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EQUITY RESEARCH
Company Report

March 1, 2016

OPKO Health, Inc. (OPK - $ 9.30)

Healthcare/Biotechnology

4Q15: Rayaldee PDUFA Date on March 29, 2016 Is Near-term Catalyst

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

OPK reported 4Q15 financial results with earnings of $1.6MM vs. estimates of ($2.3MM) net loss of Laidlaw and $2.9MM earnings of the Street. Earnings per share were $0.00 vs. ($0.00) for Laidlaw and $0.01 for the Street. OPK ended 2015 with cash of ~$194MM.

- **Rayaldee development update.** The Rayaldee in 2nd hyperparathyroidism (SHPT) of stage 3/4 CKD and vitamin D insufficiency patients PDUFA date is on track on March 29, 2016. If approved, OPK is scheduled to launch the drug in 2H16. OPK plans to start with 25 sales reps with a goal of a total of 75 reps plus 20 scientific liaisons. Potential Rayaldee benefits for stage 3/4 CKD patient include increasing serum 25-hydroxyvitamin D (25D) level higher than 30ng/mL, since plasma parathyroid hormone (iPTH) continued to fall even at such level. OPK suggested that its marketing strategy is to sell Rayaldee in retail (75%) and specialty (25%) pharmacy channels. We estimate a more substantial sales ramp up could start once Rayaldee is included in multiple formularies.
- **Diagnostic operation updates.** Management indicated that Bio-Reference has trained ~200 sales reps for selling the 4Kscore test to primary care physicians; and we anticipate increasing marketing and selling efforts in 2016 as the test gains more public/private reimbursement coverages. A favorable CMS decision, possibly in mid-2016, we believe could help set off a more substantial sales ramp up. OPK also indicated that urologists prescribing the 4Kscore test have increased month over month at a double-digit rate. OPK reported in January 2016 that >1,500 urologists have used the 4Kscore test in routine practice and we estimate 4Kscore-prescribing urologists could approach 1,900+. OPK also indicated that development of Claros 1 tests are on track with testosterone and PSA tests to start clinical work in 2H16. We estimate both tests could be approved in 2017 with the testosterone test via a 510(k) filing, and the PSA test via a PMA filing.
- **Analyst day.** OPK is scheduled to host an analyst day on June 15, 2016 to highlight the pharmaceutical and diagnostic developments.
- **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 (02/29/2016)	$ 9.30
52–Week High (6/3/2015)	$ 19.20
52–Week Low (1/20/2016)	$ 7.12
Market Cap. (MM)	$ 5,069
Shares Out. (MM)	545

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.07	-0.04	-0.01	-0.01	-0.14	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
FY-13A	-0.11	-0.01	-0.17	-0.04	-0.32	NM

Source: Laidlaw & Company estimates

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- **Other pharmaceutical updates.** Management reiterated that top-line results from the ongoing hGH-CTP (MOD-4023) in adult human growth hormone (hGH) deficiency Phase III trial would be available in 2H16. In addition, Pfizer is scheduled to commence an hGH-CTP in pediatric hGH deficiency Phase III in 2H16. Also, Tesaro reported at its 4Q15 conference call that the company is on track to submit an IV rolapitant sNDA in 1H16 (TSRO estimated a 12-month review timeframe) with expected potential approved in 1Q17. Given IV anti-CINV medications account for majority of the use in the U.S., we believe the potential IV rolapitant approval would be critical for the commercial outlook of this franchise.

Table 1: Estimated and reported 4Q15 results

4Q15 Estimates and Reported Results			
($ MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$313.8**	**$276.2**	**$286.5**
Total op. profit (loss)	**($14.4)**	**($7.9)**	**$1.2**
R&D	$22.3	$25.5	
SG&A	$141.0	$102.9	
EPS	**($0.00)**	**$0.00**	**$0.01**
Net income (loss)	($2.3)	$1.6	$2.9

Source: Bloomberg, SEC filings and Laidlaw and Co.

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Start to build M&S organization	**1H16**	***
		PDUFA date	**March 29, 2016**	****
		Product launch	**2H16**	***
		Potential include in for formulary of healthcare plans	**2017**	****
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	Potential approval of the IV version	**1H17**	****
hGH-CTP (MOD-4023)	hGH deficiency	Report of Phase III study top-line results	**2H16**	****
		Potential product approval for adult hGH deficiency	**2H17**	***
		Potential commencement of pediatric Phase III study	**2H16**	***
		Report of Phase III pediatric study top-line results	**2018**	****
4Kscore test	Prostate cancer diagnostics	CMS reimbursement decision	**2016**	****
		Potential private payer reimbursement decision	**2016 - 2017**	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	**2H16**	***
		Potential approval	**2017**	****
Claros 1 PSA test	POC PSA test	Modular PMA filing	**2H16**	***
		Potential approval	**2017**	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	**1Q17**	****
		Potential approval	**2017**	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study top-line results	**4Q16**	****
		Potentially start Phase II/III study	**1H17**	***
		Potentially report Phase II/III study results	**2Q18**	****
MOD-5014 (s.c)		Potentially start Phase I study	**Mid-16**	***
		Potentially report Phase I study results	**1Q17**	****
		Potentially start Phase II study	**2H17**	***
		Potentially report Phase II study results	**Mid-18**	***
Analyst Day			**June 15, 2016**	***

