

## OPKO Health, Inc. (OPK - \$ 10.25)

### Royaldee CRL Is Just a Small Speed Bump for Approval and the Drug's Fundamentals Remain Intact

This morning, OPK announced that the FDA has issued a complete response letter (CRL) to the NDA filing of Royaldee in secondary hyperparathyroidism (SHPT) in patients with stage 3/4 CKD and vitamin D insufficiency. The only issue cited on the CRL relates to third-party (Catalent Pharma Solutions) manufacturing observations of deficiencies, which were not specific to Royaldee production.

- Details.** The CRL did not request for additional clinical studies prior to FDA approval and also did not cite any safety, efficacy or labeling issues. Further, the agency and OPK have reached an agreement for Royaldee's potentially approvable package insert and labeling. The FDA inspection was initiated on March 14 and Catalent received the feedback from the FDA on March 25. OPK indicated that Catalent would likely submit an action plan to ameliorate the problem by or before April 15; and after receiving the feedback from the agency, OPK will resubmit the NDA for approval. Depending on whether a plant re-inspection by the FDA is needed, the time required for the approval could be either two months (Class I resubmission) or six months (Class II resubmission). OPK will likely provide greater visibility on the route for potential approval when they resubmit the NDA. Despite slight delay of product launch, OPK indicated that the overall resource allocation and activities for commercialization will not be changed materially.
- Implications.** Although we are slightly disappointed on the minor delay of a likely approval and product launch, we do not believe the fundamental of the Royaldee outlook has been altered. Given that the observations of deficiencies cited by the CRL are seemingly more routine in nature and could be resolved rather quickly, we estimate potential Royaldee approval could slate to 3Q16 (under Class I) or 4Q16 (under Class II). Another takeaway of the CRL is that the regulatory approval risks for Royaldee, which are a major overhang for OPK shares, have been significantly diminished. This is based on the fact that an additional Phase III study is not required for approval, the accepted safety profile of the drug and that an agreement of approvable package insert and container labeling was reached.
- 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, Royaldee, VARUBI (rolapitant) and hGH-CTP (MOD-4023). Our valuation is based on our DCF analyses.

*Healthcare/Biotechnology*

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

#### Trading Data:

Last Price (03/30/2016)	\$ 10.25
52-Week High (6/3/2015)	\$ 19.20
52-Week Low (1/20/2016)	\$ 7.12
Market Cap. (MM)	\$ 5,568
Shares Out. (MM)	546

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.07	-0.04	-0.03	-0.05	-0.20	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

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Source: Laidlaw & Company estimates

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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	***
		NDA resubmission	2Q16	***
		Potential FDA approval	2Q or 3Q16	****
		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	***	
MOD-6031	Obesity	Potentially report Phase I study top-line results	2H16	
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.

