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): June 6, 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 7.01. Regulation FD Disclosure.

On June 6, 2018, OPKO Health, Inc. (the "Company") will participate in meetings with investors at the Jefferies 2018 Global Healthcare Conference. A copy of the Company's presentation materials is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The presentation materials are also available on the Company's website at www.opko.com under Investor Relations. The information contained on the Company's website shall not be deemed part of this report.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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 by the Company under the Securities Act of 1933 as amended ("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	OPKO Health, Inc. Presentation Materials

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

Date: June 6, 2018

Name: Adam Logal

Title: Senior Vice President, Chief Financial Officer

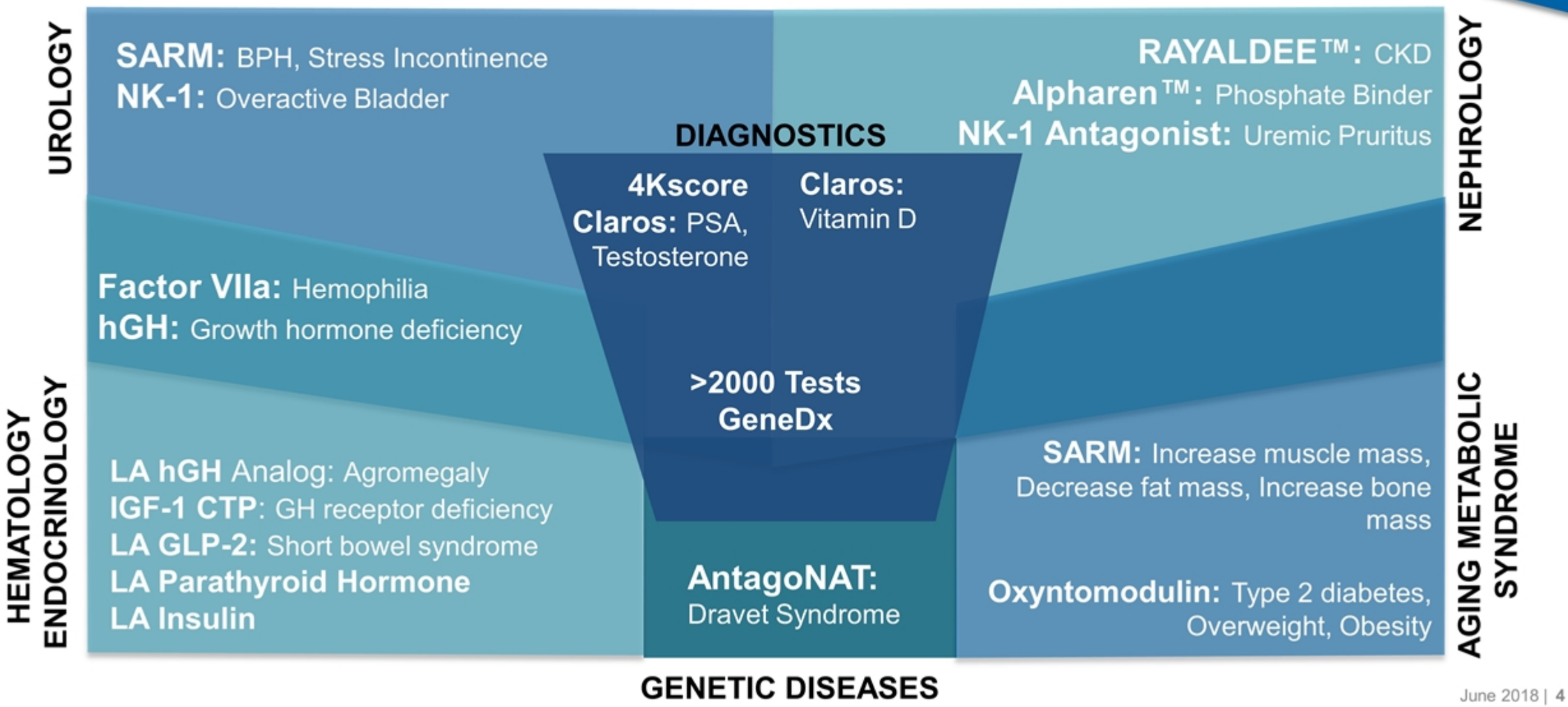
Exhibit 99.1

Forward Looking Statements

This presentation contains “forward-looking statements,” as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as “expects,” “plans,” “projects,” “will,” “may,” “anticipates,” “believes,” “should,” “intends,” “estimates,” “potential,” and other words of similar meaning, including statements regarding our estimated revenues and financial projections, expected milestones and royalties from the outlicense of our products, our ability to achieve high levels of growth, the potential for our products under development, the potential of the 4Kscore® to influence 89% of biopsy decisions and predict the risk of aggressive prostate cancer, the expected timing of the clinical studies and regulatory approval for our products under development, the outcome of our clinical trials and validation studies and that such outcomes will support marketing approval or commercialization, the expected market penetration and size of the market for our products, including without limitation, Rolapitant, Rayaldee®, hGH-CTP, the 4Kscore, Factor VIIa-CTP, Alpharen, oxyntomodulin, the SARM candidate, and our point-of-care diagnostic products, the potential benefits of our products under development, including whether the 4Kscore will predict the risk of 20 year metastasis free survival and result in 40-55% cost savings, the expected response date from the FDA and approval for the PMA for PSA and submission date for 510k for testosterone and expected launch date for each, that oxyntomodulin will provide superior long-term therapy for obesity and Type II diabetes patients, our ability to successfully commercialize our product candidates such as Rolapitant, the 4Kscore, hGH-CTP, Rayaldee, Alpharen, the SARM, and oxyntomodulin, and whether Rayaldee will take significant market share in stage 3 and 4 CKD patients with SHPT, whether Rayaldee will raise serum total 25-hydroxyvitamin D (25D) more effectively than any over-the-counter (OTC) or prescription (Rx) products currently marketed without the risk of hypercalcemia, our ability to develop Rayaldee for new indications including stage 5 CKD and the timeline for doing so, whether the clinical data and post hoc sensitivity analysis for hGH-CTP will support submission