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OKPO Health, Inc. Second Quarter 2015 Financial Results Conference Call

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C O R P O R A T E P A R T I C I P A N T S

Steven Rubin, *Executive Vice President Administration*

Adam Logal, *Senior Vice President and Chief Financial Officer*

Jane Hsaio, *Vice Chairman and Chief Technical Officer*

Charles Bishop, *Chief Executive Officer, OPKO Renal Division*

David Okrongly, *President of OPKO Diagnostics*

Dr. Phillip Frost, *Chief Executive Officer and Chairman*

C O N F E R E N C E C A L L P A R T I C I P A N T S

Rohit Vanjani, *Oppenheimer & Co.*

Kevin DeGeeter, *Ladenburg Thalmann & Co. Inc.*

P R E S E N T A T I O N

Operator:

Good afternoon and welcome to the OPKO Health Second Quarter 2015 Earnings Call. Today s presentation is being recorded.

I would now like to turn the conference over Executive Vice President Administration, Steve Rubin.

Steven Rubin:

Thank you and good afternoon. Before we begin, I d like to remind you that any statements made during this call which are historical will be considered forward-looking and as such will be subject to risks and uncertainties which could materially affect our expected results, including, without limitation, the various risks described in our Annual Report on Form 10-K for the year ended December 31, 2014, and our subsequent filings with the SEC.

I d like to discuss the format for today s call. Adam Logal, our Chief Financial Officer, will first talk about our financial and operating results for the quarter. Jane Hsiao, our Vice Chairman and Chief Technical Officer, will then provide a brief update on our Biologic programs. Charlie Bishop, the CEO of our Renal Division, will next provide a brief update on our Rayaldee development program, followed by David Okrongly, President of our Diagnostics Division, who will provide an update on Diagnostics projects. Finally, Dr. Frost will follow up with a brief wrap-up. We do have the entire team here with us to answer any questions you might have after our remarks.

With that, I ll turn it over to Adam Logal, our CFO. Adam?

Adam Logal:

Thank you, Steve, and good afternoon everyone. We ended June with a cash balance of $221 million reflecting the $295 million up front payment received from Pfizer for the hGH-CTP global collaboration agreement, partially offset by cash used in our acquisition of EirGen, as well as cash used in our continued investment in research and development during the first half of 2015.

We strengthened our balance sheet during the first half of 2015 by exchanging approximately $41 million of our 3% convertible notes for shares of our common stock. Both the Pfizer transaction and the convertible notes continue to have a significant impact on our results of operations for the first half of 2015.

As a result of the significant increase in our share price since December 31st, the fair value of the embedded derivative associated with our convertible debt increased and as a result we recorded non-cash charges in Other Income and Expense for the three and six months ended of approximately $17 million and $66 million, respectively. Importantly, this non-cash expense is a result of our share price appreciation and with the exchange of $41 million of principal notes during 2015 future changes in our share price will have a lesser impact. Further, the remaining $46 million of principal notes continue to be convertible by the holders through September 30th as our share price exceeds the pre-defined conversion premium under the indenture.

During the six months ended June 30th, 2015, we also recorded a non-recurring operating expense of approximately $26 million related to our hGH-CTP technology as we licensed that technology out of Israel, triggering a repayment obligation to the Israeli Office of the Chief Scientist. The OCS had previously funded a portion of the development of our hGH-CTP program. Further, we recognized $17.7 million and $30.2 million of revenue during the three and six month periods related to the Pfizer collaboration agreement. As a reminder, we are recording the $295 million up front payment as revenue on a straight line basis over the anticipated development period.

Revenue during the three months ended June 30th, 2015 increased approximately $19 million to $42.4 million, principally as a result of the revenue recognized in connection with the Pfizer transaction and revenue generated by EirGen post acquisition. Revenue for the first six months of 2015 increased $26.7 million to $72.5 million as a result of revenue recognized from Pfizer and EirGen, partially offset by lower revenue at OPKO Health Europe as we negotiated a long-term supply arrangement with one of our customers as well as a planned temporary shutdown at our OPKO Mexico manufacturing facility. The arrangement at OPKO Health Europe was completed during the first quarter and the manufacturing facility in Mexico was also brought back online during the first quarter.

