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EQUITY RESEARCH
Company Report

June 23, 2017

OPKO Health (OPK - $6.69)

Healthcare/Biotechnology

Ticker:	**OPK**
Rating:	**Buy**
Price Target:	**$19.00**

Updated KDIGO Guidance Could Afford Rayaldee More Physician Recognition for Stage 3-4 CKD in SHPT Treatment

Yesterday, OPK reported that updates to the Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend against the use of calcitriol and vitamin D analogs as routine treatment in CKD Stage 3-4 patients with SHPT.

- **Details.** The KDIGO organization recently updated its Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease—Mineral and Bone Disorder (CKD-MBD). The guidance, which was last updated in 2009, includes amendments to the treatment of adult patients with chronic kidney disease (CKD) Stages 3-4 with secondary hyperparathyroidism (SHPT). Specifically, KDIGO guidelines suggest that adult CKD Stage 3-5 patients who were not under dialysis should not routinely use calcitriol and vitamin D analogs. Further, it suggests that the use of such treatments should be reserved for Stage 4 or 5 CKD patients with severe or progressive SHPT, given recent clinical studies in which vitamin D analogs failed to demonstrate improvements in clinically relevant outcomes but demonstrated increased risk of hypercalcemia. Additionally, use of vitamin D supplementation (cholecalciferol and ergocalciferol) as therapy in these patients remains unproven. For Rayaldee (extended-release calcifediol), KDIGO updates cited the outcomes from the clinical study, which included the reduction of catabolism of both 25(OH) vitamin D and $1,25(OH)_2$ vitamin D, resulting in increased levels of both. Further, the treatment has no significant impact on calcium, phosphate, and FGF23 levels. However, since no patient level outcomes were reported, this study did not impact the current KDIGO recommendation for treatment in CKD stage 3-4 patients with SHPT.
- **Implications.** We view this news as a positive given it highlighted the shortcoming of the current therapy from an evidence-base perspective. As such, it potentially creates a vacuum for treating Stage 3-4 CKD patients with SHPT. It also likely puts Rayaldee in a much more favorable position to potentially having more physicians to consider Rayaldee as a better treatment option.
- **Action.** We are reiterating our Buy rating and $19 target price to reflect our bullish view on progress in OPK's multiple drivers in place, especially the 4Kscore test, Rayaldee, VARUBI (rolapitant) and hGH-CTP (MOD-4023). Our valuation is based on our DCF analyses.

Trading Data:

Last Price (6/22/2017)	$6.69
52–Week High (12/15/2016)	$12.15
52–Week Low (6/1/2017)	$5.99
Market Cap. (MM)	$3,849
Shares Out. (MM)	550.847

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.06A	-0.06	-0.06	-0.05	-0.22	NM
FY-16A	-0.02	0.03	-0.03	-0.02	-0.05	NM
FY-15A	-0.26	-0.09	0.26	0.00	-0.06	NM
FY-14A	-0.11	-0.06	-0.11	-0.12	-0.41	NM

Source: Laidlaw & Company estimates

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Potential include in for formulary of healthcare plans	**2017/2018**	****
		Potential EMEA filing	**1H17**	***
		Potential EU approval	**1H18**	****
	SHPT in ESRD patients	Start Phase III study	**2H17**	***
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	Potential approval of the IV version	**2H17**	****
hGH-CTP (MOD-4023)	hGH deficiency	FDA feedback and additional adult GHD Phase III data analysis	**2H17**	***
		Report of Versartis' Somavaratan in pediatric GHD Phase III study top-line results	**3Q17**	***
		Potential file BLA for adult GHD	**2H17**	****
		Report of Phase III pediatric study top-line results	**1H19**	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	**2017**	****
		Potential more private payer reimbursement decision	**2017**	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	**2H17**	***
		Potential approval	**2018**	****
Claros 1 PSA test	POC PSA test	Modular PMA filing	**2Q17**	***
		Potential approval	**2018**	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	**1H17**	****
		Potential approval	**2018**	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study tinterim results	**1H17**	***
		Potentially report Phase I/IIa study top-line results	**2H17**	****
		Potentially start Phase II/III study	**2018**	***
		Potentially report Phase II/III study results	**2020**	****
MOD-5014 (s.c)		Potentially report Phase I study results	**2H17**	****
		Potentially start Phase II/III study	**2018**	***
		Potentially report Phase II/III study results	**2020**	***
NK-1 inhibitor	Pruritus	Potentially start Phase IIa study	**2H17**	***
MOD-6031	Obesity	Potentially report Phase I study top-line results	**1Q17**	***
OPK88004	Obesity	Start Phase IIb study	**1Q18**	***
OPK88003	Benign prostate hypertrophy	Start Phase II study	**2H17**	***
		Potentially report Phase II study results	**Mid-2018**	****
OPK88001	Dravet Syndrome	Potentially start Phase I/II trial	**2018**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major risks

Risks of clinical study failure. One of the key risks for healthcare product developer is failure of clinical studies that could potentially result in sunk costs in both capital and time lost. OPK currently has several mid- to late stage clinical trials underway. Failures of these studies, especially the Phase III pivotal trials, could have significant negative impact on share value. More specifically, clinical study success of MOD-4023 (hGH-CTP) is very important given it accounts for substantial valuation of OPK share value.

