

OPKO Health (OPK)

\$5.43 (As of 07/24/20)

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:F

Value: D

Growth: C

Momentum: F

Summary

OPKO Health outperformed its industry in a year's time. OPKO Health's RAYALDEE has contributed significantly to the last reported quarter. Further, its utilization of the 4Kscore remains strong, with nearly 16,000 tests registered in the last reported 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 somatogron to once daily GENOTROPIN. Also, BioReference Laboratories expanded nationwide COVID-19 testing. OPKO Health exited the first quarter on a weak note. Sluggishness in revenues from Services is a concern. Contraction in gross margin remains a woe. OPKO Health also faces cut-throat competition in the MedTech space.

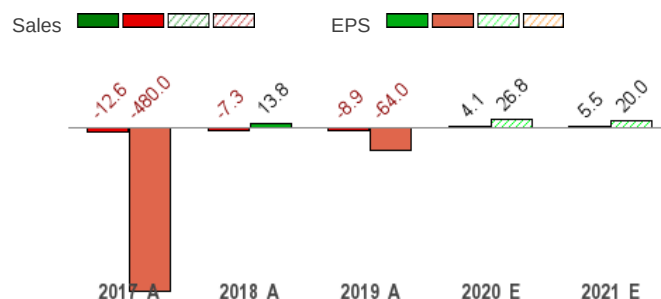
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$6.47 - \$1.12
20 Day Average Volume (sh)	23,394,248
Market Cap	\$3.6 B
YTD Price Change	260.5%
Beta	2.29
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Instruments
Zacks Industry Rank	Bottom 35% (164 out of 252)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	0.0%
Last Sales Surprise	-2.1%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	08/05/2020
Earnings ESP	0.0%
P/E TTM	NA
P/E F1	NA
PEG F1	NA
P/S TTM	4.0

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	246 E	254 E	251 E	272 E	991 E
2020	212 A	235 E	244 E	247 E	939 E
2019	223 A	226 A	229 A	224 A	902 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	-\$0.07 E	-\$0.07 E	-\$0.06 E	-\$0.04 E	-\$0.24 E
2020	-\$0.09 A	-\$0.07 E	-\$0.07 E	-\$0.07 E	-\$0.30 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 07/24/2020. The reports text is as of 07/27/2020.

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.

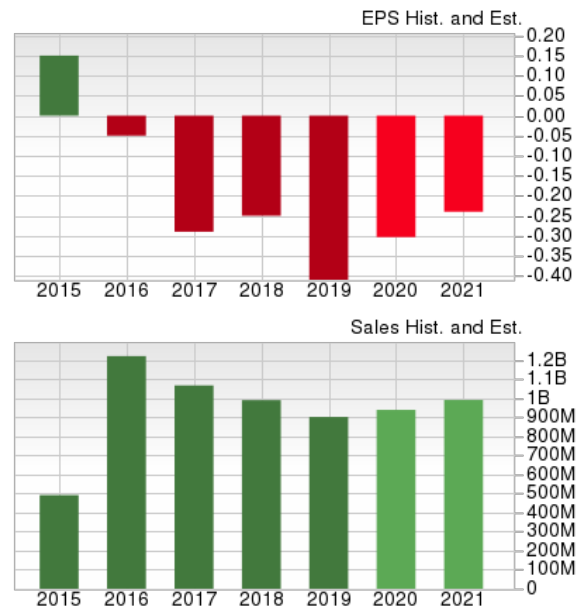
OPKO Health has a development and commercial supply pharmaceutical unit in Ireland along with a global supply chain operation and holding wing. The company also owns specialty active pharmaceutical ingredients (APIs) manufacturer in Israel.

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 152.4% in a year's time compared with the industry's rally of 14.4%. 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 78% year over year in the first quarter. Around 280 physicians or above 9% of the total number of prescribers were new RAYALDEE prescribers in the first 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. It also plans to launch it commercially later this year. Moreover, the company is progressing well with its ongoing clinical trial to RAYALDEE to expand its indications.

For instance, the open-label Phase 2 trial for RAYALDEE in hemodialysis patients is on track to complete enrollment in third-quarter 2020 with full top-line data anticipated in first-quarter 2021. At the end of first-quarter 2020, the company reported interim results from an ongoing Phase 2 clinical trial 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. Also, at the end of the first quarter, the company reported interim results from an ongoing Phase 4 clinical trial that compares RAYALDEE with three common treatment regimens for secondary hyperparathyroidism in adult patients with stage 3 or 4 CKD and vitamin D insufficiency.

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.

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 to over 30 drive-through sites around the country. Further, the company entered in partnerships with numerous states, cities and healthcare systems, which included New York State, New York City, the State of New Jersey and other cities.

In April, the company entered into a partnership with Rite Aid and the U.S. Department of Health and Human Services to offer testing services for Rite Aid self-swab testing sites at 25 store locations with a plan to grow this number in the immediate near term.

The next plan in this diagnostic journey with respect to the pandemic will be the antibody and serology testing in addition to the ongoing PCR testing. OPKO Health has also started to offer COVID-19 antibody blood testing on a nationwide basis from the end of April.

- ▲ **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 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 first-quarter 2020, research and development expenses amounted to \$21.8 million, down 40.3% year over year. Per management, the

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.

company will continue to make solid investments in R&D programs throughout 2020.

▲ **Stable Liquidity Position:** OPKO Health exited the first quarter of 2020 with cash and cash equivalents amounting to \$34.5 million, down from \$85.5 million sequentially. Meanwhile, the company's long-term debt came up to \$242.5 million in the first quarter, compared with \$238.9 billion sequentially. The long-term debt level is noticeably higher than the quarter's cash and cash equivalent level. However, we can see that the current debt level of \$24.3 million in the fourth quarter, although higher than \$21.7 million from the previous quarter, is somewhat lower than the cash and cash equivalent level. This is good news in terms of the company's solvency level as, at least during the year of economic downturn, the company is holding sufficient cash for debt repayment. The total debt-to-capital came in at 14.7%, lower than the industry average of 32.1%, thereby indicating healthier financial structure.

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.

In the first quarter, OPKO Health incurred an operating loss of \$40.7 million, noticeably narrower than the year-ago quarter's loss of \$75.3 million.

Last Earnings Report

OPKO Health Reports Q1 Loss, Lags Revenue Estimates

OPKO Health, Inc. incurred adjusted loss of 9 cents per share in first-quarter 2020, in line with the Zacks Consensus Estimate. Notably, the company had reported a loss of 14 cents in the prior-year quarter.

First-quarter revenues of the company totaled \$211.5 million, which missed the Zacks Consensus Estimate by 2.1%. Also, the top line declined 4.9% on a year-over-year basis.

Quarter Ending **03/2020**

Report Date	May 06, 2020
Sales Surprise	-2.05%
EPS Surprise	0.00%
Quarterly EPS	-0.09
Annual EPS (TTM)	-0.36

Segmental Revenues in Q1

Revenues from Services grossed \$170.8 million in the reported quarter, down 4.5% year over year. The decline can be attributed to COVID-19 as lockdowns resulted in a substantial decline in the company's routine and genetic testing businesses since the beginning of March.

Revenues from Products rose 22.9% to \$31.1 million. Per management, revenues from products include \$9.9-million contributions from RAYALDEE.

Revenues from Transfer of intellectual property came in at \$9.6 million, plunging 47.5% year over year.

Per management, total RAYALDEE prescriptions reported by IQVIA improved 78% year over year in the first quarter. Further, the open-label Phase 2 trial for RAYALDEE in hemodialysis patients is on track to complete enrollment in third-quarter 2020 with full top-line data anticipated in first-quarter 2021.

Margin Analysis

Gross profit in the reported quarter came in at \$71.2 million, down 9.3% from the prior-year quarter. Gross margin was 33.7% of net revenues, down 4160 basis points (bps) year over year.

Selling, general and administrative expenses totaled \$76.1 million, down 20.1% year over year. Research and development expenses amounted to \$21.8 million, down 40.3% year over year.

Operating loss in the first quarter was \$40.7 million, noticeably narrower than the year-ago quarter's loss of \$75.3 million.

Financial Update

The company exited the first quarter with cash, cash equivalents and marketable securities of \$34.5 million, compared with \$85.5 million at the year-end 2019.

Net cash used in operating activities for the three months ended Mar 31, 2020, came in at \$43.4 million, narrower than \$48.9 million in the year-ago period.

Guidance

In the quarter under review, OPKO Health did not issue any guidance.

Recent News

OPKO Health's subsidiary, BioReference Laboratories, Inc. 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 260.5% and 152.4% in the year-to-date period and trailing 12-month periods, respectively. Stocks in the Zacks sub-industry and Zacks Medical sector are up 14% and up 0.1% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry and sector are down 14.4% and up 5.5%, respectively.

The S&P 500 index is up 0.1% in the year-to-date period while up 6.9% in the past year.

The stock is currently trading at 3.7X Forward 12-months sales, which compares to 4.3X for the Zacks sub-industry, 2.8X for the Zacks sector and 3.6X for the S&P 500 index.

Over the past five years, the stock has traded as high as 8.7X and as low as 0.9X, 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 4.2X 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	3.67	4.31	2.81	3.55
	5-Year High	8.67	4.31	3.74	3.55
	5-Year Low	0.86	2.49	2.22	2.53
	5-Year Median	2.52	2.98	2.90	3.02
P/B TTM	Current	2.29	4.40	4.37	4.40
	5-Year High	9.43	4.67	5.07	4.56
	5-Year Low	0.50	2.69	2.94	2.83
	5-Year Median	1.60	3.83	4.30	3.71

As of 07/24/2020

Industry Analysis Zacks Industry Rank: Bottom 35% (164 out of 252)



Top Peers

Company (Ticker)	Rec	Rank
Quest Diagnostics Incorporated (DGX)	Outperform	1
Laboratory Corporation of America Holdings (LH)	Outperform	2
Jazz Pharmaceuticals PLC (JAZZ)	Neutral	3
Luminex Corporation (LMNX)	Neutral	3
Mallinckrodt public limited company (MNK)	Neutral	2
Novartis AG (NVS)	Neutral	3
Pfizer Inc. (PFE)	Neutral	3
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral	3

Industry Comparison Industry: Medical - Instruments				Industry Peers		
	OPK	X Industry	S&P 500	DGX	LH	LMNX
Zacks Recommendation (Long Term)	Outperform	-	-	Outperform	Outperform	Neutral
Zacks Rank (Short Term)	2	-	-	1	2	3
VGM Score	F	-	-	B	B	F
Market Cap	3.55 B	133.87 M	22.16 B	16.72 B	19.32 B	1.62 B
# of Analysts	3	2	14	5	8	3
Dividend Yield	0.00%	0.00%	1.81%	1.79%	0.00%	1.02%
Value Score	D	-	-	A	B	D
Cash/Price	0.01	0.08	0.06	0.02	0.02	0.03
EV/EBITDA	-19.92	-1.26	13.07	12.91	12.04	83.76
PEG Ratio	NA	4.47	3.03	1.26	2.43	NA
Price/Book (P/B)	2.29	3.83	3.11	2.84	2.75	3.48
Price/Cash Flow (P/CF)	NA	22.40	12.27	13.74	10.22	82.79
P/E (F1)	NA	45.51	21.88	16.55	18.18	204.12
Price/Sales (P/S)	3.98	4.25	2.38	2.22	1.67	4.73
Earnings Yield	-5.66%	-3.76%	4.34%	6.04%	5.50%	0.48%
Debt/Equity	0.16	0.09	0.76	0.68	0.92	0.04
Cash Flow (\$/share)	-0.22	-0.13	7.01	9.09	19.44	0.43
Growth Score	C	-	-	C	B	D
Hist. EPS Growth (3-5 yrs)	NA%	13.32%	10.82%	8.03%	9.93%	-21.53%
Proj. EPS Growth (F1/F0)	26.02%	-5.63%	-9.01%	15.15%	-3.42%	182.54%
Curr. Cash Flow Growth	258.18%	5.04%	5.47%	10.66%	12.16%	-57.32%
Hist. Cash Flow Growth (3-5 yrs)	-1.35%	11.49%	8.55%	6.08%	17.70%	-15.21%
Current Ratio	1.12	2.64	1.31	1.29	1.18	4.00
Debt/Capital	13.54%	13.54%	44.41%	41.06%	48.11%	3.49%
Net Margin	-32.92%	-14.56%	10.46%	9.99%	2.77%	-1.81%
Return on Equity	-13.56%	-14.20%	15.13%	13.78%	15.03%	-1.25%
Sales/Assets	0.38	0.58	0.54	0.60	0.65	0.63
Proj. Sales Growth (F1/F0)	4.11%	0.00%	-2.06%	10.01%	2.67%	14.56%
Momentum Score	F	-	-	D	C	C
Daily Price Chg	-5.36%	-0.31%	-0.65%	-2.05%	-0.01%	-3.60%
1 Week Price Chg	14.43%	3.47%	3.82%	7.10%	12.14%	11.56%
4 Week Price Chg	97.76%	3.93%	4.96%	15.41%	23.20%	15.09%
12 Week Price Chg	138.74%	10.74%	9.30%	13.51%	20.85%	-1.86%
52 Week Price Chg	154.81%	-11.91%	-2.82%	22.28%	15.70%	71.58%
20 Day Average Volume	23,394,248	237,540	2,026,477	1,380,579	763,035	809,183
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	-3.86%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	0.15%	36.35%	6.35%	0.00%
(F1) EPS Est 12 week change	16.51%	-10.08%	-3.24%	100.15%	43.16%	1,633.33%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	0.00%	1.63%	0.59%	-128.57%

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	F
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.

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