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OPK - Q4 2019 OPKO Health Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, everyone, and welcome to the OPKO Health Fourth Quarter 2019 Financial Results Conference Call. (Operator Instructions) And as a reminder, this conference is being recorded.

I would now like to hand the conference over to your speaker today, Ms. Yvonne Briggs.

Yvonne Briggs - LHA Investor Relations - VP

Thank you, operator. Good afternoon. This is Yvonne Briggs with LHA. Thank you all for joining today's call to discuss OPKO Health's financial results for the fourth quarter of 2019.

I'd like to remind you that any statements made during this call by management other than statements of historical facts will be considered forward-looking and as such, will be subject to risks and uncertainties that could materially affect the company's expected results. Those forward-looking statements include, without limitation, the various risks described in the company's SEC reports, including the annual report on Form 10-K for the year ended December 31, 2019, to be filed within the next few days. Importantly, this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, today, February 26, 2020. Except as required by law, OPKO undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this call.

Before we begin, let me review the format for today's call. Dr. Phillip Frost, Chairman and Chief Executive Officer, will open the call. Then Steve Rubin, OPKO's Executive Vice President, will provide a business update and pipeline review. And Dr. Jon Cohen will discuss BioReference Laboratories. After that, Adam Logal, OPKO's CFO, will review the company's fourth quarter financial results. And then we'll open the call to questions.

Now let me turn the call over to Dr. Frost.



Phillip Frost - *OPKO Health, Inc. - Chairman & CEO*

Good afternoon and thank you for joining the call today. 2019 was a noteworthy year for OPKO, with significant accomplishments across the company's business units. We reported favorable top line results for the somatrogen Phase III trial in children with growth hormone deficiency, meeting our end point of noninferiority for somatrogen injected weekly versus the current standard of daily injections. Now we're looking forward to the ENDO conference at the end of March, where more detailed Phase III trial data will be presented.

Under the new executive leadership that's been in place since the beginning of last year, BioReference Laboratories is making great progress to improve its top and bottom line financial performance. We believe the business is stable and is poised for growth in 2020. In November, our 4Kscore test received a final Local Coverage Determination, effective December 30, 2019, to reestablish reimbursement for the important Medicare patient population. Also, RAYALDEE continues to make good progress each quarter in terms of sales, number of prescriptions and number of prescribers, with clinical trials underway to expand the spectrum of indications. With these milestones now behind us, we plan to focus on execution to realize the value of OPKO's assets.

I'm going to turn the call over to Steve now to get into more detail on our business units.

Steven D. Rubin - *OPKO Health, Inc. - Executive VP of Administration & Director*

Thanks, Phil. Good afternoon, everyone, and thank you for joining us today. As Phil indicated, we are very pleased with the company's accomplishments with progress across multiple programs and important milestones. One of the year's biggest highlights was obtaining the favorable top line results of our global Phase III trial evaluating somatrogen dosed once weekly in prepubertal children with growth hormone deficiency. Somatrogen represents a significant advance in the treatment of children with growth hormone deficiency that should improve adherence to treatment and enhance quality of life compared with the current standard of daily injections.

The trial successfully met its primary end point of noninferiority to GENOTROPIN injected daily with respect to height velocity after 12 months. We are delighted that 2 abstracts of the data set have been accepted for oral presentation at the Endocrine Society's 2020 meeting in San Francisco in March: one pertaining to the results of our pivotal Phase III study and the other to insulin-like growth factor or IGF-1 levels following the administration of somatrogen. It is worth noting that our Phase III trial included 83 sites in 21 countries, including parts of Asia and Latin America.

The global enrollment is part of a strategy that enables Pfizer, our commercial partner, to seek approval to commercialize somatrogen on a worldwide basis. We expect Pfizer to submit the Biologics License Application to the FDA in the second half of 2020. In Europe, we expect a Market Authorization Application to be submitted upon the completion of an open-label study, demonstrating greater benefit and compliance with reduced treatment burden, which is expected to be completed in the third quarter of 2020. The registration study in pediatric GHD patients in Japan is on track for completion by the end of the first quarter with top line data readout expected in the second half of 2020.

Under our agreement with Pfizer, OPKO is eligible to receive up to \$275 million upon the achievement of certain regulatory and pricing milestones. In addition, following product launches in certain major markets, we are entitled to regional tiered gross profit sharing for both somatrogen and Pfizer's GENOTROPIN.

Turning now to our commercial pharmaceutical business. I would like to focus on RAYALDEE. From a commercial performance perspective, the RAYALDEE numbers for the quarter break down as follows: total prescriptions of RAYALDEE in Q4 2019, as reported by IQVIA, increased 89% compared with Q4 2018 and showed continual sequential growth with a 20% increase compared with Q3 of 2019. New patient starts increased 15% in Q4 versus Q3. Since launch, over 17,000 patients have had RAYALDEE prescribed by over 2,600 physicians. Over 260 physicians or 10% were new RAYALDEE prescribers in Q4.

As of January 1, approximately 86% of the addressable market has access to RAYALDEE without prior authorization by payers or other restrictions. Our partner, Vifor Fresenius, anticipates European approvals for RAYALDEE and first commercial launch later this year.

We are seeking to expand our RAYALDEE franchise with approvals for additional indications. In September 2018, we initiated Cohort 1 of a global Phase II trial for higher-strength RAYALDEE in patients with stage 5 chronic kidney disease and vitamin D insufficiency who require regular dialysis. We expect an interim data readout later this quarter. Also, we have an ongoing comparative Phase IV study designed to demonstrate that RAYALDEE is superior to commonly used therapies. Initial readout of top line data is anticipated later this quarter.

Finally, we are planning a Phase III study with RAYALDEE in pediatric patients as part of a postmarketing requirement, and we expect this study to commence in Q3 2020. We believe these efforts will broaden RAYALDEE's label and further increase its market penetration to become a meaningful contributor of sales and earnings for our company. We have several additional programs in both preclinical and late-stage clinical development in our pipeline. We continue to advance clinical development of these technologies while seeking a partner for some.

Following the successful Phase III trial evaluating once-weekly CTP growth hormone to treat children with growth hormone deficiency, we are now focused on the development of other long-acting therapies for our rare disease platform. The rare disease platform includes a long-acting GLP-2 compound for short bowel syndrome, CTP-hGH antagonist for acromegaly and our CTP-IGF-1 for growth failure associated with severe primary insulin-like growth factor deficiency. We are also exploring various indications for our selective androgen receptor modulator or SARM given the promising clinical data from prior studies demonstrating increased lean body mass and physical function and decreased PSA levels in aging males.

Recently, Dr. Bhasin and his colleagues at Brigham and Women's Hospital confirmed previous data in prostate cancer patients who have undergone radical prostatectomy in a Phase II study following treatment with our compound for 12 weeks. Top line data demonstrated that our compound had a good safety profile, increased lean body mass and decreased fat mass with no elevated levels of PSA. Over several studies now, our compound has consistently demonstrated improvement in lean body mass and decreased fat mass in aging males, particularly in patients with low levels of testosterone.

It is well-known that many end-stage renal disease patients on dialysis have low testosterone levels and suffer from frailty and muscle wasting, symptoms that diminish their quality of life. We are considering a late-stage clinical trial evaluating our SARM for the treatment of muscle wasting symptoms such as muscle strength and physical function in this patient population.

And with that overview, let me turn the call over to Jon Cohen for a discussion of our diagnostic business. Jon?

Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

Thanks, Steve, and good afternoon, everybody. I am pleased to report that BioReference Laboratories continues to make progress towards its goal to improve top line and bottom line results. We are beginning to see the positive impact of the organizational changes we put in place to specifically grow our oncology, urology, women's health and genetics businesses.

In addition, our plan to develop a vigorous business development infrastructure to identify, develop and pursue a pipeline of new strategic partnerships to deliver large books of businesses is beginning to bear fruit. We have seen growth in our accounts related to accountable care organizations, IPAs, clinically integrated networks, federally qualified health systems, prisons, large medical groups and physician office labs. We are in various stages of discussions with some additional strategic partners, and hope to make some very positive announcements in the next several months.

The centerpiece of our strategy remains a commitment to the best possible patient-centric experience and to differentiate ourselves in the market with an obsession to patient service and convenience. The journey significantly to improve patient experience has just begun. And over the next several months, we will announce new technology investments and partnerships in this space.

We continue to make progress with our initiatives to improve payer access with new in-network relationships to an increasing number of health plans. This includes increasing our access to Medicaid patients via new and expanded contracts with Aetna Better Health, AmeriHealth, Centene and Molina. In addition, we have had success at gaining in-network status with local and regional plans such as the Harvard Pilgrim Health Care, Health Net, TRICARE West, Sentara and AllWays Health plans for GeneDx. At the same time, as a result of our UnitedHealth preferred provider lab relationship, we continue to aggressively pursue out-of-network providers and targeted specialty programs.

As Phil mentioned, Medicare coverage for 4Kscore resumed on January 1 of this year as a result of the new local coverage decision by Novitas. January, the first month with coverage, saw an increase of 16% in test orders compared to December. We continue to invest in the 4Kscore sales force, and we'll be doubling the number of sales reps within the next couple of months.

In addition, I am pleased to report that in December, the FDA accepted our Premarket Approval Application or PMA for the 4Kscore. We expect to receive a determination from the FDA this year.

With regard to GeneDx, this quarter saw volume increases in Q4 compared to Q4 of 2018, and year-over-year growth, we saw an increase of 9%. GeneDx continues to strengthen its relationships with leading children's hospitals and academic medical centers around the country to drive increases in growth and revenue. And as a result, our exome business increased 16% for the year.

I want to briefly mention the coronavirus outbreak. We have been in constant contact with the CDC, FDA and various state departments of health. Currently, only the CDC and other public health labs are authorized to provide testing for the virus in the United States. No commercial lab -- no commercial test for the virus is currently available. We are prepared to launch the diagnostics for the virus depending on the advice from the state departments of health as to when commercial testing for the virus will be permitted.

With that overview, let me turn it over to Adam for a discussion of our fourth quarter financial performance. Adam?

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

Thank you, Jon. Overall, we saw improvement in the financial results from operations.

Starting with BioReference, revenues were \$178 million, which exceeded the guidance we provided during our third quarter call. The results from operations for BioReference remained consistent with the third quarter and on a comparative basis to 2018, showing decreased expenses as controlled by our management team. With the cost reductions that Jon and Geoff and their teams implemented during 2018 and 2019, we are well positioned to show continued improvement in our operating results throughout 2020.

Our diagnostics segment had an operating loss during the fourth quarter of 2018 of \$27.3 million compared to an operating loss of \$45.4 million for the fourth quarter of 2019, which included a noncash impairment charge related to our Claros point-of-care device of \$38.7 million. The year-to-year comparative results reflect the elimination of over \$20 million in cost of revenue and selling, general and administrative expense compared to Q4 of 2018. RAYALDEE revenues of \$12.6 million also exceeded our guidance, attributable primarily to the strong prescription growth that Steve highlighted and improvement in our net realized price.

The noncash impairment charges we recorded during the quarter were triggered by the decline in our market cap during the fourth quarter and the allocation and timing of capital available to advance certain of our programs. These factors impacted the assumptions and estimated timing of the program's future cash flows. The noncash impairment charges impact both our pharmaceutical and diagnostic operating segments by approximately \$53 million and \$39 million, respectively, totaling approximately \$92 million recorded during the fourth quarter.

Overall, our costs and expenses, including the noncash impairment charge, totaled \$337 million for the fourth quarter of 2019, which compares to \$311.9 million for the fourth quarter of 2018, which included a noncash impairment charge of \$21.8 million. Our guidance of costs and expenses of \$265 million to \$275 million didn't take into account the significant noncash impairment charge taken during the quarter. Cost of revenue, selling, general and administrative and other operating expenses were otherwise in line with our expectations with R&D being slightly below our previous guidance, coming in at \$23 million, reflecting lower costs associated with our hGH program.

We announced today that we entered into a credit facility with Dr. Frost, providing us with \$100 million of liquidity on a nondilutive basis. We believe the availability of these funds, along with our cash balance as of December 31 of \$85 million, provide us with sufficient liquidity to fund our development programs into 2021. Our RAYALDEE commercial organization is now providing positive cash flow. With BioReference's continued improvement in operating activities, 2020 should result in a reduction in cash used by operations.