of a Biologics License Application (BLA) and approval for hGH-CTP in adults, whether we will submit a BLA and the timing for doing so, whether we will be required to make any changes to our development plans for hGH-CTP, expectations regarding patent coverage, the expected timing for commencing, enrolling, completing and announcing results for our clinical trials, the timing for release of trial data and seeking and obtaining FDA and European regulatory approvals as well as reimbursement coverage for our products, our ability to obtain a positive coverage determination for the 4Kscore and whether we have enough scientific and clinical data to justify a positive coverage determination, whether Novitas and other payors will reimburse us for the 4Kscore test, and the timing of commercial launch of our product candidates. These forward-looking statements are only predictions and reflect our views as of the date they were made, and we undertake no obligation to update such statements. Such statements are subject to many risks and uncertainties that could cause our activities or actual results to differ materially from the activities and results anticipated in forward looking statements, including integration challenges with Bio-Reference and other acquired businesses, liquidity issues and risks inherent in funding, developing and obtaining regulatory approvals of new, commercially viable and competitive products and treatments, the success of our collaboration with Pfizer, general market factors, competitive product development, product availability, federal and state regulations and legislation, delays associated with development of novel technologies, unexpected difficulties and delays in validating and testing product candidates, the regulatory process for new products and indications, manufacturing issues that may arise, the cost of funding lengthy research programs, the need for and availability of additional capital, the possibility of infringing a third party’s patents or other intellectual property rights, the uncertainty of obtaining patents covering our products and processes and in successfully enforcing them against third parties, and the potential for litigation or government investigations, among other factors, including all of the risks identified under the heading Risk Factors in our Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.

Multinational biopharmaceutical and diagnostics company establishing important positions in large, underserved markets

Multi-Faceted Growth Strategy



Investment Highlights

Mature Diagnostic Business

with ~900MM in revenue & growing

Marketed Pharmaceuticals

in early life-cycle with multi $B market opportunities in large underserved markets

Robust Development Pipeline

Multiple late-stage clinical trials addressing indications with large unmet medical needs

Strategy & Execution

Management team with a track record of success and commitment to opportunistic development

Diversified assets across business units

Marketed Pharmaceuticals

- RAYALDEE addresses unmet need in CKD market, ~9 million patients
- RAYALDEE partnered with Vifor Fresenius; Up to $837 million in milestones, double-digit royalties
- RAYALDEE partnered in Japan with Japan Tobacco; up to $112 milestones with tiered double-digit royalties

