

## OPKO Health, Inc. (OPK - \$ 9.72)

### Negative Palmetto 4KScore Test LCD Could Be a Headline Risk, While Critical Novitas Decision to Come Possibly in 1Q17

Yesterday, Medicare administrative contractor (MAC) Palmetto published a negative final local coverage decision (LCD) of the 4Kscore test; while we believe a more important reimbursement decision by Novitas could be rendered in 1Q17.

- Details.** After reviewing full dossier for 4Kscore test, Palmetto's MolDX issued a final non-coverage decision for the 4Kscore test because their concerns on the test's assay validation and the absence of clinical utility. For example, Palmetto pointed out issues related to intended use population and modifications of the algorithm. A more materially important LCD by Novitas, which has the jurisdiction of the 4Kscore test facility in Elmwood Park, NJ and with potential Medicare beneficiaries' reimbursements of all 50 states, could be made later, possibly in February 2017.
- Implications.** Although we view Palmetto's non-coverage decision as discouraging as its MolDX division is typically considered more experienced in evaluating novel diagnostic tests, we believe the more materially relevant decision would be Novitas'. Given each MAC makes its own coverage decision independently, we do not believe the negative decision by Palmetto would be concurred with automatically by others; especially since the 4Kscore test has positive supports like NCCN and EAU prostate cancer guidelines, and Category I CPT code by the AMA. Palmetto's decision, however, could have a certain negative impact on reimbursement decisions by commercial payers. Overall, the MAC reimbursement decisions could represent a headline risk for OPK shares given one of the major objectives for the Bio-Reference Lab acquisition is to provide a better platform for 4Kscore test commercialization. The news has pushed one of the major 2H16 catalysts for OPK into 2017; while the other (Rayaldee launch) remains on track. Even under the worse scenario of denial by Novitas, the overall financial impact with a more diminished 4Kscore test sales prospect remains very limited as potential 4Kscore revenues, in our current estimate, only account for a very small portion of the projected diagnostic (~7%) and total revenues (~5%) based on our model of 2019.
- 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.

### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.02A	0.03A	-0.01	-0.02	-0.02	NM
<b>FY-15A</b>	-0.26	-0.09	0.26	0.00	-0.06	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

Source: Laidlaw & Company estimates

### Healthcare/Biotechnology

Ticker:	<b>OPK</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 22.00</b>

### Trading Data:

Last Price (10/07/2016)	\$ 9.72
52-Week High (3/22/2016)	\$ 11.85
52-Week Low (1/20/2016)	\$ 7.12
Market Cap. (MM)	\$ 5,415,050
Shares Out. (MM)	557

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## Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Build M&S organization	2H16	***
		Product launch	4Q16	***
		Potential include in for formulary of healthcare plans	2017	****
		Potential EMEA filing	1H17	***
		Potential EU approval	1H18	****
	SHPT in ESRD patients	Start Phase III study	2017	***
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	Potential approval of the IV version (PDUFA date)	Feb. 11, 2017	****
hGH-CTP (MOD-4023)	hGH deficiency	Report of Phase III study top-line results	4Q16	****
		Potential product approval for adult hGH deficiency	1Q18	***
		Report of Phase III pediatric study top-line results	2018/2019	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	1Q17	****
		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	1Q17	***
		Potentially report Phase I study results	2H17	****
		Potentially start Phase II study	2H17	***
	Potentially report Phase II study results	Mid-18	***	
MOD-6031	Obesity	Potentially report Phase I study top-line results	4Q16	***