As a result of the prior items, including the non-cash derivative expenses and the non-recurring one-time repayment to the OCS, net loss for the three months increased $17 million to $43 million, and for the six months net loss increased $90 million to $160 million in comparison to the 2014 period. In addition, we continue to focus on our R&D programs and as such R&D expense increased for the three months ended June 30th, 2015, by $13.3 million to $29.6 million, and R&D expense for the six months ended June 30th increased by $17.8 million to $55.1 million.

I would now like to turn the call over to Jane Hsaio, our Vice Chairman and CTO. Jane?

Jane Hsaio:

Thank you, Adam. I have the pleasure of working with the OPKO Biologics team since the acquisition. I would say that it s I m very proud to say OPKO Biologics based in Israel is an extremely productive team. The team is working tirelessly to apply the proprietary technologies to extend the half lives of therapeutic peptides and proteins. The most advanced program is the once a week injection instead of once daily recombinant human growth hormone product. Since the beginning of this year, the partnership with Pfizer has given this project a boost in building commercial success. We have extended experienced resources from Pfizer and we expect to have very favorable cost of goods structure.

We have completed the enrolment of the pivotal Phase 3 study for the treatment of growth hormone deficiency in adult patients. We plan to file the biological license application as soon as the data clean-up and compilation can be completed. All 52 eligible patients have completed the 12-month mandatory treatment period of the Phase 2 pediatric dose ranging study and of that over 90% of the patients have elected to continue receiving the treatment in the open (ph) level phase of the trial. Some patients have even gone into the second years of treatment. OPKO and Pfizer teams are working together to develop the optimum global regulatory strategy for the US, Eastern and Western Europe, and the Asian-Pacific countries. Recently, we also consulted with PMDA to discuss registration requirements for Japan, which holds about one-third of the total market and has its own unique regulatory pathway. We expect our strong long-term Phase 2 data in pediatric growth hormone deficiency patients will facilitate the development timeline in Japan.

The second program is a long-acting Factor VIIa. This is a recombinant product using the same CTP technology as that for the growth hormone product, to extend the half life of Factor VIIa. Some hemophilia patients, A or B patients, who have developed antibodies to their factor replacement therapy and become unresponsive are treated with Factor VIIa, which is formulated by Novo Nordisk NovoSeven product. The reported market size of this product is $1.2 billion to $1.6 billion a year. Our product MOD-5014 studied side by side to NovoSeven has shown the potential in animal model studies for an on-demand and prophylactic use by IV and more important by subQ. In June, five posters were accepted and presented at the International Society of Thrombosis and Haemostasis Annual Meeting in Toronto, Canada. We presented the clinical toxicology, pharmacokinetic and pharmacology with comprehensive assessment of the safety and efficacy of our product in animals. This data set is the basis of the FDA-approved IND to support a first-in-human trial of this product. We expect to dose the first patient as a Phase 2a dose-escalating study as soon as the necessary IRB approval and external laboratory service contracts are in place.

Another product which is almost ready for first clinical study is a long-acting oxyntomodulin. Oxyntomodulin is a peptide hormone released from the gut after a meal. It activates both the glucagon-like peptide 1 and the glucagon receptors, and is known to reduce the food intake and to increase energy consumption for an effective weight loss control. The half life or natural oxyntomodulin is in minutes while OPKO s modified long-acting product can be administered once a week. Studies in diabetic overweight mice have demonstrated greater weight loss than the natural hormone itself. We are completing the necessary toxicology and pharmacokinetic studies in animals and the first-in-human study is being planned.

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Thank you. Now, Charlie?