Robust Pipeline

- hGH-CTP partnered with Pfizer, $570 million pre-commercial milestones; double digit royalties and profit-sharing,
  - ~$3 billion growing market for hGH
  - Pivotal Phase 3 pediatric hGH-CTP study to complete enrollment in 2018
- Initiating multiple Phase 2 clinical studies in various areas of unmet need

Diagnostics

- Bio-Reference Laboratories revenue of ~900MM in 2017
- 400-person sales and marketing team drives industry-leading esoteric testing, ~70% of revenues
- Facilitates uptake of 4Kscore® prostate cancer test and Claros® 1 point-of-care platform

Diversified Assets
Early Life Cycle Pharmaceuticals

Marketed Pharmaceuticals

Robust Pipeline

Diagnostics

Chronic Kidney Disease (CKD) – The Silent Killer

- 9th Leading cause of death, ahead of breast and prostate cancer
- Prevalence expected to increase due to obesity, diabetes and hypertension
- Most patients die from cardiovascular disease, precipitated by secondary hyperparathyroidism (SHPT)
- SHPT is driven by vitamin D insufficiency (VDI) and characterized by elevated blood levels of parathyroid hormone (PTH)
- High PTH levels promote calcification (hardening) of vascular and renal tissues, the major cause of CKD mortality
- New KDIGO Clinical Practice Guidelines recommend against routine use of VDRAs in CKD and highlight the unproven effectiveness of vitamin D supplementation

Healthcare providers have no good options to treat SHPT in stage 3-4 CKD except for RAYALDEE

Rayaldee®
calcifediol ER capsules
30 mcg

RAYALDEE® Overview

Product Launched November 30, 2016

- Extended-Release (1x daily) oral formulation of 25D3* addresses significant unmet need
- FDA-approved for SHPT (elevated PTH) in patients with stage 3-4 CKD and VDI
- Reduces plasma PTH and increases serum 25D with a safety profile similar to placebo
- Minimal effects on serum calcium or phosphorus (key drivers of vascular calcification)
- Expected to take significant market share in stage 3-4 CKD patients with SHPT & VDI (~9M patients in US)
- Potential for new indications including stage 5 CKD, institutionalized elderly, osteoporosis and cancer

* 25-Hydroxyvitamin D_3 or Calcifediol

RAYALDEE® Sends Clear Message

RAYALDEE signals changes in treatment of SHPT

- First and only extended-release prohormone of active form of vitamin D3
- Brings 25-hydroxyvitamin D levels up
- Brings iPTH levels down

RAYALDEE® Commercialization

- 50-Person sales and marketing team launched RAYALDEE on November 30, 2016
  - Increased field sales force from 35 to 64 reps (October 2017)
  - Commercial insurance under contract for >83% of U.S. covered lives
  - Medicare Part D insurance under contract for >53% of U.S. covered lives
- Total RAYALDEE prescriptions increased approximately 730% in 1Q18 compared to 1Q17, and 38% compared to 4Q17
- 1Q18 RAYALDEE revenue of $3.7MM
- International partnership with Vifor Fresenius; up to $837 MM in milestones, double digit royalties
- Japanese partnership with Japan Tobacco; up to $112 MM in milestone payments, tiered double-digit royalties
- Initial line extension plans
  - Phase 2 clinical trials for higher-dose RAYALDEE to treat stage 5 CKD to begin 2H18
  - Phase 2 clinical trial of NK-1 antagonist to treat pruritus in CKD patients to begin 2H18

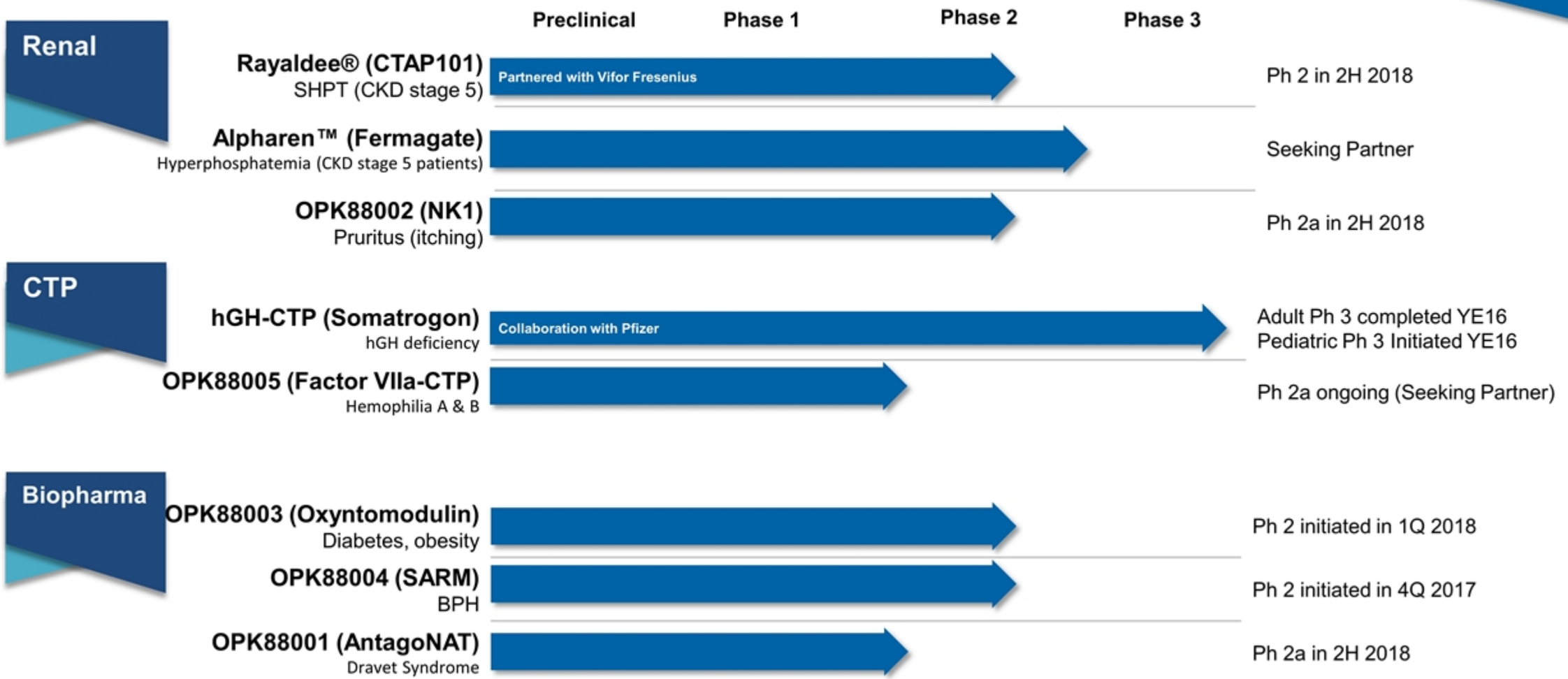
Diversified Assets
Broad Development Pipeline

Marketed Pharmaceuticals

Robust Pipeline

Diagnostics

Robust Late-Stage Pipeline



hGH-CTP Competitive Advantages

New molecular entity (NME) that maintains native sequence of growth hormone

- Once weekly injection vs. current products requiring daily injections
- Phase 3 study in growth hormone deficient adults completed at the end of 2016
- Phase 3 study in naive growth hormone deficiency pediatric population underway
- Final presentation:
  - Refrigerated, liquid, non viscous formulation
  - Disposable easy-to-handle pen injection device with thin needle and small injection volume
- Orphan drug designation in the U.S. and the EU for children and adults

[1] National Center for Biotechnology Information: [2] http://www.childgrowthfoundation.org/

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Pfizer

Partnered with Pfizer

$570M Pre-commercial milestones

Double digit royalties

1 in 10K

Adults diagnosed with GHD[1]

1 in 3.8K

Children in U.S. have growth failure due to growth hormone deficiency[2]

hGH-CTP (Somatrogon) Program Status

Initiated Phase 3 pediatric hGH-CTP study in December 2016

- 220 patients, non-inferiority comparison of weekly hGH-CTP to daily growth hormone
- Global study sites initiated in December 2016
- Easy-to-use, disposable, refrigerated pen device

Phase 3 adult hGH-CTP

- In December 2016 reported that primary endpoint of change in trunk fat mass from baseline to 26 weeks did not demonstrate a statistical significance between the hGH-CTP treated group and placebo
- Completed post hoc outlier analysis in June 2017 to eliminate the influence of outliers on the primary endpoint results
- Analyses, which excluded outliers, showed a statistically significant difference between hGH-CTP and placebo on the change in trunk fat mass; additional analyses that did not exclude outliers showed mixed results
- No safety concerns
- Correspondence and communication with FDA indicated that:
    - There is a path for submission whereby FDA would assess the totality of the data – all relevant efficacy and safety data in adults and pediatric patients
    - The number of patients to be included in the safety database seems sufficient
    - The design of the bioequivalence study for the change from vial to pen formulation is generally acceptable
- Next Steps
    - Assess regulatory strategy for adult indication based on response from FDA

hGH-CTP pediatric registration study in Japan underway

- 44 patients, comparison of weekly hGH-CTP to daily growth hormone
- Same pen device, dosage and formulation used in global Phase 3 pediatric study

Selective Androgen Receptor Modulator (SARM)

OPK-88004 Once Daily Oral Tablet

- Phase 2 study of 350 male subjects for another indication showed significantly increased lean body mass and muscle strength and significant fat mass reduction with no change or lower prostate specific antigen (PSA) levels
- Animal studies resulted in decreased size of prostate

Clinical Plan

- Initiated 125-patient Phase 2 trial in benign prostatic hypertrophy (BPH) or enlarged prostate to determine optimal dose
  - Complete enrollment by YE18
  - Top-line data mid-2019

[1] Deters LA. Benign prostatic hypertrophy. Emedicine http://emedicine.medscape.com/

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50 Million

men in the U.S. are affected by BPH

90%

Men 80 years old and older are affected by enlarged prostate[1]

14M

Men in the U.S. with lower urinary tract symptoms suggestive of BPH[1]

NK 1 Antagonist

Pruritus

- Acute and chronic pruritus ("itching") occurs in 10% to 15% of the population
  - Most prevalent in skin, kidney and liver diseases
- Substance P is implicated in pruritus
- NK-1 antagonists block substance P activity and have been shown to reduce itching in human trials

Pruritus in Dialysis Patients

- Major medical need and requires management

OPK-88002 Clinical Development

- Phase 2a Clinical Study expected to begin in 2H 2018

[1] Medscape.com, International Society of Nephrology (ISN)/

OPKO

52%

Uremic pruritus associated with CKD in adults[1]

70-90%

Of kidney dialysis patients suffer from Pruritus

40%

Patients undergoing hemodialysis suffer ***chronic*** pruritus[1]

Oxyntomodulin Analog
for Treatment of Type 2 Diabetes and Obesity

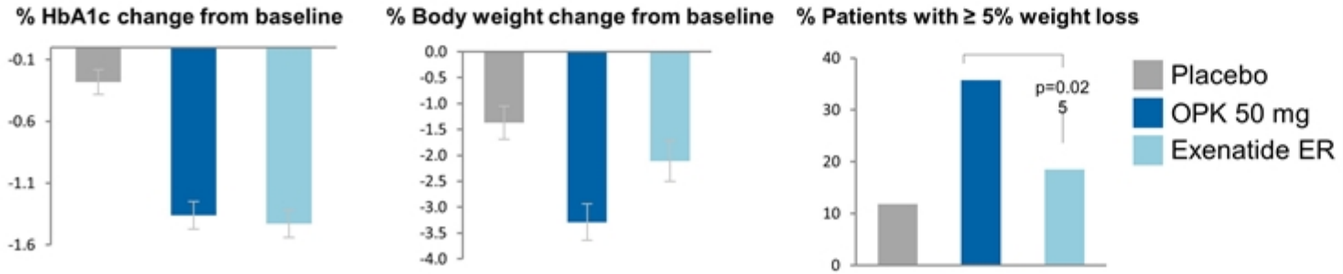
OPK-88003

- Drug development focused on: blood glucose control and reducing body weight
- Once-weekly analog with potentially first to market dual GLP-1/glucagon agonist
- Data support that combining GLP-1 and glucagon activity provides superior weight loss

Clinical Development

- Phase 2b dose-escalation study initiated in March 2018
- Expect to complete enrollment in June 2018
- Preparation of pen and formulation for phase 3 is ongoing

Phase 2 study in 420 type 2 diabetes patients (week 12)



[1] http://www.diabetes.org; [2] https://www.cdc.gov/diabetes

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9.3%

Of the American population suffers from diabetes[1]

$176B

Direct medical costs related to Diabetes in U.S.[1]

17.7M

Adults diagnosed with diabetes reported taking any medication[2]

Diversified Assets
Core $900 MM Business And Growing

Marketed Pharmaceuticals

Robust Pipeline

Diagnostics

OPKO Diagnostics
Near-term Opportunities

Leveraging National Marketing, Sales and Distribution Resources to Drive Uptake of Diagnostic Platforms

- Over 12 million patients served during 2017
- Revenue of ~$900MM in 2017; 4Q17 revenue of ~$150MM
- GeneDx is a genomics leader known for its expertise in rare disease and whole exome testing
- Utilizing BRL commercial infrastructure to drive 4Kscore adoption and will use for Claros 1 launch and adoption upon approval

BioReference Labs is third largest full service reference laboratory in the U.S.

- ~400 Person sales and marketing team
- ~5,000+ People working together to support the needs of clients and patients
- ~200+ Patient service centers located throughout the U.S

4Kscore® Test

Blood Test Alternative To Biopsy

More Than 2 Million Prostate Biopsies/Year WW

- Clinical utility based on decades of biomarker research and >20,000 men tested in Europe and U.S.
- In long-term outcome data, 4Kscore test can predict 20 year metastasis free survival for individual patient
- Included in the 2015-2017 NCCN and 2016-2017 EAU Prostate Cancer Guidelines
- Health economics study shows 40–55% cost savings by avoiding unnecessary MRI, prostate biopsy, and additional treatment or monitoring of indolent cancer
  - ***80% of men undergoing prostate biopsy based on PSA are found to have no cancer or indolent cancer***
- Clinical utility study shows 4Kscore influences 89% of decisions about performing prostate biopsy

OPKO

4Kscore®

Only blood test that accurately identifies risk for aggressive prostate cancer

>5K

Physicians have used 4Kscore in practice

21K

Tests performed during 1Q18, a 13% increase compared with 1Q17

4Kscore Clinical and Commercial Update

- Category I CPT published and effective January 1, 2017; CMS national rate for 2018 increased to $760 vs $600 in 2017
- Novitas Solutions (Medicare Administrative Contractor for OPKO Elmwood Park, NJ facility)
  - Novitas issued a draft non-coverage determination in May 2018 subject to a public comment period ending July 5, 2018
  - Novitas has been and continues to pay for 4Kscore Medicare submissions pending finalization of the draft non-coverage decision.
  - OPKO is taking a multiple pronged approach to address the concerns raised in the Novitas draft LCD
- Data from study at VA hospitals confirming the 4Kscore's ability to accurately predict aggressive prostate cancer presented
  - Demonstrated equally effective and vital clinical test for African American men, who have the highest rates of prostate cancer mortality
- Radical prostatectomy study demonstrated 4Kscore can effectively differentiate biopsy Gleason 6 cancer from those likely to harbor adverse pathology

Claros 1 Platform

Addresses Large Point of Care Test Market

25M PSA Tests in U.S. Annually;

- Novel diagnostic system can provide rapid, quantitative blood test results in 10 minutes – right in the physician's office
- Modular PMA with FDA for PSA test filed in 4Q17; expect response 2H18
- Expect testosterone 510(k) filing YE18
- Claros 1 point of care platform will leverage BioReference Labs distribution and marketing
- Menu expansion following initial FDA filings

Select Financial Information
March 31, 2018

Balance Sheet

- Cash, cash equivalents & marketable securities: $99.9 million
- Net investments: $297.5 million
- Current portion of line of credit and notes payable: $11.9 million
- Senior notes: $31.8 million
- $55 million convertible note issued February 2018

Capital Structure

- Common shares outstanding: 559.47 million

Revenue

- Consolidated revenues for the three months ended March 31, 2018 were $254.9 million compared with $266.4 million for the comparable period of 2017
  - Revenue from services were $211.3 million for the three months ended March 31, 2018 compared with $228.6 million for the comparable 2017 period
    - While not directly comparable, this represents a marked improvement from the most recently completed quarter ended December 31, 2017

Upcoming milestones

Progress Across Multiple Business Areas

✓ 4Kscore	Launched TV ads in FL 1Q18
✓ Oxyntomodulin Phase 2b	Initiated March 2018
RAYALDEE Stage 5 CKD Phase 2	Initiate 2H18
NK-1 Antagonist Pruritus Phase 2a	Initiate 2H18
Claros 1 PSA approval	3Q18
SARM Phase 2 complete enrollment	YE18
Claros 1 Testosterone 510(k) submission	YE18
Phase 3 Pediatric hgh-CTP study complete enrollment	YE18


OPKO
Thank You