***** / ***** 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	1Q15	2Q15	3Q15	4Q15	2015	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue																
Products (Pharmaceuticals)	68.2	77.0	15.5	22.8	20.8	21.0	80.1	21.9	23.7	37.3	59.0	142.0	256.5	373.2	588.3	759.0
Revenue from services (Diagnostics)	11.7	8.7	2.1	1.9	103.9	221.8	329.7	215.4	227.1	232.6	240.0	915.2	1,063.0	1,234.6	1,440.9	1,652.9
Revenue from transfer of intellectual property	16.7	5.5	12.5	17.7	18.4	33.3	81.9	16.7	16.0	17.0	17.9	67.6	68.3	69.0	69.6	70.3
Total revenue	96.5	91.1	30.1	42.4	143.0	276.2	491.7	**254.1**	266.8	287.0	316.9	1,124.9	1,387.8	1,676.7	2,098.9	2,482.2
Costs of revenues	48.9	48.0	10.3	14.4	67.3	167.9	260.0	128.9	136.3	141.7	149.8	556.7	680.1	808.8	966.7	1,122.8
Gross Incomes	47.7	43.1	19.8	28.0	75.7	108.3	231.7	125.2	130.5	145.2	167.1	568.2	707.6	867.9	1,132.2	1,359.4
Selling, general and administrative	55.3	57.9	17.4	20.9	55.2	102.9	196.6	109.8	113.6	115.9	118.2	457.5	534.2	609.4	694.4	791.0
Research and development	53.9	83.6	25.5	29.6	18.9	25.5	99.5	26.5	28.4	29.8	31.0	115.6	123.7	129.9	135.0	140.4
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	5.2	(0.3)	1.6	(1.4)	5.1	3.0	4.0	(2.0)	3.3	8.3	8.3	8.3	8.3	8.3
Amortization of intangible assets	11.1	10.9	2.7	3.2	8.1	14.0	28.0	14.0	13.0	13.0	13.0	53.0	53.0	53.0	53.0	53.0
Grant repayment	0.0	0.0	25.9	-	-	-	25.9	-	-	-	-	0.0	0.0	0.0	0.0	0.0
Total Operating Expenses	127.3	188.9	76.7	53.4	83.9	141.0	355.0	153.3	159.0	156.7	165.5	634.3	719.2	800.5	890.8	992.7
Total costs and expenses	176.2	236.9	87.0	67.8	151.3	308.9	615.0	282.1	295.3	298.4	315.3	1,191.0	1,399.3	1,609.3	1,857.5	2,115.5
Operating Incomes (losses)	(79.6)	(145.8)	(56.9)	(25.4)	(8.2)	(7.9)	(98.5)	(28.1)	(28.4)	(11.4)	1.7	(66.2)	(11.5)	67.4	241.4	366.7
Interest income	0.4	0.8	0.0	0.1	0.0	0.2	0.3	0.2	0.2	0.2	0.2	0.8	0.9	1.0	1.1	1.1
Interest expense	(13.8)	(12.3)	(2.6)	(1.0)	(2.7)	(2.1)	(8.4)	(2.7)	(2.7)	(2.7)	(2.7)	(10.8)	(10.8)	(10.8)	(10.8)	(10.8)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(49.8)	(16.6)	32.2	(5.0)	(39.1)	(15.0)	(1.0)	2.0	(4.0)	(18.0)	(6.0)	(6.0)	(6.0)	(6.0)
Other income (expense), net	34.8	(3.1)	(1.5)	0.8	17.5	(9.0)	7.7	6.0	8.0	6.0	(1.0)	19.0	29.0	29.0	29.0	29.0
Total Other Income, net	(24.6)	(25.2)	(53.9)	(16.7)	47.0	(15.9)	(39.5)	(11.5)	4.5	5.5	(7.5)	(9.0)	13.1	13.2	13.3	13.3
Income before tax	(104.2)	(171.0)	(110.8)	(42.1)	38.8	(23.8)	(138.0)	(39.6)	(23.9)	(5.9)	(5.8)	(75.2)	1.6	80.6	254.7	380.0
Tax	(1.7)	(0.0)	(5.5)	(0.3)	93.0	26.5	113.7	0.0	0.0	0.0	0.0	0.0	(0.6)	(29.8)	(94.2)	(140.6)
Loss before investment losses	(105.9)	(171.1)	(116.3)	(42.4)	131.7	2.6	(24.3)	(39.6)	(23.9)	(5.9)	(5.8)	(75.2)	1.0	50.8	160.5	239.4
Loss from investments in investees	(11.5)	(3.6)	(1.8)	(0.8)	(3.5)	(1.0)	(7.1)	(0.9)	(0.7)	(0.6)	(0.8)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(118.0)	(43.2)	128.2	1.6	(31.4)	**(40.5)**	(24.6)	(6.5)	(6.6)	(78.2)	(2.0)	47.8	157.5	236.4
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(0.9)	(0.5)	(0.8)	-	(1.4)	(0.8)	(0.8)	(0.8)	(0.8)	(1.4)	(3.0)	(3.0)	(3.0)	(3.0)
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(117.1)	(42.7)	129.0	1.6	(30.0)	(39.7)	(23.9)	(5.7)	(5.8)	(76.8)	1.0	50.8	160.5	239.4
Net Earnings (Losses) Per Share—Basic and Diluted	($0.32)	($0.41)	($0.26)	($0.09)	$0.26	$0.00	($0.06)	($0.07)	($0.04)	($0.01)	($0.01)	($0.14)	$0.00	$0.09	$0.32	$0.42
Shares outstanding—basic	355.1	422.0	446.5	456.5	500.6	548.7	488.1	551.7	555.7	559.7	563.7	557.7	496.1	565.7	504.1	573.7
Shares outstanding—diluted	355.1	422.0	446.5	456.5	514.3	535.0	488.1	551.7	555.7	559.7	563.7	557.7	496.1	565.7	504.1	573.7
Margin Analysis (% of Sales/Revenue)																
Costs of goods	61%	56%	59%	58%	54%	69%	63%	54%	54%	52%	50%	53%	52%	50%	48%	47%
Gross margin	39%	44%	41%	42%	46%	31%	37%	46%	46%	48%	50%	47%	48%	50%	52%	53%
R&D	56%	92%	85%	70%	13%	9%	20%	10%	11%	10%	10%	10%	9%	8%	6%	6%
MG&A	57%	64%	58%	49%	39%	37%	40%	43%	43%	40%	37%	41%	38%	36%	33%	32%
Operating Income (loss)	-82%	-160%	-189%	-60%	-6%	-3%	-20%	-11%	-11%	-4%	1%	-6%	-1%	4%	12%	15%
Net Income	-119%	-188%	-389%	-101%	90%	1%	-6%	-16%	-9%	-2%	-2%	-7%	0%	3%	8%	10%
Financial Indicator Growth Analysis (YoY%)																
Products (Pharmaceuticals)	50%	13%	-22%	7%	20%	14%	4%	42%	4%	80%	180%	77%	81%	45%	58%	29%
Revenue from services (Diagnostics)	567%	-26%	5%	-11%	4087%	10664%	3705%	10313%	11805%	124%	8%	178%	16%	16%	17%	15%
Revenue from transfer of intellectual property	N.A.	-67%	2532%	N.A.	N.A.	566%	1395%	33%	-9%	-7%	-46%	-17%	1%	1%	1%	1%
Total Revenue	105%	-6%	35%	80%	623%	982%	440%	745%	529%	101%	15%	129%	23%	21%	25%	18%
R&D	176%	55%	21%	82%	-8%	-1%	19%	4%	-4%	57%	22%	16%	7%	5%	4%	4%
SG&A	99%	5%	26%	41%	294%	575%	239%	529%	443%	110%	15%	133%	9%	9%	9%	8%
Operating income (loss)	114%	83%	88%	-27%	-83%	-76%	-32%	-51%	12%	39%	-121%	-33%	-83%	-685%	258%	52%
Total Other Income, net	-15001%	3%	343%	-280%	-3277%	-24%	57%	-79%	-127%	-88%	-53%	-77%	-245%	1%	1%	0%
Net Income	267%	49%	163%	68%	-365%	-103%	-82%	-66%	-44%	-104%	-467%	155%	-101%	5070%	216%	49%
EPS	206%	26%	143%	52%	-326%	-102%	-85%	-73%	-54%	-104%	-457%	124%	-101%	4434%	255%	31%