With that, I wanted to review our expectations for 2020's financial performance based on what we know today and more specifically our anticipated first quarter 2020 financial results. We expect revenue from services for Q1 to be between \$168 million and \$173 million. The revenue range provided is based on a mix of volume and reimbursement assumptions and compares to \$178 million for the first quarter of 2019. And looking at the full year, revenue from services are expected to come in between \$715 million and \$740 million, which compares to the \$716 million for the full year of 2019. The revenue ranges for Q1 and the full year forecast reflects our assumptions around the impact of PAMA, along with the expected benefit of a full year of 4Kscore revenues, overall volumes in our clinical lab testing being similar to 2019 volumes and continued growth of our genetic testing business.

Turning to product revenues. We expect the first quarter to be between \$30 million and \$32 million, including revenues from RAYALDEE of between \$9.3 million and \$10.5 million, while revenues from the transfer of intellectual property are expected to be between \$15 million and \$18 million. For the full year, we anticipate product revenue to be between \$130 million and \$150 million, including RAYALDEE revenues of \$50 million to \$60 million. The revenue range for RAYALDEE reflects assumptions around our unit growth as well as our net realized price, which fluctuates from quarter-to-quarter, with the highest net price typically realized in the first and fourth quarters of the year, as well as various assumptions of ranges for our international businesses.

For revenue from the transfer of intellectual property, we expect this to be between \$20 million and \$30 million for the full year but will be less predictable during 2020 as it is somewhat dependent on reimbursement of expenses related to our partnered programs rather than the historical amortization of upfront payments from Pfizer.

Looking at anticipated expenses for the first quarter. We expect costs and expenses to be between \$265 million and \$275 million, including research and development expense of \$23 million to \$28 million. For the full year, we expect costs and expenses to be between \$1.08 billion and \$1.13 billion, including research and development expense of \$85 million to \$125 million. There are 2 significant factors impacting our R&D spend. One reflects the available capital to allocate to new R&D programs, and the other is how we record costs associated with our license revenue, which represents about 50% of the range.

Expense rationalization and capital allocation will remain a top priority throughout 2020 as we work to ensure we have the right infrastructure to support our growth. We continue to have expectations for improved cash flows and financial performance within our diagnostics and RAYALDEE commercial businesses, both of which are important for our continued investments into R&D.

With that, I'll open the call for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from the line of Maury Raycroft.

Farzin Haque

This is Farzin on for Maury. So the question is regarding the ENDO abstracts that are posted already. And we're wondering if you can provide some more specifics on what analysis will be included in the update on the main study and the IGF abstract.

Steven D. Rubin - OPKO Health, Inc. - Executive VP of Administration & Director

Yes, both -- well, one of the abstracts is demonstrating top line data, particularly the secondary -- primary but also the secondary end points. The study showed -- I can give you a general overview. I won't get into the specifics or take away anything from the abstract. But generally, as was mentioned earlier, we met our primary end point. It favored the somatrogon over GENOTROPIN. This was true not only at 12 months but also at 6



months. We also looked at the secondary end points such as IGF-1. We also looked at height SDS. And again, it showed consistent data favoring the somatrogen treatment.

Something that I think the data will show, and when you do see it if you -- later when it's presented, is that there's a consistency finding that the data favored somatrogen, both in terms of age, when you separate the patients as per age, or gender or also at the baseline, their severity of growth hormone deficiency. In terms of -- so that, I think, consistently really demonstrates well for the program or the product. Also the safety was, again, comparable to GENOTROPIN. And we'll have more details on that.

The -- we will also have an analysis, which I think has become important as the IGF-1 -- on IGF-1. There will be an oral presentation on that where one of our presenters, the person who actually did a lot of statistics on it, to demonstrate what are the changes in IGF-1 throughout the treatment, throughout the year. And as you know, it's used as a way to monitor treatment with growth hormone to ensure that we're dosing properly throughout the year.

And all I can say is, I think, what the abstract will show is that when you take the IGF-1, the estimated mean IGF-1 for those patients throughout the 12 months, that we have a very low percentage of patients that have higher than and in 2, which is the -- what's required is below -- an IGF-1 SDS below 2. So I think we're in very good shape from that aspect. But again, it's going to be presented at the meeting in more detail.

