UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): August 7, 2018

OPKO Health, Inc.
(Exact Name of Registrant as Specified in 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)

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

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. ☐

ITEM 2.02. Results of Operations and Financial Condition.

On August 7, 2018, OPKO Health, Inc., a Delaware corporation (the "Company"), held a conference call to provide a business update and discuss its operating and financial highlights for the quarter ended June 30, 2018, which included revenue guidance for the third quarter of 2018 and an update on the Company's development programs. A copy of the conference call transcript is being furnished herewith as Exhibit 99.1.

The information included herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 as amended ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 as amended (the "Securities Act") or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 7.01. Regulation FD Disclosure.

The disclosure contained in Item 2.02 of this Current Report on Form 8-K is incorporated by reference into this Item 7.01.

The information included herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of conference call held on August 7, 2018

Exhibit List

Exhibit No.	Description
99.1	Transcript of conference call held on August 7, 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.

By: /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

Date: August 8, 2018

Lippert Heilshorn & Associates

Moderator: Miriam Miller
August 07, 2018
4:30 p.m. ET

OPERATOR: This is Conference #9243717

Operator: Welcome to the OPKO Health business update conference call. At this time, all participants are in a listen only mode. Following management's prepared remarks, we will hold a question and answer session.

To ask a question, please press star followed by one on your touchtone telephone. As a reminder, this conference is being recorded today, August 7, 2018. I would now like to turn the conference over to Miriam Miller. Please go ahead, ma'am.

Miriam Miller: Thank you, operator. Good afternoon. This is Miriam Miller with LHA. Thank you all for joining today's call.

I'd like to remind you that any statements made during this call by management 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, and its quarterly report on Form 10-Q for the quarter ended June 30, 2018. Importantly, this conference call contains time-sensitive information that is accurate only as of the date of the live call, August 7, 2018.

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. Philip 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 business and clinical program.

After that, Adam Logal, OPKO's Chief Financial Officer, will review the company's second

quarter financial performance. Dr. Frost will provide closing remarks, and then we'll open up the call to questions. Now let me turn the call over to Dr. Frost.

Philip Frost: Thank you for participating in OPKO's second quarter call. During my introduction to our first quarter call, I said, "If I had to characterize the quarter, I'd say good progress on all fronts." I'm happy to report that this also applies to the second quarter.

Our largest commercial unit, BioReference Laboratories, has been the object of a great deal of our attention. Geoff Monk, now the General Manager of BioReference, is now in full control and has made several operational changes to improve efficiency and overall results. He has moved people around and brought in new talent.

Sales are, of course, the life's blood of the business, and Geoff recently brought in (Cindy Jacke) to accelerate sales growth. (Cindy's) previous experience as sales director for the East region of Quest has prepared her well for the challenge.

And of course, (Ben Solomon) continues to be a star at our GeneDx unit from which we expect great things, which he continues to deliver.

RAYALDEE is beginning to look like the commercial success we had thought it would be. Kirk Miller, our new Director of Nephrology Sales, working with Tom Nusbickel, our Nephrology Commercial Director, have made great strides.

After Charles Bishop, developer of RAYALDEE, Dr. (Akhtar Ashfaq), a terrific academic nephrologist working at OPKO, are working together to meet with important nephrology groups around the country to explain how RAYALDEE can be important for them in the management of their stage 3 and 4 chronic disease patients, with considerable success, I might add.

Last time, I mentioned that several clinical trials were ongoing, with patient enrollment proceeding nicely. Well, the pace has accelerated, and we recently announced completed enrollment in our Phase III worldwide pediatric human growth hormone trial, as well as our Phase IIb trial for OPK88003, or oxyntomodulin, weekly injectable medicine in the for Type 2 diabetes and obesity, both sooner than anticipated and both proceeding nicely under the direction of Dr. Jane Hsiao and Dr. Tony Cruz.

As you will recall, I've expressed considerable enthusiasm for the market potential for our oxyntomodulin product, which has also already been shown in a previous 420-patient trial to be safe and effective with respect to blood HbA1c and lipid control, as well as weight loss.

The current trial aims to achieve even greater weight loss by administering the larger doses required for more weight loss while avoiding or minimizing the limitations of nausea and vomiting that may occur with higher doses.

The trial is proceeding as expected. All in all, we're looking forward to the positive events of

the remainder of the year. And I now pass you on to Steve Rubin, who will continue with more detail.

Steven Rubin: Thanks, Phil, and good afternoon, everyone, and thank you for joining us today. I'll discuss OPKO's strategies for continued commercial and clinical advancement and our overall progress toward meeting our long-term growth and business goals.

Let's start with our clinical diagnostic business, BioReference laboratories, or BRL, which is the countries third largest reference lab. We are pleased to report sequential quarter gains in revenues. As Phil noted, we are very pleased to see good early momentum for BRL under the leadership of Geoff Monk.

From an operations perspective, we remain particularly excited about the potential for BRL's GeneDx subsidiary, which continues to demonstrate growth and innovation in its high complexity and related tests. For the second quarter, GeneDx achieved a 38 percent year-over-year increase in exome-based testing volumes.

As an impressive milestone in June, GeneDx announced that they have performed clinical exome sequencing on more than 100,000 individuals, representing one of the largest cohort sequence exomes by independent clinical laboratories in the world.

The achievement also greatly expands the database of known clinically relevant genetic variance used as tools to help diagnose rare diseases. GeneDx continues to be a BRL standout as we have helped discover and contribute to phenotypic understanding of more than 62 novel disease genes in the last 3 years alone.

In addition to its exome and genome test, GeneDx continues to post growth in its overall product portfolio with year-over-year volume growth of more than 13 percent. During Q2, GeneDx finalized a major overhaul of its clinically driven testing menu and launched 20 new tests and also revised and updated 51 tests.

During the remainder of this year, GeneDx plans to launch an additional 36 test and will revise and update 57 more tests. These tests were selected based on specific clinical need and reimbursement potential.

Moving on, our 4Kscore blood test gives a man with elevated PSA level a personalized prediction of his chance of having or developing an aggressive form of prostate cancer.

During the second quarter, we've processed nearly 20,500 4Kscore tests, representing a 10 percent increase compared with the second quarter of 2017. The retention rate among urologists utilizing the test is also an important metric, with 80 percent of the urologists who have ordered 4Kscore in Q1 2018 continuing to order this test in Q2 2018.

As you know, Novitas released draft noncoverage guidance for the 4Kscore tests in May.

While our final coverage determination from Novitas hasn't been issued, I will show an overview of the activities we, with the support of experienced urologists, undertook during the public comment period, which ended on July 30.

On May 31, OPKO made a presentation for -- I'm sorry, made a presentation of key publications with data demonstrating long-term predictability for a man with elevated PSA of prostate cancer metastases and mortality of 15 years or 20 years later.

In addition, eight leading urologists from academia and large neurology practices spoke about the clinical value of the 4Kscore test, in many cases indicating why they couldn't actually care for the patient without the 4Kscore test.

We believe that the messages were well received. We also subsequently met with Novitas' medical directors to address certain concerns and provide further clarity on clinical validity data.

We have followed up with the data, evaluating how the 4Kscore test would perform in a Medicare population. We were also aware that many professional organizations, physicians and patients, submitted written comments directly to Novitas in support of the 4Kscore test.

We appreciate the time everyone took to speak out on behalf of the 4Kscore, which we consider to be an important test in the diagnostic paradigm of prostate cancer. We've been asked about the timing for Novitas to issue their final coverage decision, as we understand that there is no specific deadline for Novitas' decision, but in the meantime, Novitas continues to process Medicare payments for 4Kscore tests.

Turning now to our pharmaceutical business. Let me start with 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.

We are pleased to see Vifor Fresenius receive approval last month to market RAYALDEE in Canada for the treatment of SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency.

We also expect to announce shortly the initiation of Phase II clinical study to study the safety and efficacy of RAYALDEE as a new treatment for SHPT in adults with vitamin D insufficiency and stage 5 CKD requiring hemodialysis. This trial will be conducted in multiple dialysis centers in the U.S.

From a quarterly performance perspective, the RAYALDEE numbers breakdown as follows, in Q2, the total number of RAYALDEE prescriptions increased approximately 36 percent versus Q1.

Importantly, since the start of the year, we have seen a steady month-to-month increase in the total number prescriptions. Our expanded sales team of 64 representatives had a significant positive impact this quarter, with 49 percent of prescriptions being new to brand and 54 percent of those prescribers new for RAYALDEE.

Since launch, the number of physicians who prescribe RAYALDEE has increased steadily. We had 929 active prescribers in quarter two, 764 in Q1, and 594 in Q4 of last year.

So you can see the sustained momentum here. We ended Q2 with RAYALDEE being available to 83 percent of the overall insurer population and 53 percent of the Medicare population. RAYALDEE is covered by plans representing 90 percent of the commercial population.

Overall, we continue to see progress in adoption, reimbursement, and awareness of RAYALDEE. Our expanded sales team continues to demonstrate improving performance as our market penetration continues to grow.

Regarding our clinical development programs, we remain focused on progressing our portfolio addressing indications with significant, unmet medical needs in (in our large) markets.

And we have a robust pipeline of candidates at various stages of development, which provides attractive opportunities for creating near- and long-term value for our shareholders.

Starting with our work in nephrology, as I just discussed, Vifor Fresenius has received marketing approval for RAYALDEE in Canada in late July. They also remain on track to file a marketing authorization application with the European Medicines Agency later this year as a treatment for SHPT and CKD patients.

As also discussed, we will be initiating a global Phase II trial with a higher strength RAYALDEE in patients with stage 5 CKD and vitamin D insufficiency who require a regular dialysis. We expect to share the cost of the study with our development partners, Vifor Fresenius and Japan Tobacco.

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. This includes of a single-dose Phase IIa trial that evaluates our NK1 antagonist in dialysis patients for euremic pruritis, or itching.

This is a serious problem for many patients on dialysis. In our metabolic and endocrinology pipeline, we have several late-stage programs underway or nearing initiation that could reach important inflection points this year.

As you know, our long-acting human growth hormone product, Somatrogon, or hGH-CTP, is currently in a global Phase III pivotal trial in growth hormone deficient children. The pediatric indication represents 80 percent of the growth hormone market. This program is partnered with Pfizer for worldwide commercialization.

We recently announced the completion of enrollment in the 225-patient trial in 30 countries. Based on this major milestone, the completion of the trial is now expected to occur in Q3 of 2019. This is a trial comparing single weekly injection of Somatrogon with daily injections of

GENOTROPIN.

This study uses a multi-dose disposable pen device intended for commercial launch. We are hopeful that the outcome will support a standard of care dosing change from daily to weekly administration, which will improve the quality of life for children with growth hormone deficiency.

Last summer, we also initiated a pediatric registration study in Japan to assess pharmacokinetics and compare efficacy of weekly Somatrogon to daily GENOTROPIN in 44 pre-pubertal growth hormone deficient subjects. We expect enrollment in Japan study to be completed before the end of this year.

Last November, we began a Phase IIb dose ranging trial from once daily oral selective androgen receptor modulator, or SARM, to treat BPH, or enlarged prostate patients. BPH affects approximately half of all men aged 50 and 90 percent of men over the age of 80.

This 4-month study is expected to enroll 125 patients at 30 sites in the U.S. to identify appropriate doses to reduce prostate size, the primary efficacy endpoint of the study. The study will also assess blood PSA levels, lean body mass, and fat mass at secondary endpoints. Completion of enrollment is expected before Q1 of 2019.

In mid-June, we reported that enrollment in our Phase IIb dose escalation trial for OPK88003, our once-weekly combined glucagon dual agonist to treat Type 2 diabetes and obesity was complete.

This is a study of 110 Type 2 diabetics at 35 clinical sites in the U.S. You may recall that we initiated this trial mid-March, and we are pleased with enrollment completed so quickly, less than 3 months after initiation.

This study is evaluating HbA1c as a primary endpoint in weight loss, blood lipid levels, and safety as secondary endpoints. The data obtained in this trial will be used to support the dose escalation regimen for Phase III studies.

Previously, preclinical and clinical and Phase II data showed that once-weekly dual agonist such as our OPK88003 improved glucose control, caused more weight loss and improved the blood lipid levels compared to GLP-1 products on the market. In our previous Phase II study of 420 diabetic patients, greater weight loss was achieved compared to the approved extended release exenatideand placebo.

These data also showed improvement in the lipid profile and a similar reduction in HbA1c levels compared to the approved once-weekly product. We are happy to report good momentum with our commercial products, and this is (special) efforts of our sales team, particularly related to RAYALDEE.

We applaud the approval of RAYALDEE in Canada and look forward to pursuing additional regulatory approvals for RAYALDEE in conjunction with our partners. We are very pleased to have

completed enrollment in our Phase IIb trial evaluating OPK88003, our oxyntomodulin drug for Type 2 diabetes and weight loss, and in our global Phase III study of Somatrogon in children with growth hormone deficiency.

We are enthusiastic about GeneDx' achievement, sequencing the exomes of 100,000 individuals and are proud of the contribution this data may have on the development of new approaches to treat rare diseases.

We have put forth every effort to provide the data that Novitas requires to reach a positive final coverage decision for the 4Kscore test. And at a high level, we're advancing a robust clinical development program that addresses several large markets.

We expect to make meaningful progress with these programs and to achieve several important milestones. And with that overview, let me turn the call over to Adam for a discussion of our second quarter financial performance. Adam?

Adam Logal: Thanks, Steve. As we make -- as we continue to make significant progress on our R&D and commercial activities, we've also made significant improvements in our financial performance. We reported financial results that were in line with the guidance we provided during our call in May.

Overall, our net loss decreased to $6.2 million, or $0.01 a share, on net revenue of $264 million for the second quarter of 2018, compared to a net loss of $17 million, or $0.03 per share, on revenues of $293 million for the comparable period of 2017.

While we are still early in our operational overviews, under our new leadership at BioReference, we've made significant progress in our efforts to improve our operating efficiency.

During the second quarter of 2018, we were able to reduce our costs of revenue as well as selling, general and administrative expenses by 9 percent, or almost $26 million, compared to the second quarter of 2017. Our investments in R&D were $29 million for the second quarter of 2018, compared to $33 million for the 2017 period.

During the second quarter of 2018, operating and net loss benefited from a reduction of contingent consideration expense of $19.7 million related to changes in the assumptions related to the timing of milestone payments due in connection with our acquisitions.

Moving to Diagnostics revenue. On a sequential basis, Revenue increased by approximately $5 million from the first quarter of 2018, resulting from increased volumes in the current period on consistent reimbursement rates.

Revenues in comparison to the prior year second quarter reflect a volume decrease in the clinical lab testing of approximately 1.4 percent, as well as overall reimbursement pressures, including the impact of PAMA. These decreases were partially offset by volume in reimbursement increase is in our genomics testing.

As I mentioned on our call last quarter, revenues and cash flows are benefiting from the revenue cycle management program we initiated last year, and accounts receivables balances and DSO continue to decrease. The improved collection cycle and overall yield on each session has continued to improve throughout 2017 and to the first half of 2018.

We continue to focus our efforts on improving our collection yield, despite challenging market dynamics, particularly in our genomics testing where we are currently focused and have the largest area of opportunity for further improvements.

Regarding our pharmaceutical division's performance, we recognized $4.8 million of revenue related to the sales of RAYALDEE during the quarter, a 36 percent increase on a sequential basis from the first quarter of 2018.

Total pharmaceutical product revenue for the quarter was $28.5 million compared to $29 million for the 2017 period. Revenue related to the transfer of an intellectual property during the second quarter of 2018 was $19.1 million compared to $29.7 million for the 2017 period.

As a reminder, the 2017 period included a $10 million nonrecurring milestone payment related to VARUBI ™. We closed the quarter with approximately $80 million in cash, cash equivalents, and marketable securities.

Our improving cash flows from BioReference and RAYALDEE led to a 52 percent reduction in cash used in operations when comparing the second quarter to the first quarter of 2018 and reflects a 25 percent reduction in cash used in operations compared to the second quarter of 2017.

We are mindful of our cash balance while we make investments into both our R&D pipeline and commercial activities. Based on our current expectations, RAYALDEE's commercial activities will become cash flow positive on a run-rate basis during the third quarter, resulting in further reductions and cash flow used in operations.

Improving operating margins and associated cash flow are anticipated to continue at BioReference and results are expected to further reduce our overall cash used in operations. Looking forward to the third quarter, we expect revenue from services to be between $200 million and $220 million.

This range reflects reimbursement rates remaining consistent with the first half of 2018, with a slight increase in overall volumes. As a reminder, the comparable period of 2017 have revenue from services of $200.9 million after adjustment for the adoption of ASC 606 earlier this year.

Turning to product revenues, we expect the third quarter to come in between $28 million and $32 million, including revenues from RAYALDEE between $5.7 million and $6.5 million.

While revenues from the transfer of an intellectual property expected to be between $18 million and $23 million, including several nonrecurring milestone payments anticipated related to our

RAYALDEE partnerships.

Looking at expenses for the third quarter, we expect costs and expenses to be between $285 million and $305 million, including research and development expense of $33 million to $38 million.

For the full year, we continue to expect our effective tax rate to be in the single digits, and we look forward to providing further details on fourth quarter expectations during our third quarter update in November. With that, I'll turn the call back over to Phil.

Philip Frost: Thank you. I think we can open the session for questions now.

Operator: OK, ladies and gentlemen, if you wish to register for a question for today's question and answer session, you will need to press star, then the number one on your telephone. If your question has been answered and you wish to withdraw your polling request, you may do so by pressing the pound key.

If you are using a speakerphone, please pick up your handset before entering your request. One moment please for the first question. And our first question comes from Louise Chen with Cantor.

Louise Chen: hi, thanks for taking my questions here, I had a few. First question I had was on your diagnostics business. As we look into second half of '18 and beyond, how do you think about growth for that business? What are you doing to reach that growth potential?

And what other factors should we think about here in terms of headwinds or tailwinds in that business? And the second question I have was on RAYALDEE. Where do you think sales can grow from here? I know you give some guidance for the third quarter.

What kind of pick up do you expect in the fourth quarter and beyond? And what's going to drive that? Then I have a question on your hGH program, but I'll ask after the first two.

Adam Logal: So for -- thanks, Louise, for the question. For diagnostics, I think we're going to continue to expect to see that business remain in a stable position. And that is what we expect for the remainder of this year, with some growth opportunities coming. I think where focus has been and what we've talked most about is improving the margins.

And I think the first -- in this first quarter and second quarter of the year, we've made some pretty significant progress on that front. So I think long term, we should be able to get the operating cash flow and operating margins up into the mid to upper teens on a long-term basis.

Thomas Nusbickel: In regards to RAYALDEE, we continue to be optimistic that if we continue to focus on growing new patients with existing writers and adding new writers that with the improved reimbursement with the improved situation with our access help, that we will be able to continue to see significant

growth in Q2 forward and beyond.

Louise Chen: OK. And then just one last question here on the hGH program. Do you have any color on the pre-BLA meeting? And then also, what additional studies in adults might look like? Thank you.

Tony Cruz: Well, we've had feedback from the FDA, and it was very positive in providing us the path forward. The decision that we've made internally is -- sorry?

Male: (Inaudible).

Tony Cruz: (Inaudible) -- is we have to do a (bioequivalence) study, which we are planning to begin in September of -- well, planning to begin towards the end of the year. So that is an additional study that we have to do.

Once that's done, I think that will also coincide with the end of the Phase III pediatric study. And at that time, we'll make -- along with our partner, Pfizer, we'll make a decision on how to best move forward with that BLA.

Steve Rubin: Louise, as you may recall, that the adult, unlike the pediatric, was study was ran with a syringe of the pediatric was ran completely from the get-go in the pen device.

So we need to bioequivalence study that Tony mentioned, is basically just to show the equivalence of drugs supplements and the pen device for adults as well. That's what will be commercialized and so it should pretty -- simple quick study, but it's necessary prior to submission.

Louise Chen: OK, thank you.

Operator: Our next question comes from the line of Brandon Couillard with Jefferies. Please go ahead with your question.

(Mike Kobin): Hey, thanks for taking my question. This is actually (Mike Kobin) on for Brandon. First on that hGH, when can you expect or when will we expect to see any initial data from that trial? And do you expect any interim data readouts?

Steven Rubin: There won't be anything interim. It's a one year trial so you can -- the simple math on the date we did the administration on the last patient, 1 year later. So on the trial, we'll complete in the third quarter of next year. I'm not sure how long it will take to get...

Tony Cruz: It will take a couple -- it normally takes about a couple of months to clean the data and then database locks. So I would say couple of months after, say, August. So probably October-November, November-December.

(Mike Kobin): Got you.

Tony Cruz: It depends on the data cleaning process, but it normally takes two to three months -- two months.

(Mike Kobin): Got you, got you, thanks. And then as far as the Claros PSA test, have you guys -- or could you walk us through how you're thinking about the unit economics of that offering? And as we try and start to think about commercial launch, and have you finalized the interim ASPs and anything like that you can tell us would be helpful?

David Okrongly: So commercially, we're still obviously pending FDA clearance for the device. It's a premarket approval process we're going through. And that is now at a stage where we've filed back in November, we received some feedback from FDA about the PMA and they've asked for some other studies.

We filed our first amendment with them and we're now in the process of gathering the second amendment information from the field. Commercially, we've got the analyzer really pretty much where we've always said it was. Right now, it's a first-generation analyzer. It's about a $2,000 unit.

But there's obviously a commercial flexibility in how we would have that paid for in the course of testing where partial payment for the analyzer is reflected in the cost of the cartridges.

The cost of goods, this is something we're focused on as well. We have plans for automation of the process. Again, pending final approval from FDA for that. So we're gearing up for PSA, but I also want to remind you that there's a great deal of menu expansion capability.

And that expansion happens via a very different regulatory process. First off, it will be the second and third and fourth, et cetera, filings we will do, and these will be done by five, 10k processes, which are quite lower in terms of the bar for clinical trial requirements.

(Mike Kobin): Great. And then -- thanks very much. And I'll just squeeze one last one there. Just on the GeneDx line, I believe that you said that they grew 13 percent in 2Q. Could you give us any sense of maybe how that -- how do you think about that in terms of revenue?

Adam Logal: Yes. So we don't necessarily break out GeneDx from BioReference. And I think we always report that as a single line item so it is blended in there.

I think the volumes do translate and overall, just into direct dollars. So GeneDx makes up about 17 percent of our overall revenue -- 17 percent to 20 percent of our overall revenue and services.

(Mike Kobin): Great, thanks guys, that’s all I've got.

Philip Frost: Thank you.

Operator: Our next question comes from the line of Kevin DeGeeter with Ladenburg. Please go ahead with your question.

Kevin DeGeeter: Hey, thanks for taking my questions, guys, and congrats on some really nice performance. As we think about the series of new tests (revised) has been launched in BioReference, is really sort of the

leverage there and profitability skewed towards growing the top line?

Or should we think about particularly the revised has to being less impactful in terms of improving margins and potential profitability?

Steven Rubin: I think you're definitely -- as we noted, they are definitely based upon margins of reimbursement. What's key is as we've mentioned before, especially, in this area of sequencing, is reimbursement.

And so you'll see a lot of the work that's being done is either whether there's an unmet need or where there's clearly a test with some tinkering modification that we're confident will have a quicker path reimbursement. So it's clearly focus on -- it's both top line growth and margins for sure.

Philip Frost: And to a certain extent, GeneDx and the reference (line that) we call BioReference, are slightly different business models. Whereas in GeneDx they depend and constantly introducing new tests and also depends on reimbursement, of course.

In BioReference, their gross usually comes almost entirely from expansion of the market. And of course, again, depending upon reimbursement. And in both cases, I would say the teams have been working very hard to develop new approaches to help ensure growth. So we're pretty optimistic about the business.

Kevin DeGeeter: Great. And then maybe two questions, if I may, on RAYALDEE. First off, how do we think about sales force sizing? And I guess we're about 64 reps. What kind of traction would you need to see or improve -- further improvement patient access would you need to see to consider expanding on sales force further?

And then just with regard to the dialysis study, is that going to be the same capsule, just in a significantly greater number of capsules? Or do you complete a optimization or different-sized capsule to accommodate potential dose for dialysis patients?

Thomas Nusbickel: Yes, I'll take the first question first. There will be a signal capsule, which will be taken in different doses, which is different than the capsule that's on the market today for the dialysis study.

In regards to the sales force optimization, we will continue to grow the sales force when the opportunity in regards to the physician and the coverage warrants it.

So we're always looking at how can we continue to drive growth and when we can make a case to do that through expansion, the sales force will be doing that. So we'll be continuing look at to do that over time.

Philip Frost: The better they do, the more sales people we want to hire.

Kevin McGeeter: Agreed, definitely nice progress in that business.

Operator: Our next question comes from the line of Yale Jen with Laidlaw.

Yale Jen: Thanks -- good afternoon and thanks for taking the questions. As you guys have a number of clinical trials that completed patient recruitment, I think that data release probably will be one of the highlights over the next maybe few quarters.

Could you sort of summarize some of the data releases possibly expected over the next maybe two or three quarters of different programs?

Steve Rubin: So I mean, I think the first data that we will have is some data on oxyntomodulin trial. As we said, that was fully enrolled and it's going quite well. So we expect to have data later this year. Some preliminary top line data.

Following that, sure, they will have data on the SARM, where that's going to finish enrollment either end of this year or early part next year. Growth hormone, of course, as I mentioned, will have data hopefully towards the end of next year.

Yale Jen: OK, that's helpful. And just (a couple more items) that you have -- appreciate the guidance on the different revenues of different units.

(If this is) BioReference lab that you said third quarter may not have too much growth versus this quarter. Were there any specific headwinds for that guidance, or just more conserve? Or can you see the (narrative) associated with that?

Adam Logal: I think as we just look at volume trends kind of over the years, the first half of the year typically has slightly higher volumes than the second half.

So it's going to -- we expect volumes to be consistent with last year, but also we kind of in line with where we sell volumes in the second quarter. So its consistent business in comparative to last year of $209 million gives us an opportunity there to show some growth.

Yale Jen: Maybe -- and maybe I can just squeeze one more question here, regarding the growth hormone. And you mentioned that you want to do another bioequivalence study and then contemplate for the future path of adult population -- patient population.

I'm just curious at the communication you had with FDA, had -- what kind of feedback they may have regarding the proposal to take away one outliers and make -- and the data looks -- actually was more in line with what originally anticipated. Is there any feedback from the agency on that aspect?

Steve Rubin: Yale, we mentioned in our last call last quarter that we had the FDA and the feedback sort of gave us a path for submission of the data we have with a modified analysis. And what they're allowing us to do is to submit the pediatric data along with the adult data to supplement the submission.

The discussion of strategy is however, do we wait for the completion of the full Phase III data in pediatric, which is obviously 200 and -- or do we just submit the smaller number in the Phase II,

which, of course, is three different doses.

Given the timing and the size of the market for the pediatric segment versus the adult, it may be prudent to wait, but I mean it is, as Tony mentioned we do have to do a quick bioequivalence study. Anyway, independent by a set short trial before we can submit anything.

And so we haven't made a final decision, I guess, is a long answer, but that -- there certainly is -- the FDA certainly is willing to look at our data with the modified analysis without requirements to repeated trial.

Yale Jen: OK. Great. And maybe just tag on that, in terms of Japanese study. Is that potentially inline -- on time for sort of a global filing? Or you think that problem will come after the -- you file for the U.S. in the year?

Steven Rubin: No. We definitely believe it is in line for global filing.

YaleJen: OK, great. Thanks you all, I appreciate it.

Operator: We do have time for one last question from Eric Joseph with JPMorgan.

Eric Joseph: Hey guys, thanks for fitting me in here, and congrats on the progress this quarter. Just as it relates to diagnostics and services business, I wonder if you could just elaborate a little on what opportunities you're seeing per volume growth longer term.

Is there other opportunities for expansion of footprints or certain sort of particular opportunities from the current product offering or portfolio offering?

And with -- it's sounding like the genomics testing business being important part of the operational review process here. Can you just kind of characterize sort of where you view GeneDx as longer term -- as a, I guess, how it makes up or what it constitutes services business longer term? Thanks.

Adam Logal: And so this is Adam, I'll start off. So we certainly think that GeneDx is going to continue to grow at a much faster rate than the larger clinical lab business. We've seen double-digit growth throughout this year and last year in overall testing volumes.

So that continues. And we continue to navigate the reimbursement environment within the genomics space, we'll continue to expect that business to grow and outpace the growth at the clinical lab.

As far as opportunities, there -- we're not going to go out and necessarily compete head-to-head on acquiring large outreach businesses, but we do think there are sizable pieces of business to be had outside of some of the hospital business, whether it be partnering up with independent physician

associations or more regionalized ACOs.

And we certainly think there are good growth opportunities for the clinical lab in some of the niche spaces. And we've had some recent successes in that space as well.

Eric Joseph: Great, thanks for taking the question.

Operator: OK, that is all the time we have today. Please proceed with your presentation or any closing remarks.

Philip Frost: I just want to thank you all for participating, and we look forward to meeting up with you again next quarter.

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 at this time.

END