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): January 13, 2021

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)

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. ☐

ITEM 7.01. Regulation FD Disclosure.

On January 13, 2021, members of management for OPKO Health, Inc. (the "Company") took part in the 39th Annual J.P. Morgan Healthcare Conference and participated in one on one meetings with investors. A copy of the Company's presentation as 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 is 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 (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 8.01. Other Events.

On January 13, 2021, the Company's BioReference Laboratories, Inc. introduced Scarlet Health™, an in-home, fully integrated digital platform providing access to on-demand diagnostic services.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	OPKO Health, Inc. Presentation Materials
99.2	Press Release of the Company dated January 13, 2021
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Exhibit Index

Exhibit No.	Description
99.1	OPKO Health, Inc. Presentation Materials
99.2	Press Release of the Company dated January 13, 2021

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

Date: January 13, 2021

Name: Steven D. Rubin

Title: Executive Vice President-Administration


OPKO
OPKO
January 2021
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 the success of our strategic ventures, whether the Scarlet Health mobile service and the integrated platform will function or perform as designed, the role and value of the service to patients and healthcare providers and whether there is a demand for the service or whether it will be available, our product development efforts and the expected benefits of our products, our estimated revenues and financial projections, whether we will maintain profitability or continue growth at BioReference, whether prescriptions for Rayaldee will continue to increase, 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 use of hGH-CTP in adults and pediatric patients will be approved, whether we will be required to make any changes to our development plans for hGH-CTP and increase our expenditures, 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 foreign 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, 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, 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 and Commission.

Pharmaceutical and Diagnostic platforms in growing healthcare markets

BioReference LABORATORIES an OPKO Health Company

Third largest full service lab in US, 300-person commercial team drives industry-leading esoteric testing

4Kscore®

Blood test for the detection of aggressive prostate cancer

GeneDx an OPKO Health Company

Best-in-breed genetic test offerings and most comprehensive menu in the industry, specializes in whole exome and genome sequencing and informatics

Rayaldee® calcifediol ER capsules 30 mcg

- Approved for secondary HPT in Stage 3-4 CKD
- Cashflow supports 80-person commercial team

Indication	PC	Ph 1	Ph 2	Ph 3
Rayaldee Stage 5 CKD	→	→	→	
Rayaldee COVID-19	→	→	→	
Adult Growth Hormone Deficiency	→	→	→	→
Pediatric Growth Hormone Deficiency	→	→	→	→
Additional Pediatric Growth Hormone Disorders	→	→	→	
Hemophilia	→	→		
IGF-1 Deficiency	→			
Short Bowel Syndrome	→			

- Robust pipeline of rare disease drug candidates
- Two platform technologies enable novel long-acting therapeutics
- High unmet needs and long-dated IP

Somatrogon© Summary

PEDIATRIC INDICATION-ACHIEVED PRIMARY ENDPOINT

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

PEDIATRIC INDICATION-SUCCESSFUL JAPANESE REGISTRATION STUDY

- Height velocity at 12 months of treatment was higher in the somatrogon© group (9.65 cm/year) than in the somatropin group (7.87 cm/year)
- Study met all primary and secondary endpoints

PEDIATRIC INDICATION-SECONDARY ENDPOINTS ACHIEVED

- Change in height standard deviation scores at six and 12 months were higher with somatrogon© in comparison to somatropin
- At six months, change in height velocity was higher with somatrogon© 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.

PEDIATRIC INDICATION-SUCCESSFUL PHASE 3 CROSSOVER STUDY

- Treatment with somatrogon© once-weekly improved the mean overall Life Interference total score after 12 weeks of treatment compared to treatment with somatropin administered once-daily.
- Key secondary endpoints showed an overall benefit in treatment experience with the somatrogon© once-weekly dosing regimen compared to the somatropin once-daily dosing regimen