\*\*\*\* / \*\*\*\*\* 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)	2013	2014	2015	1Q16	2Q16	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
<b>Revenue</b>												
Products (Pharmaceuticals)	68.2	77.0	80.1	19.9	22.8	25.5	34.2	103.7	213.2	328.5	563.8	729.0
Revenue from services (Diagnostics)	11.7	8.7	329.7	252.5	266.0	285.3	304.9	1,109.8	1,284.4	1,486.2	1,726.8	1,977.7
Revenue from transfer of intellectual property	16.7	5.5	81.9	18.6	68.3	18.0	17.9	122.8	124.0	125.3	126.5	127.8
<b>Total revenue</b>	<b>96.5</b>	<b>91.1</b>	<b>491.7</b>	<b>291.0</b>	<b>357.1</b>	<b>328.8</b>	<b>357.0</b>	<b>1,336.3</b>	<b>1,621.7</b>	<b>1,940.0</b>	<b>2,417.2</b>	<b>2,834.5</b>
Costs of revenues	48.9	48.0	260.0	147.5	153.4	164.9	178.0	643.8	795.8	940.6	1,119.1	1,295.6
Gross Incomes	47.7	43.1	231.7	143.5	203.7	164.0	179.0	692.4	825.8	999.4	1,298.1	1,538.9
Selling, general and administrative	55.3	57.9	196.6	128.0	117.5	129.3	131.8	506.6	534.2	609.4	694.4	791.0
Research and development	53.9	83.6	99.5	27.8	31.3	32.9	34.2	126.3	135.2	141.9	147.6	153.5
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	5.1	1.8	10.8	(2.0)	3.3	13.8	13.8	13.8	13.8	13.8
Amortization of intangible assets	11.1	10.9	28.0	13.4	15.8	15.8	15.8	60.8	60.8	60.8	60.8	60.8
Grant repayment	0.0	0.0	25.9	-	-	-	-	0.0	0.0	0.0	0.0	0.0
<b>Total Operating Expenses</b>	<b>127.3</b>	<b>188.9</b>	<b>355.0</b>	<b>171.0</b>	<b>175.4</b>	<b>176.0</b>	<b>185.2</b>	<b>707.5</b>	<b>744.0</b>	<b>825.9</b>	<b>916.6</b>	<b>1,019.1</b>
Total costs and expenses	176.2	236.9	615.0	318.6	328.8	340.8	363.2	1,351.4	1,539.8	1,766.5	2,035.7	2,314.6
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(27.5)	28.3	(12.0)	(6.2)	(15.1)	81.9	173.5	381.5	519.8
Interest income	0.4	0.8	0.3	0.0	0.1	0.2	0.2	0.6	0.6	0.7	0.8	0.8
Interest expense	(13.8)	(12.3)	(8.4)	(1.8)	(2.2)	(2.7)	(2.7)	(9.4)	(9.4)	(9.4)	(9.4)	(9.4)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	(1.4)	1.2	2.0	(4.0)	(2.2)	(6.0)	(6.0)	(6.0)	(6.0)
Other income (expense), net	34.8	(3.1)	7.7	0.5	6.0	6.0	3.0	15.5	29.0	29.0	29.0	29.0
Total Other Income, net	(24.6)	(25.2)	(39.5)	(2.6)	5.1	5.5	(3.5)	4.5	14.2	14.3	14.4	14.4
<b>Income before tax</b>	<b>(104.2)</b>	<b>(171.0)</b>	<b>(138.0)</b>	<b>(30.2)</b>	<b>33.4</b>	<b>(6.5)</b>	<b>(9.7)</b>	<b>(10.6)</b>	<b>96.1</b>	<b>187.8</b>	<b>395.8</b>	<b>534.2</b>
Tax	(1.7)	(0.0)	113.7	20.5	(15.9)	0.0	0.0	4.6	(35.6)	(69.5)	(146.5)	(197.6)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(9.6)	17.5	(6.5)	(9.7)	(6.0)	60.5	118.3	249.4	336.5
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(2.4)	(2.0)	(0.6)	(0.8)	(5.8)	(3.0)	(3.0)	(3.0)	(3.0)
<b>Net income (loss)</b>	<b>(117.3)</b>	<b>(174.6)</b>	<b>(31.4)</b>	<b>(12.0)</b>	<b>15.5</b>	<b>(7.1)</b>	<b>(10.5)</b>	<b>(11.7)</b>	<b>57.5</b>	<b>115.3</b>	<b>246.4</b>	<b>333.5</b>
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	(0.8)	-	(0.8)	(0.8)	(1.4)	(3.0)	(3.0)	(3.0)	(3.0)
<b>Net Income (Loss) Applicable to Common Shareholders</b>	<b>(114.8)</b>	<b>(171.7)</b>	<b>(30.0)</b>	<b>(12.0)</b>	<b>15.5</b>	<b>(6.3)</b>	<b>(9.7)</b>	<b>(10.3)</b>	<b>60.5</b>	<b>118.3</b>	<b>249.4</b>	<b>336.5</b>
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.32)	(\$0.41)	(\$0.06)	(\$0.02)	\$0.03	(\$0.01)	(\$0.02)	(\$0.02)	\$0.12	\$0.21	\$0.49	\$0.59
Shares outstanding—basic	355.1	422.0	488.1	545.8	547.6	551.6	555.6	550.1	496.1	558.1	504.1	566.1
Shares outstanding—diluted	355.1	422.0	488.1	545.8	557.0	551.6	555.6	552.5	496.1	560.5	504.1	568.5
<b>Margin Analysis (% of Sales/Revenue)</b>												
Costs of goods	61%	56%	63%	54%	53%	53%	52%	53%	53%	52%	49%	48%
Gross margin	39%	44%	37%	46%	47%	47%	48%	47%	47%	48%	51%	52%
R&D	56%	92%	20%	10%	9%	10%	10%	9%	8%	7%	6%	5%
MG&A	57%	64%	40%	44%	33%	39%	37%	38%	33%	31%	29%	28%
Operating Income (loss)	-82%	-160%	-20%	-9%	8%	-4%	-2%	-1%	5%	9%	16%	18%
Net Income	-119%	-188%	-6%	-4%	4%	-2%	-3%	-1%	4%	6%	10%	12%
<b>Financial Indicator Growth Analysis (YoY%)</b>												
Products (Pharmaceuticals)	50%	13%	4%	28%	0%	23%	63%	29%	106%	54%	72%	29%
Revenue from services (Diagnostics)	567%	-26%	3705%	12104%	13842%	175%	37%	237%	16%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	49%	286%	-2%	-46%	50%	1%	1%	1%	1%
Total Revenue	105%	-6%	440%	867%	742%	130%	29%	172%	21%	20%	25%	17%
R&D	176%	55%	19%	9%	6%	74%	34%	27%	7%	5%	4%	4%
SG&A	99%	5%	239%	634%	461%	134%	28%	158%	9%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-52%	-211%	46%	-22%	-85%	-642%	112%	120%	36%
Total Other Income, net	-15001%	3%	57%	-95%	-131%	-88%	-78%	-111%	216%	0%	0%	0%
Net Income	267%	49%	-82%	-90%	-136%	-105%	-707%	-66%	-685%	95%	111%	35%
EPS	206%	26%	-85%	-92%	-130%	-104%	-700%	-69%	-749%	74%	133%	20%

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

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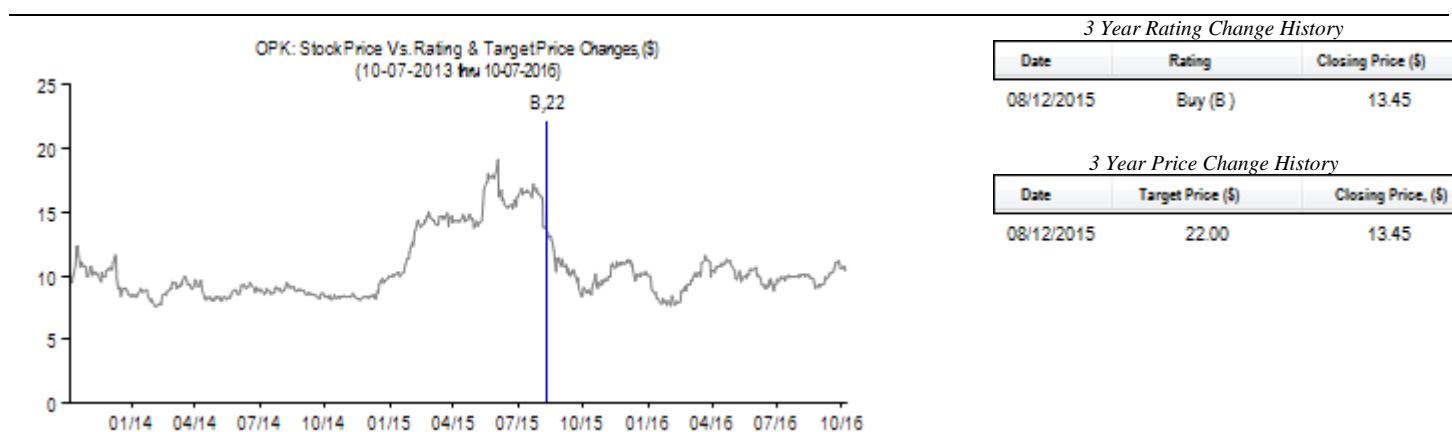
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