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EQUITY RESEARCH
Company Report

November 10, 2015

OPKO Health, Inc. (OPK - $ 9.95)

Healthcare/Biotechnology

Ticker:	**OPK**
Rating:	**Buy**
Price Target:	**$ 22.00**

3Q15: 4Kscore Test Commercialization is Underway and Rayaldee PDUFA Date on March 29, 2016

OPK reported 3Q15 financial results with earnings of $129MM vs. net loss estimates of Laidlaw ($38MM) and the Street ($49MM). Earnings per share were $0.26 vs. ($0.08) for Laidlaw and the Street. The discrepancies were mainly due to recognition of a greater portion of the Bio-Reference revenue and a larger non-recurring tax benefit. OPK ended 3Q15 with cash of $212MM.

- **4Kscore test commercialization update.** Management indicated that the decision on Category I CPT code application and publication by the American Medical Association would be "any day now." If approved, the effective date for the Category I CPT code would start on 1/1/2017. This would give OPK critical leverage to negotiate with payers for reimbursement prior to this date if the 4Kscore test carries this status. A health economic analysis of the 4Kscore test to be published in the near future could also be another valuable support for OPK during negotiations. Given the process is time consuming; OPK's guidance was toward greater visibility on the reimbursement front over the next six months. Approximately one-quarter (~100) of Bio-Reference reps (mainly from oncology) are in preparation to promote the 4Kscore test to family doctors starting 1Q16. More reps might participate as the reimbursement landscape improves.
- **Drug pipeline updates.** The hGH-CTP in adult GHD Phase III trial study is expected to complete in 2H16, with a potential BLA submission thereafter if the results are positive. The pediatric GHD Phase III trial is scheduled to start in mid-2016 with the drug to be delivered via a pen device. OPK is scheduled to commence a Phase IIa trial in 4Q15 to evaluate intravenous factor VIIa-CTP in hemophilia. It will be a dose-finding (n=4) trial with a one year treatment duration and three to six months follow-up. The primary endpoint is to assess the acute safety and tolerability. We estimate top-line results will be available in 2017. Further, we believe clinical studies to evaluate subcutaneously (s.c.) delivered factor VIIa-CTP is under consideration. A Phase I trial for evaluating long-acting oxyntomodulin in obesity and diabetes is expected to start in 1H16. We also expect that a $15MM milestone payment for first sales of VARUBI to OPK could occur in Dec. 2015.
- **Action.** We are reiterating our Buy rating and $22 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 (11/09/2015)	$ 9.95
52–Week High (6/3/2015)	$ 19.20
52–Week Low (11/20/2014)	$ 8.08
Market Cap. (MM)	$ 5,423
Shares Out. (MM)	545

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.26A	-0.09A	0.26A	0.01	-0.06	NM
FY-14A	-0.11	-0.06	-0.11	-0.12	-0.41	NM
FY-13A	-0.11	-0.01	-0.17	-0.04	-0.32	NM
FY-12A	-0.03	-0.04	-0.03	-0.01	-0.11	NM

Source: Laidlaw & Company estimates

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- **Rayaldee update.** The Rayaldee PDUFA date is March 29, 2016, and if approved, OPK is scheduled for product launch in 2H16. The proposed indication for Rayaldee is as a treatment for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 CKD and vitamin D insufficiency. Recent data presented at the Kidney Week 2015 suggested that stage 3 or 4 CKD patient could benefit from having serum 25-hydroxyvitamin D (25D) level higher than 30ng/mL as suggested by the published practice guideline, since plasma parathyroid hormone (iPTH) continued to fall even at such level.

Table 1: Estimated and reported 3Q15 results

3Q15 Estimates and Reported Results			
($ MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$123.4**	**$143.0**	**$133.0**
Total op. profit (loss)	**($23.5)**	**($8.2)**	**($24.9)**
R&D	$30.5	$18.9	
SG&A	$48.3	$55.2	
EPS	**($0.08)**	**$0.26**	**($0.08)**
Net income (loss)	($37.9)	$129.0	($48.7)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Start to build M&S organization	**2H15**	***
		PDUFA date	**March 29, 2016**	****
		Product launch	**Mid-2016**	***
		Potential include in for formulary of healthcare plans	**2017'**	****
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	Potential product launch	**4Q15**	***
hGH-CTP (MOD-4023)	hGH deficiency	Report of Phase III study top-line results	**2H16**	****
		Potential product launch for adult hGH deficiency	**2H17**	***
		Report of Phase III pediatric study top-line results	**2018**	****
4Kscore test	Prostate cancer diagnostics	Category 1 CPT code approval decision	**4Q15/1Q16**	***
		CMS reimbursement decision	**2016**	****
		Potential private payer reimbursement decision	**2016 - 2017**	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	**1H16**	***
		Potential approval	**2017**	****
Claros 1 PSA test	POC PSA test	Modular PMA filing	**1H16**	***
		Potential approval	**2017**	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	**4Q16**	****
		Potential approval	**2017**	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially start Phase I/IIa study	**4Q15**	***
		Potentially report Phase I/IIa study top-line results	**4Q16**	****
		Pontentially start Phase II/III study	**1Q17**	***
		Pontentially report Phase II/III study results	**2Q18**	****
MOD-5014 (s.c)		Pontentially start Phase I study	**1H16**	***
		Pontentially report Phase I study results	**1H16**	****
		Pontentially start Phase II study	**4Q16**	***
		Pontentially report Phase II study results	**4H17**	***
MOD-6031 (Oxyntomodulin)	obesity	Potentially start Phase I study	**1Q16**	***