Charles Bishop:

Thanks, Jane. Good afternoon. I m pleased to update you on the Renal Division s progress in bringing Rayaldee to the US market. OPKO submitted a New Drug Application for calcifediol modified release capsules to the FDA on May 29. The proposed trade name for this product is Rayaldee. In the NDA we requested FDA approval of Rayaldee for the prevention and treatment of secondary hyperparathyroidism in patients with Stage 3 or 4 chronic kidney disease and Vitamin D insufficiency. Our application is supported by data from three randomized double-blind placebo-controlled studies and one open-label extension study conducted in the targeted patient population. The two pivotal studies were covered by a Special Protocol Assessment established in advance. They met all primary efficacy and safety endpoints.

The Agency informed us by telephone on July 28th that the NDA was sufficiently complete for review and that it had been filed. We expect to receive a written notification of NDA acceptance along with the PDUFA date in the forthcoming 74-day letter. We anticipate receiving this letter by mid August. Our next milestone with the FDA is the submission of a 120-day safety update due on September 25th.

During the course of FDA review of the NDA, we are undertaking efforts to prepare for a product launch in the first half of 2016. Our plans of course will be continually adjusted in accordance with any comments received from the Agency and the forthcoming PDUFA date. Assuming that the NDA is approved, OPKO will launch the product in the US with our own dedicated salesforce targeting nephrologists and endocrinologists who care for patients with Stage 3 or 4 chronic kidney disease.

Before I pass the teleconference over to David Okrongly, I d like to briefly mention that we are now discussing a final global Phase 3 trial with Fermagate, our calcium-free phosphate binder. The design of this trial will be further discussed with FDA and with selected European regulatory authorities with the goal of finalizing a study protocol in the first half of 2016. The initiation of the trial is planned to follow as soon as possible thereafter.

David?

David Okrongly:

Thank you, Charlie. I m going to give an update now on the Diagnostics Division of OPKO Health and I ll break it down into two categories. First I ll give you an update on the 4Kscore, our test for predicting the risk of aggressive prostate cancer, and then I ll conclude with the Claros update which is our finger-stick whole blood point-of-care analyzer.

So in July, the 4Kscore test achieved a major milestone when the 4Kscore test was included in the 2015 National Comprehensive Cancer Network Guidelines for prostate cancer early detection. The NCCN Guidelines represent a transition phase for the 4Kscore test in that it is now included in one of the leading guidelines directing physicians on how to manage early detection of prostate cancer. Also very notable in the National Comprehensive Cancer Network Guidelines Update is a shifting emphasis on the detection of aggressive cancer. It s now very clearly being recognized that we want to develop biomarker tests that ll allow us to sort out the aggressive form of prostate cancer and leave behind men who have indolent forms of cancer or have no cancer at all, and that plays perfectly to the message and the validation that s been conducted on the 4Kscore test over the last 10 years and is now represented in 12 peer review publications on over 22,000 patients.

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Importantly in that Guidelines Update by NCCN, the 4Kscore test is now indicated as being appropriate before both a first prostate biopsy, that is a biopsy that might be conducted after a PSA is tested and found to be elevated. It s also indicated for use in the repeat biopsy setting. This would be for a patient who s been found to have no cancer, no prostate cancer on an initial biopsy but may still have other clinical symptoms such as elevated PSA or a digital rectal exam that s abnormal.

Also important in the Guidelines was the highlighted superior performance of the 4Kscore test for aggressive disease. The review panel clearly reviewed and acknowledged the performance of the 4Kscore test in aggressive prostate cancer. We re very excited about this development and it s further buoyed our efforts to pursue reimbursement as well as a Category 1 CPT code.

The administrative code is a code that we currently have for the 4Kscore test and this became active on July 1 and shortly thereafter we began billing both Medicare and private insurance for the 4Kscore tests. A Category 1 CPT code would catapult us up to the very highest level of CPT code and medical evidence. That application on July 15th will be reviewed by the AMA CPT Editorial Board in October and we expect to have a favorable review of that finalized by the beginning part of 2016.

As I mentioned, we ve been billing Medicare and private insurance now for several weeks in four of our current territories, and that billing program is still in its very early days and I do not have any feedback for you on that just yet.

What I would also like to point out is that as part of our ongoing efforts to seek reimbursement with both Medicare and private insurance, we are conducting a clinical utility study looking at how the 4Kscore test has changed clinician behavior. The physicians that we are interviewing are physicians who have treated approximately 400 patients and used the 4Kscore test to make a treatment decision. We believe that that evidence is going to show very favorably that the 4Kscore test is influencing clinician behavior and thus will achieve the targeted savings that the 4Kscore test can show in managing patients with elevated PSA or an abnormal DRE.

I ll give an update also on where we are at with BRL, Bio-Reference Laboratories. This acquisition should be closing in the next couple of weeks and will allow the 4Kscore test to now take advantage of the tremendous capability within the Bio-Reference Laboratories for both access to blood draw centers where patients can be sent by their urologists or primary care physician, get their blood drawn and then have that sample transported directly to the Bio-Reference laboratory facility in Elmwood Park, New Jersey. We also have a great advantage in that the Bio-Reference contracts they have with virtually every major private insurance company across the United States will now be put under contract for the 4Kscore test and other pathology services. Vice versa, we could use the contract that OPKO has that are important to BRL, particularly in Tennessee and also a national coverage contract, and they can be listed as a place of service under that contract. So that s one of the very important integration activities that s going on now and we will be moving towards the informing of our private insurance contractors coming up in the next couple of weeks.

I m going to conclude the Diagnostics summary with an update on Claros. As you know, we are developing the PSA and testosterone diagnostic tests for clinical trials and that continues according to the timelines we ve previously announced. We re looking to do a 510(k) filing on testosterone in the first half of 2016 and to have a PSA filing beginning also in the first half of 2016.

Clinical development of testosterone, which is an assay that requires a release step of the testosterone from a binding protein in the blood, is a prelude for our Vitamin D product that we are still looking to have available in time for the Rayaldee launch and reimbursement decisions that are going to be coming up for Rayaldee. So we expect to be able to have the testosterone cassette be able to be used for Rayaldee and be ready to support Rayaldee when it s under coverage by insurance companies.

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With that, I ll conclude the remarks for Diagnostics and I ll turn it over to Phillip Frost, our Chairman and CEO at OPKO Health.

Dr. Phillip Frost:

Thank you, David. Well, you ve heard a review of various parts of the Company and its activities during the last quarter and first half. I d like to highlight another acquisition that we made during this period and that s the EirGen company in Ireland. This is a company that was founded several years ago by a very talented group who worked for us at Ivax. They were talented with respect to formulation ability, manufacturing, quality and regulatory affairs, all the ingredients needed for a successful company. They also had a superb strategy and this was to focus on products that are considered high potency. The consequence of this is that among those products there tends to be very few players with each one. This means that for a high-potency generic product, because there are fewer companies selling them, there s less competition and the margins tend to be higher. So this strategy is a way of achieving higher margins and profits by concentrating on a smaller group of products that we can both develop and manufacture in Ireland. I stress this because Ireland turns out to be a very, very good place to concentrate one s efforts. It s important because the government essentially pays for the R&D work going on there, and secondly, we, as others, enjoy a very low tax rate in Ireland. So we plan to make this an area of future concentration so far as our development and manufacturing activities are concerned.

I ll close by simply stating that in future quarters we hope to, on an ongoing basis, report better financial results, and I ll leave it there to lead into any questions that you might have.

Operator:

Thank you. Please press star, one to ask a question. Make sure your mute button is disengaged to allow your signal to reach our equipment. That is star, one to queue, and we ll pause to give everyone an opportunity to signal.

Our first question comes from Rohit Vanjani with Oppenheimer.

Rohit Vanjani:

Hi everybody. Thanks for taking the questions. So I m not sure, this might be for Jane, but a couple of weeks back you provided updated guidance on Lagova in the adult indication noting that the study is expected to end towards the second half of 2016 and then with a regulatory submission to follow study completion. I would think the potential launch would happen in the second half of 17 or early 2018. I guess I always thought of the adult indication being launched in 2016 with the pediatric launch in 2018. What changed there for the timelines?

Jane Hsaio:

You know, with collaboration with Pfizer it s very important for us to look at the market opportunities and with that in mind that we look at how best to introduce the product. So from that point of view we are already thinking ahead about introducing the pen and things like that that will be one of the considerations. Another thing is the original enrolment for the Phase 3 adult study, it was a challenge. We actually pulled through and just are completing all the enrolment just recently. So based on finishing the 12 months study from the last patient enrolled to having the data clean up and preparing the BLA information, indeed, yes, we are behind from our original projection.

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Rohit Vanjani:

Okay. Is the pediatric indication, are you still planning to launch that for 2018, so they ll be together side by side?

Jane Hsaio:

No. The pediatric study we are looking to we are still talking to the regulatory authorities, so the protocol won t be finalized until maybe the best will be beginning of next year, so once we have the protocol and that s really getting all the study sites online and getting the study to initiate, so we re looking at maybe more of a not a 2018 timeline, more like a 2019 timeline.

Rohit Vanjani:

Okay. Is it how long will the study take? I m sorry. So you ll the protocol will be finalized beginning first half 16 and the study will start then and it s a two-year study?

Jane Hsaio:

Basically it s a one-year study and as you know, the enrolment itself will take somewhere from 12 to 18 months for a pivotal study. Because it s an orphan indication and each site basically can only produce a couple of naïve patients that qualify to enter into the trial, so that unlike the other indications this is a particularly challenging and now we have to have many, many, many sites to first qualify and get them signed up. So we can even though we want to do it faster, but unfortunately that s not the case even though we will try our best.

Rohit Vanjani:

I should have said that, yes. I meant a two-year timeline for the study including enrolment.

Jane Hsaio:

Yes, it s more of a two-year right.

Rohit Vanjani:

Including enrolment, yes. I m sorry. Okay. So do you see the launch of Lagova as being in line with some of the other anticipated competitive products should they get approval, or is it kind of now behind maybe some of those other competitors?

Jane Hsaio:

I think from the data we have seen with our competitors, we have the most comprehensive long-term safety and efficacy data. So I m very comfortable with what we have and I think at the end of the day this product should be pretty good, should be very competitive.

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Rohit Vanjani:

Then I know it s still fairly early and well ahead of the Lagova launch, but what does it mean to you if anything that only Lilly s Humatrope and Novo Nordisk Norditropin were left on CVS s preferred formulary for 2016 and only Nutropin, Omnitrope, Saizen and Zomacton were left on Express Scripts preferred formulary for 2016, because the Pfizer product was left off I guess?

Jane Hsaio:

On that, I really cannot comment on that, not on this side of the commercial. Sorry.

Rohit Vanjani:

Okay. Then Dave, for Claros 1, just wanted to be clear about the timeline. So it s first half 16 launch of testosterone and PSA and then would the Vitamin D potentially launch?

David Okrongly:

No. Sorry, Rohit. First half is going to be our filing date for testosterone for both PSA and for testosterone.

Rohit Vanjani:

Okay and then it would be a three-month timeline from that filing?

David Okrongly:

That s, you know, hard to predict but we assume three to six months typically with a filing for diagnostic.

Rohit Vanjani:

Okay. So launch maybe second half 16 and then for Vitamin D? I m sorry.

David Okrongly:

For Vitamin D, we re really looking to we re going to learn from testosterone exactly how to do the Vitamin D. We think that there s great value in the cassette, the special cassette for testosterone. We would look to do that filing by the end of 2016 and that would kind of line us up with when we expect Rayaldee to be on the formulary.

Rohit Vanjani:

Okay. It s the same three to six month maybe anticipated filing timeline. I know there s like a little bit.

David Okrongly:

Yes. These should go a little quicker once the first one goes through, and, you know, Vitamin D is a straightforward 510(k) so I would be looking I would be expecting more the three-month timeframe there.

Rohit Vanjani:

Okay.

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Jane Hsaio:

David, this is Jane. I have a different estimate as you do in terms of FDA review time three to six months. Bear in mind this Claros 1, this device itself is the first time presented to FDA. My personal opinion is it s going to take longer than three to six months.

Rohit Vanjani:

Okay. Then in and this might be for Adam. So in the S-4, the BRLI documents you provided Management s revenue projection for 2015 to 2019, what s included in that 2016 to 2018 timeframe for Lagova if the adult and pediatric indications got pushed out?

Adam Logal:

Yes, so Rohit, as you would imagine, for Lagova we are projecting kind of in connection with the timelines that Jane had just walked through.

Rohit Vanjani:

So whatever those projections were in that S-4 maybe some of that would have to come out because that had the original anticipated.

Adam Logal:

I think it had the revised or updated timelines in it already.

Rohit Vanjani:

Okay. So those projections are still accurate?

Adam Logal:

Yes. Well, as we disclosed they re not necessarily risk-adjusted or probability adjusted, but yes.

Rohit Vanjani:

Okay. Then I think Dave, yes. This is going back to Dave. I m sorry. For 4Kscore, what would that mean well how many territories are you in, first of all? You said that you ve begin billing to four territories. How many total territories are you in and have you been paid in the couple of weeks that you ve billed?

David Okrongly:

Well, I think what we re going to do, Rohit, is just withhold discussion about the payment yet because it s still a very early stage and we re having discussions actively right now. The four territories that we re billing in are four of the 12 territories. We look to the United States though as really requiring about 25 different sales reps, so we re representative in just a very small portion right now of the country with our billing. But I will say that the physicians that we re working with are very excited about the fact that they can now offer this to their patients with the expectation that reimbursement is going to be on the horizon and they re very, very happy to partner with us, pursuing the reimbursement should those rejections come.

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Rohit Vanjani:

Then just my last question: what would that mean kind of practically if you get that Category 1, when did you say? In October is when they re going to determine that?

David Okrongly:

Yes, so they what the process is it s fairly long but it s kind of an essential follow-on to our administrative code. So the review process is October for final decision by the AMA CPT Editorial Board. The code, we would get approval or we would get indications that it s been approved sometime in December or January and then that would become active in 2017. That is about the same time that other regulations come into play or other law comes into play which is PAMA. We don t know if PAMA is going to be delayed or not but that also sort of makes these advanced laboratory diagnostic tests like the 4Kscore test kind of fall under an automatic payment from Medicare and then it would adjusted down the road by what the private payers are paying for it. So, we wanted to do this because we think it s an important designation. It puts it up there in a standard-of-care kind of categorization. It s not essential though to get paid for the test.

Rohit Vanjani:

Okay. So sorry, so just to be clear. So it s an automatic payment from Medicare; it would almost be a virtual automatic from private too? It s just kind of whatever the negotiated rate is?

David Okrongly:

Yes, there s nothing automatic about this but, you know, typically Category 1 CPT codes would be paid by Medicare. But we expect that we re going to be paid by Medicare even without having the Category 1. It s just that it s something that we now have the guidelines evidence to put in there and we also have gotten additional publications supporting the use of the test. So we think it actually quite exceeds the requirements for a Category 1.

Rohit Vanjani:

Okay. Great. Thanks for taking the questions. I appreciate it.

Operator:

That is star, one for your questions today, or star, two to exit the queue if your question has already been addressed.

We ll go next to Kevin DeGeeter with Ladenburg.

Kevin DeGeeter:

Hey, good afternoon. A few questions. Let s go ahead and get Charlie in here. Charlie, do you expect there to be an FDA Advisory Panel meeting for Rayaldee?

Charles Bishop:

Hi Kevin. No I don t. To date to the best of my knowledge FDA has not used an Advisory Panel for a drug that s in the Vitamin D pharmacology class.

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Kevin DeGeeter:

Terrific. With regard to pre-commercialization, when should we look for the initial hiring of a salesforce and perhaps some pharmacoeconomic studies being published and other relatively standard pre-commercialization activity?

