

# **OPKO Health (OPK)**

\$1.39 (As of 04/08/20)

Price Target (6-12 Months): \$3.00

Long Term: 6-12 Months	Zacks Recor	nmendation:	Neutral	
	(Since: 11/19/19)			
	Prior Recomm	endation: Outpe	rform	
Short Term: 1-3 Months	Zacks Rank:	(1-5)	3-Hold	
	Zacks Style So	VGM:F		
	Value: D	Growth: F	Momentum: C	

## Summary

OPKO Health gained significantly from the RAYALDEE contribution recently. Further, OPKO Health's utilization of 4Kscore remains strong, with nearly 18,000 tests registered in the fourth quarter. Apart from these, the company's clinical development programs look promising with a robust pipeline of candidates. Furthermore, OPKO Health and Pfizer announced positive top-line results on the pediatric global Phase 3 trial, comparing once weekly somatrogon to once daily GENOTROPIN. Expansion in gross margin is heartening. OPKO Health exited the fourth quarter on a strong note. However, the company faces cut-throat competition in the MedTech space. Sluggishness in the Services revenue segment remains concerning. OPKO Health has underperformed its industry in a year's time.

# Price, Consensus & Surprise



# **Data Overview**

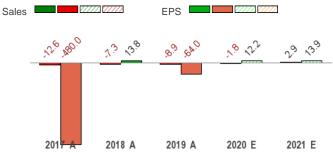
52 Week High-Low	\$2.91 - \$1.12
20 Day Average Volume (sh)	21,787,594
Market Cap	\$931.1 M
YTD Price Change	-5.4%
Beta	1.74
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Instruments
Zacks Industry Rank	Top 13% (32 out of 253)

	<b>******</b>	
try	Medical - Instruments	
Industry Rank	Top 13% (32 out of 253)	

Last EPS Surprise	25.0%
Last Sales Surprise	3.5%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	05/05/2020
Earnings ESP	0.0%

P/E TTM	NA
P/E F1	NA
PEG F1	NA
P/S TTM	1.0

# Sales and EPS Growth Rates (Y/Y %)



# Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	215 E	225 E	224 E	249 E	912 E
2020	216 E	223 E	221 E	226 E	886 E
2019	223 A	226 A	229 A	224 A	902 A

# **EPS Estimates**

	Q1	Q2	Q3	Q4	Annual*
2021	-\$0.11 E	-\$0.10 E	-\$0.10 E	-\$0.09 E	-\$0.31 E
2020	-\$0.09 E	-\$0.09 E	-\$0.09 E	-\$0.09 E	-\$0.36 E
2019	-\$0.14 A	-\$0.10 A	-\$0.11 A	-\$0.06 A	-\$0.41 A

<sup>\*</sup>Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 04/08/2020. The reports text is as of 04/09/2020.

### Overview

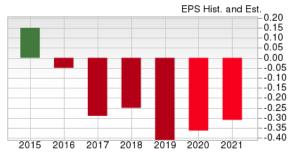
Headquartered in Miami, Florida, OPKO Health, Inc (OPK) engages in the diagnostics and pharmaceuticals business in the United States, Ireland, Chile, Spain, Israel and Mexico.

The Diagnostics segment operates Bio-Reference Laboratories, a clinical facility that offers testing services in the detection, diagnosis, evaluation, monitoring and treatment of diseases

The company's pharmaceutical business features Rayaldee, an FDA-approved treatment for secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency (launched in November 2016) and VARUBI for chemotherapy induced nausea and vomiting.

OPKO Health has a development and commercial supply pharmaceutical unit in Ireland along with a global supply chain operation and holding wing. The company also owns specialty active pharmaceutical ingredients (APIs) manufacturer in Israel.

The company operates through three revenue segments — Revenues from services, revenues from products and revenues from transfer of intellectual property.

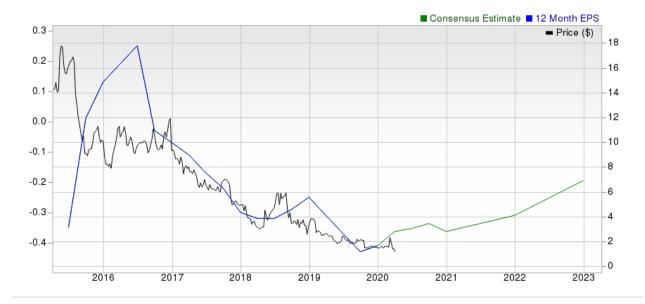




#### 2019 at a Glance

Net revenues in 2019 totaled \$901.9 million, down 8.9% on a year-over-year basis. Notably, this Florida-based diagnostics and pharmaceuticals company reports through three major segments — Services, Products and Transfer of intellectual property.

While revenues from services accounted for 79.4% of net revenues, the same from products comprised 12.4%. Transfer of intellectual property accounted for 8.1% of net revenues.



# **Reasons To Buy:**

▲ RAYALDEE Gains Prominence: Within the pharmaceutical business, RAYALDEE is OPKO Health's leading renal product in the U.S. market since the last two years. RAYALDEE is the first and only therapy approved by the FDA for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease. RAYALDEE has been witnessing a decent momentum, courtesy of successful efforts from the sales team.

Per management, total RAYALDEE prescriptions reported by IQVIA improved 89% year over year in the fourth quarter. With the acceptance of several Marketing Authorization Applications and a few that are under review in other European countries, Vifor Fresenius anticipates receiving approvals in several European countries during 2020 to market RAYALDEE for the treatment of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. Per the fourth-quarter 2019 earnings call, Vifor Fresenius expects European approval for RAYALDEE and first commercial launch later in 2020. Further, the open-label Phase 2 trial for RAYALDEE in hemodialysis patients has been advancing and initial data is anticipated in first-quarter 2020.

The company expects interim data readout to take place in first-quarter 2020 associated with the open-label Phase 2 trial with RAYALDEE in adults with vitamin D insufficiency and stage 5 chronic kidney disease (CKD) requiring dialysis.

Solid prospects in **RAYLDEE** and **BioReference** platforms have been providing **OPKO** Health with competitive edge in MedTech the **OPKO** Industry. Health's strong focus in R&D bodes well.

Additionally, the company is planning a Phase 3 study with RAYALDEE and pediatric patients as part of a post-marketing requirement and this study is anticipated to commence third-quarter 2020. The company is optimistic about such efforts as it expects these to expand RAYALDEE's label and further bolster its market presence to become a meaningful contributor to sales and earnings for OPKO Health. The company has several additional programs in both preclinical and late-stage clinical development in the pipeline.

▲ BioReference — the Third Largest Clinical Lab: OPKO Health's BioReference platform is the third largest full-service clinical laboratory. BioReference has almost 400 employees in the sales and marketing team and operates a network of approximately 275 patient service centers.

Through BioReference, the company operates in five highly specialized laboratory divisions that have been raking in strong revenues lately. These include BioReference Laboratories, GenPath (Oncology), GenPath (Women's Health), GeneDx and Laboratorio Bueno Salud.

Notably, per management, BioReference and its GeneDx subsidiary have expanded access to commercially insured lives.

During the second quarter, BioReference formed a strategic collaboration with SOMOS, New York City's largest multi-cultural physician led network. This collaboration is expected to streamline patient care and provide communication efficiencies between BioReference and the SOMOS network.

Per management, BioReference Laboratories has been making excellent progress when it comes to the improvement of both its top and bottom-line performance and is poised for growth in 2020.

▲ Highly Unique 4Kscore Test Holds Promise: Through BioReference, the company offers the 4Kscore test in a laboratory located in Elmwood Park, New Jersey. The 4Kscore test is a laboratory developed procedure that measures the blood plasma levels of four different prostate-derived kallikrein proteins — Total PSA, Free PSA, Intact PSA and Human Kallikrein-2 ("hK2"). The company has obtained a positive coverage decision from at least one national private payer and pricing agreements from several regional payers as of now.

In fourth-quarter 2019, 4Kscore test utilization was strong, with around to 18,000 tests performed. In December 2019, FDA accepted a premarket approval submission for the 4Kscore test for review.

In November 2019, 4Kscore test received a final local coverage determination (LCD) from Novitas Solutions, which was effective Dec 30, 2019, with respect to reestablishing reimbursement for the important Medicare patient populations. Moreover, the Medicare coverage for 4Kscore resumed in January 2020 as a result of the aforementioned coverage decision. In January, the coverage witnessed a rise of 16% in test orders when compared to December 2019.

▲ Solid R&D Focus: OPKO Health's strong focus in research and development (R&D) is a positive factor. The company's strong commitment toward innovation led to the introduction of several new products, improvements in the existing products and expansion of product lines as well as enhancements and new equipment in the R&D facilities.

In fourth-quarter 2019, research and development expenses totaled \$30 million, down 0.7% year over year. Per management, the company will continue to make solid investments in R&D programs throughout 2020. OPKO Health projects R&D expenses of \$23-\$28 million in first-quarter 2020 and in the range of \$85-\$125 million for the full year of 2020.

▲ Solid Guidance: OPKO Health did not issue any guidance. Nonetheless, the company estimates revenues from Services between \$168 million and \$173 million in first-quarter 2020. For the full year, revenues are expected within \$715-\$740 million.

Revenues from Products are anticipated in the range of \$30-\$32 million in the first quarter. This includes revenues from RAYALDEE between \$9.3 million and \$10.5 million. Full-year revenues are expected between \$130 million and \$150 million, which includes revenues from RAYALDEE between \$50-\$60 million.

Revenues from Transfer of intellectual property are projected in the range of \$20-\$30 million for 2020.

For first-quarter 2020, OPKO Health expects costs and expenses between \$265 million and \$275 million, including R&D expenses of \$23-\$28 million in the same time period. For the full-year 2020, costs and expenses are estimated to be in the band of \$1.08-\$1.13 billion, which

includes R&D expense of \$85-\$125 million.

### **Reasons To Sell:**

- ▼ Shares Lack Luster: Shares of OPKO Health have lost 45.3% in a year's time compared with the industry's fall of 12.1%. Falling operating margins remain a persistent headwind. The company's unsuccessful attempts to control cost efficiencies were prominent in the last two years. Further, declining revenues in the Services and Transfer of intellectual property segments have been disappointing. Strong volume decline of the clinical labs has been a major concern for OPKO Health of late. Also, the ongoing economic volatility on account of the global coronavirus outbreak is weighing on the stock.
- Cutthroat Competition in the Niche Space: The medical instrument industry is highly competitive. The industry calls for extensive research for technological innovation continuously. In fact, there are several companies that have been trying to outpace OPKO Health in terms of cost efficiency and diverse portfolio. Per management, major pharmaceutical bigwigs, specialty pharmaceutical companies and specialized biotechnology companies are direct competitors of OPKO Health's pharmaceutical business.

OPKO Health faces cutthroat competition in the niche space. The company has been incurring operating losses due to limited revenues from the pharmaceutical operations.

Competitors of the diagnostics business include major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and research institutions.

We believe that most of these companies are financially stronger than OPKO Health with larger research and development staffs along with more extensive marketing and manufacturing organizations. The strength of these companies is likely to dent OPKO Health's customer base in the quarters to come.

▼ Infamous History Operating Losses: The company has an infamous history of incurring huge operating losses. Till date, OPKO Health has generated only limited revenues from the pharmaceutical operations in the United States, Chile, Mexico, Israel, Spain and Ireland.

The company continues to incur substantial R&D as well as general and administrative expenses related to operations. Per management, OPKO Health devoted most of its financial resources to R&D, including our pre-clinical development activities and clinical trials, which has dampened margins.

Management is also apprehensive about difficulties in cash flow and profit generation in the recently-launched BioReference and other commercial businesses.

In the fourth quarter, OPKO Health incurred an operating loss of \$112.4 million, noticeably wider than the year-ago quarter's loss of \$76.1 million.

# **Last Earnings Report**

#### OPKO Health Q4 Loss Narrower Than Estimates, Sales Up

OPKO Health, Inc. incurred adjusted loss of 6 cents per share in the fourth quarter of 2019, narrower than the Zacks Consensus Estimate of a loss of 8 cents. The company had incurred a loss of 8 cents a year ago.

For 2019, loss per share was 53 cents compared with a loss of 27 cents a year ago. The figure was wider than the Zacks Consensus Estimate of a loss of 43 cents.

Report Date	Feb 26, 2020
Sales Surprise	3.48%
EPS Surprise	25.00%
Quarterly EPS	-0.06
Annual EPS (TTM)	-0.41

12/2019

**Quarter Ending** 

Fourth-quarter revenues of this Zacks Rank #3 (Hold) company totaled \$224.3 million, which surpassed the Zacks Consensus Estimate by 3.5%. Also, the top line rose 1.1% on a year-over-year basis.

Revenues were \$901.9 million, down 8.9%. The metric however outpaced the Zacks Consensus Estimate of \$894.4 million.

#### Segmental Revenues in Q4

Revenues from Services grossed \$177.9 million in the reported quarter, down 2.8% year over year.

Revenues from Products rose 26% to \$32 million. Per management, revenues from products include \$7.4-million contributions from RAYALDEE.

Revenues from Transfer of intellectual property came in at \$14.4 million, up 7.5% year over year.

### **RAYALDEE Update**

Per management, total RAYALDEE prescriptions reported by IQVIA improved 89% year over year in the fourth quarter. Further, the open-label Phase 2 trial for RAYALDEE in hemodialysis patients has been progressing and the initial data is anticipated in first-quarter 2020.

## **Margin Analysis**

Gross profit in the reported quarter came in at \$82 million, up 13.4% from the prior-year quarter. Gross margin was 36.6% of net revenues, expanding 400 basis points (bps) year over year.

Selling, general and administrative expenses totaled \$79.1 million, down 16.8% year over year. Research and development expenses amounted to \$23 million, down 30.9% year over year.

Operating loss in the fourth quarter was \$112.4 million, noticeably wider than the year-ago quarter's loss of \$76.1 million.

# Guidance

OPKO Health did not issue any guidance. Nonetheless, the company estimates revenues from Services between \$168 million and \$173 million in the first quarter of 2020. For the full year, revenues are expected within \$715-\$740 million.

Revenues from Products are anticipated in the range of \$30-\$32 million in the first quarter. This includes revenues from RAYALDEE between \$9.3 million and \$10.5 million. Full-year revenues are expected between \$130 million and \$150 million.

Revenues from Transfer of intellectual property are projected in the range of \$20-\$30 million for 2020.

### **Recent News**

On Mar 13, 2020, BioReference Laboratories, Inc., an OPKO Health company started accepting specimens for testing of coronavirus disease 2019 (COVID-19) from healthcare providers, clinics and health systems throughout the United States.

#### Valuation

OPKO Health's shares are down 5.4% and 45.3% in the year-to-date period and the trailing 12-month periods, respectively. Stocks in the Zacks sub-industry are down 13.4% while in the Zacks Medical sector are down 13.6% in the year-to-date period. Over the past year, the Zacks sub-industry is down 12.1% and sector is down 12.5%, respectively.

The S&P 500 index is down 17.3% in the year-to-date period and 8% in the past year.

The stock is currently trading at 1X Forward 12-months sales, which compares to 3.2X for the Zacks sub-industry, 2.4X for the Zacks sector and 2.9X for the S&P 500 index.

Over the past five years, the stock has traded as high as 49X and as low as 0.9X, with a 5-year median of 2.7X.

Our Neutral recommendation indicates that the stock will perform in line with the market. Our \$3 price target reflects 2.2X forward 12-months sales.

The table below shows summary valuation data for OPK.

	Valuation Multiples - OPK					
		Stock	Sub-Industry	Sector	S&P 500	
	Current	1.04	3.2	2.42	2.94	
P/S F12M	5-Year High	49.04	3.66	3.84	3.44	
	5-Year Low	0.94	2.18	2.26	2.54	
	5-Year Median	2.71	2.6	2.96	3	
	Current	0.58	2.9	3.33	3.54	
P/B TTM	5-Year High	10.63	4.23	5.05	4.55	
	5-Year Low	0.48	2.4	2.9	2.84	
	5-Year Median	1.7	3.35	4.3	3.63	

As of 04/08/2020

#### Industry Analysis Zacks Industry Rank: Top 13% (32 out of 253) ■ Industry Price ■ Price 18 55 - Industry

# **Top Peers**

Allergan plc (AGN)	Neutral
Quest Diagnostics Incorporated (DGX)	Neutral
Jazz Pharmaceuticals PLC (JAZZ)	Neutral
Laboratory Corporation of America Holdings (LH)	Neutral
Mallinckrodt public limited company (MNK)	Neutral
Novartis AG (NVS)	Neutral
Pfizer Inc. (PFE)	Neutral
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral

Industry Comparison Industry: Medical - Instruments				Industry Peers			
	OPK Neutral	X Industry	S&P 500	AGN Neutral	DGX Neutral	LH Neutra	
VGM Score	E	-	-	В	С	С	
Market Cap	931.06 M	89.86 M	19.05 B	59.58 B	11.72 B	13.71 E	
# of Analysts	3	2	13	5	8	3	
Dividend Yield	0.00%	0.00%	2.23%	1.63%	2.55%	0.00%	
Value Score	D	-	-	С	С	В	
Cash/Price	0.11	0.11	0.06	0.10	0.12	0.03	
EV/EBITDA	-5.75	-0.50	11.47	38.54	9.18	9.38	
PEG Ratio	NA	2.47	2.00	1.45	3.07	2.7	
Price/Book (P/B)	0.57	2.88	2.56	1.02	2.08	1.81	
Price/Cash Flow (P/CF)	NA	19.97	10.14	4.93	9.66	7.26	
P/E (F1)	NA	29.00	16.97	10.33	17.49	14.25	
Price/Sales (P/S)	1.03	2.96	2.01	3.70	1.52	1.19	
Earnings Yield	-25.90%	-3.19%	5.81%	9.68%	5.71%	7.02%	
Debt/Equity	0.15	0.10	0.70	0.32	0.70	0.86	
Cash Flow (\$/share)	-0.22	-0.13	7.01	36.72	9.09	19.4	
Growth Score	F	-	-	В	В	C	
Hist. EPS Growth (3-5 yrs)	NA%	13.63%	10.92%	4.06%	8.95%	10.73%	
Proj. EPS Growth (F1/F0)	11.38%	13.03%	-0.64%	-0.66%	-23.46%	-12.48%	
Curr. Cash Flow Growth	258.18%	5.72%	5.93%	-3.45%	10.66%	12.16%	
Hist. Cash Flow Growth (3-5 yrs)	-1.35%	11.07%	8.55%	11.44%	6.08%	17.70%	
Current Ratio	1.30	2.52	1.24	1.01	1.25	1.1	
Debt/Capital	12.89%	15.55%	42.36%	24.18%	41.55%	46.20%	
Net Margin	-34.92%	-13.83%	11.64%	-32.76%	11.10%	7.13%	
Return on Equity	-14.42%	-20.88%	16.74%	9.82%	16.15%	15.37%	
Sales/Assets	0.37	0.58	0.54	0.17	0.64	0.6	
Proj. Sales Growth (F1/F0)	-1.82%	4.43%	0.61%	-0.85%	-4.34%	-0.75%	
Momentum Score	[C]	-	-	В	F	F	
Daily Price Chg	9.45%	1.74%	4.33%	1.58%	5.31%	5.78%	
1 Week Price Chg	-17.14%	-1.32%	-4.40%	1.57%	-11.72%	-11.96%	
4 Week Price Chg	-17.75%	-5.99%	-1.70%	-2.38%	-11.92%	-11.22%	
12 Week Price Chg	-10.32%	-22.58%	-20.64%	-6.59%	-17.70%	-20.80%	
52 Week Price Chg	-45.28%	-36.71%	-12.97%	23.94%	-2.80%	-11.56%	
20 Day Average Volume	21,787,594	176,551	4,016,075	5,153,050	2,514,805	1,371,16	
(F1) EPS Est 1 week change	0.00%	0.00%	-0.26%	0.00%	-5.64%	-3.86%	
(F1) EPS Est 4 week change	0.00%	0.00%	-5.64%	-0.01%	-24.59%	-17.35%	
(F1) EPS Est 12 week change	-32.93%	-6.63%	-7.49%	3.37%	-25.50%	-17.09%	
(Q1) EPS Est Mthly Chg	0.00%	0.00%	-9.90%	0.00%	-73.30%	-54.419	

# **Zacks Style Scores**

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	D
Growth Score	F
Momentum Score	C
VGM Score	F

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

#### **Disclosures**

This report contains independent commentary to be used for informational purposes only. The analysts contributing to this report do not hold any shares of this stock. The analysts contributing to this report do not serve on the board of the company that issued this stock. The EPS and revenue forecasts are the Zacks Consensus estimates, unless indicated otherwise on the reports first page. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts personal views as to the subject securities and issuers. ZIR certifies that no part of the analysts compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report.

Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Any opinions expressed herein are subject to change.

ZIR is not an investment advisor and the report should not be construed as advice designed to meet the particular investment needs of any investor. Prior to making any investment decision, you are advised to consult with your broker, investment advisor, or other appropriate tax or financial professional to determine the suitability of any investment. This report and others like it are published regularly and not in response to episodic market activity or events affecting the securities industry.

This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. ZIR or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. ZIR is not a broker-dealer. ZIR may enter into arms-length agreements with broker-dealers to provide this research to their clients. Zacks and its staff are not involved in investment banking activities for the stock issuer covered in this report.

ZIR uses the following rating system for the securities it covers. **Outperform-** ZIR expects that the subject company will outperform the broader U.S. equities markets over the next six to twelve months. **Neutral-** ZIR expects that the company will perform in line with the broader U.S. equities markets over the next six to twelve months. **Underperform-** ZIR expects the company will underperform the broader U.S. equities markets over the next six to twelve months.

No part of this report can be reprinted, republished or transmitted electronically without the prior written authorization of ZIR.