 study, we have guided in this call in about the first half of next year. As soon as we have the interim results of the DART 1 trial, that would be a good time to think about the start of the DART 2 trial with potential readouts then to be communicated at a later stage. Right now we are very focused on this interim readout analysis on H1 next year which will give us the confidence to start our DART 2 trial which then will be an interventional trial.

Alex Nowak - ***Piper Jaffray - Analyst***

Okay, great and then last question from me for cell-free DNA heart filling into an actual analytical test versus just a research use only test. I believe you are still looking for December 2015 and do you expect to launch any or publish any analytical studies or even clinical utility studies before launching that test, thanks?

Peter Maag - ***CareDX - President, CEO***

Alex, thank you very much. I think we have all along mentioned that with cell-free DNA we will piggyback that onto our AlloMap results. We are very excited that we demonstrate that AlloMap and cell-free DNA in combination have actually additive value.

So we'll continue to make that test available while we have not foreseen any formal launch in cell-free DNA in heart and have communicated the timeline on this, we'll continue to be in close conversations and discussions with key opinion leaders that are generating data and insights on cell-free DNA in heart.

Alex Nowak - ***Piper Jaffray - Analyst***

Great, thanks.

Operator

Thank you and our next question comes from the line of Nicholas Jansen of Raymond James & Associates. Your line is now open.

Nicholas Jansen - ***Raymond James and Associates - Analyst***

Hey, guys. I'd like to get a little more color on the strong revenue growth this quarter relative to the test volume growth that might have been impacted a little bit by the weather dynamics, it certainly seems like it might have been more the cash revenue, but just wanted to get a sense of what drove the out performance on revenue versus test volume growth? Thank you.

Ken Ludlum - ***CareDX - CFO***

Yes Nick, thanks for the question. So we had a better mix, there is two things we had a better mix of Medicare versus non-Medicare volume and Medicare volume is accrued right off the bat. And so when that mix favors Medicare that generates revenue in the quarter that the test occurred.

Secondly, we had a couple of accounts that converted from cash accounting to accrual accounting through becoming a roster account.

And then the third thing that generally we accelerated some of our cash payments on the general collection side, so there are really three factors: Medicare mix, conversion of couple of accounts to accrual basis, and better job on reimbursement team for collecting cash.

Nicholas Jansen - ***Raymond James and Associates - Analyst***

That's great color. And then secondly, regarding the significant increase in kind of the number of heart transplants have official protocols now, when we see an official protocol established what is the timeline for kind of adoption from the transplant doctors how do we think about once their official protocol, how does it usually impact general volumes over a period of time?

Peter Maag - ***CareDX - President, CEO***

Nick, thank you very much for that excellent question. I think well we've been very successful in establishing formal protocols and I think you are absolutely right that the next step is actually driving adherence to these protocols. That's why I mentioned in my call that we continue to follow a center by center strategy on those.

And we'll be updating on the volume growth going forward but really the establishment of protocols is a very strong basis for our strategy to drive volume growth going forward. The next thing is adherence to protocol and that's actually the biggest lever for us as a business and you will see that pull through, and be successful going forward based on the very strong adoption of protocols in these centers.

Nicholas Jansen - ***Raymond James and Associates - Analyst***

Thanks and then last one for me regarding kind of the international news that was discussed this afternoon on plans, just want to get a little background in terms of how those discussions evolved, how long did it take for you guys to kind of close this opportunity and what are the regions or countries in Europe are actively looking at AlloMap as a potential solution currently, thanks?

Peter Maag - ***CareDX - President, CEO***

Nick, again excellent question. I think we, as a company, have realized that having a very strong partner that helps us in the distribution of AlloMap in Europe is the right thing to do. And establishing, I've always called it a clone map in [Strasburg] is a very fundamental step for us to be successful.

Now if you have a partner and you have a lab, the third thing is reimbursement and there we go country-by-county. France is a national reimbursement decision, the same will be true for Germany, the same will be true for England and these are really the big transplant markets in Europe if you are adding Spain to it.

Spain is somewhat a little bit different because there you have regional reimbursement authorities and in Italy you actually have 25 different reimbursement authorities that you need to work with. Let's take this country-by-country as they come but clearly France, Germany, and Spain are the three countries to watch out for, for us to be successful.

Germany being the next one with a very centralized reimbursement process and we hope to be reporting on news, positive news going forward. ISHLT needs in Europe has given us the opportunity to make a big splash and having France adopting the test in 15 of their 25 centers is giving us very, very positive and news flow in Europe overall.

Nicholas Jansen - ***Raymond James and Associates - Analyst***

Great to hear guys, thanks for the color.

Operator

(Operator Instructions).

Our next question comes from the line of Peter Lawson of Mizuho, your line is now open.

Peter Lawson - ***Mizuho Securities - Analyst***

Hey Peter, on the DART 2 -- that push back I thought it was yearend event, now you are saying first half 2016?

Peter Maag - ***CareDX - President, CEO***

I don't think we are very consistent with reporting on the interim results in the first half of 2016. So we are consistent Peter there. It does take time to recruit these patients and then the interim analysis that we will be conducting requires a number of samples. So I think all along we've been communicating in the first half of next year.

Peter Lawson - ***Mizuho Securities - Analyst***

Got it, thank you and then how did that affect volumes in the quarter?

Peter Maag - ***CareDX - President, CEO***

Peter, it's very difficult to put a specific number to that. If you look at the overall competitive space we've been following on some on the earnings call there has been a number of companies that mentioned bad weather as a function. It is right that in a setting where surveillance visits occur in the transplant setting that in the North East there was heavy, heavy snow and impact.

But I think it's hard for us to measure that, so I did mention that in a half a sentence on the sideline that weather might have played a role but overall I think weather did play a role in the first quarter by how much I wouldn't be able to tell you and quantify.

Peter Lawson - ***Mizuho Securities - Analyst***

Got you and then just wonder if you could just talk through the commercialization plans for cell-free DNA.

Peter Maag - ***CareDX - President, CEO***

No I think there is no changes at all. I think we are piggy banking on to AlloMap, the cell-free DNA in heart and then we are laser sharp focused on cell-free DNA in kidney. So, kidney is a huge opportunity for us. There is a huge unmet medical need, we saw that at the ATC meeting, and so I think there is no change in terms of updating our commercial strategy on neither heart nor on kidney.

Peter Lawson - ***Mizuho Securities - Analyst***

Do you do any kind of pre-commercialization priming for the kidney opportunity?

Peter Maag - ***CareDX - President, CEO***

Excellent question, Peter. I think the DART 1 and then the DART 2 trial are the unique opportunity for the company to build these relationships with these transplant centers. And once they have adopted the test in a clinical study protocol, we would like to convert these type of tests then into a real testing opportunity.

When I am talking to kidney nephrologists, the kidney transplant nephrologists, they have a big unmet medical need in optimizing the immune suppressive therapy. And they do say that serum creatinine is a very, very old marker and a very late marker. So they would like -- they are looking for a new tool, and cell-free DNA might well be that.

Peter Lawson - ***Mizuho Securities - Analyst***

Great. Thanks so much.

Operator

Thank you, and I am showing no further questions at this time. I will hand over the call to Peter Maag for any closing remarks.

Peter Maag - ***CareDX - President, CEO***

Thank you very much, Nicole. Thank you, we look forward to updating you on our progress in the future and have a great evening. Thank you for joining the call.

Operator

Ladies and gentlemen, thank you for participating in today's conference. That does conclude today's program.