

**OPKO Health, Inc. (OPK - \$ 10.09)**

*Healthcare/Biotechnology*

**4Kscore Test Reimbursement Decisions in 2016 With Greater Revenue Growth Starting in 2017.**

Our recent discussion with OPK management suggested the company is active in post-merger integration of the Bio-Reference acquisition, and in discussions with various parties for potential 4Kscore test reimbursement.

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

- Details.** Our discussion with OPK management focused on the progress of Bio-Reference acquisition and an update on the 4Kscore test reimbursement status of CMS for Medicare and private payers. Management indicated that the deal for Bio-Reference acquisition has already closed and the company is actively executing post-merger integration. This includes preparing the Bio-Reference sales force to promote and sell the 4Kscore test to general practitioners in the primary care market. Portions of patients who undertook PSA tests are potential prospects to take the 4Kscore test as a reflex test for making a more cost-effective decision of their next treatment option, such as whether taking a biopsy. Only 20% of biopsies are of high grade aggressive tumors that require subsequent treatment. It is reported that the majority (~90%) of PSA tests annually in the U.S. are prescribed by general practitioners. We estimate Bio-Reference processes roughly 400,000+ PSA tests yearly. The 4Kscore test has received an administrative CPT code; and OPK has applied for a Category I CPT code with a potential decision in late 2015/early 2016. OPK has already started reimbursement discussions with several payers via Bio-Reference’s in-network status with major private payers.
- Implication.** OPK already has made substantial advances in preparing the Bio-Reference sales force to sell the 4Kscore test to the primary care market, concurrent with progress toward a reimbursement decision (Category I CPT code) and discussions with private payers. Should the 4Kscore test be granted a Category I code, the Relative Value Update Committee (RUC) of CMS later could make a pricing recommendation with a final pricing decision by CMS, possibly later in 2016. The new 4Kscore test CPT code could be effective at the beginning of 2017. As such, we estimate a modest increase in 4Kscore test sales in 2016 with greater increases starting in 2017.
- 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 (09/11/2015)	\$ 10.09
52-Week High (6/3/2015)	\$ 19.20
52-Week Low (10/13/2014)	\$ 8.02
Market Cap. (MM)	\$ 5,450
Shares Out. (MM)	540

**Earnings Estimates: (per share)**

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-15E</b>	-0.26A	-0.09A	-0.08	0.03	-0.37	NM
<b>FY-14A</b>	-0.11	-0.06	-0.11	-0.12	-0.41	NM
<b>FY-13A</b>	-0.11	-0.01	-0.17	-0.04	-0.32	NM
<b>FY-12A</b>	-0.03	-0.04	-0.03	-0.01	-0.11	NM

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Source: Laidlaw & Company estimates

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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	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)		Potentially report Phase I/IIa study top-line results	4Q16	***
		Potentially start Phase II/III study	1Q17	***
		Potentially report Phase II/III study results	2Q18	****
MOD-5014 (s.c)	Hemophilia A/B with inhibitors	Potentially start Phase I study	1H16	***
		Potentially report Phase I study results	1H16	****
		Potentially start Phase II study	4Q16	***
		Potentially 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.

## Major risks

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**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 successful 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.