Charles Bishop:

You ll see activities like these all through the NDA review. We will start our hiring of the salesforce effort in Q4. I expect that sales reps will be employed in the beginning of Q1. Publications, you re going to see coming out over the entire period, and of course after approval should we be approved.

Kevin DeGeeter:

Okay. Great. Then just kind of returning to Lagova for a moment, as we think about the timelines discussed for the pediatric Phase 3 and potential approval, does this planning process allow for the transition of the manufacturing over to Pfizer prior to initiation of the Phase 3? Or do you anticipate using material from the OPKO Israel facilities and protocols and then subsequently bridging to Pfizer for following the Phase 3?

Jane Hsaio:

Well Kevin, as we speak, this transition process is ongoing from day one of the collaboration.

Kevin DeGeeter:

So your anticipation at this point is for the pediatric study that we would be able to use product manufactured at the Pfizer facility and thus not need to do a bridging, is that correct?

Jane Hsaio:

No. There will still be bridging because our Phase 2 is from a different site.

Kevin DeGeeter:

Okay. That s helpful. Then just with regard to the Factor VII program, when is a realistic timeline to provide to get an update with regard to just pharmacokinetics for that product?

Jane Hsaio:

You re talking about clinical trial?

Kevin DeGeeter:

Clinical trial, yes.

Jane Hsaio:

Well we have the IND approved. We expect the first in-patient. As I mentioned, we are waiting and working on getting the IRB approval and the laboratory contract in place. So we re looking in the next few months time.

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Kevin DeGeeter:

Okay. Great. Then maybe just one more with regard to for Dave on the Claros platform. Can you just kind of walk us through from a development standpoint what the gating factors for the Vitamin D tests sort of are at this point? Is it more sort of a regulatory component of getting the testosterone cassette through FDA as part of the initial review? Or is there technical considerations with regard to the time to deal with the binding protein that still need to be addressed?

David Okrongly:

Vitamin D is a challenging test for all manufacturers and testosterone is really our entrée into this world of immunodiagnostics that require release steps, and with the bandwidth we have here in development, we ve really focused on testosterone to get that right. Then we re going to have resources that are freed up to now take what we ve learned about the testosterone program and apply it to Vitamin D. I think a successful testosterone program bodes very well for Vitamin D.

Kevin DeGeeter:

Okay. Great. I appreciate the clarity. Thanks so much.

Operator:

This concludes the Q&A section of our call. I d now like to turn the call back to Dr. Frost for closing remarks.

Dr. Phillip Frost:

I just want to thank you all for attending and participating and we look forward to being together with you in a few months. Bye now.

Operator:

This concludes today s call. We thank you for your participation.

Important Information For Investors And Shareholders

This communication does not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities or a solicitation of any vote or approval. This communication relates to a proposed business combination between Bio-Reference Laboratories, Inc. (Bio-Reference Laboratories) and OPKO Health, Inc. (OPKO). In connection with this proposed business combination, Bio-Reference Laboratories and/or OPKO will file relevant materials with the Securities Exchange Commission (the SEC), including an OPKO registration statement on Form S-4, which was filed with the SEC on July 2, 2015, was amended by Amendment No. 1 on July 15, 2015, and was declared effective on July 17, 2015, and a definitive proxy statement/prospectus in connection with the proposed transaction, which was filed by Bio-Reference Laboratories and OPKO on July 20, 2015. Bio-Reference Laboratories first mailed the definitive proxy statement/prospectus to Bio-Reference Laboratories shareholders on July 20, 2015. INVESTORS AND SECURITY HOLDERS OF BIO-REFERENCE LABORATORIES AND OPKO ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT/PROSPECTUS AND OTHER DOCUMENTS THAT MAY BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION.

Investors and security holders may obtain free copies of the definitive proxy statement/prospectus and other documents filed with the SEC by Bio-Reference Laboratories and/or OPKO through the website maintained by the SEC at www.sec.gov. Copies of the documents filed with the SEC by Bio-Reference Laboratories are available free of charge on Bio-Reference Laboratories website at http://www.bioreference.com or by contacting Bio-Reference Laboratories Investor Relations Department by email at tmackay@bioreference.com or by phone at (201) 791-2600. Copies of the documents filed with the SEC by OPKO are available free of charge on OPKO s website at www.opko.com or by contacting OPKO s Investor Relations Department by email at contact@opko.com or by phone at (305) 575-4100.

Participants in Solicitation

Bio-Reference Laboratories, OPKO, their respective directors and certain of their respective executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about the directors and executive officers of Bio-Reference Laboratories is set forth in its Annual Report on Form 10-K for the year ended October 31, 2014, which was filed with the SEC on January 13, 2015, its Quarterly Report on Form 10-Q for the quarter ended April 30, 2015 which was filed with the SEC on June 9, 2015 and its Current Reports on Form 8-K, which were filed with the SEC on March 5, 2015, April 29, 2015, June 4, 2015, June 8, 2015, June 10, 2015 and June 11, 2015. Information about the directors and executive officers of OPKO is set forth in its amended Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on February 27, 2015 and April 30, 2015, its proxy statement for its 2015 annual meeting of stockholders, which was filed with the SEC on May 7, 2015, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 which was filed with the SEC on May 11, 2015 and its Current Reports on Form 8-K, which were filed with the SEC on March 19, 2015, June 4, 2015, June 9, 2015, June 10, 2015, June 18, 2015 and July 2, 2015.

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These documents can be obtained free of charge from the sources indicated above. Additional information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, is contained in the definitive proxy statement/prospectus and other relevant materials filed with the SEC.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements in this communication regarding the proposed acquisition of Bio-Reference Laboratories by OPKO, including any statements regarding the expected timetable for completing the proposed transaction, synergies, benefits and opportunities of the proposed transaction, future opportunities for the combined company and products, future financial performance and any other statements regarding OPKO s and Bio-Reference Laboratories future expectations, beliefs, plans, objectives, financial conditions, assumptions or future events or performance that are not historical facts are forward-looking statements made within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words anticipate, believe, ensure, expect, if, intend, estimate, probable, project, forecasts, predict, outlook, aim, will, potential, may, might, anticipate, likely plan, positioned, strategy, and similar expressions, and the nega are intended to identify forward-looking statements.

All forward-looking information are subject to numerous risks and uncertainties, many of which are beyond the control of Bio-Reference Laboratories and OPKO, that could cause actual results to differ materially from the results expressed or implied by the statements. These risks and uncertainties include, but are not limited to: failure to obtain the required vote of Bio-Reference Laboratories shareholders; the timing to consummate the proposed transaction; the risk that a condition to closing of the proposed transaction may not be satisfied or that the closing of the proposed transaction might otherwise not occur; the risk that a regulatory approval that may be required for the proposed transaction is not obtained or is obtained subject to conditions that are not anticipated; the diversion of management time on transaction-related issues; ability to successfully integrate the businesses; risk that the transaction and its announcement could have an adverse effect on Bio-Reference Laboratories ability to retain customers and retain and hire key personnel; the risk that any potential synergies from the transaction may not be fully realized or may take longer to realize than expected; new information arising out of clinical trial results; and the risk that the safety and/or efficacy results of existing clinical trials will not support continued clinical development, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this communication may become outdated over time. OPKO and Bio-Reference Laboratories do not assume any responsibility for updating any forward-looking statements. Additional information concerning these and other factors can be found in Bio-Reference Laboratories and OPKO s respective filings with the SEC and available

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through the SEC s Electronic Data Gathering and Analysis Retrieval system at www.sec.gov, including Bio-Reference Laboratories and OPKO s most recent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and the definitive proxy statement/prospectus. The foregoing list of important factors is not exclusive. Bio-Reference Laboratories and OPKO assume no obligation to update or revise any forward-looking statements as a result of new information, future events or otherwise, except as may be required by law. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof.