

OPKO Health, Inc. (OPK - \$ 11.14)

Healthcare/Biotechnology

Category I CPT Code for 4Kscore Test Approved by the AMA Should Accelerate Discussions with Payers

OPKO announced this morning that a Category I CPT code for the 4Kscore test was approved by the Current Procedural Terminology (CPT) Editorial Panel of the American Medical Association (AMA).

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

- Details.** The 4Kscore test already has received a Category III Administrative code earlier in 2015 and the approval of the Category I CPT code could have a significantly positive impact on the current and upcoming reimbursement negotiations with various payers. The current added Multianalyte Assays with Algorithmic Analyses (MAAA) code for the 4Kscore test is 814X1. The code containing "X" indicates it as a placeholder code and the final CPT datafiles would be different and it will be distributed on August 31st of each year. In addition to benefits for reimbursement discussion, criteria of a Category I CPT code would suggest: 1) performance of the test in an appropriately regulated laboratory environment, 2) ordering of the test by many physicians and at a volume consistent with the intended clinical use, 3) demonstration that the use of the test is consistent with current medical guidelines, and 4) published scientific evidence of clinical efficacy.
- Implication.** We view today's news an important positive for the 4Kscore test commercialization given it establishes one of the cornerstones to create a greater acceptance and possibly more favorable reimbursement by payers. Being reimbursed at an appropriate level by multiple payers is critical for a diagnostic test to be used broadly by a large patient population. Coupled with the recently published NCCN guidelines for prostate cancer early detection and the upcoming promotion by BRL sales reps (start in early 2016 with n~100), this complete 4Kscore test package could accelerate buy-in by primary care physicians and patients. OPK indicated during the 3Q15 conference call that greater visibility on the reimbursement front could be available over the next six months. Given OPK's recent comments on the use of the 4Kscore test growing by almost double every month, we anticipate continued growth near term before various payers announce their decision on reimbursement price.
- 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 (11/12/2015)	\$ 11.14
52-Week High (6/3/2015)	\$ 19.20
52-Week Low (11/20/2014)	\$ 8.08
Market Cap. (MM)	\$ 6,071
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

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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 (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	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	****
		Potentially start Phase II/III study	1Q17	***
		Potentially report Phase II/III study results	2Q18	****
MOD-5014 (s.c)		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

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.

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	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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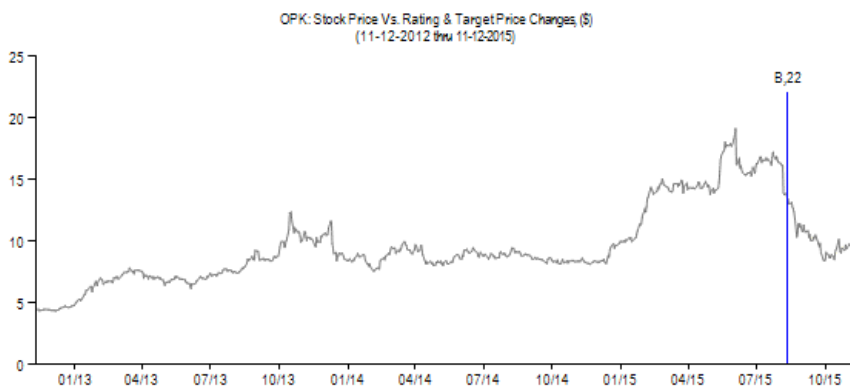
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Rating and Price Target Change History



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

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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%
Buy (B)	Expected to outperform the sector average over 12 months.	71.88%	25.00%	6.25%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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