CareDx's (CDNA) CEO Peter Maag on Q4 2014 Results - Earnings Call Transcript

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CareDx, Inc. (NASDAQ:CDNA)

Q4 2014 Results Earnings Conference Call

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Executives

Leigh Salvo – IR, Westwicke Partners

Peter Maag - CEO

Ken Ludlum - CFO

Analysts

Dan Leonard - Leerink

Bill Quirk - Piper Jaffray

Nicholas Jansen - Raymond James & Associates

Eric Criscuolo - Mizuho Securities

Operator

Good day, ladies and gentlemen and welcome to the CareDx Q4 Quarter Financial Results Conference Call. At this time, all participant lines are in a listen-only mode to reduce background noise. But later, we will be conducting a question-and-answer session and instructions will follow at that time. [Operator Instructions] As a reminder, this conference is being recorded.

I would now like to turn the call over to your host for today Leigh Salvo with Investor Relations. Ma'am you have the floor.

Leigh Salvo - IR, Westwicke Partners

Thank you. And thank you for participating in today's call. Joining me from CareDx are Peter Maag, President and CEO and Ken Ludlum, CFO.

Earlier today, CareDx released financial results for the quarter ended December 31, 2014. The release is currently available on the company's website at www.caredxinc.com. Before we begin, I would like to remind you that management will make statements during this call that include 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 materially differ 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. This conference call contains time sensitive information and is accurate only as of the live broadcast today March 17, 2015.

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

Peter Maag - CEO

Thanks, Leigh. Good afternoon, everyone. It's Saint Patrick's Day and since we are always starting with the patient story, I wanted to share this with you. I found Ernesto Antonio, an Irish, online. Since his transplant at the Mater Hospital, Dublin in 1999 he has undertaken a multitude of physical challenges on land and in water. He has done numerous half marathons, triathlons and an Ironman in Galway.

He holds the marathon record for heart transplant patients. He swam the English Channel in a relay, cycled London to Paris last spring, climbed Kilimanjaro, raced across Scotland in two days and represented Ireland at the European Heart and Lung Transplant Games. His aim is to create awareness and promote organ donation. I find this inspirational, something Irish on Saint Patrick's Day. And one more patient story that makes CareDx employees and myself come to work every day.

Now in this call I will touch on 2014 full year and our Q4 performance. I will also focus on a business update with a view on our growth drivers. I will then ask Ken to dive deeper into the financials for the fourth quarter and full fiscal year and he will provide guidance on 2015. I will close with some remarks and then we look forward to your questions.

2014 was a transformational year for CareDx and I'm proud of our many accomplishments. Highlights of the year included revenues were 27.3 million for the year 2014, which translated into a year-over-year revenue growth of 24%, largely driven by the solid volume growth from new and recurring use of AlloMap which had a 19% increase in 2014 over 2013.

To recap other milestones, our strategic partner Illumina made a $5 million investment in support of our cell-free DNA initiatives and in the ImmuMetrix acquisition. Late last year the successful resolution of our royalty arbitration with Roche provided upside to our income statement and will further enhance our gross margin going forward, and of course, the completion of our IPO which has provided proceeds of 35.5 million that enables us to expand our R&D efforts.

Now starting with our fourth quarter financial highlights, revenue was 8 million in the fourth quarter of 2014, increased 36% compared to the same period in 2013. AlloMap revenues were 6.7 million in the quarter, an increase of 16% versus 2013. We also posted a positive operating income of 0.4 million. I'll let Ken speak to some of the details. Overall, we see these strong financials as a healthy platform for CareDx's future.

Turning to our business highlights along our three major activities. Number one, increase the utilization of AlloMap. Two, develop donor derived cell free DNA test and transplantation, and three, build on our

strong foundations through adding inorganic growth opportunities. I will spend a few minutes providing an update on each of these objectives.

Starting with AlloMap, we saw steady growth throughout the year. AlloMap was used for heart transplantations approximately 3,100 times in the quarter, representing an increase of 14% versus the fourth quarter of 2013. The number of centers adopting our technology through [formal] [ph] protocol development and incorporating AlloMap into their practice is a strong indicator of our progress in this area.

Out of the now 129 transplant hospitals in the U.S., AlloMap is being used in a 110. In fact, as of the end of the fourth quarter, there were 48 centers with established AlloMap protocols up from 45 in the previous quarter.

