

OPKO Health (OPK)

\$4.86 (As of 08/21/20)

Price Target (6-12 Months): **\$6.00**

Long Term: 6-12 Months

Zacks Recommendation: **Outperform**

(Since: 05/10/20)

Prior Recommendation: Neutral

Short Term: 1-3 Months

Zacks Rank: (1-5)

2-Buy

Zacks Style Scores:

VGM:D

Value: D

Growth: C

Momentum: D

Summary

OPKO Health exited the second quarter on a strong note. The company's RAYALDEE has contributed significantly to the last reported quarter. Further, its utilization of the 4Kscore remains strong. The company also witnessed strong segmental performance in the quarter under review. Apart from these, its clinical development programs look promising with a robust pipeline of candidates. OPKO Health continues to progress with its Phase 2 trial for RAYALDEE in hemodialysis patients with full top-line data anticipated in first-quarter 2021. Also, BioReference Laboratories expanded nationwide COVID-19 testing. OPKO Health outperformed its industry in a year's time. However, contraction in gross margin remains a woe. Further, the company faces cut-throat competition in the MedTech space.

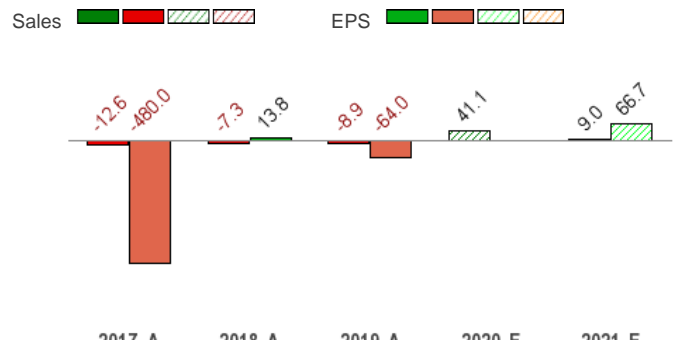
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$6.47 - \$1.12
20 Day Average Volume (sh)	16,522,088
Market Cap	\$3.3 B
YTD Price Change	230.6%
Beta	2.47
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Instruments
Zacks Industry Rank	Top 48% (120 out of 252)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	171.4%
Last Sales Surprise	28.4%
EPS F1 Est- 4 week change	111.0%
Expected Report Date	NA
Earnings ESP	0.0%
P/E TTM	NA
P/E F1	162.0
PEG F1	13.5
P/S TTM	3.4

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	371 E	358 E	336 E	333 E	1,387 E
2020	212 A	301 A	372 E	395 E	1,273 E
2019	223 A	226 A	229 A	224 A	902 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.04 E	\$0.03 E	\$0.01 E	\$0.02 E	\$0.05 E
2020	-\$0.09 A	\$0.05 A	\$0.04 E	\$0.05 E	\$0.03 E
2019	-\$0.14 A	-\$0.10 A	-\$0.11 A	-\$0.06 A	-\$0.41 A

*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 08/21/2020. The reports text is as of 08/24/2020.

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.

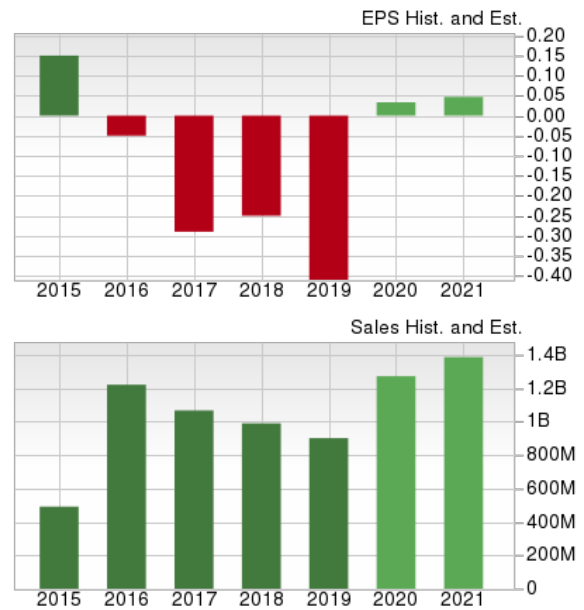
OPKO Health has a development and commercial supply pharmaceutical unit in Ireland along with a global supply chain operation and holding wing. The company also owns specialty active pharmaceutical ingredients (APIs) manufacturer in Israel.

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:

- ▲ **Price Performance:** Shares of OPKO Health have gained 164.1% in a year's time compared with the industry's rally of 24.9%. Solid prospects in RAYALDEE, promising 4Kscore tests and strong research and development (R&D) focus continue to favor the stock.
- ▲ **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 45% year over year in the second quarter. Around 200 physicians or above 6% of the total number of prescribers were new RAYALDEE prescribers in the second quarter. Since launch, over 20,500 patients have had RAYALDEE prescribed by nearly 3,200 physicians. 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. It also plans to launch it commercially later this year. Moreover, the company is advancing well with its ongoing clinical trial to RAYALDEE to expand its indications.

OPKO Health continues to progress with its Phase 2 trial for RAYALDEE in hemodialysis patients with full top-line data anticipated in first-quarter 2021. The ongoing Phase 2 clinical trial is engaged in the safety and efficacy of a high strained formulation of RAYALDEE as a new treatment for secondary hyperparathyroidism in adult patients for Stage 5 chronic kidney disease (CKD) requiring regular hemodialysis and vitamin D insufficiency. Due to the ongoing pandemic, enrollment was slower than anticipated but has been completed.

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. Irrespective of the ongoing pandemic, OPKO Health showed progress with its pharmaceutical business as the company is on track with respect to Pfizer's submission of Biologics License Application (BLA) for a human growth hormone product to the FDA in the second half of 2020. Additionally, the company reported favorable top-line results for the somatrogen Phase 3 trial in Japan wherein children with growth hormone deficiency, exhibited non-inferiority to the current standard of daily injections. In Europe, OPKO Health's open-label study displaying benefit and compliance with reduced treatment burden will be completed later in the third quarter, thereby allowing Pfizer to submit a marketing authorization application with the EMA in Europe by early 2021. 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.

In June, the company announced that the FDA had authorized OPKO to start a Phase 2 trial of RAYALDEE as a treatment for patients with mild-to-moderate COVID-19. This authorization comes after publication of numerous independent studies that reported a correlation between vitamin D status and COVID-19 risk and severity.

- ▲ **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.

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.

With respect to COVID-19 response efforts, the company built a specific expertise in offering testing with reasonable turnaround times. BioReference has been chosen to offer testing services by the Centers for Disease Control and Prevention (CDC) to various states, cities and large healthcare systems, multiple drive-through around the United States, urgent care centers, and several very important professional sports organizations. It will also provide testing in partnerships with both Rite Aid and CVS at around 500 different locations. Moreover, the company continues to see a massive demand for COVID-19 testing across all segments of the economy.

Notably, COVID-19 testing was a strong contributor to OPKO Health's second-quarter growth and profitability. With daily case numbers continuing to increase, the company expects solid demand for COVID-19 tests during third-quarter 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 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.

On Jan 1, 2020, Medicare coverage for 4Kscore resumed because of the new Local Coverage Determination by Novitas. The company has commenced sales force expansion and approximately 16,000 4Kscore tests were performed in first-quarter 2020. In December 2019, FDA

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

accepted a premarket approval submission for the 4Kscore test for review.

▲ **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 second-quarter 2020, research and development expenses amounted to \$17.6 million, down 37.8% year over year. Nonetheless, per management, the company will continue to make solid investments in R&D programs throughout 2020.

Risks

- **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.

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.

- **Balance Sheet View:** OPKO Health exited the second quarter of 2020 with cash and cash equivalents amounting to \$22 million, down from \$34.5 million sequentially. Meanwhile, the company's long-term debt totaled \$245 million in the second quarter, compared with \$242 billion sequentially. The long-term debt level is noticeably higher than the quarter's cash and cash equivalent level. Moreover, we can see that the current debt level of \$25 million in the second quarter, slightly higher than \$24.3 million in the previous quarter, is somewhat higher than the cash and cash equivalent level. So, both the long-term debt level and current debt level are significantly higher than the company's short-term cash level, which is not particularly good when it comes to company's solvency position, as at least during a year of economic downturn, the company does not have sufficient cash for debt repayment.
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Last Earnings Report

OPKO Health Q2 Earnings and Revenues Beat Estimates

OPKO Health, Inc. reported second-quarter 2020 adjusted earnings per share of 5 cents per share against the Zacks Consensus Estimate of a loss of 7 cents. Notably, the company had reported a loss of 10 cents in the prior-year quarter.

Second-quarter revenues of this Zacks Rank #2 (Buy) company were \$301.2 million, which outpaced the Zacks Consensus Estimate by 28.4%. The top line also improved 33% on a year-over-year basis.

Quarter Ending **06/2020**

Report Date	Jul 30, 2020
Sales Surprise	28.41%
EPS Surprise	171.43%
Quarterly EPS	0.05
Annual EPS (TTM)	-0.21

Segmental Revenues in Q2

Revenues from Services amounted to \$251 million in the reported quarter, up 41% year over year. The upside can be attributed to increased COVID-19 testing volumes. However, lower clinical and genomic test volumes on account of physician office shut-downs and stay-at-home orders associated with the pandemic partially offset the upside.

Revenues from Products rose 2.1% to \$29.3 million. Per management, revenues from products include contributions from RAYALDEE worth \$8.6 million.

Revenues from Transfer of intellectual property totaled \$20.9 million, up 8.9% year over year.

Per management, total RAYALDEE prescriptions reported by IQVIA improved 45% year over year in the second quarter. Further, the open-label Phase 2 trial for RAYALDEE in hemodialysis patients has completed enrollment (it was slower than anticipated owing to the pandemic) with full top-line data anticipated in first-quarter 2021.

Further, on Jun 1, 2020, the FDA authorized OPKO Health to undertake a Phase 2 trial with RAYALDEE as a treatment for patients with mild-to-moderate COVID-19.

Margin Analysis

Gross profit in the reported quarter was \$138.5 million, up 68.5% from the prior-year quarter. Gross margin was 45.9% of net revenues, up 960 basis points (bps) year over year.

Selling, general and administrative expenses totaled \$77.7 million, down 12.2% year over year. Research and development expenses amounted to \$17.6 million, down 37.8% year over year.

Operating income in the second quarter was \$27.2 million, against the year-ago quarter's loss of \$47.2 million.

Financial Update

The company exited the second quarter with cash, cash equivalents and marketable securities of \$21.6 million, compared with \$85.5 million at the year-end 2019.

Guidance

In the quarter under review, OPKO Health refrained from issuing any guidance.

Recent News

OPKO Health's Unit, BioReference Laboratories Collaborates with MagnaCare: May 18

OPKO Health's subsidiary, BioReference Laboratories, Inc., recently collaborated with MagnaCare — a division of Brighton Health Plans Solutions, LLC — to offer COVID-19 antibody testing to Labor clients in the New York metropolitan area. With this antibody testing, Labor groups in the area will be able to gather information and take decisions regarding back-to-work procedures and safety measures for the protection of workers and the public.

Valuation

OPKO Health's shares are up 230.6% and 164.1% in the year-to-date period and trailing 12-month periods, respectively. Stocks in the Zacks sub-industry and Zacks Medical sector are up 17.7% and up 0.5% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry and sector are up 24.9% and 9.6%, respectively.

The S&P 500 index is up 5.4% in the year-to-date period and 18.3% in the past year.

The stock is currently trading at 2.4X Forward 12-months sales, which compares to 4.5X for the Zacks sub-industry, 2.8X for the Zacks sector and 3.7X for the S&P 500 index.

Over the past five years, the stock has traded as high as 6.8X and as low as 0.8X, with a 5-year median of 2.5X.

Our Outperform recommendation indicates that the stock will perform above the market. Our \$6 price target reflects 2.9X forward 12-months sales.

The table below shows summary valuation data for OPK.

Valuation Multiples - OPK					
		Stock	Sub-Industry	Sector	S&P 500
P/S F12M	Current	2.42	4.46	2.8	3.71
	5-Year High	6.8	4.46	3.41	3.71
	5-Year Low	0.82	2.52	2.22	2.53
	5-Year Median	2.5	3.09	2.89	3.05
P/B TTM	Current	2.05	5.46	3.76	4.56
	5-Year High	6.4	5.5	5.07	4.56
	5-Year Low	0.5	2.75	2.94	2.83
	5-Year Median	1.6	3.9	4.28	3.75

As of 08/21/2020

Industry Analysis Zacks Industry Rank: Top 48% (120 out of 252)



Top Peers

Company (Ticker)	Rec	Rank
Quest Diagnostics Incorporated (DGX)	Neutral	3
Jazz Pharmaceuticals PLC (JAZZ)	Neutral	3
Laboratory Corporation of America Holdings (LH)	Neutral	3
Luminex Corporation (LMNX)	Neutral	2
Mallinckrodt public limited company (MNK)	Neutral	3
Novartis AG (NVS)	Neutral	3
Pfizer Inc. (PFE)	Neutral	3
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral	3

Industry Comparison Industry: Medical - Instruments

	OPK	X Industry	S&P 500	DGX	LH	LMNX
Zacks Recommendation (Long Term)	Outperform	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	2	-	-	3	3	2
VGM Score	D	-	-	A	A	C
Market Cap	3.26 B	147.27 M	23.62 B	15.82 B	17.59 B	1.46 B
# of Analysts	3	2	14	7	8	4
Dividend Yield	0.00%	0.00%	1.65%	1.90%	0.00%	1.14%
Value Score	D	-	-	B	A	C
Cash/Price	0.01	0.12	0.07	0.06	0.03	0.20
EV/EBITDA	-18.44	-1.63	13.29	11.93	10.94	72.57
PEG Ratio	13.50	4.23	3.03	0.89	1.52	NA
Price/Book (P/B)	2.05	4.03	3.11	2.69	2.39	2.89
Price/Cash Flow (P/CF)	NA	23.08	12.69	12.96	9.29	73.64
P/E (F1)	162.00	47.52	21.51	14.03	13.05	38.85
Price/Sales (P/S)	3.37	4.35	2.43	2.10	1.53	3.95
Earnings Yield	0.62%	-3.92%	4.46%	7.13%	7.66%	2.57%
Debt/Equity	0.15	0.13	0.76	0.68	0.83	0.42
Cash Flow (\$/share)	-0.22	-0.13	6.93	9.09	19.44	0.43
Growth Score	C	-	-	B	B	B
Hist. EPS Growth (3-5 yrs)	NA%	10.12%	10.44%	6.83%	8.86%	-26.00%
Proj. EPS Growth (F1/F0)	108.13%	7.56%	-5.53%	28.05%	22.29%	485.71%
Curr. Cash Flow Growth	258.18%	5.04%	5.20%	10.66%	12.16%	-57.32%
Hist. Cash Flow Growth (3-5 yrs)	-1.35%	10.65%	8.52%	6.08%	17.70%	-15.21%
Current Ratio	1.29	2.94	1.33	1.29	1.12	7.25
Debt/Capital	13.37%	18.18%	44.50%	41.06%	45.50%	29.75%
Net Margin	-20.69%	-25.57%	10.13%	9.99%	3.16%	3.04%
Return on Equity	-7.96%	-17.25%	14.67%	13.78%	14.39%	2.38%
Sales/Assets	0.42	0.53	0.51	0.60	0.65	0.62
Proj. Sales Growth (F1/F0)	41.10%	0.00%	-1.54%	12.80%	9.87%	26.10%
Momentum Score	D	-	-	A	B	F
Daily Price Chg	-1.42%	-0.34%	-0.15%	-0.07%	-0.58%	-0.73%
1 Week Price Chg	-14.74%	-0.09%	1.09%	-4.15%	-1.69%	-3.71%
4 Week Price Chg	-13.21%	-1.77%	1.64%	-7.66%	-9.13%	-14.25%
12 Week Price Chg	126.05%	1.22%	6.72%	-0.20%	2.82%	5.53%
52 Week Price Chg	149.23%	1.50%	1.00%	14.82%	7.55%	54.64%
20 Day Average Volume	16,522,088	252,469	1,873,576	1,099,533	729,004	847,094
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	-0.04%	-2.80%
(F1) EPS Est 4 week change	110.99%	5.06%	1.79%	4.68%	26.62%	367.31%
(F1) EPS Est 12 week change	110.10%	4.63%	3.35%	64.19%	44.60%	367.31%
(Q1) EPS Est Mthly Chg	157.14%	5.74%	0.42%	53.45%	52.84%	2,175.00%

Zacks Stock Rating System

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

Zacks Recommendation

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

Zacks Rank

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

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	C
Momentum Score	D
VGM Score	D

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.

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