**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.

Figure 1: Income Statement

OPKO Health – Income Statement													
(\$'MM)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Revenue</b>													
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	66.9	66.6	67.2	67.9	68.6
<b>Total revenue</b>	<b>47.0</b>	<b>96.5</b>	<b>91.1</b>	<b>30.1</b>	<b>42.4</b>	<b>123.4</b>	<b>311.8</b>	<b>507.7</b>	<b>1,325.7</b>	<b>1,622.5</b>	<b>1,938.4</b>	<b>2,366.9</b>	<b>2,781.8</b>
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
<b>Gross Incomes</b>	<b>19.2</b>	<b>47.7</b>	<b>43.1</b>	<b>19.8</b>	<b>28.0</b>	<b>65.7</b>	<b>150.7</b>	<b>264.2</b>	<b>701.0</b>	<b>902.1</b>	<b>1,112.0</b>	<b>1,422.3</b>	<b>1,704.0</b>
Selling, general and administrative	27.8	53.9	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	55.3	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
<b>Total Operating Expenses</b>	<b>56.4</b>	<b>127.3</b>	<b>188.9</b>	<b>76.7</b>	<b>53.4</b>	<b>89.2</b>	<b>147.3</b>	<b>366.6</b>	<b>629.0</b>	<b>710.2</b>	<b>793.3</b>	<b>885.3</b>	<b>989.2</b>
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
<b>Operating Incomes (losses)</b>	<b>(37.3)</b>	<b>(79.6)</b>	<b>(145.8)</b>	<b>(56.9)</b>	<b>(25.4)</b>	<b>(23.5)</b>	<b>3.4</b>	<b>(102.4)</b>	<b>72.0</b>	<b>191.9</b>	<b>318.7</b>	<b>537.0</b>	<b>714.8</b>
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)
<b>Income before tax</b>	<b>(37.1)</b>	<b>(104.2)</b>	<b>(171.0)</b>	<b>(110.8)</b>	<b>(42.1)</b>	<b>(36.5)</b>	<b>18.8</b>	<b>(170.6)</b>	<b>49.8</b>	<b>169.8</b>	<b>296.7</b>	<b>515.1</b>	<b>692.9</b>
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)
<b>Net income (loss)</b>	<b>(29.5)</b>	<b>(117.3)</b>	<b>(174.6)</b>	<b>(118.0)</b>	<b>(43.2)</b>	<b>(38.7)</b>	<b>16.4</b>	<b>(183.5)</b>	<b>28.4</b>	<b>104.0</b>	<b>183.9</b>	<b>321.5</b>	<b>433.5</b>
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)
<b>Net Income (Loss) Applicable to Common Shareholders</b>	<b>(31.3)</b>	<b>(114.8)</b>	<b>(171.7)</b>	<b>(117.1)</b>	<b>(42.7)</b>	<b>(37.9)</b>	<b>17.3</b>	<b>(180.4)</b>	<b>31.5</b>	<b>107.0</b>	<b>186.9</b>	<b>324.5</b>	<b>436.5</b>
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
<b>Margin Analysis (% of Sales/Revenue)</b>													
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%
<b>Financial Indicator Growth Analysis (YoY%)</b>													
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 &amp; Company estimates.

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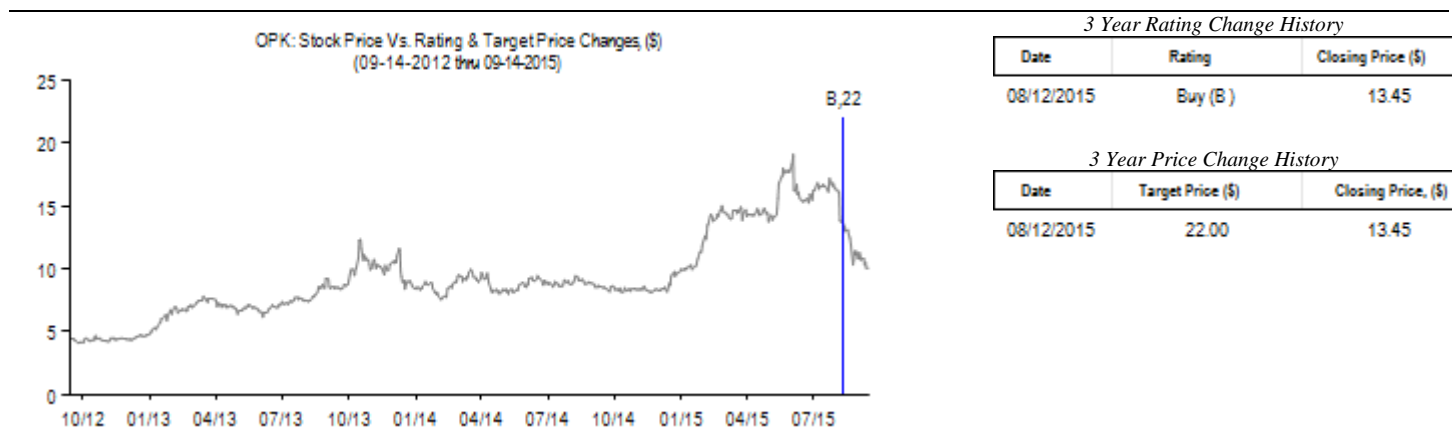
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Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	77.42%	29.03%	6.45%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.23%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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