Regulatory success is important. Given the company currently has several products (in-house development and partnered) under regulatory agency review, whether to receive positive response and approval could have significant impact on share value. Although clinical study results for the several drugs currently under FDA review are rather robust; it remains possible that the agency may not grant approval or request additional clinical information or studies before considering approval. A scenario of this nature could have significant and immediate negative impact on OPK shareholder value.

Merger and acquisition risks. Although acquisition is a faster way to accomplish financial and strategic goals, it bears a number of risks especially post-merger. For example, due to the differences of corporate culture and mentality of operation, there are no assurance a successfully integration can be accomplished immediately.

Successful reimbursement is critical for commercial success. Given the high price of medical products, it is important for most patients who will use them only if the diagnostic test or pharmaceutical products are reimbursed by third party payers, such as Medicare or private insurers. There is no certainty that the company's current or future products can be reimbursed by private or public parties. If so, we believe the revenue growth for such drug or diagnostic test could be limited.

Products may not be approved or reach anticipated sales. Although OPK's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect OPK shareholder value.

Ex-U.S. market risks. Given several OPK operations are out-side of the U.S. and some are in emerging markets, certain risks, such as macroeconomic volatility, geopolitical risk and currency fluctuations could all impact on the revenue generated from and operation in these territories.

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Concentrated insider ownership. Given senior management and other insiders own near 50% of OPK shares, the insider ownership is very concentrated. As such, insiders could have significant control and therefore, with the potential risk of creating price volatility. Highly concentrated insider ownership could also have impact on delaying or preventing a change in control of the company.