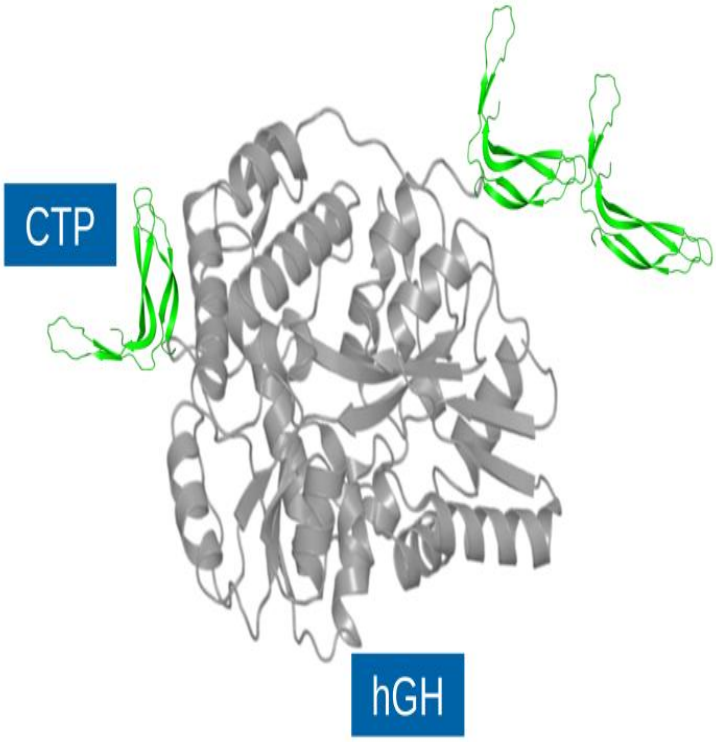
GLOBAL PARTNERSHIP WITH PFIZER

- Pfizer to commercialize somatrogon©
- Highly committed to maintaining global hGH franchise

U.S. BLA SUBMISSION ACCEPTED

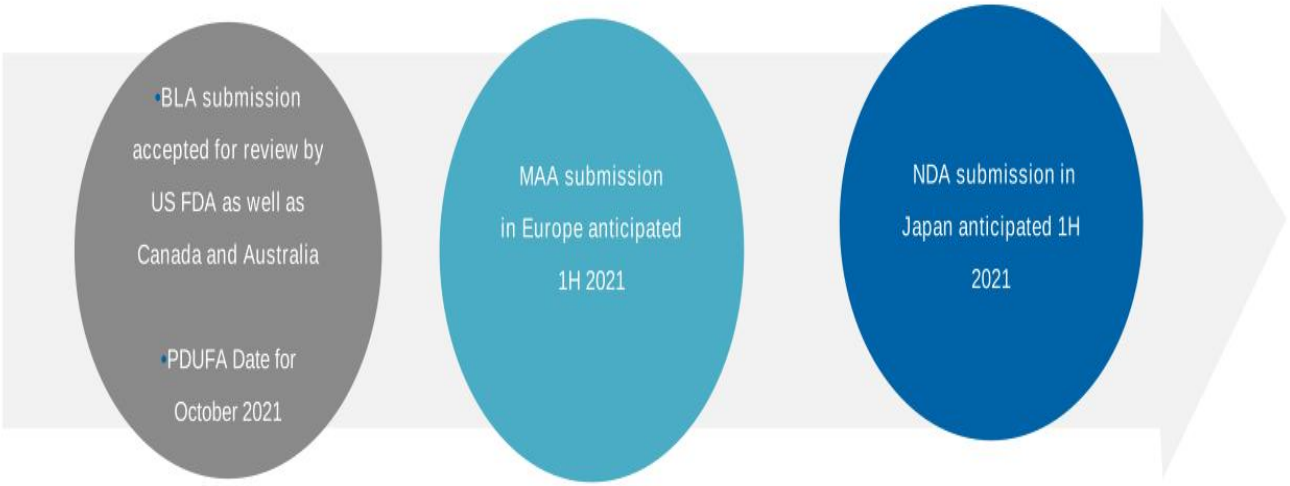
- Prescription Drug User Fee Act (PDUFA) date in October 2021

Somatrogon© CTP Technology



Somatrogon© (hGH-CTP) consists of the natural peptide sequence of native growth hormone and three copies of the 28 amino acids of the C-Terminus Peptide of human chorionic gonadotropin hormone. This NCE, 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© Path To Approval



Diversified Assets

Rayaldee® calcifediol ER capsules 30 mcg

Rayaldee
calcifediol ER capsules
30 mcg

First and only extended-release prohormone of active form of vitamin D_3

- Once daily oral formulation of the prohormone $25D_3$* 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 13%** in 3Q 2020 compared to 3Q 2019 and were consistent with the second quarter 2Q 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 guideline recommends against routine use of vitamin D receptor activators and highlights unproven effectiveness of vitamin D supplements (ie., cholecalciferol and ergocalciferol)

** As reported by IQVIA

* 25-Hydroxyvitamin D_3 or Calcifediol

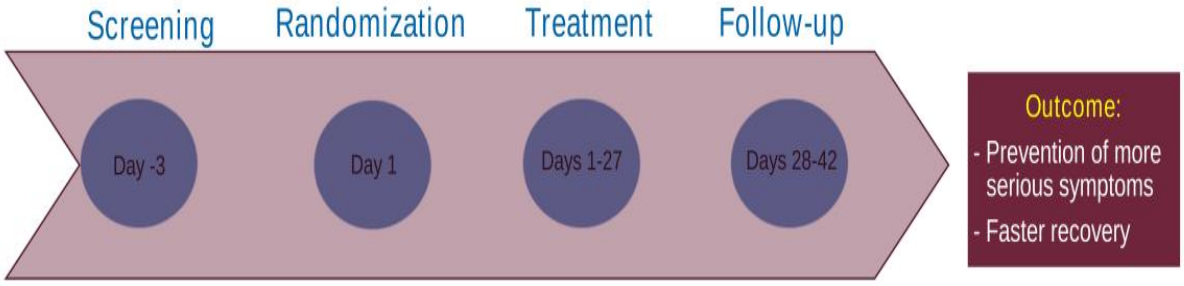
Rayaldee for Patients with Stage 5 CKD and Vitamin D Insuffiency

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 treated for 26 weeks
    - Interim data released in March 2020
    - Topline data expected in 1Q 2021
  - Costs shared with Vifor Fresenius and Japan Tobacco

ONGOING 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)



~160 patients with mild-to-moderate COVID-19 (many with stage 3 or 4 CKD)

1:1 randomization (~80 per treatment group)

Loading Dose: 300 mcg/day for 3 days

Maintenance Dose: 60 mcg/day for 24 days

Observation only for 14 days

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

Sites: Multiple US sites located in southern Florida, the Central Gulf coast, the Midwest and the Southwest. Enrollment on-going.

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)	Pfizer $4.0B	Once-weekly injection			
	hGH-CTP (Children)		Once-weekly injection			
Other Pediatric Growth Hormone Disorders	hGH-CTP					
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 Nation's Largest Reference Laboratories

OPKO's BioReference 2020 Overview

Patients Served Annually

2019 → 2020

11M → 19M

Requisitions Daily

2019 → 2020

40,000+ → 115,000

Staff

2019 → 2020

4,000 → 8,100

Clinical Staff

2019 → 2020

120 → 300

Areas of Focus with Customized Solutions

COVID-19

Digital Health

Core Business

Strategic Venture Services

COVID-19 Response

Physicians & Hospitals

Large scale screening and point-of-care testing

Sports | Travel & Leisure | Education | Employers | Government | Retail

NFL Enhancement

COVID-19 Diagnostic Offerings

10,000,000+
Molecular Tests Performed*

100,000+
Molecular Tests Per Day Capacity*

60,000+
Point-of-Care Tests Performed*

*numbers as of January. 2021

The Future of COVID-19 Testing for 2021

BioReference will continue to lead the industry with custom solutions, point-of-care testing and large-scale screening programs

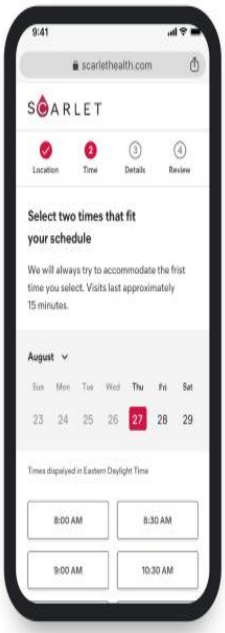
- Many factors continue to drive demand for COVID-19 testing at BioReference Laboratories.
  - Retail access remains imperative for the general public.
  - Physicians will continue to test their patients.
  - Employers are working through their strategies for employees to return-to the-office.
  - Transportation and hospitality will continue to need testing.
  - Schools and universities will continue to need testing.
  - Testing strategies as related to improving the economy will continue to be needed.

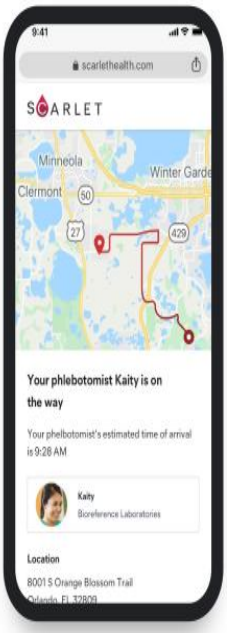
Core Business Areas

Digital Health

SCARLET

- BioReference is the only national laboratory to offer an in-home, fully integrated digital solution of mobile phlebotomy and laboratory services
- About Scarlet:
  - Efficient, convenient and safe to use for physicians and patients.
  - Inspired by digital platforms consumers use daily to provide ease-of-use and ubiquitous services.
  - Demonstrates new delivery of health care, meeting the demand of patients and physicians.





Strategic Venture Services

A mid-Atlantic integrated health care provider with more than 2,600 physicians

Provides laboratory management and reference testing.

Services include:

- Design and buildout of the core laboratory
- Day-to-day management of the operations
- Implementation and operation of the courier network

A Texas-based women's healthcare network with care centers located across 60 locations with approximately 150 providers

Serves as primary reference laboratory.

Services include:

- Design and build laboratory space
- Phlebotomy placement in qualifying care centers
- Account management teams of day-to-day activities

GeneDx – Global Leader in Rare Genetic Disorders

Leader in rapid exome and genome testing

Largest provider of exome sequencing, performing nearly 5,000 exomes per month.

Leader in pediatric rare disease with most Children's hospitals across the country as a client.

One of the largest test menus in the world as a result of two decades of experience.

DETECT GENOMIX™

Partnership with Pediatrix Medical Group with over 2,200 affiliated neonatologists.

Rapid exome and genome testing to the NICU setting across the country.

Leverages the unique expertise of Pediatrix caring for NICU babies along with GeneDx expertise in rapid diagnosis resulting in patient, provider and payer benefits.

Broad utility in leveraging our expertise

Focus on leveraging our expertise in genetics with other organizations to broaden our commercial reach.

Leading with our exome experience, build a leadership position in genomes.

Make diagnostic genetics accessible to all patients and providers with actionable results.

Select Financial Information

September 30, 2020

Balance Sheet

- Cash, cash equivalents & marketable securities: $36.3 million
- Un-utilized $100m unsecured credit facility and $64.7m available under ABL with J.P. Morgan Chase resulting in more than $200m of capital available
- Net investments: $14.3 million
- Convertible notes, net: $219.2 million

Capital Structure

- Common shares outstanding: 670.0 million

Income Statement

- Consolidated revenues for 3Q 2020 were $428.1 million compared with $228.8 million for 3Q 2019
  - Revenue from services were $382.5 million in 3Q 2020 compared with $181.1 million for 3Q 2019
- Net income for 3Q 2020 was $23.7 million ($0.04 per share) compared with net loss of $62.0 million ($(0.11) per share) for 3Q 2019

OPKO Health's BioReference Laboratories Introduces Scarlet Health™, In-Home Diagnostic Service to Expand Digital Health Access

Scarlet brings diagnostic service to patients' homes, offices and other preferred locations, delivering an on-demand, safe and convenient diagnostic experience for patients and healthcare providers

ELMWOOD PARK, N.J., January 13, 2021 – BioReference Laboratories, Inc., an OPKO Health company (NASDAQ:OPK), today introduced Scarlet Health™, an in-home, fully integrated digital platform providing access to on-demand diagnostic services. Scarlet has been designed similarly to tools consumers use daily, in order to provide ease-of-use and ubiquitous conveniences.

Backed by BioReference's national presence and infrastructure, with laboratory facilities and professionals across the country, Scarlet delivers an innovative, flexible, mobile alternative to traditional patient service centers or other draw locations when phlebotomy and other specimen collection services are needed.

Patients will no longer need to travel for laboratory services. Healthcare providers will secure vital diagnostic information about patients reliably, quickly and easily to enable a faster diagnosis.

To use Scarlet's convenient, secure and safe approach to mobile specimen collection services, patients will obtain a link after visiting or connecting virtually with their healthcare provider. After confirming the services needed, a patient will verify their identity and schedule a date and time, and choose their preferred location (i.e., at their office or home) for a qualified healthcare professional to collect their test specimen. Patients will then receive real-time updates and relevant information, such as learning how to prepare for the visit or track the healthcare professional's arrival. Specimens will be sent to BioReference for testing, and the results will be securely shared online with the patient and their ordering healthcare provider.

"Scarlet reimagines the delivery of health care, creating an accessible, consumer-centric approach to the way patients receive laboratory services," said Richard Schwabacher, Senior Vice President of Digital Health and Chief Digital Officer for BioReference Laboratories. "Scarlet is the first of many digital health advances at BioReference that aim to increase flexibility and convenience for patients. We're proud to bring this kind of innovation and technology to patients and are looking forward to expanding access to critical health care needs with Scarlet."

Investment in telemedicine has more than doubled in the last year to $1.6 billion, a dramatic acceleration attributable to the COVID-19 pandemic and the growing demand for the tools and flexibility that digital health offers.[1] Scarlet provides a much-needed service that is efficient, secure, convenient, flexible, digitally enabled and easy to use, providing access to a variety of tests, from COVID-19 to chronic conditions, and more.

"The future of health care is at home. We're helping to make in-home health care real for millions of Americans by bringing diagnostic services directly to the patient," said Jon R. Cohen, M.D., Executive Chairman of BioReference Laboratories. "According to PwC Health Research Institute Health's 2020 executive survey, 40% of healthcare providers cited laboratory challenges as a concern with growing telehealth programs. By adding just a few key strokes to what healthcare providers are already doing, Scarlet improves and encourages patient-centered

health care, utilizing a similar on-demand format that patients use every day from the comfort of their homes. With Scarlet, BioReference removes a disconnect between telemedicine and traditional health care, and revolutionizes how healthcare is provided."

Scarlet services are currently available in select markets. For more information on Scarlet, visit www.scarlethealth.com.

About BioReference Laboratories, Inc.
BioReference provides comprehensive testing to physicians, clinics, hospitals, employers, government units, correctional institutions, and medical groups. BioReference offers test services that yield high-quality and accurate results, including a molecular test for helping with COVID-19 diagnosis and a serology test to help indicate possible COVID-19 exposure. The company is in network with the five largest health plans in the United States, operates a network of 11 laboratory locations, and is backed by a medical staff of more than 120 M.D., Ph.D. and other professional level clinicians and scientists. With a leading position in the areas of genetics, women's health, maternal fetal medicine, oncology, and urology, BioReference and its specialty laboratories, GenPath and GeneDx, are advancing the course of modern medicine. For more information, visit www.bioreference.com.

About OPKO Health
OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

Cautionary Statement Regarding Forward-Looking Statements
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References:

1. PwC Health Research Institute Health's 2020 executive survey

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