Operator

And your next question comes from the line of Dana Flanders.

Dana Carver Flanders - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

I had just a couple. I guess my first one on RAYALDEE. Obviously, very nice quarter. Just curious how you expect gross to net to kind of trend throughout 2020 and if you could see just a year-over-year improvement in gross to net. I know you talked about it fluctuating by quarter, but just from a year-over-year perspective, should net price be improving?

And then my second question, just on the labs business. Surprised not seeing a bigger step-up in revenue given the 4Kscore is back in that services line. Can you help us understand some of the pushes and pulls to BioReference? And I know you mentioned PAMA, but just underlying volume versus price and how we should think about the sustainability of revenue growth for BioReference Labs going forward. And then I have one quick follow-up.

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

Sure. Thanks, Dana. So just maybe I'll take RAYALDEE first, and then Jon and I can tackle the labs question. So on the gross to net, we still expect RAYALDEE to be in the low 40% range. We saw fluctuations during 2019 to go between -- as low as 37% and as high as 47%. So really, it depends on the quarter and the utilization.

Q1 guidance is expecting the impact of one payer coming on board and seeing how the utilization of that payer impacts the gross to net. But beyond that, we don't expect any other new payer contracts or agreements to come in place to drive pricing down. Actually, converse to that, we actually are working hard to bring that net price up and get better realization throughout the year.

So Jon, do you want to maybe touch on the...



Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

Yes. Relative to 4K, just remember, the LCD went into effect at January 1, which -- so we have all of 1 -- almost 2 months data where we're seeing a turn compared to the decrease significantly that occurred while we had nonreimbursement. So I think we're -- as you also heard me talk about, we basically have doubled the sales force, but we'll be doubling the sales force within the next several months to specifically sell the 4K test. So we remain optimistic and bullish on 4K.

In terms of the other revenues and volumes, we've seen a leveling off last year relative to where we are compared to the rest of the industry. We're making significant progress on the strategic partnerships that I've talked about and in addition to beginning to win new accounts in urology and particularly in the cancer vertical. The women's health, we're still working through with a new leader. What we're going to do relative to the volumes of women's health, we're again relatively optimistic about turning women's health around the reproductive segment, the issues around sexually transmitted diseases and the issues around the path. The only issue on the women's health side is how we continue to address the inherited genetic portion of that business.

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

Yes. So Dana, when -- with the revenue guide that we provided, it does reflect the impact of PAMA, mostly offset by 4K and then the growth initiatives that Jon is working on, on the rest of the business. So certainly, as some of that sales pipeline, that matures throughout the year, we would likely come back and provide a little bit more clarity on how we think the rest of the year is going to shape up. But as we sit here today, I think that the revenue guide is -- shows a pretty consistent and stable business that should show better profitability within that range as a result of the 4K contributions.

Dana Carver Flanders - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

Okay. Great. And just one quick follow-up. Maybe a bigger picture question. And I know you're not -- you haven't given longer-term guidance, but just wondering how you're balancing kind of initiating new R&D programs versus the kind of push to get cash flow positive. I know you're doing a nice job managing expenses this year, and RAYALDEE is growing, and you could hopefully have hGH on the market long acting in the 2021 time frame. So just curious, how big of a push is that for you? And how are you balancing some of the earlier-stage pipeline programs versus that need to start generating some cash flow?

Phillip Frost - *OPKO Health, Inc. - Chairman & CEO*

Yes, I'll take that. So far as the programs that require a lot of capital, we're going to not go forward without a partner who will provide the cash to do that. The other projects, as they come along, and we have a couple now, and we may see some other interesting projects, we'll only get involved with if the cash required is limited so that we don't anticipate that there will be a big jump in the need for cash for R&D during this year.

Operator

Next question comes from the line of Ted Tenthoff from Piper Sandler.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Congrats on a good quarter and good strong finish to the year. A couple of questions, if I may. Firstly, I saw that you guys filed the PMA for the 4Kscore. And I want to try to understand sort of what that does for that product and also kind of get a little more color on what's leading to the strong RAYALDEE growth and what should be our expectations from that dialysis readout this quarter.