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Figure 1: Income Statement

OPKO Health – Income Statement

($'MM)	2013	2014	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	83.5	22.2	27.7	28.8	41.3	120.5	218.7	395.3	515.6
Revenue from services (Diagnostics)	11.7	8.7	329.7	1,012.1	255.3	264.4	278.0	270.7	1,059.1	1,231.0	1,425.9	1,645.1
Revenue from transfer of intellectual property	16.7	5.5	81.9	126.0	18.6	21.0	17.5	26.9	84.0	84.8	85.6	86.5
Total revenue	96.5	91.1	491.9	1,221.7	296.1	313.1	324.3	338.8	1,263.6	1,534.5	1,906.8	2,247.2
Costs of revenues	48.9	48.0	260.0	611.4	154.8	161.4	168.1	167.5	646.0	779.9	920.7	1,077.6
Gross Incomes	47.7	43.1	231.9	610.2	141.3	151.7	156.2	171.4	620.6	754.6	986.1	1,169.5
Selling, general and administrative	55.3	57.9	196.6	490.9	136.7	139.4	140.7	143.5	560.3	599.0	682.9	778.1
Research and development	53.9	83.6	99.5	111.2	26.0	29.1	34.1	35.8	125.0	131.2	136.5	141.9
In process research and development	0.0	12.1	0.0	0.0	-	-	-	-	0.0	0.0	0.0	0.0
Contingent consideration	6.9	24.4	5.1	17.0	2.4	3.4	1.9	1.8	9.5	9.5	9.5	9.5
Amortization of intangible assets	11.1	10.9	28.0	64.4	17.9	19.0	18.0	19.0	73.9	73.9	73.9	73.9
Grant repayment	0.0	0.0	25.9	0.0	-	-	-	-	0.0	0.0	0.0	0.0
Total Operating Expenses	127.3	188.9	355.0	683.5	183.0	191.0	194.7	200.1	768.7	813.6	902.7	1,003.4
Total costs and expenses	176.2	236.9	615.0	1,294.9	337.8	352.3	362.8	367.5	1,414.7	1,593.5	1,823.5	2,081.1
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(73.3)	(41.7)	(39.2)	(38.5)	(28.7)	(151.1)	(59.0)	83.3	166.1
Interest income	0.4	0.8	0.3	0.5		0.1	0.1	0.1	0.4	0.5	0.5	0.5
Interest expense	(13.8)	(12.3)	(8.4)	(7.4)		(2.3)	(2.3)	(2.3)	(6.9)	(6.9)	(6.9)	(6.9)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	2.8		3.0	(4.4)	1.8	0.4	0.4	0.4	0.4
Other income (expense), net	34.8	(3.1)	7.7	3.9	5.9	1.5	(4.5)	3.0	5.9	5.9	5.9	5.9
Total Other Income, net	(24.6)	(25.2)	(39.5)	(0.3)	5.9	2.3	(11.1)	2.6	(0.2)	(0.1)	(0.1)	(0.1)
Income before tax	(104.2)	(171.0)	(138.0)	(73.5)	(35.8)	(36.9)	(49.6)	(26.1)	(151.3)	(59.2)	83.2	166.0
Tax	(1.7)	(0.0)	113.7	56.1	6.9	7.0	16.2	0.0	30.1	25.0	(30.8)	(61.4)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(17.4)	(28.9)	(29.9)	(33.4)	(26.1)	(118.2)	(34.2)	52.4	104.6
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(7.7)	(2.1)	(1.0)	(0.9)	(2.0)	(6.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(25.1)	(31.0)	(30.9)	(34.3)	(28.1)	(124.2)	(37.2)	49.4	101.6
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	0.0	-	0.0	-	-	0.0	0.0	0.0	0.0
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(30.0)	(25.1)	(31.0)	(30.9)	(34.3)	(28.1)	(124.2)	(37.2)	49.4	101.6
Net Earnings (Losses) Per Share—Basic and Diluted	($0.32)	($0.41)	($0.06)	($0.05)	($0.06)	($0.06)	($0.06)	($0.05)	($0.22)	($0.07)	$0.09	$0.18
Shares outstanding—basic	355.1	422.0	488.1	550.8	550.0	552.0	556.0	560.0	554.5	558.8	562.5	566.8
Shares outstanding—diluted	355.1	422.0	488.1	550.8	550.0	552.0	556.0	560.0	554.5	558.8	562.5	566.8
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	56%	56%	55%	55%	54%	55%	54%	51%	50%
Gross margin	39%	44%	37%	44%	44%	45%	45%	46%	45%	46%	49%	50%
R&D	56%	92%	20%	9%	9%	9%	11%	11%	10%	9%	7%	6%
MG&A	57%	64%	40%	40%	46%	45%	43%	42%	44%	39%	36%	35%
Operating Income (loss)	-82%	-160%	-20%	-6%	-14%	-13%	-12%	-8%	-12%	-4%	4%	7%
Net Income	-119%	-188%	-6%	-2%	-10%	-10%	-11%	-8%	-10%	-2%	3%	5%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	4%	12%	21%	40%	104%	44%	81%	81%	30%
Revenue from services (Diagnostics)	567%	-26%	3705%	207%	1%	-1%	7%	15%	5%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	54%	0%	-69%	-5%	30%	-33%	1%	1%	1%
Total Revenue	105%	-6%	440%	148%	2%	-12%	9%	23%	3%	21%	24%	18%
R&D	176%	55%	19%	12%	37%	-7%	39%	30%	12%	5%	4%	4%
SG&A	99%	5%	239%	150%	7%	19%	13%	19%	14%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-26%	51%	-239%	63%	-43%	106%	-61%	-241%	99%
Total Other Income, net	-15001%	3%	57%	-99%	-325%	-54%	5%	-66%	-34%	-23%	-33%	0%
Net Income	267%	49%	-82%	-16%	158%	-299%	129%	106%	395%	-70%	-233%	105%
EPS	206%	26%	-85%	-26%	156%	-297%	127%	121%	391%	-70%	-232%	104%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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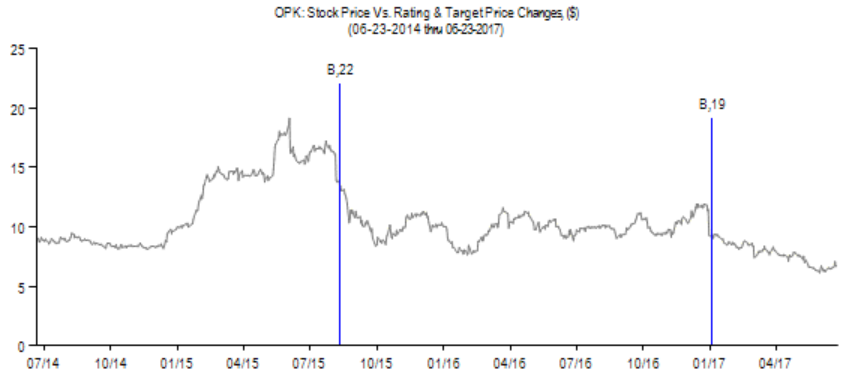

3 Year Rating Change History

Date	Rating	Closing Price ($)
08/12/2015	Buy (B)	13.45

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/12/2015	22.00	13.45
01/03/2017	19.00	9.09

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.22%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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