***** / ***** 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)	2012	2013	2014	1Q15	2Q15	3Q15	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Products (Pharmaceuticals)	45.3	68.2	77.0	15.5	22.8	20.8	39.1	98.2	142.0	256.5	373.1	588.3	758.9
Revenue from services (Diagnostics)	1.7	11.7	8.7	2.1	1.9	103.9	269.5	377.4	1,110.3	1,300.3	1,499.2	1,712.1	1,956.1
Revenue from transfer of intellectual property	0.0	16.7	5.5	12.5	17.7	18.4	18.4	66.9	67.6	68.2	68.9	69.6	70.3
Total revenue	47.0	96.5	91.1	30.1	42.4	143.0	326.9	542.4	1,319.9	1,625.0	1,941.3	2,370.0	2,785.3
Costs of revenues	27.9	48.9	48.0	10.3	14.4	67.3	159.4	251.5	683.1	825.1	968.4	1,117.9	1,289.6
Gross Incomes	19.2	47.7	43.1	19.8	28.0	75.7	167.5	290.9	636.7	799.9	972.9	1,252.1	1,495.8
Selling, general and administrative	27.8	55.3	57.9	17.4	20.9	55.2	141.0	234.6	471.8	544.2	620.5	706.9	804.9
Research and development	19.5	53.9	83.6	25.5	29.6	18.9	22.3	96.4	104.1	111.3	116.9	121.6	126.5
In process research and development	0.0	0.0	12.1	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Contingent consideration	0.8	6.9	24.4	5.2	(0.3)	1.6	4.0	10.5	10.5	10.5	10.5	10.5	10.5
Amortization of intangible assets	8.3	11.1	10.9	2.7	3.2	8.1	8.5	22.5	34.0	34.0	34.0	34.0	34.0
Grant repayment	0.0	0.0	0.0	25.9	0.0	0.0	0.0	25.9	0.0	0.0	0.0	0.0	0.0
Total Operating Expenses	56.4	127.3	188.9	76.7	53.4	83.9	175.9	389.9	620.3	700.0	781.9	873.0	975.8
Total costs and expenses	84.3	176.2	236.9	87.0	67.8	151.3	335.3	641.4	1,303.5	1,525.1	1,750.4	1,990.9	2,265.4
Operating Incomes (losses)	(37.3)	(79.6)	(145.8)	(56.9)	(25.4)	(8.2)	(8.4)	(98.9)	16.4	99.9	190.9	379.1	519.9
Interest income	0.2	0.4	0.8	0.0	0.1	0.0	0.0	0.1	0.8	0.9	1.0	1.1	1.1
Interest expense	(1.4)	(13.8)	(12.3)	(2.6)	(1.0)	(2.7)	(2.7)	(9.0)	(9.0)	(9.0)	(9.0)	(9.0)	(9.0)
Fair value changes of derivative instruments, net	1.2	(45.9)	(10.6)	(49.8)	(16.6)	32.2	18.0	(16.1)	(18.0)	(18.0)	(18.0)	(18.0)	(18.0)
Other income (expense), net	0.2	34.8	(3.1)	(1.5)	0.8	17.5	(1.7)	15.0	15.0	15.0	15.0	15.0	15.0
Total Other Income, net	0.2	(24.6)	(25.2)	(53.9)	(16.7)	47.0	13.6	(10.0)	(11.2)	(11.1)	(11.0)	(10.9)	(10.9)
Income before tax	(37.1)	(104.2)	(171.0)	(110.8)	(42.1)	38.8	5.2	(109.0)	5.2	88.8	179.9	368.2	509.0
Tax	9.6	(1.7)	(0.0)	(5.5)	(0.3)	93.0	(1.0)	86.2	(1.9)	(32.8)	(66.6)	(136.2)	(188.3)
Loss before investment losses	(27.5)	(105.9)	(171.1)	(116.3)	(42.4)	131.7	4.2	(22.8)	3.3	55.9	113.3	232.0	320.7
Loss from investments in investees	(2.1)	(11.5)	(3.6)	(1.8)	(0.8)	(3.5)	(1.4)	(7.5)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(29.5)	(117.3)	(174.6)	(118.0)	(43.2)	128.2	2.8	(30.2)	0.3	52.9	110.3	229.0	317.7
Net loss attributable to noncontrolling interests	(0.5)	(2.9)	(3.0)	(0.9)	(0.5)	(0.8)	(0.9)	(3.1)	(3.1)	(3.0)	(3.0)	(3.0)	(3.0)
Net Income (Loss) Applicable to Common Shareholders	(31.3)	(114.8)	(171.7)	(117.1)	(42.7)	129.0	3.7	(27.1)	3.4	55.9	113.3	232.0	320.7
Net Earnings (Losses) Per Share—Basic and Diluted	($0.11)	($0.32)	($0.41)	($0.26)	($0.09)	$0.26	$0.01	($0.06)	$0.01	$0.11	$0.20	$0.46	$0.57
Shares outstanding—basic and diluted	295.8	355.1	422.0	446.5	456.5	500.6	543.3	486.7	551.3	494.7	559.3	502.7	567.3
	295.8	355.1	422.0	446.5	456.5	514.3	543.3	490.1	551.3	498.1	559.3	506.1	567.3
Margin Analysis (% of Sales/Revenue)													
Costs of goods	59%	61%	56%	59%	58%	58%	52%	53%	55%	53%	52%	49%	47%
Gross margin	41%	39%	44%	41%	42%	42%	48%	47%	45%	47%	48%	51%	53%
R&D	41%	56%	92%	85%	70%	13%	7%	18%	8%	7%	6%	5%	5%
MG&A	59%	57%	64%	58%	49%	39%	43%	43%	36%	33%	32%	30%	29%
Operating Income (loss)	-79%	-82%	-160%	-189%	-60%	-6%	-3%	-18%	1%	6%	10%	16%	19%
Net Income	-67%	-119%	-188%	-389%	-101%	90%	1%	-5%	0%	3%	6%	10%	12%
Financial Indicator Growth Analysis (YoY%)													
Products (Pharmaceuticals)	63%	50%	13%	-22%	7%	20%	112%	28%	45%	81%	45%	58%	29%
Revenue from services (Diagnostics)	1196%	567%	-26%	5%	-11%	4087%	12974%	4254%	194%	17%	15%	14%	14%
Revenue from transfer of intellectual property	N.A.	N.A.	-67%	2532%	N.A.	N.A.	267%	1122%	1%	1%	1%	1%	1%
Total Revenue	68%	105%	-6%	35%	80%	623%	1180%	495%	143%	23%	19%	22%	18%
R&D	72%	176%	55%	21%	82%	-8%	-13%	15%	8%	7%	5%	4%	4%
SG&A	45%	99%	5%	26%	41%	294%	825%	305%	3%	9%	9%	9%	8%
Operating income (loss)	61%	114%	83%	88%	-27%	-83%	-74%	-32%	-117%	509%	91%	99%	37%
Total Other Income, net	-116%	-15001%	3%	343%	-280%	-3277%	-165%	-60%	12%	-1%	-1%	-1%	0%
Net Income	754%	267%	49%	163%	68%	-365%	-107%	-84%	-112%	1559%	103%	105%	38%
EPS	711%	206%	26%	143%	52%	-326%	-106%	-86%	-111%	1749%	79%	128%	23%