## 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					2016E	2017E	2018E	2019E	2020E
				1Q16E	2Q16E	3Q16E	4Q16E					
<b>Revenue</b>												
Products (Pharmaceuticals)	68.2	77.0	80.1	21.9	23.7	25.5	34.2	105.4	215.3	331.0	566.8	732.5
Revenue from services (Diagnostics)	11.7	8.7	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	81.9	16.7	16.0	17.0	17.9	67.6	68.3	69.0	69.6	70.3
<b>Total revenue</b>	<b>96.5</b>	<b>91.1</b>	<b>491.7</b>	<b>254.1</b>	<b>266.8</b>	<b>275.2</b>	<b>292.1</b>	<b>1,088.2</b>	<b>1,346.5</b>	<b>1,634.5</b>	<b>2,077.4</b>	<b>2,455.8</b>
Costs of revenues	48.9	48.0	260.0	128.9	136.3	140.5	147.3	553.1	676.0	804.6	964.6	1,120.1
<b>Gross Incomes</b>	<b>47.7</b>	<b>43.1</b>	<b>231.7</b>	<b>125.2</b>	<b>130.5</b>	<b>134.6</b>	<b>144.8</b>	<b>535.2</b>	<b>670.5</b>	<b>830.0</b>	<b>1,112.8</b>	<b>1,335.6</b>
Selling, general and administrative	55.3	57.9	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	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	5.1	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	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	-	-	-	-	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>153.3</b>	<b>159.0</b>	<b>156.7</b>	<b>165.5</b>	<b>634.3</b>	<b>719.2</b>	<b>800.5</b>	<b>890.8</b>	<b>992.7</b>
Total costs and expenses	176.2	236.9	615.0	282.1	295.3	297.2	312.8	1,187.4	1,395.2	1,605.1	1,855.3	2,112.8
<b>Operating Incomes (losses)</b>	<b>(79.6)</b>	<b>(145.8)</b>	<b>(98.5)</b>	<b>(28.1)</b>	<b>(28.4)</b>	<b>(22.0)</b>	<b>(20.7)</b>	<b>(99.2)</b>	<b>(48.7)</b>	<b>29.5</b>	<b>222.0</b>	<b>342.9</b>
Interest income	0.4	0.8	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)	(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)	(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)	7.7	6.0	8.0	6.0	(1.0)	19.0	29.0	29.0	29.0	29.0
<b>Total Other Income, net</b>	<b>(24.6)</b>	<b>(25.2)</b>	<b>(39.5)</b>	<b>(11.5)</b>	<b>4.5</b>	<b>5.5</b>	<b>(7.5)</b>	<b>(9.0)</b>	<b>13.1</b>	<b>13.2</b>	<b>13.3</b>	<b>13.3</b>
<b>Income before tax</b>	<b>(104.2)</b>	<b>(171.0)</b>	<b>(138.0)</b>	<b>(39.6)</b>	<b>(23.9)</b>	<b>(16.5)</b>	<b>(28.2)</b>	<b>(108.2)</b>	<b>(35.6)</b>	<b>42.6</b>	<b>235.3</b>	<b>356.2</b>
Tax	(1.7)	(0.0)	113.7	0.0	0.0	0.0	0.0	0.0	0.0	(15.8)	(87.1)	(131.8)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(39.6)	(23.9)	(16.5)	(28.2)	(108.2)	(35.6)	26.9	148.2	224.4
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(0.9)	(0.7)	(0.6)	(0.8)	(3.0)	(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>(40.5)</b>	<b>(24.6)</b>	<b>(17.1)</b>	<b>(29.0)</b>	<b>(111.2)</b>	<b>(38.6)</b>	<b>23.9</b>	<b>145.2</b>	<b>221.4</b>
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	(0.8)	(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>(39.7)</b>	<b>(23.9)</b>	<b>(16.3)</b>	<b>(28.2)</b>	<b>(109.8)</b>	<b>(35.6)</b>	<b>26.9</b>	<b>148.2</b>	<b>224.4</b>
<b>Net Earnings (Losses) Per Share—Basic and Diluted</b>	<b>(\$0.32)</b>	<b>(\$0.41)</b>	<b>(\$0.06)</b>	<b>(\$0.07)</b>	<b>(\$0.04)</b>	<b>(\$0.03)</b>	<b>(\$0.05)</b>	<b>(\$0.20)</b>	<b>(\$0.07)</b>	<b>\$0.05</b>	<b>\$0.29</b>	<b>\$0.39</b>
Shares outstanding—basic	355.1	422.0	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	488.1	551.7	555.7	559.7	563.7	557.7	496.1	565.7	504.1	573.7
<b>Margin Analysis (% of Sales/Revenue)</b>												
Costs of goods	61%	56%	63%	54%	54%	54%	54%	54%	53%	51%	48%	47%
Gross margin	39%	44%	37%	46%	46%	46%	46%	46%	47%	49%	52%	53%
R&D	56%	92%	20%	10%	11%	11%	11%	11%	9%	8%	7%	6%
MG&A	57%	64%	40%	43%	43%	42%	40%	42%	40%	37%	33%	32%
Operating Income (loss)	-82%	-160%	-20%	-11%	-11%	-8%	-7%	-9%	-4%	2%	11%	14%
Net Income	-119%	-188%	-6%	-16%	-9%	-6%	-10%	-10%	-3%	2%	7%	9%
<b>Financial Indicator Growth Analysis (YoY%)</b>												
Products (Pharmaceuticals)	50%	13%	4%	42%	4%	23%	63%	31%	104%	54%	71%	29%
Revenue from services (Diagnostics)	567%	-26%	3705%	10313%	11805%	124%	8%	178%	16%	16%	17%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	33%	-9%	-7%	-46%	-17%	1%	1%	1%	1%
Total Revenue	105%	-6%	440%	745%	529%	92%	6%	121%	24%	21%	27%	18%
R&D	176%	55%	19%	4%	-4%	57%	22%	16%	7%	5%	4%	4%
SG&A	99%	5%	239%	529%	443%	110%	15%	133%	9%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-51%	12%	168%	162%	1%	-51%	-160%	654%	54%
Total Other Income, net	-15001%	3%	57%	-79%	-127%	-88%	-53%	-77%	-245%	1%	1%	0%
Net Income	267%	49%	-82%	-66%	-44%	-113%	-1868%	265%	-68%	-175%	452%	51%
EPS	206%	26%	-85%	-73%	-54%	-111%	-1821%	220%	-64%	-166%	520%	33%

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

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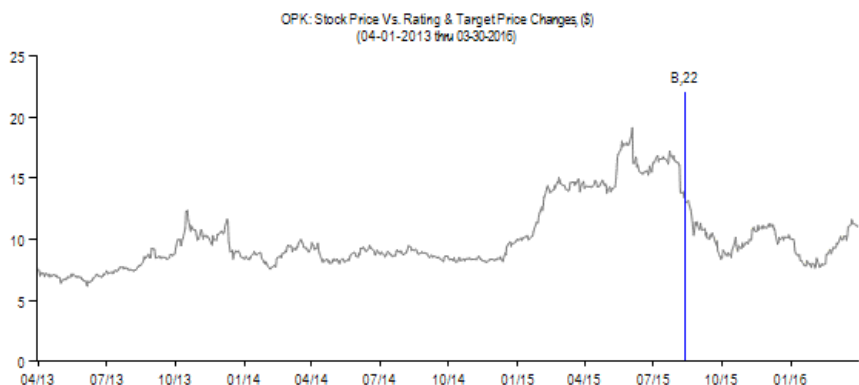
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*Additional information available upon request.*

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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

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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.	65.71%	25.71%	2.86%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	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%

### ADDITIONAL COMPANIES MENTIONED

Catalent Inc. (CTLT – NYSE; Not Rated)

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