Now let me move to newly published clinical data. Validating the benefit of early use of AlloMap in transplant surveillance, the results of the e-IMAGE trial were accepted for publication by Circulation, the medical journal of the American Heart Association.

e-IMAGE was a randomized controlled study of 60 patients performed at Cedars-Sinai Medical Center in Los Angeles, which has performed more heart transplant procedures than any other medical center in the U.S. for the past two years. This study was led by Dr. Jon Kobashigawa, an internationally recognized leader.

The e-IMAGE study observed clinical outcomes of heart transplant recipient who underwent rejection surveillance management with AlloMap beginning at 55 days post transplantation. The outcome at 18-month post transplantation in patients managed with AlloMap were similar to outcomes in patients managed with biopsy.

In the AlloMap cohort, the gene expression profiling results were used to guide the tapering of steroids during the first 12 months post transplantation. The trial also suggests that AlloMap can be useful for guiding immunosuppression dosage reduction. Patients, as anticipated were more highly satisfied with their AlloMap surveillance care than patients in the biopsy cohort.

This is a very encouraging outcome for CareDx as it establishes the use and benefits of early use of AlloMap post transplantation. This study follows our overall expectation that among the most compelling unmet medical needs in post-transplant surveillance is the personalization of care for patients. Namely, the more precise or optimized use of immune suppression therapy.

On the reimbursement front, we continue to have positive coverage decisions from all the major carriers, an accomplishment that few other molecular diagnostic companies can claim. As of December 31, 2014, we have been reimbursed for approximately 79% of all AlloMap results delivered in the 12-month ended June 30, 2014. We expect this level to remain constant going forward.

As part of our strategic objective to expand utilization of AlloMap we recently received expanded coverage decisions from two MAC jurisdictions. These decisions raised AlloMap reimbursements to four of the 12 MAC jurisdictions and it enables Medicare patient increased flexibility when seeking the benefits of AlloMap.

The American Medical Association recently included AlloMap in its recommendations for a test-specific category 1 CPT code. This demonstrates that an additional independent organization has reviewed both the clinical evidence and adoption of AlloMap and has since a unique CPT code is warranted.

As we assume that Medicare will continue to look to Palmetto for pricing. We don't anticipate that this will impact AlloMap as most of our tests are covered by Medicare already. But we see the category 1 CPT code as a recognition of the strong evidence for AlloMap.

Now let me turn to AlloMap usage. Our outcomes AlloMap registry study, OAR, continues see growing enrollment. This is an important initiative for us. Over a 1,000 samples from 364 patients enrolled in the study were received as of December 31, 2014, an impressive level in heart transplantation.

The long-term outcome data collected will continue to build clinical evidence concerning the use of AlloMap as a surveillance solution in heart transplantation. We are often asked how we plan to fill grow AlloMap utilization? We estimate the total addressable market for AlloMap is roughly a $100 million. Let me break this into three segments.

We believe that AlloMap surveillance protocols generally specific six to eight AlloMaps in the first year, which translates into 40% of the total addressable market. And two to four AlloMaps in the years two to five year post transplant, which captures another 40% and decreasing surveillance after five years that captures the remaining 20% of the addressable market.

Commercial excellence and execution is critical to the success of CareDx. In order to further penetrate the market we will continue to follow a center by center approach and develop specific programs that allow us to further demonstrate the benefits of increasing the usage in three segments.

For those transplants center with lower than anticipated testing in the early months post-transplant, the one year segment, we now have results from e-IMAGE to further demonstrate clinical utility from early use of AlloMap, 55 days post-transplant. If the leading transplant center in the world is using the test early why can't other centers follow suite? Dr. Kobashigawa is a leader in the field and he is using our surveillance solution early. This might have significant impact in the future.

For the second segment, two to five years post-transplant, we believe the key to success of the establishment of a protocol and the optimization of workflow management. If we enable the centers to comply with their protocols, the number of AlloMaps per patient will increase.

In many centers initiation of the OAR registry study have been a great starting point for establishing an AlloMap protocol. Furthermore, the registry intends to report an outcome and makes protocol adherence ever so important. Both segments two to five years post-transplant and greater than five years post-transplant can benefit from our AlloMap variability initiatives.

Working with thought leaders in the field, we further investigate the hypothesis that the variability of AlloMap scores may inform clinicians about the long-term outcome of transplant patients.

Ultimately, we believe that we will demonstrate that the standard deviation of sequential AlloMap scores enables patient stratification and helps clinicians to identify patients that are at a lower risk of poor outcome. We will continue to report on our AlloMap variability initiatives going forward.

Partnerships are another key component to our strategy. Recently Diaxonhit, our partner in Europe, entered into an agreement with the Strasbourg University Hospital to facilitate AlloMap's implementation in Europe. This is a significant step towards providing European heart transplant patients' access to AlloMap.

In parallel, Diaxonhit is working with individual European health authorities to obtain reimbursement coverage. We continue to forecast very little revenue from Europe in 2015. Very timely the upcoming ISHLT congress is held in France and provides an unique platform to increase awareness in European clinicians of AlloMap and its use in transplant care.

Next, I would like to spend a few minutes discussing the status of our cell-free DNA research and development. We continue to make significant progress in developing our pipeline of cell-free DNA test for heart and kidney transplant patients.

Before I move into an update on individual activities, I would like to describe how we are thinking about the development in a broader framework. And this framework would be including the progress on our development trial programs, some regulatory considerations, our results and reimbursements and our intellectual property efforts.

Now, we have structured our development trial program along three elements, analytical validity as the first one. Second is the clinical validity and three the clinical utility. Regarding the analytically validity part we have a cell-free DNA prototype test today and we anticipate having an analytically validated cell-free DNA test by the end of April. This is an important milestone.

Using our heart samples we have been able to build a prototype for cell-free DNA test with which we can measure different levels of cell-free DNA accurately. We also have a dataset from our CARGO II sample that has been accepted as abstracts at the ISHLT. These results will be thoroughly discussed at the ISHLT meeting on April 12, 2017.

Regarding clinical validity, with CARGO II, KARGO and D-OAR samples we have gathered insights that will further enhance our clinical validation effort. Let me mention that we are excited to contribute to this emerging field of cell-free DNA. There is a lot of buzz in the industry for non-invasive prenatal testing and early detection of cancer, and we are proud to contribute to the clinical translation of the port for the role of cell-free DNA in the field of transplantation.

The cell-free DNA analysis in our D-OAR clinical trial provides valuable information for clinician and scientists to reflect on the specific use of cell-free DNA technology for heart transplant recipients with AlloMap. We are building scale in this trial with participation by three centers, 22 enrolled patients and 52 samples from as of December 31, 2014.

The number of patients impacted by the additional information from cell-free DNA testing is limited, all the more reason to further advance our kidney studies to impact a much larger number of patients.

Analysis of cell-free DNA in our 300 KARGO samples collected in 2004 were used to determine the range of cell-free DNA in kidney transplant patients. Samples with the adequate clinical information demonstrate the trends of increased cell-free DNA in samples with a rejection versus samples without one.

As in separate studies by others, we confirmed observations in our study that serum samples have significant limitations. While KARGO has been informative, it has become clear that we need additional samples beyond KARGO to fully develop our cell-free DNA program for kidney. Therefore, we have made changes to our development program.

For kidney we are now focused on the DART initiative. DART has two phases and replaces our anticipated KIDNA trial. DART is shorthand for the cell-free DNA in acute rejection in transplantation study. DART is anticipated to start earlier than our previously considered KIDNA trial and has the aim to collect samples from 200 patients in 10 or more centers and run for a minimum of 18 months with an interim readout opportunity after approximately 6 months.

I mentioned that there are two phases to this study. DART 1 will establish clinical validity of cell-free DNA in kidney. DART 2 is intended to establish clinical utility. We will provide further details regarding timeline and further milestones for DART 2 later this year.

Let me also touch on regulatory. Our plan is to move progressing of -- processing of cell-free DNA test from our research lab to our state-of-the-art CLIA licensed laboratory near South San Francisco at the end of the year in 2015.

Our plans are progressing well. While we anticipate launching the cell-free DNA assay as a laboratory developed test, our prior experience in establishing FDA clearance for the AlloMap test positions us well regardless of when and how the FDA decides to regulate CLIA labs.

Now I move to reimbursement. Since many transplantations are covered by Medicare, our reimbursement strategy has prioritized Medicare reimbursements. Most of you are aware that the Palmetto/MolDx evaluation process increased the level of evidence for application of reimbursement.

In their communications last year they noted that clinical validity even though, used in the past for reimbursement decisions, will not be sufficient for seeking Medicare reimbursement in the future. Our plan, as outlined previously and concordance with our AlloMap studies will focus on establishing the clinical utility of cell-free DNA. As we are considering these changes in our reimbursement strategy, we anticipate that there won't be revenues for cell-free DNA in 2016.

We also touched in this call on intellectual property. We continue to build our patent estate around the patent acquired with the ImmuMetrix acquisition and our previous efforts for approaches, applying targeted and shotgun sequencing technology to the field of post-transplant care.

Now let me conclude the development section this call. We are really looking forward to the ISHLT this year. We have nine abstracts accepted by ISHLT. This included three abstracts on our OAR study, three on cell-free DNA and three investigator initiated trials on long-term outcomes and immune suppressant optimization. Two of the three cell-free DNA abstracts were accepted as oral presentations. We are looking forward to discuss in details after the congress.

Before I turn the call over to Ken, I also want to welcome and introduce two experts in the diagnostic space to our leadership team. John Sninsky joins us in January as Chief Scientific Officer. John will head our product development initiative. He most recently served as the VP of Discovery Research at Celera Corporation. Following Celera’s acquisition by Quest Diagnostics, he served as the Alameda site head for Quest's Science & Innovation and oversaw organization-wide Bioinformatics.

Earlier this month we welcomed Bill Hagstrom to our Board. Bill is an experienced and successful molecular diagnostic expert and operating executive. Bill was the founder and served as CEO of Crescendo Bioscience, which was acquired by Myriad Genetics in 2014.

Both John and Bill support our passion for the advancement of diagnostics technology and post-transplant surveillance solutions to improve patient management and I look forward to their contributions.

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

Ken Ludlum - CFO

Thank you, Peter. Starting with revenue in the fourth quarter, revenue was 8 million, up 36% from the fourth quarter of 2013. Note that 1.1 million of the 8 million was a combination of $500,000 cash payment and $600,000 in deferred revenue from LabCorp. This came around from the transfer of assets and rights to them for our lupus project that was previously a collaborative initiative.

AlloMap revenue in the fourth quarter of 6.7 million was up 16% from the fourth quarter of 2013. Cost of testing in the fourth quarter was 2.2 million compared to 2.3 million in the fourth quarter of 2013. The major reason for the better cost of testing were increased efficiencies in absorbing overhead in our lab as well as lower overall cost. Also helping was the positive effect of our lower royalty payments. This resulted in a gross margin in the fourth quarter of 67%, up from 60% a year ago.

R&D was $1.3 million in the fourth quarter compared to $660,000 in the fourth quarter of 2013, and roughly a $1 million in Q3. As expected, R&D expenses have increased as our cell-free DNA program moved beyond the initial development stage and into enrolment of a cell-free DNA study in heart as well as towards more extensive kidney research and development.

Sales and marketing expenses for the fourth quarter were on plan at $1.6 million, and steady with the third quarter.

G&A expenses were $2.3 million for the quarter. We have a new line item on our P&L which started last quarter. This is the change in contingent consideration owed to the ImmuMetrix shareholders.

Remember that this is the accounting estimate of the value of our future milestone payment. This payment is payable in stock and if the stock price fluctuates quarter-to-quarter, the accounting value changes.

The change in stock price this quarter brought about a modest increase of $37,000 in the accounting estimate of its value for the fourth quarter. And the change in value flows through the income statement every quarter, but there is no cash effect from this change this quarter.

The $1.1 million in revenue from LabCorp created positive operating income of $429,000 for the quarter. After interest expense and other expenses, net income was breakeven and EPS was $0.00 for both basic and diluted earnings per share.

Turning to the full year, as Peter mentioned, revenues for the year were $27.3 million, up 24% from 2013. AlloMap revenue was $25.8 million and that was up 19% from the previous year.

Net income for the full year was $781,000 compared to a net loss in 2013 of $3.5 million. Incomes went positive in 2014, partly due to LabCorp revenue in the fourth quarter and from three one-time expense items that totaled about $3.2 million.

The first was a $1.2 million benefit in operating expense resulting from a change in the valuation of the future ImmuMetrix milestone payment and that occurred in the third quarter.

The second item was $1.5 million tax benefit associated with the ImmuMetrix acquisition and that was booked in the second quarter. That was a non-cash benefit by the way.

And the third item was a one-time benefit to cost of testing of approximately $500,000 from our license fee renegotiation that Peter previously mentioned.

Turning to the balance sheet, at the end of the fourth quarter we had $36.4 million in cash and cash equivalents. Share outstanding for quarter were 11.8 million and 12.1 million share for basic and diluted shares outstanding.

Turning to our revenue guidance, for the full year 2015, we expect revenue to be range of $28 million to $30 million.

I will now turn this call back to Peter for some closing comments.

Peter Maag - CEO

Thanks Ken. We enter 2015 in a position of strength, stemming from the continued traction we have achieved with AlloMap. As we continue to pursue AlloMap adoption, our strategy for 2015 includes the advancement of our cell-free DNA surveillance program which has the potential to directly detect organ health.

We believe that our rejection surveillance management solutions could become a new diagnostic alternative in the estimate 1 billion post-transplant surveillance market for heart and kidney.

Given our strong financial foundation and our market presence in molecular diagnostics, we expect to continue to seek inorganic opportunity.

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 Session

Operator

[Operator Instructions]

And our first question for the day is from the line of Dan Leonard from Leerink. Your line is open.

Dan Leonard - Leerink

Great. Thank you. First off on kidney, is your expectation that you'll launch the kidney product as an LDT by year end 2015 or is that a 2016 event?

Peter Maag - CEO

Thank you very much for the question Dan. Really appreciate you picking up on our kidney transplant program. Where we'll focus right now is on the clinical validation of our test with the DART I program.

We believe that ultimately we will need clinical utility to seek reimbursement, but we haven't guided yet on the launch date of the LDT of the kidney transplant program. So, we'll update you on that launch of the LDT at a later stage.

Dan Leonard - Leerink

Got it. Appreciate that clarification. And Peter can you elaborate further on the difference in mechanics between DART and KARGO?

Peter Maag - CEO

Yeah, we call it KARGO. The KARGO sample set was a sample set of 300 samples where we qualified 222 samples for analysis. This was -- this sample set was collected in 2004 and had a number of limitations as was outlined in the call.

We learned that the KARGO sample set is probably not valid for a full clinical validation study as it has been collected in serum samples and these serum samples had some limitations. We'll need to go back and collect kidney samples in our new initiative called DART. The quality of these samples will be significantly different, but it will also be the same as in KARGO a longitudinal sample set for kidney transplant patients.

Dan Leonard - Leerink

Got it. And then my final question on the lupus, do you still own lupus IP and is that something you can monetize? Or does this payment from LabCorp close that?

Peter Maag - CEO

Yeah, no, absolutely, we do continue to have lupus samples in our freezers. We have given LabCorp their rights to revert back to the joint data set that has been generated by the collaboration. But we continue to hold relative -- relevant IP and samples in our freezers here in South San Francisco.

Dan Leonard - Leerink

Got it. Thank you.

Operator

Thank you. Our next question is from the line of Bill Quirk from Piper Jaffray. Your line is open.

Bill Quirk - Piper Jaffray

Great. Thanks and good afternoon everyone. Peter just taking with kidney for a moment here, you mentioned a couple of times now that serum was problematic, you need to collect some additional kidney samples. Are you referring to actually kidney tissue samples, or I guess I'm a little confused there?

Peter Maag - CEO

No, it is really serum sample. So, what we learn is that we need to collect in plasma to really have the high quality sample for cell-free DNA. We were using serum's pour offs in the KARGO sample set as well as in the CARGO II sample set for heart.

Remember that the CARGO II sample set are also -- was valid for the clinical validity studies for cell-free DNA. But in -- we need to collect in plasma and need to do that in these extract tubes to get the high quality and high integrity samples for the development of cell-free DNA.

Bill Quirk - Piper Jaffray

Okay, good. Thanks for the clarification there. And just thinking a little bit about I guess the time to run the DART I and then DART II study recognizing that we're going to talk more about DART II later in the year. So, help us think a little bit about -- you mentioned 200 patients at 10 or greater centers with an 18 month follow with the potential for six months early access to that.

