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EQUITY RESEARCH
Company Report

October 14, 2015

OPKO Health, Inc. (OPK - $ 8.51)

Healthcare/Biotechnology

Encouraging Discussions with Management on Developments

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

Our recent meeting with OPK management and investors indicated that investors are focused on programs with significant near term developments including 4Kscore test commercialization, Rayaldee regulatory development, the Bio-Reference outlook and hGH-CTP advancements. Key takeaways include:

- **4Kscore test commercialization is kicking up to a higher gear.** Several near term developments could further help OPK's reimbursement discussions with payers: 1) The Category I CPT code application is underway with a potential decision in 4Q15; 2) OPK conducted a retrospective real world study (n=550) demonstrating that in patients with a low 4Kscore reading, ~94% of them did not require biopsy. The average reduction of unnecessary biopsies was 64%; and 3) due to Bio-Reference, patients taking the test are considered in-network with most payers, and this scenario also expedites reimbursement negotiations. Further, Bio-Reference reps (n~400) are in preparation to promote 4Kscore test to family doctors starting 1Q16. Approximately 94% of PSA tests (Bio-Reference: ~600K/yr) in the U.S. are prescribed by family doctors. Many of them frequently lack a clear direction when advising patients, even with PSA test result. A 4Kscore test result could provide actionable advice following a PSA test as it could differentiate indolent vs. aggressive prostate cancer. Like the PSA test, the 4Kscore test could also use a serum sample. If successful, the 4Kscore test could potentially change the practice of early prostate cancer screening/diagnosis.
- **Rayaldee update.** The Rayaldee PDUFA date is March 29, 2016, and if approved, OPK is scheduled for product launch in 2H16. Sales reps are expected to ramp up from mid-teens to ~70 as Rayaldee starts to be included in various formularies for reimbursement. Rayaldee is a modified released oral vitamin D prohormone. Major benefits of Rayaldee over current treatments (nutritional vitamin D and vitamin D hormone) in CKD patients are overcoming insufficient vitamin D supply (caused by increased catabolism); and without calcium elevation (which could lead to mortality-increasing vascular calcification). We believe the probability of approval is high since the pivotal trial met the primary and several secondary endpoints. Publication of detailed results is expected in 1Q16.
- **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 (10/13/2015)	$ 8.51
52–Week High (6/3/2015)	$ 19.20
52–Week Low (10/13/2014)	$ 8.02
Market Cap. (MM)	$ 4,597
Shares Out. (MM)	540

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.26A	-0.09A	-0.08	0.03	-0.37	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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- **Cash flow improvement for Bio-Reference.** In addition to the organic growth of the current Bio-Reference business, management indicated two factors could further enhance cash flow for Bio-Reference going forward. The first is the net losses carrying forward from OPK's prior operation, which could reduce the actual tax paid by Bio-Reference in the combined entity. The second is the improvements of account receivable, specifically in reduction of accounts receivable days, mainly in the GeneDx operation.

- **MOD-4023 (hGP-CTP) development updates.** OPK expects the pediatric GHD Phase III study to start in mid-2016 after Pfizer completes and validates a pen device for delivering MOD-4023. Market analysis suggests that a pen is a more favorable delivery device, especially in the pediatric population, and could facilitate greater market penetration. Based on this timeline, regulatory filing in the U.S. for MOD-4023 in pediatric GHD could slate to late 2018 with possibly approval in 2H19. Top-line results of MOD-4023 in adult GHD Phase III study could be available in 2H16 with possible approval in 2H17. OPK might run a relatively short MOD-4023 delivered by a pen device in adults bridging study after MOD-4023 (by syringe) approved for adults with potential supplement approval for the pen version MOD-4023 in 2018.

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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	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Products (Pharmaceuticals)	45.3	68.2	77.0	15.5	22.8	20.3	23.6	82.2	140.8	255.1	371.4	586.2	756.4
Revenue from services (Diagnostics)	1.7	11.7	8.7	2.1	1.9	85.6	270.7	360.3	1,119.0	1,300.8	1,499.8	1,712.7	1,956.8
Revenue from transfer of intellectual property	0.0	16.7	5.5	12.5	17.7	17.5	17.5	65.3	65.9	66.6	67.2	67.9	68.6
Total revenue	47.0	96.5	91.1	30.1	42.4	123.4	311.8	507.7	1,325.7	1,622.5	1,938.4	2,366.9	2,781.8
Costs of revenues	27.9	48.9	48.0	10.3	14.4	57.7	161.0	243.5	624.7	720.3	826.4	944.5	1,077.8
Gross Incomes	19.2	47.7	43.1	19.8	28.0	65.7	150.7	264.2	701.0	902.1	1,112.0	1,422.3	1,704.0
Selling, general and administrative	27.8	55.3	57.9	17.4	20.9	48.3	106.1	192.8	471.8	544.2	620.5	706.9	804.9
Research and development	19.5	53.9	83.6	25.5	29.6	30.5	30.8	116.3	125.6	134.4	141.1	146.8	152.6
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
Contingent consideration	0.8	6.9	24.4	5.2	(0.3)	4.0	4.0	12.8	12.8	12.8	12.8	12.8	12.8
Amortization of intangible assets	8.3	11.1	10.9	2.7	3.2	6.5	6.5	18.8	18.8	18.8	18.8	18.8	18.8
Grant repayment	0.0	0.0	0.0	25.9	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	89.2	147.3	366.6	629.0	710.2	793.3	885.3	989.2
Total costs and expenses	84.3	176.2	236.9	87.0	67.8	147.0	308.4	610.2	1,253.8	1,430.5	1,619.8	1,829.8	2,067.0
Operating Incomes (losses)	(37.3)	(79.6)	(145.8)	(56.9)	(25.4)	(23.5)	3.4	(102.4)	72.0	191.9	318.7	537.0	714.8
Interest income	0.2	0.4	0.8	0.0	0.1	0.1	0.1	0.2	0.8	0.9	1.0	1.1	1.1
Interest expense	(1.4)	(13.8)	(12.3)	(2.6)	(1.0)	(1.0)	(1.0)	(5.5)	(5.5)	(5.5)	(5.5)	(5.5)	(5.5)
Fair value changes of derivative instruments, net	1.2	(45.9)	(10.6)	(49.8)	(16.6)	(15.0)	18.0	(63.3)	(18.0)	(18.0)	(18.0)	(18.0)	(18.0)
Other income (expense), net	0.2	34.8	(3.1)	(1.5)	0.8	3.0	(1.7)	0.6	0.6	0.6	0.6	0.6	0.6
Total Other Income, net	0.2	(24.6)	(25.2)	(53.9)	(16.7)	(12.9)	15.4	(68.2)	(22.2)	(22.1)	(22.0)	(21.9)	(21.9)
Income before tax	(37.1)	(104.2)	(171.0)	(110.8)	(42.1)	(36.5)	18.8	(170.6)	49.8	169.8	296.7	515.1	692.9
Tax Rate									*37%*	*37%*	*37%*	*37%*	*37%*
Tax	9.6	(1.7)	(0.0)	(5.5)	(0.3)	(1.0)	(1.0)	(7.8)	(18.4)	(62.8)	(109.8)	(190.6)	(256.4)
Loss before investment losses	(27.5)	(105.9)	(171.1)	(116.3)	(42.4)	(37.5)	17.8	(178.3)	31.4	107.0	186.9	324.5	436.5
Loss from investments in investees	(2.1)	(11.5)	(3.6)	(1.8)	(0.8)	(1.2)	(1.4)	(5.2)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(29.5)	(117.3)	(174.6)	(118.0)	(43.2)	(38.7)	16.4	(183.5)	28.4	104.0	183.9	321.5	433.5
