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**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): September 15, 2020

**OPKO Health, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or Other Jurisdiction  
of Incorporation)

**001-33528**

(Commission  
File Number)

**75-2402409**

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	OPK	NASDAQ Global Select Market

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. ☐

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**ITEM 7.01. Regulation FD Disclosure.**

On September 15, 2020, members of management for OPKO Health, Inc. (the “Company”) attended the H.C. Wainwright 22nd Annual Global Investment Virtual Conference and participated in one on one meetings with investors. A copy of the Company’s slides used in the meetings is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The presentation slides are also available on the Company’s website at [www.opko.com](http://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 (the “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, or the Exchange Act, unless expressly stated otherwise.

**ITEM 9.01. Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	OPKO Health, Inc. Presentation Materials
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

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Exhibit Index

Exhibit No.	Description
99.1	<a href="#">OPKO Health, Inc. Presentation Materials</a>

## 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/ Steven D. Rubin

Name: Steven D. Rubin

Title: Executive Vice President-Administration

Date: September 15, 2020



**OPKO**

September 2020  
NASDAQ: OPK

## 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 expected financial performance and expectations regarding the market for and sales of our products, expectations about COVID-19 testing, the demand for testing, our capacity for testing and expected turnaround time, the impact of COVID-19 on all of our businesses, positively and negatively, our ability to expand our capacity should there be additional demand, the availability of resources, including labor, equipment and supplies, to meet demand for testing and the potential impact on us should these resources be constrained, whether our turnaround time will be as expected or our performance quality decline, our product development efforts and the expected benefits of our products, our estimated revenues and financial projections, including expected Rayaldee and BioReference revenues, whether we will maintain profitability or continue growth at BioReference, whether prescriptions for Rayaldee will stabilize or increase, expected milestones and royalties from the outlicense of our products, 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, our ability to successfully commercialize our product candidates such as hGH-CTP, Factor VII-CTP, and our rare disease product candidates, 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 for hGH-CTP will support submission of a Biologics License Application (BLA), the timing of such submission, and approval for hGH-CTP in adults and pediatric patients, whether we will be required to make any changes to our development plans for hGH-CTP and increase our expenditures, 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. 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 the continued prevalence of COVID-19, 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 and relationship with Pfizer and our other commercial partners, 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 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, 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

## Diversified Assets Across Business Units



- Rayaldee addresses unmet need in CKD market
- Rayaldee revenue of \$8.6 million in 2Q 2020
- Rayaldee partnered with Vifor Fresenius; Up to \$787 million in milestones with tiered double digit royalties
- Rayaldee partnered in Japan with Japan Tobacco; up to \$112 million in milestones with tiered double digit royalties



- Somatrogen once weekly (hGH-CTP) partnered with Pfizer
  - Successful pivotal phase 3 pediatric somatrogen study completed; positive topline data announced October 2019
  - Successful Japanese phase 3 pediatric somatrogen study completed; positive top line data announced in June 2020
- Initiating multiple drug study trials in various areas of unmet need



- BioReference Laboratories revenue of
  - ~\$251 million in 2Q 2020
- Significant response to COVID-19 pandemic; ~5.2 million PCR tests performed as of September 13 2020; leader in mobile testing sites and federal, state and local partnerships
- 300-person sales and marketing team drives industry leading esoteric testing
- Recognized leader in genetic testing

# Somatrogon<sup>®</sup> Summary

## Achieved Primary Endpoint

- Somatrogon<sup>®</sup> (hGH-CTP), a once weekly growth hormone replacement therapy, was proven non-inferior to daily Genotropin<sup>®</sup> (somatropin) with respect to height velocity after 12 months
- Height velocity at 12 months of treatment was higher in the somatrogon<sup>®</sup> group (10.12 cm/year) than in the somatropin group (9.78 cm/year)

## Global Partnership with Pfizer

- Pfizer to commercialize somatrogon<sup>®</sup>
- Highly committed to maintaining global hGH franchise

## Secondary Endpoints Achieved

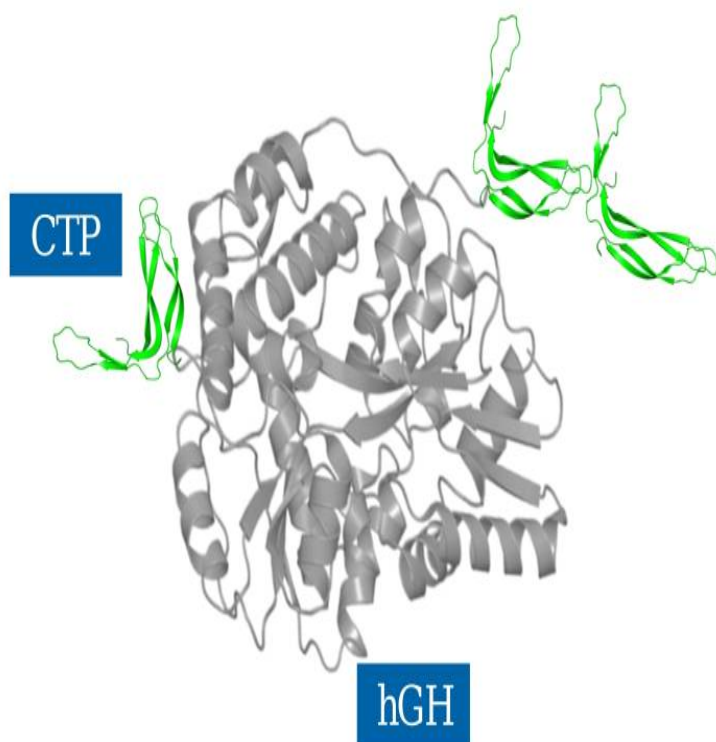
- Change in height standard deviation scores at six and 12 months were higher with somatrogon<sup>®</sup> in comparison to somatropin
- At six months, change in height velocity was higher with somatrogon<sup>®</sup> in comparison to somatropin
- Somatrogon was generally well tolerated in the study and comparable to that of somatropin dosed once-daily with respect to the types, numbers and severity of the adverse events observed between the treatment arms.

## Successful Japanese Registration Study

- Height velocity at 12 months of treatment was higher in the somatrogon<sup>®</sup> group (9.65 cm/year) than in the somatropin group (7.87 cm/year)
- Study met all primary and secondary endpoints and together with the global Phase 3 clinical trial a NDA submission is anticipated in 1H 2021

<sup>1</sup>Pfizer 2018 Annual Report

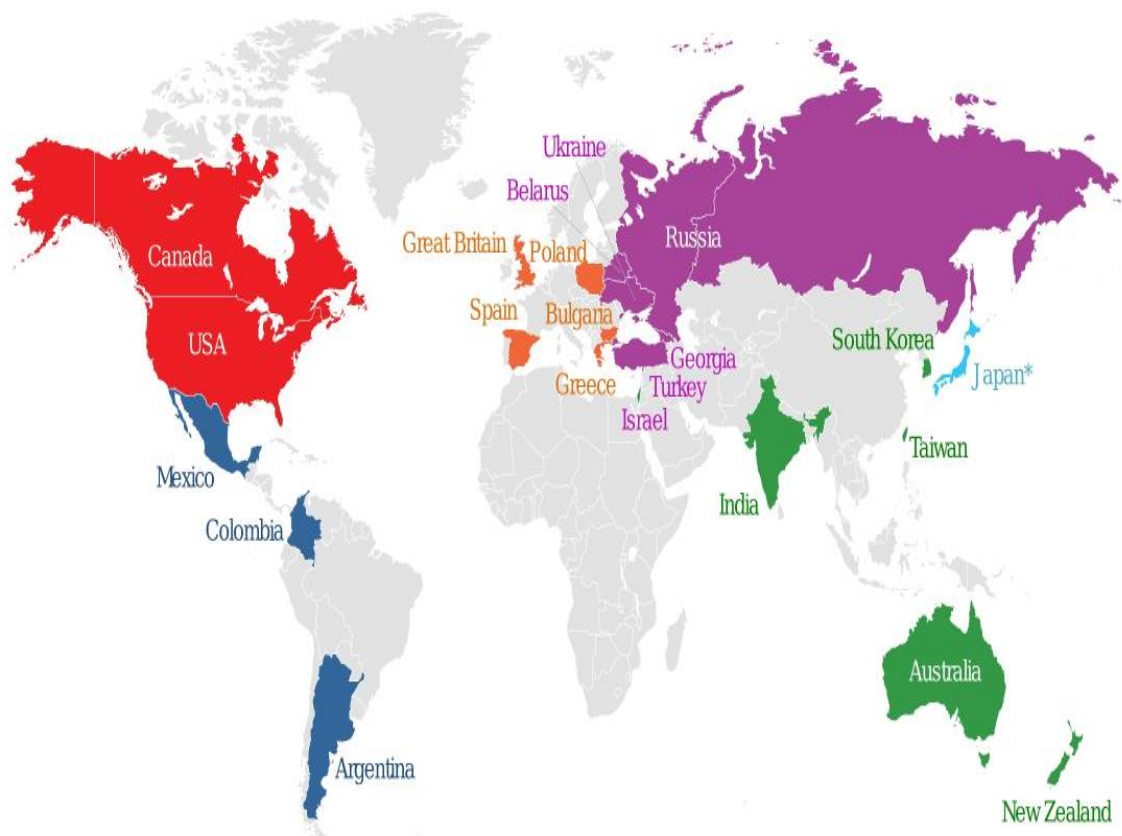
## Somatrogon® CTP Technology



Somatrogon® (hGH-CTP) consists of the natural peptide sequence of native growth hormone and the 28 amino acids of the C-Terminus Peptide of human chorionic gonadotropin hormone. This molecule, compared to current GH replacement therapies, is designed to reduce the injection frequency from daily to once a week in adults and children with GH deficiencies.

# Somatrogon® Phase 3 Participation

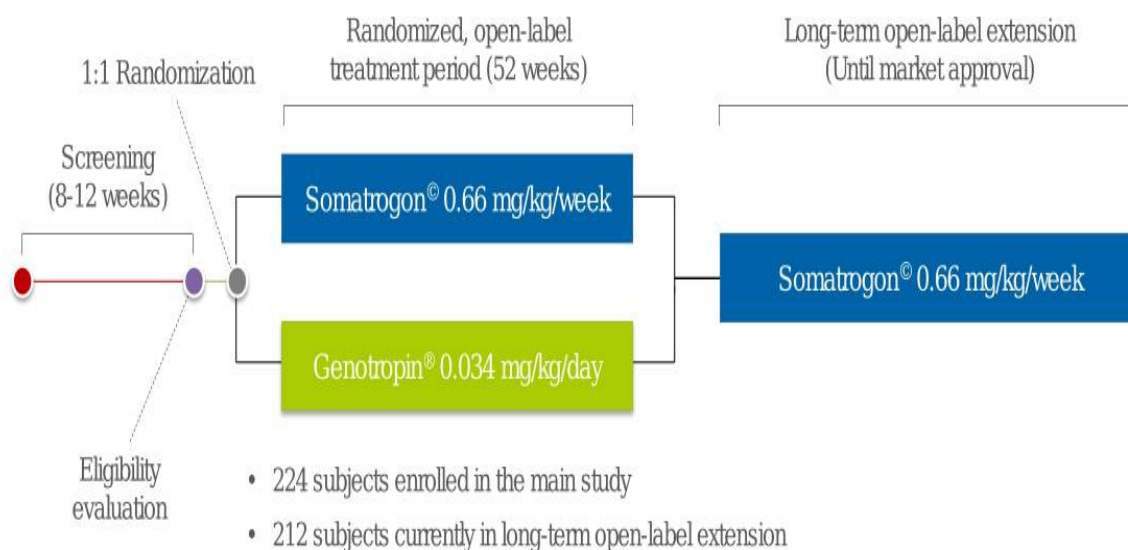
106 CLINICAL SITES ACROSS 22 COUNTRIES



\* Additional separate Phase 3 clinical trial conducted in Japan

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# Somatrogon® Phase 3 Study Design



Primary Endpoint	<ul style="list-style-type: none"> <li>• Annual height velocity at month 12</li> </ul>
Secondary Efficacy Endpoints	<ul style="list-style-type: none"> <li>• Height velocity at month 6</li> <li>• Change in height standard deviation score (SDS) at months 6 and 12</li> </ul>

## Somatrogon Path To Approval

- BLA submission in US anticipated 2H 2020
  - Completion of analysis of immunogenicity and safety data from pivotal Phase 3 study and open label extension study
- Data from two abstracts was presented at the Endo Society's "ENDO Online 2020" on June 8<sup>th</sup>, 2020
  - "Somatrogon Growth Hormone in the Treatment of Pediatric Growth Hormone Deficiency: Results of the Pivotal Phase 3"
  - "Interpretation of Insulin-like Growth Factor (IGF-1) Levels Following Administration of somatrogon (a long-acting Growth Hormone-hGH-CTP"
- MAA submission in Europe to follow upon completion of open label study demonstrating benefit and compliance with reduced treatment burden
  - Study completed in September 2020
- NDA submission in Japan anticipated 1H 2021
  - Japanese registration study successful completion announced in June 2020

## Diversified Assets Nephrology





## First and only extended-release prohormone of active form of vitamin D<sub>3</sub>

- Once daily oral formulation of the prohormone 25D<sub>3</sub>\* addresses significant unmet need
- Only product approved by FDA to treat secondary hyperparathyroidism (SHPT) in patients with stage 3-4 CKD and vitamin D insufficiency
- Reduces plasma iPTH and increases serum 25D, with safety profile similar to placebo
- Minimal adverse effects on serum calcium or phosphorus, key drivers of vascular calcification
- Total prescriptions of Rayaldee increased 54%\*\* in 2Q 2020 compared to 2Q 2019 and was consistent with the first quarter 1Q 2020 despite COVID-19 restrictions

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

## 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
- Elevated blood levels of intact parathyroid hormone (iPTH) arise from vitamin D insufficiency
- High PTH levels promote vascular calcification, a major cause of CKD morbidity and mortality
- Updated KDIGO practice guidelines recommend against routine use of vitamin D receptor activators and highlight unproven effectiveness of vitamin D supplementation

\*\* As reported by IQVIA

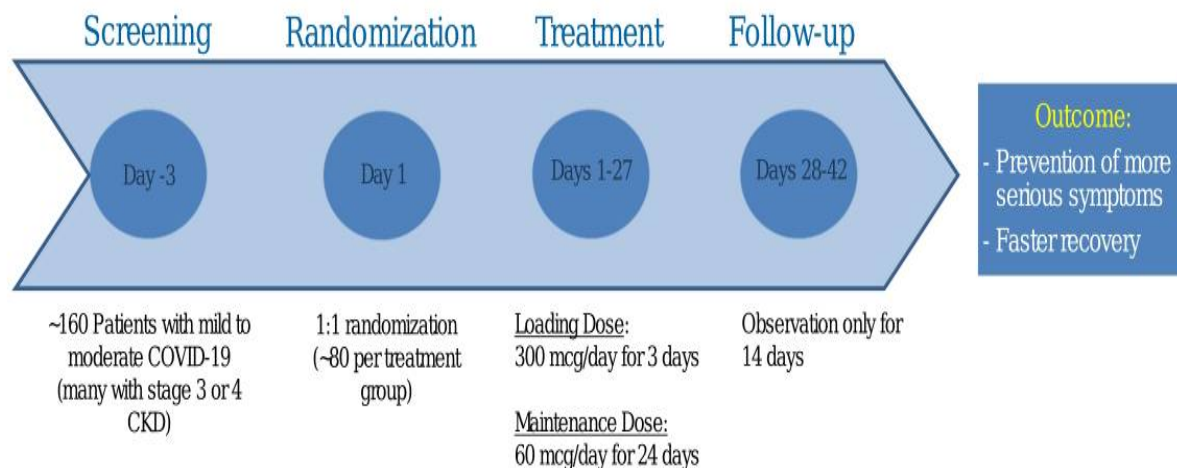
\* 25-Hydroxyvitamin D<sub>3</sub> or Calcifediol

## Rayaldee for Patients with Stage 5 CKD and Vitamin D Insufficiency

- Phase 2 open label trial to evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of higher strength Rayaldee in subjects with Vitamin D insufficiency and CKD requiring regular hemodialysis
- Commenced September 2018
  - Approximately 44 patients being treated for 26 weeks
    - Interim data released in March 2020
    - Topline data expected in 2Q 2021
  - Costs shared with Vifor Fresenius and Japan Tobacco

## FDA-Approved Phase 2 Study with Rayaldee in COVID-19 Patients

Title: A Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of Rayaldee (calcifediol) Extended-release Capsules to Treat Symptomatic Patients Infected with SARS-CoV-2 (REsCue)



**Endpoints:** Time to resolution of symptoms and attainment/maintenance of serum 25D levels within 50-100 ng/mL.

**Timeline:** Patients screening to commence later in September or in October 2020; completion expected prior to EOY 2020.

**Sites:** Multiple US sites located in southern Florida, the Central Gulf coast, the Midwest and the Southwest.

## Diversified Assets Broad Development Pipeline



# Rare Disease Pipeline In Development

INDICATION	PRODUCT	MARKET SIZE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Growth Hormone Deficiency (GHD)	hGH-CTP (Adults)		Once-weekly injection			
	hGH-CTP (Children)		Once-weekly injection			
Hemophilia	Factor VIIa-CTP (IV)	\$0.6B				
	Factor VIIa-CTP (SC)		Once-/twice-weekly injection			
IGF-1 Deficiency	IGF-1-CTP	\$0.2B	Once-/twice-weekly			
Bowel Disorders	GLP-2 Agonist	\$2.0B	Once-weekly			

## Diversified Assets

### One of the Nations Largest Reference Laboratories



# BioReference Laboratories Overview



## Areas of Focus

Targeted Expertise  
for Physicians



Strategic  
Partnerships



Patient  
Empowerment



# Targeted Areas of Expertise for Physicians



## Strategic Laboratory Collaboration

OPKO Health's BioReference Laboratories and Westchester Medical Center Health Network Enter Into Strategic Laboratory Collaboration to Deliver Operational and Diagnostic Services, May 13, 2020

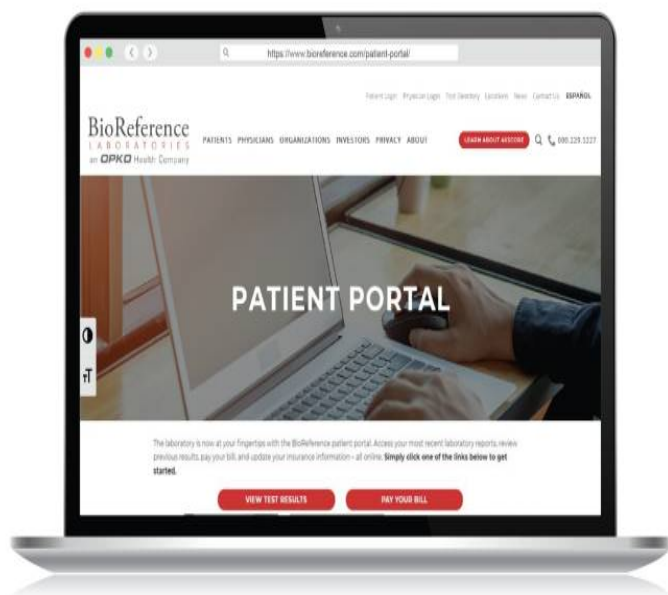


- WMCHealth, 10 hospitals through out the Hudson Valley performing over **7 million tests a year**
- Provide administrative services, laboratory equipment, supplies, reference testing and outreach services

# Patient Empowerment

"BioReference: The Lab Patients Choose"

## Patient Portal



## Consumer-initiated Testing



## BioReference's COVID-19 Response

Serving all 50 states with testing locations in: Elmwood Park, NJ; Melbourne, FL; Gaithersburg, MD; Houston, TX; Campbell, CA

- Currently, PCR and/or Antibody Testing is being performed out of NJ, FL, MD, TX and CA
- PCR & Antibody turnaround time for "Priority" account is 6 hours once in the lab
- Performed ~5.3 million COVID-19 PCR tests as of September 13, 2020
- Capacity to run more than 70,000 PCR tests per day
- Capacity to run 400,000 antibody tests per day
- Partnering with New York, New Jersey and Florida, multiple cities, municipalities and hospital systems and operating more PCR collection sites than any other commercial laboratory
- Highly visible back to work solutions including partnering with NFL, NBA and MLS



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## Leverage Strategic Partnerships to Optimize COVID-19 Testing Access

**OPKO**



Westchester  
Medical  
Center Health  
Network



Multiple Large  
Medical  
Groups



Municipalities  
and  
Government

## Looking Forward



- Many factors continue to drive demand for COVID-19 testing at BioReference Laboratories.
  - Hospitals desire more PCR testing for patients undergoing elective in-patient and outpatient procedures.
  - Hospitals will continue to test their employees for both PCR and antibody presence.
  - Physicians will continue to test their patients for COVID-19 disease.
  - The general public continues to desire to know their antibody status.
- The return of the flu season this fall and winter may have an impact on COVID-19 testing and other respiratory infection testing.
- Employers are working through their strategies for employees to return to work which includes both PCR and antibody testing programs.

## Select Financial Information

June 30, 2020

### Balance Sheet

- Cash, cash equivalents & marketable securities: \$21.6 million
- Un-utilized \$100m unsecured credit facility and \$15m available under ABL with J.P. Morgan Chase resulting in more than \$136m of capital available
- Net investments: \$26.3 million
- Convertible notes, net: \$216.5 million

### Capital Structure

- Common shares outstanding: 669.8 million

### Income Statement

- Consolidated revenues for 2Q 2020 were \$301.2 million compared with \$226.4 million for 2Q 2019
  - - Revenue from services were \$251.0 million in 2Q 2020 compared with \$178.5 million for 2Q 2019
- Net income for 2Q 2020 was \$33.7 million (\$0.05 per share) compared with net loss of \$59.8 million (\$(0.10) per share) for 2Q 2019