Steven D. Rubin - *OPKO Health, Inc. - Executive VP of Administration & Director*

So I'll take the 4K one. So as you know, and probably the base of your question, we don't need FDA approval to continue the sale because it is fully reimbursed. But it certainly helps on the non-Medicare commercial payers. There's still some out there that want to see that validation. I think it will help on validating for physician purposes as well. Going forward, it has other benefits that you're more restricted with a -- just a local clinical approval to a specific side of it and the like we can expand upon. But for now, I think it's mostly a validation from another regulatory agency of the efficacy of our test.

And on RAYALDEE?

Charles W. Bishop - *OPKO Health, Inc. - CEO of OPKO Renal*

So this is Charlie Bishop. Regarding RAYALDEE, a number of things were key drivers for the increased RAYALDEE growth that we saw in Q4. One of these, of course, was you know that earlier in the year, we expanded the sales force. That sales force has been fully trained, has now got time in the field and is getting traction with regard to sales.

Secondly, our messaging improved substantially last year with the publication of a seminal paper and the messaging that came out of that. We're getting very good traction with that.

And lastly, we had excellent exposure at the American Society of Nephrology meeting that took place in Q4. And I believe that the additional exposure that we got during that meeting with our new messaging has driven substantial sales in the past quarter.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Awesome. That's really helpful. And then just with respect to kind of what we should be expecting from the dialysis readout, what will you be sharing with us?

Charles W. Bishop - *OPKO Health, Inc. - CEO of OPKO Renal*

So we have, as Steve mentioned, the first cohort of a global study ongoing. We do -- it's an open-label study, and we do have top line data expected later this quarter. So we will be announcing in March preliminary data from that study. And the goal of the study has been to determine several key things.

First, if you administer high doses of RAYALDEE, a vitamin D analog, to patients who cannot excrete calcium and phosphorus because they don't make urine, will you see that the drug is tolerated well? So we'll be giving tolerability data first and foremost.

Second, there is, in the medical literature, a general understanding that RAYALDEE, which is calcifediol, cannot be activated unless there's a functional kidney. Dialysis patients don't have functional kidneys. So a goal of the study has been to demonstrate that patients who don't have functional kidneys can activate RAYALDEE. So we expect to be announcing the results of that aspect of the study.

And lastly, there is considerable concern in the literature that a product like RAYALDEE would be unable to reduce elevated parathyroid hormone levels in patients who have developed substantial secondary hyperparathyroidism. The advanced disease causes the glands to become hyperplastic and less responsive to a product like RAYALDEE. So we will be divulging whether or not patients with advanced secondary hyperparathyroidism can indeed respond to RAYALDEE.



Phillip Frost - *OPKO Health, Inc. - Chairman & CEO*

With respect to RAYALDEE, I think we should also emphasize that our partner, Vifor, in Europe has been working diligently on getting it approved to market. And we are hopeful that the first approval will come sometime this year, perhaps in Germany or one of the large countries. And they've turned out to be a very good partner.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

That's great. I appreciate that color, Phil. You made me think of just one thing. Jon, you were mentioning the coronavirus testing. And obviously, we've been all reading about this in the press and seeing stocks move up and down and everything on it. Maybe tell us a little bit more about the potential to be testing for coronavirus. What would have to occur to get a test that could be used?

Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

So the -- so what happens is that the CDC already has released the sequences that are needed to run it. So I would tell you that we could get a test up and running very quickly. One of the questions that's come up right now is that they prefer that you have what's called a reversible airflow lab. So having said that, is you can't get a test up relatively quickly. I'm talking about within a week or 2 once the reagents are released.

But I will tell you that having firstly lived through the issues with H1N1, Zika, there's a certain period it'd be -- at which point it will -- we hope will actually burn out. Being that it's now close to the end of February, entering the spring season in the Northeast and other places of the country, that has a significant impact on flu transmission, as you probably know.

So I'm not going to sit here and predict at all what this will and will not look like or how much testing will be -- will occur. But I will tell you this. As I said in the overview, the state departments of health are keeping it appropriately, relatively tight because they want to track the pandemic. If it does get overwhelming, then they'll release the commercial labs to begin testing. So the time is not long to get it out. The question is if it would be [low] or not, needed or not.

Operator

Next question comes from the line of I-Eh Jen of Laidlaw & Company.

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

My first question is in terms of the growth hormone for the European open-label studies. Could you give us a little bit more color? What was entailed? And I guess you mentioned when that might be completed, but maybe just give me -- give us a little bit more detail overall in that.

Steven D. Rubin - *OPKO Health, Inc. - Executive VP of Administration & Director*

So it's a test unique to Europe. It's a questionnaire-based test really showing that there is a benefit to a -- and lifestyle preference to the patient in injecting once a week versus every day. It's a little more complicated than that. And aligned to the questionnaire, that's pretty much it.

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

So it is not any clinical element related, and it's more of, I guess, survey type of things?



Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

No, there is no clinical element. It's really just determining a benefit and compliance.

Phillip Frost - *OPKO Health, Inc. - Chairman & CEO*

It's a preference.

Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

It's a preference. Yes, at the end of the day, it's a preference.

Steven D. Rubin - *OPKO Health, Inc. - Executive VP of Administration & Director*

No clinical, questionnaire based, yes.

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

And would you remind us, what might be the filing time for Europe based on Pfizer's suggestion?

Phillip Frost - *OPKO Health, Inc. - Chairman & CEO*

We said Q -- for filing on -- for Europe -- you're talking about Europe? Or are you talking about the U.S.?

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

For Europe.

Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

First half of 2021.

I-Eh Jen - *Laidlaw & Company (UK) Ltd., Research Division - MD of Healthcare Research & Senior Biotechnology Analyst*

And maybe one more follow-up question here is that, again, get to the coronavirus. Is this a rapid test or a test with a rapid readout? And how does that differ from any other -- at least some test in development at this point? Are they mostly PCR test?

Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

Yes. So it will be relatively rapid. I mean once we have the test up and running, it will be 24 or 48 hours, if not sooner. It's relatively quick.

Operator

Next question comes from the line of Mike Petusky of Barrington Research.



Michael John Petusky - *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

I may have missed this earlier, but was there any catch-up in revenue element to the RAYALDEE reported revenue for Q4? Or was that truly a clean number?

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

Yes, there was no catch-up, Mike. It was the fourth quarter activity.

Michael John Petusky - *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Okay. All right. And then I think I heard that the GeneDx volume was up 9%. Or was that revenue? Can you just confirm what that was...

Jon R. Cohen - *BioReference Laboratories, Inc. - Executive Chairman*

That was volume year-over-year. It was up 9%. The whole exome was up 16%.

Michael John Petusky - *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Okay. What about revenue in GeneDx year-over-year?

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

So we don't break out that separately, Mike. We just -- it still remains in that 17% to 20% of total revenue from services.

Michael John Petusky - *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Okay. But you can't give growth year-over-year?

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

We haven't broken it out separately now.

Michael John Petusky - *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Okay. All right. All right. And then I was wondering, do you have handy what the EBITDA margin in BRL was in Q4 by any chance?

Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

I don't, Mike. We can -- yes, the 10-K will come out a little bit later tonight, if it's not out yet.

Michael John Petusky - *Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst*

Do you know if it was positive?



Adam E. Logal - *OPKO Health, Inc. - Senior VP, CFO, CAO & Treasurer*

We do. Yes, it was.

Operator

And I'm showing no further questions at this time. I would now like to hand the conference back to Mr. Phil Frost.

Phillip Frost - *OPKO Health, Inc. - Chairman & CEO*

Thank you. I mentioned Vifor is a great partner for RAYALDEE. And on that vein, I might also say that Pfizer has been a terrific partner for our human growth hormone product. And from the top of the company, the CEO down to the people with whom we work, there's been a tremendous spirit of cooperation, and at this point, a very high level of energy to get the application for approval of this important product into the FDA. And so they have been working very hard with Jane Hsiao and Tony Cruz and their staff, both in Israel and in Toronto. And we really appreciate the fact that with a little luck, we may pick up some time on the submission.

So I'll leave you with that positive thought and thank you all for participating.

Operator

Thank you so much to our presenters and to everyone who participated. This concludes today's conference call. You may now disconnect. Have a great day.

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