So, when I guess are you guys thinking you might be able to get that kind of early look at those samples and I know you probably don't want to commit to it, but I assume as soon as you get that then that might trigger the LDT release.

Peter Maag - CEO

Now, Bill -- and I think the -- you know me well enough that I don't want to commit to it. So, I appreciate that half sentence. And I think we're right now laser-sharp focused on making DART I a reality even prior to the [KIDNA] [ph] trial.

We always said that we want to start KIDNA in the second half of the year and since we're guiding on DART I starting earlier than KIDNA, I think we would be hoping that KIDNA -- DART I could start even in the first half of this year.

Then the question will really be how quickly can we recruit patients into the DART I trial and the excitement in the community is very significant on cell-free DNA, so we believe that we can recruit very quickly.

But you know that the reality in these centers will be determined by how quickly we can have investigators going through an IRB process and so on. I think it would be premature to inform right now on the DART I study. But think of this as a minimum of nine to 12 months in terms of given where we are at -- in this current program.

Bill Quirk - Piper Jaffray

Okay. That's very helpful color. Thank you. And then just I guess a design or conceptual question, lot of the data that we've seen thus far in cell-free DNA has been from female donors into male recipients. And it strikes us that designing an assay to identify female DNA in a male donor is relatively easy as compared to say a male-male donor and transplant.

And so I guess what I'm kind of driving at Peter is how many potentially different assays do you think you would need to cover both heart as well kidney cell-free DNA? I mean it sounds like it's going to require at least a couple, but just trying to get better handle on that.

Peter Maag - CEO

No, thank you very much for that question. We call this the gender mismatch studies. And in gender mismatch, it's relatively easy because you can use QT-PCR technology in order to detect donor versus recipient cell-free DNA.

And this in early studies, 1989, [Lowe] [ph] has actually demonstrated that you can detect this based on this phenomena of gender mismatch. So, we're not concerned at all about gender mismatch. That is relatively easy and straightforward as scientific evidence.

To speak to your specific question, we, in our technology, use probably 200 to 300 SNPs to detect the type of forensic panel that you're referring to in terms of differentiating donor to recipient-specific cell-free DNA.

So, think of this as 200 to 300 SNP panel that allows us to make the right analytics in the targeted cell-free DNA.

Bill Quirk - Piper Jaffray

Okay.

Peter Maag - CEO

Does that address your question?

Bill Quirk - Piper Jaffray

It does. Yeah, it's very helpful, thank you, Peter.

Operator

Thank you. Our next question comes from the line of Nicholas Jansen from Raymond James Associates. Your line is open.

Nicholas Jansen - Raymond James & Associates

Hey guys. Just going back to kidney in terms of the timeline now, which looks a little bit -- a little bit more elongated. Just trying to get a sense of when we should anticipate some potential for revenue here. I think when the process was unfolding over the summer you were hopeful that 2016 could be a year where you did get a nice little bolus of revenue, has that been pushed now to probably 2017 given the update here?

Peter Maag - CEO

I think that's a fair assumption. We have been mentioning in the reimbursement section of this call that we don't anticipate any revenue in the year 2016 for our cell-free DNA kidney test.

And I think I would reiterate that statement. Obviously, the team here is focused on establishing the clinical utility which will allow us to file for Medicare reimbursement, which will be the major component in generating a commercial success for cell-free DNA and transplantation. And that's really the core focus of the organization right now.

Nicholas Jansen - Raymond James & Associates

Okay. And then on the expense side of the house thinking that there is a change here, is there any increased R&D efforts now associated with this change or are we still thinking about the development timeline costing the same amount as before.

Peter Maag - CEO

I think that's a very good question. We always guided that we only start the significant cost component of a clinical outcome trial once we are -- have established the clinical validity of the test.

So, think of the bolus of the R&D expense also shifting somewhat. We continue to track on our R&D spending, but I'll let also Ken comment on that component.

Ken Ludlum - CFO

Yeah, so we always discussed the overall cell-free program costing $13 million to $15 million. We think it might be a couple million dollars above that given that we'll be doing DART I and DART II now. And that's spread out over three years.