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

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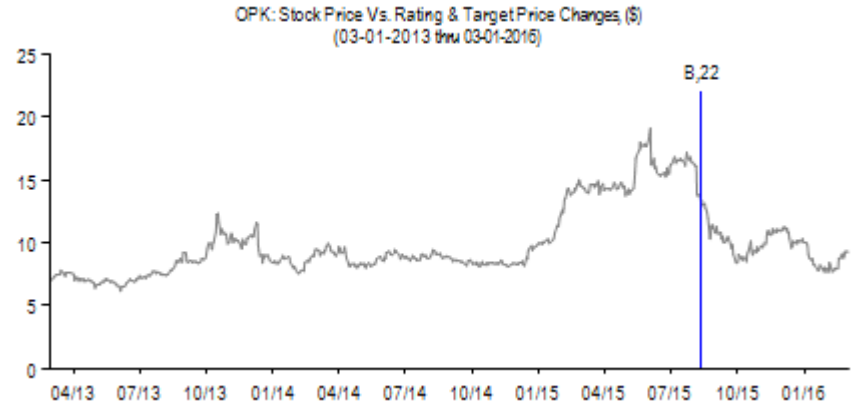
Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

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.	65.71%	25.71%	2.86%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Pfizer (PFE – Not Rated)
Tesaro (TSRO – Not Rated)

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NOTES: