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PRESENTATION

Operator

Good day ladies and gentlemen, and welcome to the CareDx Third Quarter 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 today's conference is being recorded. I would now like to turn the call over to Leigh Salvo.

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

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

Earlier today, CareDx released financial results for the quarter ended September 30, 2014. The release is currently available on the company's website, www.caredxinc.com.

Before we begin, I'd like to remind you that management will make statements during this call that include forward-looking statements within the meaning of federal securities laws. Forward-looking statements can often be identified by the use of terminology, such as subject to, believe, anticipate, plan, expect, intend, estimate, project, may, will, should, would, could and can, or the negatives thereof, and similar expressions or by discussions of strategy.

All forward-looking statements including without limitation our examination of historical operating trends, our future financial expectations and statement about our test development and commercialization efforts are based upon our current estimates and various assumptions. These statements involved material risks and uncertainties that could cause actual results or events to materially differ from those anticipated or implied by these forward-looking statements.

These risks include without limitation, risks relating to our test development and commercialization, which is a long and complex process that may not be successful, regulatory requirements applicable to our current tests and solutions under development, continued market acceptance and adoption of our AlloMap test, competition, risk relating to reimbursement and risk relating to our intellectual property.

For a complete list and description of those risks and uncertainties, please see the company's filings with the SEC.

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

Peter Maag - ***CareDx, Inc. - CEO, President***

Thanks, Leigh. Good afternoon everyone. As we did on the call last quarter, I'd like to begin my remarks by offering a quote from a patient benefitting from AlloMap, our molecular diagnostic surveillance solution for heart transplantation.

A couple of weeks ago, I was able to spend an evening with Pat Sullivan, one of the founders of the HeartBrothers Foundation in Boston, an organization that works with heart transplant recipients and patients with heart failure. Pat had his own heart transplant in 2012 and shares his opinion of AlloMap with me, "I did not have to think twice about having the AlloMap test versus worrying about which doctor's hand would be doing the biopsy that day. AlloMap was a much, much easier experience compared to biopsy." This is another one of these many examples of the feedback we received from patients who are benefitting from our technology.

Now, turning to our third quarter performance, I'd like to make some brief comments, recapping our results during the quarter, and then we'll highlight the key growth drivers and catalysts we see on the horizon for 2015 and beyond, including the important trials we have underway. Ken Ludlum will then provide financial highlights and guidance for the year. And then, we will invite you to ask you questions.

Let me turn to recent highlights, third quarter results demonstrated important progress across all aspects of our business, revenues of $6.7 million to 15% year-over-year primarily from new and recurring demand of AlloMap.

Third quarter net income was $1.2 million, driven in part by beneficial change s to our accounting estimates and one-time events which Ken will detail in his later remarks. Let me point out, while these results are driven by one-time event, I see this positive number as a signal of the overall health of our business and our potential to generate positive returns with our core business in the future.

Other highlights of the third quarter included a 16% year-over-year increase in the use of AlloMap, which underscores our continued growth momentum in most transplant centers in the US, the successful resolution of our royalty arbitration with Roche molecular diagnostics which provided upsize to our income statement in the quarter as well as for the future.

We also increased enrolment in the Outcomes AlloMap Registry Study or OAR, which identifies opportunities in study centers with respect to protocol adherence and patient identification.

We also made solid progress in developing our pipeline for cell-free DNA test for heart and kidney transplantations. Our Donor-Derived Cell-Free DNA Outcomes AlloMap Registry or D-OAR clinical trial provides the research use only diagnostic tool to help clinicians and scientists investigate the use of cell-free DNA technology for heart transplantation recipients with AlloMap. And finally, we have been able to bring on board additional talent to our strong team, who has the expertise and passion to drive our continued growth with a focus on patients.

I'd like to take a few minutes to review these highlights and why I'm confident in our opportunity to both grow our existing AlloMap business as well as significantly extend opportunities in the use of cell-free DNA for heart and kidney transplantations. I'd also like to take the opportunity to talk you through what we perceived as the underlying trends in our business, which may provide context for understanding our strategy and objectives.

One of these strengths you see is that genomic information leads to new clinical insights, and that chain sequencing moves into clinical applications. CareDx is well-positioned not only through our gene expression technology but also through our capability building in making sequencing information available to transplantations in their post-transplant care.

Another trend is the increasing need of outcomes data for acceptance and reimbursement of payers. We also anticipate capitation models for complex procedures in the future. Actionable clinical information is critical for these assessments and CareDx is focused on providing outcomes data to clinicians and payers.

With transplantations consuming a lot of healthcare services, we see this as a great business opportunity for us. We also see patients and their loved ones increasingly involved in the clinical decision-making. And we see them ask for access to their own data. Obviously, there is a trend for non-invasive testing solution and we at CareDx offer the reduction of biopsy as an example.

In a recent discussion I had with Dr. Mandeep Mehra, one of the leading heart transplant cardiologists at Brigham and Women's Hospital in Boston, she emphasized the trend of moving the focus in clinical decision-making away from rejection monitoring to that of achieving better long-term outcomes. Overall, we see the transplant community being very receptive to novel approaches and solutions offered by diagnostics companies like CareDx since there appears to be a limited focus from big pharma on bringing new therapeutic agents into the transplant field. CareDx, with our focus on genomic information, may fill this potential gap.

These are the points of trends and developments that I wanted to make. Now, let me focus on how we translate these into tangible business opportunity. It is easy to understand what we do at CareDx because we continue to execute against three strategic priorities that we set forth at the beginning of the year. And these are; increase

the utilization of AlloMap, launch donor-derived cell-free DNA test in transplantation and develop and commercialize post-transplant surveillance solutions through partnerships.

Now let me talk you through each of them starting with AlloMap. We have seen consistent year-over-year volume growth throughout the first nine months of the year resulting from the success of our sales and marketing activities that included programs to position AlloMap not just as an alternative to biopsy for heart transplant recipients but, with supporting data, as a surveillance tool to determine a patient's risk of acute cellular rejection in order to optimize immunosuppressive regimens.

Our strategy to engage key heart transplant centers in the development of central specific protocols continues to make progress. Out of the 125 transplant hospitals in the US, AlloMap is being used in 105. In fact, as of the end of the third quarter, there were 45 centers with established AlloMap protocols and an additional 28 centers which have a protocol or utilization policy in development. We expect to build on this number as we view establishing formal protocols in transplant centers as it's very important in confirming the use of AlloMap as a routine tool for the ongoing surveillance of heart transplantations.

Our outcome's AlloMap Registry Study OAR continues to see growing enrollment. This is an important initiative for us as it allows us to identify opportunities in centers with the respect to protocol adherence and patient identification. Nearly 750 samples from approximately 300 enrolled patients were received as of September 30, 2014. I'm impressed this level in heart transplantation.

The long-term outcome data collective will continue to build clinical evidence about the benefits of using AlloMap as a surveillance solution in heart transplantations. As this is a long-term initiative with the opportunity for ongoing interim readout, we anticipate to share some information at the 2015 ISHLT meeting in Nice, France next April. In terms of territory growth, we are pursuing a center by center approach. Our sales reps truly understand the decision making progress -- process and the treatment algorithms in each transplant center. The number of centers adopting the technology through form of protocol development incorporating AlloMap in their practice is a strong indicator of our progress in this area.

Now, turning to reimbursement, we have achieved reimbursement from the major carriers and accomplishments that few other diagnostic companies can claim. As of September 30th, 2014 we had been reimbursed for approximately 79% of AlloMap results delivered in the 12 months ended March 31st, 2014. We expect this level to remain consistent going forward.

Our second priority is the launch of donor-derived cell-free DNA test in transplantation. While we continue to expand the use of AlloMap we are also pursuing the development of products for post-transplant monitoring that used next generation sequencing to detect donor-derived cell-free DNA from the donor organ. We currently have a research use only donor-derived cell-free DNA base solutions for heart transplant recipients available.

We expect our scientific rationale and clinical understanding of donor-derived cell-free DNA to monitor rejection in heart, to strengthen our efforts, to provide surveillance solutions for additional organs with an initial focus on using a similar donor-derived cell-free DNA technology for monitoring kidney transplant recipients.

The technology is based on the premise that higher levels of donor-derived cell-free DNA is released from the organ cells in response to injury from rejection. The D-OAR study marks the first time that clinicians are using cell-free DNA as the surveillance tool together with our commercially available AlloMap test. In the second quarter we initiated this key study and have already started to add centers, enrolled patients, and received samples. We were very early in this effort; we also anticipate that there will be further discussions at the previously mentioned ISHLT congress that generate interest in this approach.

Turning to Kidney which is the key part of our future growth plan, our strategy here is based on a mix of utilizing existing samples to gain insights into the biology of donor-derived cell-free DNA and kidney transplant and execute a clinical development plan that allows us to generate outcomes data in this emerging field.

Our integration of ImmuMetrix at development-stage company focused on donor-derived cell-free DNA based solution in transplantation that we acquired in June of this year is now complete. ImmuMetrix adds to our expertise in applying donor-derived cell-free DNA technology to surveillance of transplantations and strengthens our IT position in the sector. Founder Stephen Quake from Stanford University continues to support the effort in an outstanding way.

Our third initiative is develop and commercialize post-transplant surveillance solution through partnerships. There are a number of opportunities available through CareDx in making additional surveillance solutions available to patients. We believe that through win-win relationships with commercial and academic partners we can develop -- we can help improve transplantation's life. Our commercial channel including our direct sales force and reimbursement expertise can be readily engaged to support partner products we may acquire a license.

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

Ken Ludlum - ***CareDx, Inc. - CFO***

Thank you, Peter. I'll start today by walking through our third quarter financial results and then provide our financial outlook for 2014. Revenue, our revenue of 6.7 million for the third quarter was up 15% year-over-year in the third quarter of last year, virtually all of our revenue in the third quarter was from AlloMap with only $50,000 from licensed revenue. As I indicated on our last call in the second quarter of this year we did receive some delayed revenue from Q1 and one large early payment on the last day of June, these two items added approximately $300,000 to our Q2 revenue, so I'm viewing normalized revenue in the second quarter as more like 6.5 million.

In another note for the nine months ended September 30th, revenue was up 19% on a year-over-year basis from 2013. During the cost of testing, cost of testing in the third quarter was affected by our settlement with Roche over past royalties, as a result, cost of testing received a one-time benefit in Q3 of about $550,000 because the actual back royalties we wound up owing were less than what we had accrued for over the past three years. So, this is a direct offset to actual cost of testing, so while you could think of a nominal gross margin last quarter being 73%, if you adjusted for the back royalties it would have been more like 65% on a normalized basis which is right on plan.

On the R&D side we spent $1 million in Q3 of 2014 compared to $668,000 in a year ago quarter and about $800,000 in the second quarter of this year. As expected R&D expenses increased as our cell-free DNA program moved beyond the initial validation stage and into enrollment in a cell-free DNA heart study as well as towards a more extensive kidney research and development.

Sales and marketing expenses for the third quarter were right on plan at $1.8 million and pretty steady from the second quarter. They were up only at about $150,000. We don't foresee large increases in sales and marketing going forward until we launch our kidney product some time later in 2015. And even then we expect spending increases here to be modest.

G&A expense was $2 million for the quarter up from $1.5 million in the year ago quarter but down from $2.3 million in the second quarter of this year. Expenses in the second quarter of this year were higher due to expenses related to getting system setup to be a public company. We expect to see current levels of spending in G&A increasing only marginally in Q4 and into 2015.

One other new line item on our P&L this quarter is label change and contingent consideration and this is owed to ImmuMetrix shareholders. This is the accounting estimate of a future milestone payment associated with that acquisition that we made last June, which brought DNA technology related IP and know-how into CareDx. This consideration is payable all in stock and if the stock price moves around quarter to quarter the accounting value of this changes and it is reevaluated every quarter. So, the decreased in the stock price this quarter brought about a decreased and the accounting estimate of its value. There's no cash effect and because it would distort operating expenses and we included it in G&A or R&D we have broken it out as a separate item on the P&L and we'll continue to do so until it is paid.

So, reviewing net income, the two items I mentioned the beneficial effect of releasing the over accrual of the Roche royalties and the change in contingent consideration, swung net income for the quarter into positive territory. But without these two one-time beneficial items, net loss would have been roughly $450,000.

Turning to balance sheet at the end of the third quarter; we had three $9 million in cash and cash equivalents. Our IPO raised $35.5 million in net proceeds. Note that we started a year with $5 million in cash and during the year, we raised $35.5 million from the IPO and also raised $5 million from Alumina. We also finished the quarter in September with $39 million in cash.

So if you work through the math on that, our burn rate for the first nine months of this year was only about $6 million or $2 million a quarter. This illustrates how close we are to profitability on our base to AlloMap business in the low burn rate nature of our business model. We see only incremental increases in burn rate as we move towards product development of kidney and other products.

Our share account for the quarter was $11.2 million shares, but because for part of the quarter we were still private, the account going forward should be more like $12 million. As to guidance on revenue side for the full year of 2014, we see no change here for the rest of the year and still expect revenue for the year to be in the range of $26 million to $26.5 million. This implies revenue in the next quarter between $6.6 million and about $7 million for the quarter.

So I'll now turn this back to Peter for some closing comments.

Peter Maag - ***CareDx, Inc. - CEO, President***

Thank you very much, Ken. In closing, I want to leave you with four areas that help differentiate CareDx. First, we drive our business through clinical insights, which we have clinician by clinician, center by center. Second, we have access to large and well-annotated clinical samples. Third, we have a good understanding of the

transplant center's workflow and their decision-making process. And finally, we include our customers, the clinicians from key transplant centers in the development of new products and the adaption of new technology.

We at CareDx continue to make important progress in meeting all of these elements of success to deliver meaningful solutions to the transplantation market. I am confident we will finish 2014 strong and we will enter 2015 on a clearer path towards building scale and donor-derived cell-free DNA. Our plan includes the launch of additional tests and solutions building out our services and continued growth to expanding our commercial presence.

In the next few months, we will be participating in the Piper Jaffray Healthcare Conference in New York and the ISI Conference in Boston as well as the nearing [Bus Tour] here in the Bay Area. We hope to see many of you during one of these events.

With that, thank you for joining us today. We look forward to updating you on our progress in the future calls. We will now open it up to questions, Operator.

QUESTION AND ANSWER

Operator

(Operator Instruction).

The first question comes from Bill Quirk from Piper Jaffray.

Bill Quirk - ***Piper Jaffray & Co - Analyst***

Great. Thanks. Good afternoon everybody and well done in terms of the operational expense control even adjusting for the one-time items. So Peter, first question is I was hoping you have a little bit of feedback on the RUO cell-free DNA heart products, what are you hearing from some of the early participants with that test?

Peter Maag - ***CareDx, Inc. - CEO, President***

And Bill, thank you so much for your question and thank you very much for joining this call. The opportunity of cell-free DNA making that available to heart transplantations through our RUO model, piggybacking onto our OAR study; which has already established in many centers in the US is really a key opportunity for us to learn and engage from clinicians in the field of transplantation.

There's really a vacuum so to speak for -- in the field of transplant for new technologies. And so we come at a time where there's a lot of enthusiasm about new transplant solutions. It is very early in the process as I mentioned earlier, we're guiding towards a read out of some of the data to the ISHLT in Nice and as we are generating more, more and more data that will become meaningful to engage the clinicians. So we're very excited about it Bill, but it is still very early in the process.

Bill Quirk - ***Piper Jaffray & Co - Analyst***

Understood. And then maybe just thinking about AlloMap and the importance of getting into protocols within the facilities, and Peter, do you have any data that you can perhaps share with us in terms of, I guess, the difference in AlloMap usage either on a per physician basis or perhaps you're thinking about what happened to some of these maybe physicians that are not compliant, if they can meet a compliance, et cetera, when we actually get written into the protocol, as compared to say having a champion or two within an individual center?

Peter Maag - ***CareDx, Inc. - CEO, President***

Bill, thank you so much and this is really an excellent question. We are thinking about this business in terms of two broad strokes of different centers. The one center would be a center where there is one individual at the top who's making physicians for the protocol that will be rolled out for the center. We call them almost like an individual clinician setting that the politics or the basis for that center.

In these centers, it probably takes longer to establish a protocol. But once a protocol is established, you really have one point of contact that helps you to drive that protocol to come through. Cedars-Sinai and Bailer in Dallas are excellent examples alongside with Kansas where we see that a momentum and really we have tremendous success in these centers.

It is a little bit more difficult where you have a multitude of cardiologists that are doing somewhat uncoordinated surveillance solutions for these -- for the patients. And very often AlloMap is actually the moment where these clinicians come together and form a joint opinion about surveillance solutions going forward. So we see AlloMap actually one of the opportunities for these centers to sit around the table and say, "How do we run to care for surveillance going forward?"

The Emergency study is a wonderful tool for them that allows to make this discussion among clinicians. And that also allows us just to have the transparency around the number of AlloMap surveillance opportunities that exist, and how the protocol is here until it's established. We have -- we are present in the 105 centers, but you see through our protocol guidance on 45 centers with formal and 28 with protocols in development that there's still ample room for us to grow in terms of penetrating the post transplant heart market.

Bill Quirk - ***Piper Jaffray & Co - Analyst***

Very good. Thank you, Peter.

Operator

The next question comes from Dan Leonard from Leerink.

Dan Leonard - ***Leerink Swann & Company - Analyst***

Thank you. Did AlloMap test volume grow sequentially? And can you speak to the expectations for test volume in the fourth quarter, given some of the holiday dynamics?

Peter Maag - ***CareDx, Inc. - CEO, President***

Dan, thank you very much for that question. We had a significant growth year-over-year AlloMap growth which we guided with the 16% volume growth. So we look at this business at a year-over-year growth which is substantial. In terms of guidance going forward, Dan, Ken continued to guide towards the sales number and that really is the guidance for us as a company going forward. So we're very comfortable of the $26 million, $26.5 million guidance that we gave.

Dan Leonard - ***Leerink Swann & Company - Analyst***

Okay. That's fine. And Peter, can you give us an update on where you are with the kidney product development, have you completed your proof of concept or is that still to come? And then when can we expect some disclosure on the data?

Peter Maag - ***CareDx, Inc. - CEO, President***

Dan, thank you very much for that question. I mean initially we're focused and I mentioned it, we really are piggybacking currently the cell-free DNA on our heart program and the kidney is still somewhat out. We continue to guide on the KIDNA study which is our large outcome study in the middle of next year and that they are really not being changed for the time being. But kidney program is somewhat standard to the heart program and the heart program is moving along very nicely.

Dan Leonard - ***Leerink Swann & Company - Analyst***

Okay. Thank you.

Operator

(Operator instruction)

The next question comes from Nicholas Jansen from Raymond James.

Nicholas Jansen - ***Raymond James - Analyst***

Hey, Peter and Ken. Two questions from me. In terms of the centers that are considering formal adoption, the 28th that you mentioned, how long does it usually take for them to necessarily kind of formally announce something which would result in perhaps higher utilization of those centers over a period of time?

Peter Maag - ***CareDx, Inc. - CEO, President***

Excellent question, Nick. I think it is really a driven center by center and it's something that if I were to give you a generalized number, it would probably be injustice to the complexity of what we need to do at each centers. What's absolutely correct is that each of these centers has very different decision-making modalities and sometimes having a protocol in development is as strong as having a protocol firmly written because it serves as a guidance to the center. That has to do, for example, with modalities that a certain treatment guideline would need to go to internal improvement levels.

But I think we are making good progress on this. This is a key initiative for us and we will continue to have the team laser-sharp focused on establishing these protocols.

I can just re-emphasize the establishment of the registry which is somewhat like a formal protocol for the center. Because in this registry, to engage with AlloMap, the cardiologists sit down around the table and established a formal protocol and very often that this will become the protocol that is established at the centers.

Nicholas Jansen - ***Raymond James - Analyst***

Ken, that's helpful. And then, can you just remind us in terms of thinking about the cash burn -- and thanks for bringing up the comments Ken, but how much money you guys plan on spending for the entire kidney clinical trial, so we can get a sense of when we should expect that extra dollars to be ending? And then I'm thinking about the ramp of the cash flow going forward, so I just want to get a sense of that. I think I remember it during the IPO it's somewhere around $11 million or so but I just wanted to double check there. Thanks.

Ken Ludlum - ***CareDx, Inc. - CFO***

Yes. Nick, the total cost would be more like 13 million to 15 million and -- I mean that's not all incremental spending from this point on, some of that has already in or baked into our regular R&D. But we see the 2016 as being the pivotal year when we are probably going to stop burning money and start generating cash.

Nicholas Jansen - ***Raymond James - Analyst***

Great. Nice quarter, guys.

Ken Ludlum - ***CareDx, Inc. - CFO***

Thanks.

Operator

The next question comes from Peter Lawson from Mizuho Securities.

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

Hi, Ken. Hi, Peter. Just around AlloMap, I wonder if you could just talk through the seasonality in that business and do you think it grows into Q4 over Q3?

Peter Maag - *CareDx, Inc. - CEO, President*

Peter, thank you so much and greetings to you as well. The AlloMap business is really dependent on a quarter by quarter basis because rightly what you said is we see surveillance opportunities happening where the certain rhythm, where the first quarter, second quarter, third quarter, and fourth quarter being largely driven by the number of available days in the office. And these are driven you see that on a month by month basis by more or less driven by the number of holidays, and so on, that are inside it.

So we see this as some kind of a dynamic that is recurring quarter-over-quarter. We had good quarter growth third over fourth quarter last year and we'll continue to look for growth going forward. So we guide on the top line business but there is a continuous opportunity for us to drive AlloMap adoption in the United States.

Peter Lawson - *Mizuho Securities - Analyst*

Thank you. And then just getting back to the question around the trial costs, how much do you -- as you look at next year, how much incremental trial costs could there be for '15?

Ken Ludlum - *CareDx, Inc. - CFO*

Yes. So probably about 5 million to 6 million incremental.

Peter Lawson - *Mizuho Securities - Analyst*

Got you. Thank you so much.

Peter Maag - *CareDx, Inc. - CEO, President*

And just so that we -- and like maybe I have one comment to those, Peter. We see as the clinical outcome trial of KIDNA really as the key driver of our R&D expense. And we would only engage into this R&D expense when we're comfortable to do so. So it's really -- look at the cost ramp really starting with the cost that are associated to that clinical outcome trial which then would be starting the R&D expense.

Peter Lawson - *Mizuho Securities - Analyst*

When would we see the first data for kidney and how many kidney tests have you done?

Peter Maag - *CareDx, Inc. - CEO, President*

We haven't disclosed now yet on the kidney side. There is a number of academic studies out there on the kidney trial which you'll find on our website in terms of guiding on what's out there in terms of publicly available information on kidney studies. But the -- we will communicate around kidney data prior to engaging into the KIDNA study. So look for that in the first half next year in terms of communicating some results out on our initial validations on the kidney program.

Peter Lawson - *Mizuho Securities - Analyst*

Well, so really -- sorry. I didn't quite understand that. So we get the guidance in the first half about when we're seeing results or we'll not actually see some results?

Peter Maag - *CareDx, Inc. - CEO, President*

No. You would see some results because in order to move into the KIDNA trial we would discuss with you the results of the preliminary validation. We would only make the decision to go into KIDNA if we have a solid foundation of making sure that cell-free DNA is a valid model in kidney patients.

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

Got you. Thank you so much.

Peter Maag - ***CareDx, Inc. - CEO, President***

Yes. And just maybe to re-emphasize, Ken whispered that to me and said right now we are relying on our initial validation studies on existing sample databases that are with CareDx and other academic centers. So we are in the process of profiling the biology of cell-free DNA with the existing sample that's currently happening on top of the prospective samples that we use to the cardiac program in our D-OAR study samples.

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

Thank you so much.

Operator

I am showing no further questions. I would like to turn the call back over to Peter Maag for closing remarks.

Peter Maag - ***CareDx, Inc. - CEO, President***

Thank you very much. We look forward to updating you on our progress going forward and you have a great evening. Thank you very much for joining us for the call.

Operator

Ladies and gentlemen, that does conclude the conference for today. Again, thank you for your participation. You may all disconnect. Have a good day.