Nicholas Jansen - Raymond James & Associates

Okay. And is there any -- how much dollars have been spent thus far?

Ken Ludlum - CFO

Very small amount of that. I would say less than $2 million.

Nicholas Jansen - Raymond James & Associates

Okay. And then lastly looking at the revenue guidance for 2015, very kind of consistent with what you were expecting on the core AlloMap there, is the expectation there mid-teens unit volume growth, you didn't provide kind of unit volume expectation, just wanted to get a sense of how you're thinking about heart AlloMap test orders in 2015?

Peter Maag - CEO

Yeah, we haven't guided on volume and we'd like to not continue to -- we'd like to be consistent on that in terms of volume guidance. The revenue guidance and the math that you have made Nick is right on target. So, without giving you specific volume guidance, I think the math is very consistent on we're thinking about it.

Nicholas Jansen - Raymond James & Associates

Okay. Thanks guys.

Ken Ludlum - CFO

The AlloMap revenue for this year in our plan is right smack in the middle of that revenue guidance that I just mentioned.

Operator

Are we ready for the next question?

Peter Maag - CEO

Yes.

Operator

[Operator Instructions]

Our next questioner comes from the line of Eric Criscuolo from Mizuho. Your line is open.

Eric Criscuolo - Mizuho Securities

Thanks for taking my question tonight. Just one for Peter. On the early data readout in the DART study, what type of data or results should we expect to see from that?

Peter Maag - CEO

Eric, thank you so much for stepping in on Peter and great to have you on the call. What we're looking for is clinical validation of our cell-free DNA test probably in connection with biopsy reads to be able to detect rejection in different time points post-transplant.

So, there will be a number of clinical parameters and other parameters that we're looking at. But in kidney transplantation, there are really two things important for rejection monitoring, one is the biopsy read, the other would be serum creatinine reads in combination with clinical observations.

So, these are the three things that probably build at the core of our clinical validation program of the kidney sample.

Eric Criscuolo - Mizuho Securities

Great. And then the ISHTL data, could you go over again what you'll be presenting and may call out which were the most impactful --?

Peter Maag - CEO

Yeah. We have the -- a bit of a limitation in terms of diving into the data of the ISHLT due to the scientific nature of the information and the embargos that are associated with it.

But basically what we're doing is really three buckets. The first one is we're reporting out on cell-free DNA on our CARGO II analysis and only samples of [indiscernible] that we have in heart. Very exciting data on the cell-free DNA component.

The second elements are around the usage of AlloMap in our registry study where we follow-up more than 300 patients now longitudinally and correlate AlloMap with clinical outcomes longer term.

And the third elements are really around our story that we try to continue to build on AlloMap's use in immune-suppression optimization and personalization of AlloMap. Think of this as if there is a very low risk of rejection demonstrated with AlloMap, you can actually optimize immune-suppressive therapy.

The imaging was done by tapering steroid in some of the publications that you'll see at ISHLT. Actually optimization of immune-suppression was done also on the CNI component of the immune-suppressive therapy. So, very exciting data for us at ISHLT.

Eric Criscuolo - Mizuho Securities

And lastly your expectations for European commercialization and when we might expect to see revenues from that geography? Can you provide any insight or clarity onto that?

Peter Maag - CEO

Yeah. No, thank you for asking that question. In the call, we have guided that there's relatively little expectation for us this year, but given that we have this Strasbourg Lab coming on-stream and beneath ISHLT, Congress being in front, we believe that this is the year where we will actually generate a lot of interest on AlloMap and we'll be in a much better position to then gauge AlloMap revenue for next year and we'll be in a very good position.

Just, historically, has taken the adoption of AlloMap in some centers has taken some time until it really comes from fruition and it becomes the standard-of-care in these centers. And then the reimbursement question will be question that our partner Diaxonhit will answer country-by-country.

Eric Criscuolo - Mizuho Securities

Great. Thank you very much.

Operator

Thank you. That's all the questioners that we have at this time. So, I'd like to turn the call back over to Peter for closing remarks.

Peter Maag - CEO

Well, thank you very much. We look forward to update you on our future progress and have a great evening. Thank you very much for the call.

Operator

Ladies and gentlemen thank you again for your participation in today's conference. This now concludes the program. And you may all disconnect your telephone lines. Everyone have a great day.