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)	(37.9)	17.3	(180.4)	31.5	107.0	186.9	324.5	436.5
Net Earnings (Losses) Per Share—Basic and Diluted	($0.11)	($0.32)	($0.41)	($0.26)	($0.09)	($0.08)	$0.03	($0.37)	$0.06	$0.22	$0.33	$0.65	$0.77
Shares outstanding—basic and diluted	295.8	355.1	422.0	446.5	456.5	482.1	543.3	482.1	551.3	490.1	559.3	498.1	567.3
	295.8	355.1	422.0	446.5	456.5	482.1	543.3	482.1	551.3	490.1	559.3	498.1	567.3
Margin Analysis (% of Sales/Revenue)													
Costs of goods	59%	61%	56%	59%	58%	58%	55%	55%	50%	46%	44%	41%	40%
Gross margin	41%	39%	44%	41%	42%	42%	45%	45%	50%	54%	56%	59%	60%
R&D	41%	56%	92%	85%	70%	25%	10%	23%	9%	8%	7%	6%	5%
MG&A	59%	57%	64%	58%	49%	39%	34%	38%	36%	34%	32%	30%	29%
Operating Income (loss)	-79%	-82%	-160%	-189%	-60%	-19%	1%	-20%	5%	12%	16%	23%	26%
Net Income	-67%	-119%	-188%	-389%	-101%	-31%	6%	-36%	2%	7%	10%	14%	16%
Financial Indicator Growth Analysis (YoY%)													
Products (Pharmaceuticals)	63%	50%	13%	-22%	7%	17%	27%	7%	71%	81%	46%	58%	29%
Revenue from services (Diagnostics)	1196%	567%	-26%	5%	-11%	3349%	13035%	4057%	211%	16%	15%	14%	14%
Revenue from transfer of intellectual property	N.A.	N.A.	-67%	2532%	N.A.	N.A.	251%	1092%	1%	1%	1%	1%	1%
Total Revenue	68%	105%	-6%	35%	80%	524%	1121%	457%	161%	22%	19%	22%	18%
Gross Profit	79%	149%	-10%	100%	155%	659%	1008%	513%	165%	29%	23%	28%	20%
Cost of Sales	62%	75%	-2%	-17%	15%	419%	1250%	407%	157%	15%	15%	14%	14%
R&D	72%	176%	55%	21%	82%	48%	19%	39%	8%	7%	5%	4%	4%
SG&A	45%	99%	5%	26%	41%	245%	596%	233%	3%	9%	9%	9%	8%
Contingent consideration	NA	785%	252%	98%	-118%	-80%	987%	-47%	0%	10%	5%	6%	5%
Operating income (loss)	61%	114%	83%	88%	-27%	-51%	-111%	-30%	-170%	167%	66%	69%	33%
Total Other Income, net	-116%	-15001%	3%	343%	-280%	775%	-174%	170%	-67%	0%	0%	0%	0%
Pretax Income	53%	181%	64%	161%	65%	-27%	-135%	0%	-129%	241%	75%	74%	35%
Net Income	754%	267%	49%	163%	68%	-22%	-133%	5%	-117%	240%	75%	74%	35%
EPS	711%	206%	26%	143%	52%	-31%	-126%	-8%	-115%	282%	53%	95%	18%

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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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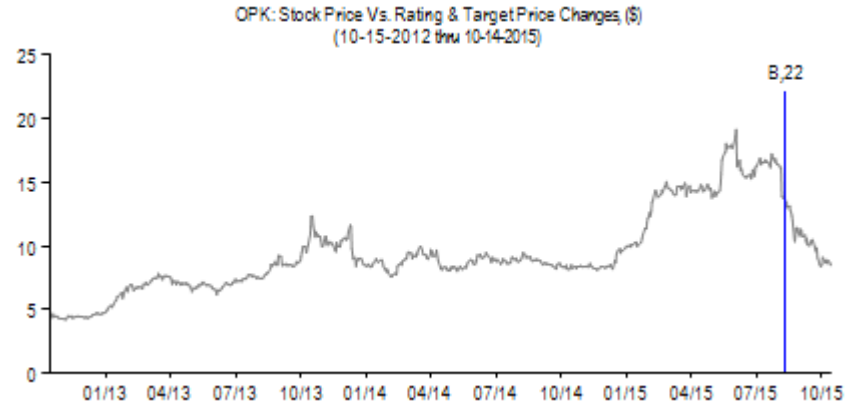
Rating and Price Target Change History



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.	74.19%	25.81%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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: