UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 1, 2018

OPKO Health, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-33528	75-2402409
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4400 Biscayne Blvd.
Miami, Florida 33137
(Address of principal executive offices) (Zip Code)

(305) 575-4100
Registrant's telephone number, including area code

Not applicable
(Former name or former address if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

EXPLANATORY NOTE

OPKO Health, Inc. (the "Company") filed an initial current report on Form 8-K on March 2, 2018 (the "Initial Form 8-K"), to announce that the Company had held a conference call to provide a business update and discuss its operating and financial highlights for the quarter and full year ended December 31, 2017, and to provide a preliminary transcript of the call. The Company is filing this Amendment No. 1 to the Initial Form 8-K solely to amend and restate Item 9.01 to provide the final transcript of the conference call.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Final Transcript of conference call held on March 1, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OPKO Health, Inc.

Dated: March 2, 2018

By: /s/ Adam Logal
Name: Adam Logal
Title: Senior Vice President – Chief Financial Officer

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

OPK - Q4 2017 OPKO Health Inc Earnings Call

EVENT DATE/TIME: MARCH 01, 2018 / 9:30PM GMT

CORPORATE PARTICIPANTS

Adam E. Logal *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

Anne Marie Fields *Lippert/Heilshorn & Associates, Inc. - SVP*

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

Philip Frost *Opko Health, Inc. - Chairman and CEO*

Steven D. Rubin *Opko Health, Inc. - EVP of Administration and Director*

CONFERENCE CALL PARTICIPANTS

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

Kevin M. DeGeeter *Ladenburg Thalmann & Co. Inc., Research Division - MD of Equity Research*

Louise Alesandra Chen *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

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

PRESENTATION

Operator

Welcome to the OPKO Health Inc. Business Update Conference Call. (Operator Instructions) As a reminder, this conference is being recorded, Thursday, March 1, 2018.

I would now like to turn the conference over to Anne Marie Fields. Please go ahead, ma'am.

Anne Marie Fields - *Lippert/Heilshorn & Associates, Inc. - SVP*

Thank you, operator. Good afternoon. This is Anne Marie Fields with LHA Investor Relations. Thank you all for joining today's call.

I'd like to remind you that any statements made during this call other than statements of historical fact 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 annual report on Form 10-K for the year ended December 31, 2017, as filed this afternoon.

Before we begin, let me review the format for today's call. Dr. Phillip Frost, Chairman and Chief Executive Officer, will open the call. Followed by Steve Rubin, OPKO's Executive Vice President who will provide an update on the company's various businesses and clinical programs. After that Adam Logal, OPKO's Chief Financial Officer, will review the company's 2017 fourth quarter and full year financial performance. Finally, Dr. Frost will provide his closing remarks and then we'll open the call to your questions.

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

Philip Frost - *Opko Health, Inc. - Chairman and CEO*

Thank you. Good afternoon. 2017 was a challenging year for OPKO. There were a number of headwinds at Bio-Reference, a slower-than-expected ramp-up in sales of RAYALDEE and some unexpected onetime impacts on our financial performance. The other hand, we've made significant

progress. We're in the process of selecting the next President of Bio-Reference from a group of highly qualified candidates that we're hopeful -- and we're hopeful that early signs of improved results there will continue.

RAYALDEE sales have been increasing steadily. The recent results appear to indicate a more rapid upward trend. We also recently signed a RAYALDEE licensing agreement with the Torii Pharmaceutical Division of Japan Tabacco. Given the breadth and potential of Opko's assets and as positive as ever upon our future, and as described in today's filing, I've confirmed that confidence by investing an additional $25 million into the company, alongside my colleague, Dr. Jane Hsiao and a highly successful Asian businessman, already an OPKO investor, for a total of $55 million.

As you've heard me say before, I can't think of a better investment for my money. We're all working hard on our strategy to build OPKO into a leading diversified health care company it was meant to be.

And I'll now pass you on to Steve who'll provide more details on our commercial and clinical programs as well as our plans for the future.

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

Thanks, Phil, and good afternoon, everyone, and thank you for joining us on today's call. As Dr. Frost just noted, despite facing certain challenges in 2017, we made meaningful progress across a number of key areas critical to OPKO's growth.

On today's call, I will discuss our strategies to address some of these challenges as well as our plans to continue to advance our clinical and commercial programs. My discussion will include a review of our diagnostics, pharmaceuticals and clinical development programs.

Let's start with our diagnostic business, Bio-Reference Laboratories, which is the country's third largest reference lab. Throughout 2017, we shared with you some of the challenges we faced with this business and how they were impacting revenue growth in the short term. We have worked hard to implement system improvements and cost reductions that over time are expected to positively impact Bio-Reference lab's financial performance. Adam will elaborate more on these efforts in his financial remarks.

In addition, we made a number of leadership changes, including a new Head of Commercial Operations. And we are in the process of recruiting a new President with the skills and industry expertise consistent with our vision for Bio-Reference's role in the rapidly evolving diagnostic market. We are highly impressed by the several outstanding candidates we have already met with and hope to announce our selection in the near future.

We remain particularly excited about the potential for Bio-Reference lab's GeneDx subsidiary, which continues to demonstrate growth and innovation in its high complexity exome and related test with a 49% year-over-year increase in exome-based testing volumes. These include new exome-based test that open up and further expand other clinical areas for testing, such as for patients with neurologic conditions and critically ill patients. Our strategy for GeneDx is to continue to expand relationships with large and leading health care systems, to continue to broaden the testing menu in order to provide testing in many additional healthcare settings, and to form other strategic alliances which GeneDx can create and add value to these partnerships.

An example of a new test offering is last week's launch of pharmacogenomics testing. Pharmacogenomics is the study of how genes affect a person's response to drugs. This relatively new field combines pharmacology, which is the science of drugs; and genomics, which is a study of genes and their functions to develop and prescribe effective, safe medications and doses that will be tailored to a person's individual genetic makeup. In January, we were delighted to announce a research collaboration with Radboud university medical center in the Netherlands, which is aimed at identifying novel genes and pathways to help diagnose and manage human genetic diseases. This supplements GeneDx' other ongoing large-scale collaborations, such as with the internationally based Deciphering Development Disorder study (sic) [Deciphering Developmental Disorders study] that was formally announced last year.

As a leader in whole exome and genome sequencing, GeneDx has helped discover and contribute to the phenotypic understanding of over 58 novo disease genes in the last 3 years alone. The shared combination of our data summaries and analytical tools to conduct meta-analysis of GeneDx and its other data sets will help us better understand the genetic basis of human health and disease and to continue to provide differentiated testing options.

Moving on, our 4Kscore blood test gives a man with elevated PSA levels a personalized prediction of his chance of having or developing an aggressive form of prostate cancer. During the fourth quarter, 20,600 4Kscore tests were performed, a 15% increase compared with fourth quarter of 2016. As many of you may have seen, we launched a series of television ads for the 4Kscore in the New York region at the end of last year and in Florida in February. We have also increased our presence on social media outlets including directed digital advertising. We believe that focused sales and marketing to professionals and expansion of consumer awareness will help increase the utilization of the 4Kscore test. Prostate cancer is the most common cancer in men and is projected to account for over 160,000 new cases and over 29,000 deaths in 2018.

The 4Kscore test is a simple blood test that has demonstrated strong clinical utility as a follow-up test after an initial screening with PSA or digital rectal exam. In several prospective clinical validity studies, it has been shown that the 4Kscore test did not miss any aggressive Gleason -- with a Gleason score of greater than or equal to 8 cancers and it reduced unnecessary biopsies in 21% of men who were scheduled for biopsy.

New payment schedules implemented on January 1, 2018, provided a 26% increase in 4Kscore reimbursement. Medicare reimbursement is now $760 per test, up from approximately $600 per test previously. In addition, we have expanded our clinical validity studies in subjects who are diagnosed at borderline Gleason 6 prostate cancer. For example, the soon-to-be published Homburg Radical Prostatectomy study has demonstrated that the 4Kscore test can effectively differentiate biopsy Gleason 6 cancer from those men likely to harbor adverse pathology. In November we filed a Premarket Approval Application with the FDA for our Claros 1 immunoassay analyzer and total PSA test. The Claros 1 immunoassay analyzer in total PSA test. The Claros 1 is a proprietary diagnostic device that can provide rapid, quantitative blood test results in 10 minutes, right in the physician's office with only a finger stick drop of whole blood and with precision and accuracy comparable to the PSA test performed in the central lab using a large instrument. The PMA filing included supportive data from 2 multicenter field studies involving a total of 864 men. We have been active in correspondence with FDA on the submission and have had a bioresearch monitoring audit at (inaudible) facility and 2 clinical trial sites with no observations issued on form 43. We are hopeful for an approval during the third quarter of this year.

This new point of care diagnostic offers a significant market opportunity as there are more than 25 million PSA tests performed annually in the United States. In addition, we continue to advance the development of an additional Claros 1 test for indications that interface with our other products and programs, such as testosterone and vitamin D. In the coming months, we plan to initiate clinical validation studies for a Claros 1 testosterone test and file a 510(k) application for approval with the FDA.

Turning now to our pharmaceutical business, let me start by discussing RAYALDEE, the first and only therapy approved by the FDA that both raises 25-hydroxy vitamin D and lowers parathyroid hormone levels in patients with chronic kidney disease with a safety profile similar to placebo. For 2017, our first full year of launch, IMS reported that nearly 8,000 prescriptions of RAYALDEE were fulfilled. It is a level of acceptance and success that we find very encouraging due to the products' ever escalating favorable trends. We believe RAYALDEE's market penetration was slow at first due to a number of factors. The gradual ramp of insurance coverage for RAYALDEE not unlike all newly launched innovative drugs. The need to educate physicians about RAYALDEE's ability to safely treat secondary hyperparathyroidism as well as the importance of lowering parathyroid hormone levels to reduce the risk of vascular calcification, a major cause of mortality in chronic kidney disease. We are continuing to build sales momentum and we have seen steady, week-over-week increases in total prescriptions since the start of the year. We have also increased the number of health care providers who prescribe RAYALDEE. We had almost 600 active prescribers in Q4, an increase of 38% from Q3, demonstrating increasing adoption by targeted providers. We ended 2017 with access to RAYALDEE being available from 51% of covered lives in the Medicare space and for over 79% of all covered lives. In view of this insurance coverage, we expanded our sales force from 35 to 64 reps last October and expect significant impact on sales in 2018. Currently, in meeting out-of-pocket patient cost for RAYALDEE is less than $5 after available financial assistance. We are more confident than ever in the importance of RAYALDEE and the well being of chronic kidney disease patients and our business. Adam will elaborate on RAYALDEE revenue in his financial discussion.

In the next few months, our renal team will be active at several important clinical meetings. The Renal Physicians Association annual meeting in Orlando, the National Kidney Foundation Spring Clinical Meeting in Austin, and the annual meeting of the Endocrinology Society in Chicago. Our team's activities at these meetings enhance our reach to renal healthcare providers and provide the clinical data and support needed to increase adoption and utilization of a new treatment option like RAYALDEE. In addition, we expanded the global market potential for RAYALDEE by entering into an exclusive agreement with the Torii Pharmaceutical unit of Japan Tobacco for the development and commercialization of RAYALDEE in Japan as a treatment for SHPT in nondialysis and dialysis chronic kidney disease patients. Under the agreement, Torii will be responsible for all regulatory approvals and commercial activities in Japan.

Turning to VARUBI, we are disappointed with TESARO's decision, a couple of days ago, to suspend distribution of the intravenous or IV form of VARUBI. As TESARO noted, they will continue to support the oral formulation of the drug. We believe that the recently reported safety issues arise from the formulation of the IV version of the drug and not the drug itself. And I tend to seek more information concerning TESARO's commercialization efforts for the drug. No episode in the anaphylactic shock or any other serious hypersensitivity reactions have been reported with respect to the oral formulation of VARUBI since its launch in 2015.

Let's turn now to our clinical development programs. Our strategy is to build a diversified portfolio addressing a number of indications with significant unmet medical needs, limited treatment options and large markets. We have a robust pipeline of product candidates at varying stages of development, which we believe mitigates the risk inherent in relying to any one product, program or study. This pipeline provides attractive opportunities for creating both near and long-term value for our shareholders.

Let me start with the programs in our renal business. Vifor Fresenius, another of our global partners has filed a new drug submission with Health Canada, and is on track to file in the third quarter of this year a Marketing Authorization Application with the European Medicines Agency for RAYALDEE as a treatment for SHTP in chronic kidney disease patient. Vifor Fresenius is an ideal partner for RAYALDEE as they are a world-leading renal pharmaceutical company with a strong presence in Europe and other territories. We are also continuing with our plans to initiate a global Phase II clinical trial of a higher strength RAYALDEE in patients with stage 5 chronic kidney disease and Vitamin D sufficiency who require regular dialysis. We have finalized regulatory strategy in trial design with our partners Vifor Fresenius and JT Torii and expect to initiate the study in the second quarter of this year. The Phase II study has a randomized dose-ranging placebo-controlled design and will proceed in 2 successive cohorts, with the first expected to enroll approximately 40 patients for 6-months of treatment and a second to enroll more than 200 patients for up to 12 months of treatment. OPKO expects to share the cost of this study with its development partners.

In addition to this Phase II study, we plan to augment our growing presence in the renal market with synergistic products that address other significant unmet needs. We plan to commence in the coming months a single dose, Phase IIa clinical study with our NK-1 antagonist for uremic pruritus or itching, which is a serious problem for more than half of the patients on dialysis. This study will evaluate the safety and pharmacokinetics of OPK88002 in the dialysis population.

Turning now to our clinical pipeline candidate and metabolic and endocrinology diseases. We have a number of big stage programs underway or nearing initiation that should reach important inflection points throughout this year.

I'll begin with our long-acting human growth hormone product, hGH-CTP, which is partnered with Pfizer for worldwide commercialization. We have good momentum in patient enrollment in our global pediatric Phase III hGH-CTP study in growth hormone deficient or GHD children, which represents more than 80% of the GHD market. This is a pivotal, noninferiority study comparing a single weekly dose of hGH-CTP with daily injections of GENOTROPIN, a currently marketed growth hormone. This study uses the pen device and formulation that will be launched commercially upon approval. The pediatric GHD subjects we treated weekly for 12 months. Last summer, we launched a pediatric hGH-CTP registration study in Japan to assess pharmacokinetics and compare efficacy of weekly hGH-CTP to daily GENOTROPIN in 44 prepubertal GHD subjects. We expect to complete enrollment in full studies before the end of this year. Our Phase II open-label extension study continues without interruption, with some patients now having been exposed to our hGH-CTP for more than 3 years, which provides us with important long-term safety and efficacy data.

Turning now to our progress with the adult hGH-CTP Phase III study. As you know, we completed a post hoc sensitivity analysis to evaluate the influence of statistical outliers on the primary endpoint results using preplanned analysis protocol. We have recently submitted a request for a meeting with FDA regarding the analysis to the efficacy and safety data and any additional work required for a potential BLA submission in this indication.

Let's turn now to OPK88004, our once-daily oral selective androgen receptor model, or SARM, which are developing for patients with benign prostatic hypertrophy also known as BPH or enlarged prostate and other urologic and metabolic conditions. BPH affects 1/2 of all men aged 51 to 60 and 90% of men over the age of 80. In November, we commenced our Phase IIb dose ranging study of OPK88004 to treat people with BPH. This trial is expected to enroll approximately 125 patients at 30 sites in the U.S., to identify appropriate doses given over 4-month period to reduce prostate size, the primary efficacy endpoint of the study. The study will also assess additional endpoints including blood PSA levels, lean body mass and fat mass. We expect to complete enrollment during the second half of this year. Our enthusiasm for this program is supported by preclinical

data that demonstrate the ability of OPK88004 to reduce prostate size in animals and PSA levels in human trials. In addition, a Phase II study of 350 elderly male subjects being studied for another indication, utilizing OPK88004 showed a significant increase in lean body mass and muscle strength and significant fat mass reduction. The study also showed an acceptable safety profile to permit clinical development.

We are excited to have initiated this Phase IIb study in men suffering from BPH as current treatment options, such as alpha blockers and 5alpha-reductase inhibitors, have undesired side effects. Surgical procedures that treat BPH are often associated with complications and lengthy recovery times.

Let me now update you on our long-acting Factor VIIa-CTP for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. The phase IIa dose escalation study of the IV or intravenous formulation of Factor VIIa-CTP is nearing completion and the dosing in the Phase I dose escalate study of the subcutaneous formulation of Factor VIIa-CTP is completed and no serious safety event has been reported. Given the recent approvals of alternative therapies for hemophilia including Roche's monoclonal antibody S9, 10, we intend to further evaluate the commercial potential for our product including potential partnerships prior to initiating the next round of clinical trials.

Let's turn now to OPK88003, our once weekly GLP1-glucagon dual agonist for the treatment of type 2 diabetes and obesity. We are in the final planning stages for a Phase IIb dose escalation study in approximately 110 Type 2 diabetes patients. Enrollment is expected to commence in the second quarter of this year and patients will be treated with a dose escalation regimen over 3 months to optimize the dose levels, increase body weight loss and reduce adverse events such as nausea and vomiting. Patients will be treated for a total of 30 weeks in the study. The key primary endpoint will be HbA1c, a marker for blood glucose levels and secondary endpoints such as weight loss, lipid profile and safety will also be analyzed.

Our decision to pursue OPK88003 supported by data from our Phase II study with 420 diabetic patients that showed great weight loss compared with the approved extended release of exenatide and placebo. In addition, the data also showed improvement in the lipid profile at similar reduction in the HBa1c levels compared with the approved once weekly product.

Moving forward into 2018, we expect our investments in expanded marketing programs and clinical studies will result in continued revenue growth for RAYALDEE and (inaudible). We are advancing a robust clinical development program that addresses a number of large markets with great unmet need. Throughout 2018, we expect to make meaningful progress with these programs and to achieve a number of important milestones. We look forward to appointing a new President for Bio-Reference lab and expect that this new leadership along with our ongoing investment in operational efficiencies and continued growth and expansion will allow us to return our laboratory business back to growth mode. We look forward to keeping you apprized of our progress in all our businesses.

With that overview, let me turn the call over to Adam for a discussion of our 2017 financial performance. Adam?

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

Thank you, Steven, good afternoon, everyone. While we made substantial progress on the business initiatives Steve discussed, our financial performance in the fourth quarter lagged behind our expectations and we faced some unexpected items, which I'll provide additional color on shortly. I'll also provide top line revenue guidance for Bio-Reference and RAYALDEE, to provide clarity on our expectations as we start the year.

We closed 2017 with just over $91 million in cash, cash equivalents and marketable securities on our balance sheet with an additional $10 million of availability under our credit facilities. As we reported today, we also raised $55 million from existing shareholders in OPKO as Dr. Frost mentioned. The investment was in the form of convertible note with a 5 year term, a conversion price of $5 per share and interest accruing at the rate of $5 -- or 5% per year, payable at maturity or conversion. This additional funding provides us with the flexibility to accelerate the timing of our development programs while cash flow from operations at Bio-Reference improve. We continue to be mindful of our cash balance and investments into both our R&D pipeline and commercial activities to align with the anticipation of our improving cash flow from both Bio-Reference and RAYALDEE, both of which remain important drivers of achieving a near-term breakeven point for cash flow from operations.

Moving on to some of the challenges we faced during the fourth quarter of 2017. You will recall that we implemented a new billing system at the clinical lab portion of Bio-Reference. As I mentioned last quarter, the early days of that implementation did not go as smoothly as we had anticipated.

While we worked aggressively on claims in the billing process, we were not as successful as we anticipated in cash collections. As we completed our review of the year, it became clear that we would not realize the cash collections on those early claims and as a result changed our estimates, which negatively affected our fourth quarter revenues. Our billing and sales teams have been working tirelessly to improve the collection rates in order to maximize the value of each requisition. We have realized an approximate 225 basis point improvement on the amount of -- collected on claims processed in the fourth quarter of 2017 in comparison to the fourth quarter of 2016, a significant improvement. Our total cash collections and the speed at which we are getting paid greatly improved during the second half of the year. And going forward, we anticipate our DSO will be significantly improved compared to prior years.

Also significantly and adversely impacting our fourth quarter results was over $73 million related to reimbursement adjustments on claims from commercial and federal payor programs.

Turning to our pharmaceutical business, we recognized $9.1 million of revenue related to sales of RAYALDEE. Of the $9.1 million, $2.9 million related to revenue during the fourth -- product shipped during the fourth quarter, while the remaining $6.2 million related to revenues deferred through September 30, 2017.

Moving to operating expenses during the quarter, we continued to make investments in our pharmaceutical and diagnostics pipeline, which resulted in R&D expense of $34 million. In addition, our investment in the RAYALDEE commercial organization was $7.9 million during the fourth quarter. As Steve mentioned a few days ago, the team at TESARO announced the discontinuation of the IV formulation of VARUBI. As a result of this discontinuation, we recorded a noncash impairment of $13.2 million, reflecting a decline in the anticipated future cash flows from our royalty stream in VARUBI.

Finally, income tax provision included a charge of approximately $31 million during the fourth quarter as a result of the recently passed Tax and Jobs Act. In addition, we recorded a valuation allowance against our U.S. deferred tax assets that resulted in the total tax provision during the fourth quarter of $63 million, compared to a $31 million income tax benefit for the comparable period of 2016.

After considering these items, revenue for the quarter ended December 31, 2017, totaled $193.7 million, and our net loss was $213.9 million. The comparable period of 2016 had total revenues of $275 million and a net loss of $13.7 million during that period.

Yet in all of the complexities we saw in 2017, I'm going to provide top line revenue guidance for Bio-Reference and RAYALDEE. Before I do, I want to cover some changes to the accounting rules for revenue recognition, which will impact our overall revenue, including our revenue of Bio-Reference. At Bio-Reference, we've historically had bad debt expense of approximately 10% to 11% of revenue recorded within SG&A expense. Under the accounting pronouncements that went into effect January 2018, bad debt for revenue from our services will move to net revenue, effectively reducing revenue and at the same time reducing SG&A expense by the same amount. This does not have an impact on our operating results as a whole, but will result in less net revenue recognized. This new accounting literature will have an impact on our other revenue streams as well, which I'll provide further clarifications on during our first quarter call. Under this new accounting, the first -- under this new accounting, the first quarter of 2017's revenue from services will be recast in our results to be reflecting approximately $228 million, compared to the $255 million recorded under the old accounting pronouncements.

I wanted to provide that detail first to set the expectations clearly for Bio-Reference's revenue for the first quarter of 2018 with the proper comparators. For the first quarter of 2018, we are assuming volume growth at GeneDx, but a volume declined at our core clinical laboratory of approximately 3%. As such, we anticipate revenue from services during the 3 months ended March 31, 2018 to be in the range of $195 million to $215 million, which include the impact of volume fluctuations, the impact of PAMA and other reimbursement challenges we faced during 2017, as well as the accounting changes I previously mentioned.

Moving to RAYALDEE, we anticipate first quarter revenues will be between $3.5 million and $5 million, which reflect the range of estimates on our gross to net calculations as well as our expectations for volume trends. In addition, we expect the first quarter operating expenses for our investments in R&D as well as the RAYALDEE commercial team to be approximately $35 million and $8 million, respectively. We'll provide additional financial guidance as the year progresses. But now, I'll turn the call back to Phil. Phil?

Philip Frost - *Opko Health, Inc. - Chairman and CEO*

When I spoke to you after the third quarter report, I said we were determined to strengthen all elements of our company. As to RAYALDEE, sales were off to a slow start, but we've exerted great effort. And although it's a bit early to be sure, sales seem to have begun a more rapid growth phase. We've increased the size of our sales force from 35 to 64 as Steve mentioned. But more important, we've refined our message to physicians and trained our people to deliver it in a compelling way. As we speak, we have a RAYALDEE National Sales Meeting underway in which we've introduced our new sales manager, Kirk Miller, a terrific guy who will play an active role in accelerating sales of RAYALDEE, the best-in-class medicine for secondary hyperparathyroidism associated with chronic kidney disease.

The 4Kscore blood test remains the most reliable predictor of serious prostate cancer in men with an elevated PSA, and we expect its use to continue to expand, hopefully at an accelerated pace. Our clinical development program is in high gear. Of course, we can't predict outcomes of [Trellis] but the need for the products we're developing is great. They all have important market potential.

Our Bio-Reference unit is a valuable asset. 2017 was a year in which we invested in infrastructure and made management changes. After the departure of its President, as we said, we began an active search process for a successor, and we've already met with several candidates more than capable of taking Bio-Reference to its next level of better performance. We hope to make a selection soon, but in the meantime, the business is being managed in a very positive way by a highly capable team of department leaders working together with us at OPKO.

OPKO is a unique company. Our management team has a history that extends back nearly 2 decades. A history that includes many successes. We're really proud of this history, and we believe it's a firm foundation for building OPKO. We've developed a diversified product platform with myriad possibilities. It's an exciting time in diagnostics, genomics and therapeutic medicine. An exciting time to be at OPKO.

We've begun 2018 on a strong footing and we look forward to achieving value-creating milestones that will position OPKO for continued growth in 2018 and beyond.

With that, let's open the call to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question will come -- our first question is from Louise Chen with Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

So first question I had is, what is your strategic vision for OPKO and what do you think the market is missing about your story? Second thing is just on the gross margin in the fourth quarter. How should we think about that and what -- how should we think about your margins in '18 based on what we saw in fourth quarter? And then you talk about, you gave a guidance of $195 million to $215 million for Bio-Reference labs. I'm just curious if you could provide a bridge on how we get from the fourth quarter number to the first quarter '18 number?

Philip Frost - *Opko Health, Inc. - Chairman and CEO*

I'll take the vision part, and I'll let my colleagues do the rest. Basically, what we tried to do is assemble valuable assets. These assets are in the form of products, 2 of which are on the market, and others that are under development. The thing that they all have in common is that they have big potential. We can't be sure that they'll all be successful, but we don't need them all to be successful for us to have great results. Although there's no reason that those under development now won't be. Bio-Reference is a great asset. We had envisioned that as a source of cash to help pay for the development program and we still believe that it will work out that way. In fact, we've taken quite a bit of cash out of our Bio-Reference over

the time we've had it. So strategically, it really was a pretty good move. And the actual value that it has, to this day, we believe is far in excess of what we paid for it. I think this is what the investment community is missing. We are a company that's in the investment mode, and our results reflect that. RAYALDEE, it's true, was off to a slow start, but we have every confidence that it's going to pick up steam and move forward more rapidly. 4Kscore still has the potential for being one of the most important tests in the history of the diagnostics industry. We believe that. I think, eventually, the market will begin to understand this. And, for the specific questions...

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

Yes. So on margins, I think the way to think about it is that most of this is going to be impacting net revenue. So gross margins will come down as a result. Obviously operating margins will remain consistent. But overall gross margin for Bio-Reference is going to come down as we bring the top line net revenue -- net revenue number down because of those accounting changes. So I think if you just take that 10% of revenue, you just knocked it off of the gross margin figure. The bridge from our fourth quarter revenue to the range that I provided, we recorded about $148 million of revenue from services. And we had a $73 million impact on related to these payer adjustments. So that would give you an adjusted $221 million. And that, as we talked about that reallocation of bad debt up to net revenue, brings you into that range that I had mentioned.

Operator

Our next question is from Yale Jen with Laidlaw.

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

Just follow up with the earlier questions. That the guidance for the first quarter, $195 million to $115 million, according to your revenue from the Bio-Reference lab, could we generalize that -- this figure to think that might be the sort of annual revenue for 2018? Or there's other consideration need to be put in?

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

Yale, so we only provided first quarter guidance. And I think we -- obviously, as we're transitioning the leadership, I think we want to be cautious about looking too far ahead of ourselves. So that's why we provided that first quarter growth number. And I think if you look at the historical trends, you could probably come in with some reasonable estimates as you try to annualize that number.

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

Okay. And just another follow-up question here is that for that growth hormone, you mentioned in the script that the -- the (inaudible) that you already completed the study, I mean, analysis, and you are in the process, I guess, try to speak with the FDA. Could you give us a little bit more color in terms of what the timeline these discussion might take place? As well as what's the current status of the patient recruitment for the children's study or maybe some expectation in terms of when we will get some top line result from that study?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

So for the adult, it's hard to tell. I mean, it's a multistep process. So we first asked FDA, based upon that analysis we discussed before in essence to get their response to that form of analysis and their willingness to accept it and then to see what other steps FDA would deem necessary for us to submit a BLA in the adult. So I can't really put -- give you a timeline on that. So it's literally in the hands of the FDA at this point. We expect to see a written response and then we'll respond to that and ultimately it may result in a meeting, but a little bit up in the air. For pediatric, it's obviously a 1-year trial, it's blinded so it depends when we complete enrollment. Enrollment momentum is going strong. We certainly expect to complete

enrollment before the year end. How far before that, it just depends on a lot of factors. So you can just -- we will announce completion of enrollment in the 12 months, but there will be no last patient administered drug. And when we can get top line results will probably a few months after that.

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

So just to extrapolate from that, that could potentially be late 2019 event in terms of the top line data if the recruitment is [you planted].

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

Right. That's correct.

Operator

Our next question is from Eric Joseph with JPMorgan.

Eric William Joseph - *JP Morgan Chase & Co, Research Division - Analyst*

Just looking for some additional color around sort of the one-time or the nonrecurring reimbursement adjustment that you noted in fourth quarter. It sounds like these were unexpected, but I'm trying to get a sense of their potential -- what gives you confidence in that they won't, I guess, mature going forward? And secondly, is it proper to kind of think about some portion of these effectively sort of getting write-offs in terms of cash received? And also, looking forward, if you could give a little color around tax guidance as a result of tax reform?

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

Sure. So I'll take the second one first. So I think, Eric, we've got a number of different tax streams. I think in a blended rate, it would likely be in the mid-teens in the out years. But certainly in the near term, the majority of our income is being generated in the U.S. So we would be higher than that in the near term. Obviously, we have pretty significant tax assets on our books in the U.S. to offset that. So then you got a fairly complicated assumption around there. Going to the $73 million, so yes, we looked -- most of this is related to claims that were processed from -- throughout 2017 and earlier. So we do feel as though that the receivables on our books and in revenues that we'll record in the future will not be negatively impacted in a meaningful way going forward. So that $73 million is related to prior quarter's numbers.

Operator

Our next question is from Kevin DeGeeter with Ladenburg.

Kevin M. DeGeeter - *Ladenburg Thalmann & Co. Inc., Research Division - MD of Equity Research*

With regard to marketing around 4Kscore, can you just -- the company has been active with some direct-to-consumer activities. Can you just provide some metrics to help us appreciate where you've been getting traction with that marketing spend and how that message may be evolving for the course of 2018 to further accelerate volume growth?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

Kevin, it's still early because we started the TV ads as kind of a pilot test in the New York region. And we obviously have an 800 number to try to track some of the calls off that, and then we saw enough activity that we launched them in Florida. We have a corresponding direct to digital

advertising and web presence and we will increase some of that spend to kind of optimize where we are in the web this year. But it's still early for me to tell. Obviously, I think the more attention and knowledge we get about the product and the more consumers themselves know about it, I think it's a plus. But it's hard this early on in the process to give you specific metrics on where they are. Clearly, we think it's going to benefit significantly from the marketing effort. But time will tell.

Eric William Joseph - *JP Morgan Chase & Co, Research Division - Analyst*

And on a separate note with regards to RAYALDEE, you mentioned in the prepared comments the change to the general setting message provided by the sales team. Can you just provide your updated thoughts with regard to the right positioning for RAYALDEE in the market? And in terms of your -- how much of that was driven by data or incremental sort of kind of data, how much of that was driven by feedback from clinicians in the field?

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

Kevin, this is Charlie. We do listen to the feedback from the field and we adjust our marketing and positioning strategies for RAYALDEE accordingly. And it is a learning process. We do find that physicians greatly are attracted to the effective physiological characteristics of RAYALDEE. And this is very consistent with the position that the KDIGO guideline has taken, that physiological treatment is probably preferred over pharmacological treatment with active vitamin D agents. So we emphasize the KDIGO guidelines in our messaging. We also emphasize the data that show that RAYALDEE very gradually raises 25 hydroxy vitamin D levels in the blood to correct vitamin D insufficiency, and that correspondingly gradually lowers parathyroid hormone levels without having any significant -- clinically significant impact on side effects, which are elevation of calcium and phosphorus.

Operator

Our next question is from Mike Petusky with Barrington Research.

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

Adam, I guess, what are the current thoughts around EBITDA margins in BRL for '18? Or whatever you can add there will be helpful.

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

Yes, Mike, so I think they're going to be in the first quarter, they're going to be compressed from the comparable period of last year, which were in the 10% range. I think we'll likely be below that with some of the volume declines that we've seen. We have put, as Steve mentioned in his remarks, we have put a number of cost control measures in place. And we are working to reduce those cost. But the volume decline in the fourth quarter, we just didn't take enough cost out of the organization to make up for that. But I do think, once we stabilize the volume and return to growth, we'll obviously be positioned to see that expand and accelerate.

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

And any kind of rough guidance for full year?

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

No. Sorry. Not -- I don't want to get ahead of myself in this call.

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

Okay. I guess, Steve, on the -- and I understand it's early going, but you obviously must have seen something in the New York DTC that caused you to say, hey, let's spend a little bit of money in Florida. I mean, can you talk at all about incremental pickup that you saw in New York, or what essentially made you decide, hey, we're going to go spend more money on this in another place?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

It's really, I mean, to be frank, the sales have been -- and use of the product has been growing already on a steady pace, as you've probably seen if you follow us in a quarter-quarter basis. But it's really the number of calls and clicks to our website that let us know that it was functioning. So I can't put a number that translates into additional sales, but the amount of activity and interest around our product and the nature and subject matter of the calls let us know that people are paying attention and trying to learn. And you can't help but think that's going to ultimately translate into further growth. That's what triggered it.

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

So I think you had said on that, that you thought the spend in New York for the 3 months would be under $1 million. Is that how it came in, roughly?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

It's actually -- TV right now is quite inexpensive. Believe it or not, it's a little more expensive to optimize your phrases on the Internet than it is to advertise on TV now.

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

So it came in under $1 million?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

Yes.

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

And what are you expecting to spend DTC on 4Kscore in '18 or any kind of guidance around that if it continues to seem to produce results?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

We don't expect. Unless it will be proportional to sales. So if sales bump up, we'll spend more, but we won't -- we're going to be prudent so far. And again, the TV ads are quite inexpensive. So we'll start on with smaller steps and see where it grows. And as growth justifies it, we'll increase the spend. So I can't -- right now, I wouldn't pencil any higher number than we did for last year. So.

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

Just last question on this. Are you continuing to run ads in New York and Florida? Or have you shifted your resources to Florida?

Steven D. Rubin - *Opko Health, Inc. - EVP of Administration and Director*

So the ones in New York have ended. And the ones right now are running in Florida and then we'll revisit growing out perhaps on an even broader platform.

Philip Frost - *Opko Health, Inc. - Chairman and CEO*

It's really, as Steve said, a pilot operation to get our systems for responding, particularly the back end to make sure that we realize the most revenue from the effort.

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

Okay. All right. And then I guess just last question, you said you went from 35 to 64 reps. I actually had a note from last quarter that it was up to 71. Did I just get that wrong a few months ago? Or did you guys let some reps go?

Adam E. Logal - *Opko Health, Inc. - CFO, CAO, SVP and Treasurer*

The 71 is inclusive of the regional business managers as well. So the entire sales organization is at that 71 which is before field reps.

Operator

There are no further questions at this time. Dr. Frost, please proceed with your closing remarks at this time.

Philip Frost - *Opko Health, Inc. - Chairman and CEO*

I think that ends our session. And we want to thank everybody for participating.

Operator

Ladies and gentlemen, that concludes your conference call for today. We thank you for your participation and ask that you please disconnect your lines.