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

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Additional information available upon request.

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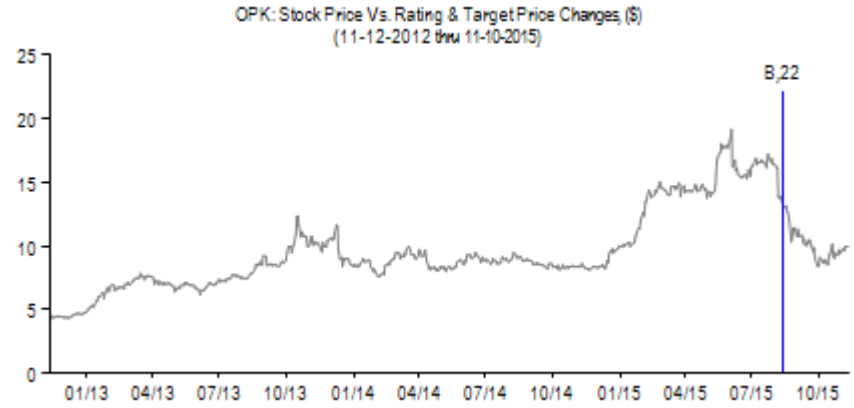
Rating and Price Target Change History



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

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

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	71.88%	25.00%	6.25%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.13%	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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NOTES: