

## OPKO Health (OPK - \$3.18)

### 4Q17: A Very Challenging Quarter with Near-term Focus on BR Turnaround

OPK reported 4Q17 financial results yesterday after the market close with a loss of (\$214MM) vs. the estimates of (\$43MM) for Laidlaw and (\$52MM) for the Street. Loss per share was (\$0.38) vs. (\$0.08) for Laidlaw and the Street. OPK ended 2017 with cash of \$91.5MM and with additional \$55MM from a February 2018 private placement.

- **A tough quarter for Bio-Reference (BR) and overall OPK operations.** BR 4Q17 revenue of \$148MM was the lowest since being acquired by OPK, including \$73.3MM of revenue adjustments from uncollected claims. Accordingly, OPK will readjust the BR revenue in 2017, such as changing 1Q17 sales to \$228MM from \$255MM. OPK guided that 1Q18 would have a possible 3% business volume reduction, and sales of \$195MM-\$215MM. In addition, BR is currently seeking its next president, and we believe the decision could be made in 1H18. In 4Q17, OPK also took an income tax provision charge of \$61MM that further worsened the quarterly losses. Further, TSRO's discontinuation of the IV Varubi, not only added a noncash \$13.2MM impairment, but also eliminates a modest revenue stream for OPK going forward. If not considering the three one-time non-recurring items, OPK 4Q17 performance is slightly below our and Street estimates. Rayaldee sales in 4Q17 were \$9.1MM, including \$6.2MM deferred revenue, and OPK guided 1Q18 sales of \$3.5-\$5.0MM. Given the selling effort has started to take hold, we estimate 2018 Rayaldee sales could grow more steadily. Although the effects of the DTC campaign of 4Kscore test remain too early to assess, we project sales could gradually improve.
- **Pipeline product clinical trial updates:** 1) Future development of the Factor VII-CTP program will be on hold pending on further assessment of its commercial outlook; 2) The hGH-CTP in pediatric GHD global and Japan Phase III studies are underway and we anticipate patient recruitment could complete in late 2018 with top-line results available in 1H20. We believe there is still limited visibility of the clinical path for hGH-CTP in adult GHD; and 3) The OPK88004 (oral selective androgen receptor modulator or SARM) in BPH Phase IIb (n=125) dose ranging study is ongoing with topline readout possibly in late 2018 or early 2019.
- **Action.** We are reiterating our Buy rating and \$19 target price to reflect our bullish view on progress in OPK's multiple drivers in place, especially the Rayaldee 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-18E</b>	-0.13	-0.14	-0.15	-0.13	-0.55	NM
<b>FY-17A</b>	-0.06	-0.03	-0.08	-0.38	-0.55	NM
<b>FY-16A</b>	-0.02	0.03	-0.03	-0.02	-0.05	NM
<b>FY-15A</b>	-0.26	-0.09	0.26	0.00	-0.06	NM

Source: Laidlaw & Company estimates

#### Healthcare/Biotechnology

Ticker:	<b>OPK</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$19.00</b>

#### Trading Data:

Last Price (3/1/2018)	\$3.18
52-Week High (3/14/2017)	\$8.54
52-Week Low (3/2/2018)	\$2.66
Market Cap. (MM)	\$1,695
Shares Out. (MM)	561.636

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**Table 1: Estimated and reported 4Q17 results**

<b>4Q17 Estimates and Reported Results</b>			
<b>(\$ MM)</b>	<b>Laidlaw Estimate</b>	<b>Actual</b>	<b>Consensus</b>
<b>Total revenue</b>	<b>\$311.4</b>	<b>\$193.7</b>	<b>\$301.5</b>
<b>Total op. profit (loss)</b>	<b>(\$43.6)</b>	<b>(\$153.6)</b>	<b>(\$47.5)</b>
R&D	\$33.9	\$34.2	
SG&A	\$134.0	\$124.6	
<b>EPS</b>	<b>(\$0.08)</b>	<b>(\$0.38)</b>	<b>(\$0.08)</b>
Net income (loss)	(\$42.9)	(\$213.9)	(\$52.2)

Source: Bloomberg, SEC filings and Laidlaw and Co.

## Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Potential include in for formulary of healthcare plans	2018	****
		Potential EU approval	1H18	****
	SHPT in ESRD patients	Start Phase II study	2Q18	***
hGH-CTP (MOD-4023)	hGH deficiency	FDA feedback and additional adult GHD Phase III data analysis	2018	***
		Potential file BLA for adult GHD	2018	****
		Potentially report of ACP-001 pediatric Phase III study top-line results by Ascendis	1H19	***
		Report of Phase III pediatric study top-line results	1H20	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	2018	****
		Potential more private payer reimbursement decision	2018	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	1Q18	***
		Potential approval	2018	****
Claros 1 PSA test	POC PSA test	Potential approval	2H18	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	2018	****
		Potential approval	2018	****
BioReference Laboratories		Hiring a new president	1H18	***
NK-1 inhibitor (OPK88002)	Pruritus	Potentially start Phase IIa study	1Q18	***
OPK88003	Obesity	Start Phase IIb study	2Q18	***
OPK88004	Benign prostate hypertrophy	Potentially report Phase II study results	4Q18/early 2019	****
OPK88001	Dravet Syndrome	Potentially start Phase I/II trial	1H18	***

\*\*\*\* / \*\*\*\*\* 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	2016	1Q17	2Q17	3Q17	4Q17	2017	1Q18E	2Q18E	3Q18E	4Q18E	2018E	2019E	2020E
<b>Revenue</b>																
Products (Pharmaceuticals)	68.2	77.0	80.1	83.5	22.2	29.0	22.8	33.8	107.8	26.8	28.0	28.7	32.7	116.2	248.6	328.5
Revenue from services (Diagnostics)	11.7	8.7	329.7	1,012.1	255.3	256.7	229.0	148.1	889.1	205.0	207.8	208.6	210.5	831.9	945.3	1,076.2
Revenue from transfer of intellectual property	16.7	5.5	81.9	126.0	18.6	28.5	11.7	11.8	70.6	11.0	12.0	13.0	11.7	47.7	48.2	48.7
<b>Total revenue</b>	<b>96.5</b>	<b>91.1</b>	<b>491.9</b>	<b>1,221.7</b>	<b>296.1</b>	<b>314.2</b>	<b>263.5</b>	<b>193.7</b>	<b>1,067.5</b>	<b>242.8</b>	<b>247.9</b>	<b>250.2</b>	<b>254.8</b>	<b>995.7</b>	<b>1,242.0</b>	<b>1,453.4</b>
Costs of revenues	48.9	48.0	260.0	611.4	154.8	157.4	151.3	156.6	620.1	133.1	132.9	131.9	133.9	531.8	590.1	676.5
<b>Gross Incomes</b>	<b>47.7</b>	<b>43.1</b>	<b>231.9</b>	<b>610.2</b>	<b>141.3</b>	<b>156.8</b>	<b>112.2</b>	<b>37.1</b>	<b>447.4</b>	<b>109.8</b>	<b>115.0</b>	<b>118.3</b>	<b>120.9</b>	<b>464.0</b>	<b>652.0</b>	<b>776.9</b>
Selling, general and administrative	55.3	57.9	196.6	490.9	136.7	128.3	131.4	124.6	521.0	128.3	130.9	133.5	136.2	529.0	653.1	744.9
Research and development	53.9	83.6	99.5	111.2	26.0	32.6	32.3	34.2	125.1	34.9	35.9	36.8	37.7	145.3	151.1	157.2
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	17.0	2.4	4.4	(11.2)	1.1	(3.3)	2.5	2.3	2.7	4.0	11.5	11.5	11.5
Amortization of intangible assets	11.1	10.9	28.0	64.4	17.9	18.0	18.0	30.8	84.7	18.0	18.0	18.0	18.0	72.0	72.0	72.0
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>683.5</b>	<b>183.0</b>	<b>183.3</b>	<b>170.5</b>	<b>190.7</b>	<b>727.5</b>	<b>183.7</b>	<b>187.1</b>	<b>191.0</b>	<b>195.9</b>	<b>757.8</b>	<b>887.7</b>	<b>985.6</b>
Total costs and expenses	176.2	236.9	615.0	1,294.9	337.8	340.7	321.8	347.3	1,347.6	316.8	320.0	322.9	329.8	1,289.5	1,477.8	1,662.1
<b>Operating Incomes (losses)</b>	<b>(79.6)</b>	<b>(145.8)</b>	<b>(98.5)</b>	<b>(73.3)</b>	<b>(41.7)</b>	<b>(26.5)</b>	<b>(58.3)</b>	<b>(153.6)</b>	<b>(280.1)</b>	<b>(74.0)</b>	<b>(72.2)</b>	<b>(72.7)</b>	<b>(75.0)</b>	<b>(293.8)</b>	<b>(235.7)</b>	<b>(208.7)</b>
Total Other Income, net	(24.6)	(25.2)	(39.5)	(0.3)	5.9	3.6	(8.5)	3.6	3.6	4.6	(2.5)	(6.5)	5.4	1.0	1.0	1.0
<b>Income before tax</b>	<b>(104.2)</b>	<b>(171.0)</b>	<b>(138.0)</b>	<b>(73.5)</b>	<b>(35.8)</b>	<b>(22.9)</b>	<b>(66.8)</b>	<b>(150.0)</b>	<b>(276.5)</b>	<b>(69.4)</b>	<b>(74.7)</b>	<b>(79.2)</b>	<b>(69.6)</b>	<b>(292.8)</b>	<b>(234.7)</b>	<b>(207.6)</b>
Tax	(1.7)	(0.0)	113.7	56.1	6.9	11.0	24.4	(61.2)	(18.9)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Loss before investment losses	(105.9)	(171.1)	(24.3)	(17.4)	(28.9)	(11.9)	(42.4)	(211.2)	(294.4)	(69.4)	(74.7)	(79.2)	(69.6)	(292.8)	(234.7)	(207.6)
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(7.7)	(2.1)	(5.6)	(4.0)	(2.7)	(14.4)	(3.0)	(4.0)	(3.7)	(4.2)	(14.9)	(3.0)	(3.0)
<b>Net income (loss)</b>	<b>(117.3)</b>	<b>(174.6)</b>	<b>(31.4)</b>	<b>(25.1)</b>	<b>(31.0)</b>	<b>(17.5)</b>	<b>(46.4)</b>	<b>(213.9)</b>	<b>(308.8)</b>	<b>(72.4)</b>	<b>(78.7)</b>	<b>(82.9)</b>	<b>(73.8)</b>	<b>(307.7)</b>	<b>(237.7)</b>	<b>(210.6)</b>
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	0.0	-	-	-	-	0.0	0.0	-	-	-	0.0	0.0	0.0
<b>Net Income (Loss) Applicable to Common Shareholders</b>	<b>(114.8)</b>	<b>(171.7)</b>	<b>(30.0)</b>	<b>(25.1)</b>	<b>(31.0)</b>	<b>(17.5)</b>	<b>(46.4)</b>	<b>(213.9)</b>	<b>(308.8)</b>	<b>(72.4)</b>	<b>(78.7)</b>	<b>(82.9)</b>	<b>(73.8)</b>	<b>(307.7)</b>	<b>(237.7)</b>	<b>(210.6)</b>
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.32)	(\$0.41)	(\$0.06)	(\$0.05)	(\$0.06)	(\$0.03)	(\$0.08)	(\$0.38)	(\$0.55)	(\$0.13)	(\$0.14)	(\$0.15)	(\$0.13)	(\$0.55)	(\$0.42)	(\$0.37)
Shares outstanding—basic	355.1	422.0	488.1	550.8	550.0	559.3	559.4	563.4	558.0	563.5	563.6	563.7	563.8	563.7	566.0	571.7
Shares outstanding—diluted	355.1	422.0	488.1	550.8	550.0	564.2	559.4	563.4	559.2	563.5	563.6	563.7	563.8	563.7	567.2	571.7
<b>Margin Analysis (% of Sales/Revenue)</b>																
Costs of goods	61%	56%	63%	56%	56%	55%	60%	86%	62%	57%	56%	56%	55%	56%	49%	48%
Gross margin	39%	44%	37%	44%	44%	45%	40%	14%	38%	43%	44%	44%	45%	44%	51%	52%
R&D	56%	92%	20%	9%	9%	10%	12%	18%	12%	14%	14%	15%	15%	15%	12%	11%
MG&A	57%	64%	40%	40%	46%	41%	50%	64%	49%	53%	53%	53%	53%	53%	53%	51%
Operating Income (loss)	-82%	-160%	-20%	-6%	-14%	-8%	-22%	-79%	-26%	-30%	-29%	-29%	-29%	-30%	-19%	-14%
Net Income	-119%	-188%	-6%	-2%	-10%	-6%	-18%	-110%	-29%	-30%	-32%	-33%	-29%	-31%	-19%	-14%
<b>Financial Indicator Growth Analysis (YoY%)</b>																
Products (Pharmaceuticals)	50%	13%	4%	4%	12%	27%	11%	67%	29%	21%	-3%	26%	-3%	8%	114%	32%
Revenue from services (Diagnostics)	567%	-26%	3705%	207%	1%	-4%	-12%	-37%	-12%	-20%	-19%	-9%	42%	-6%	14%	14%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	54%	0%	-58%	-37%	-43%	-44%	-41%	-58%	11%	-1%	-32%	1%	1%
Total Revenue	105%	-6%	440%	148%	2%	-12%	-12%	-30%	-13%	-18%	-21%	-5%	32%	-7%	25%	17%
R&D	176%	55%	19%	12%	37%	4%	32%	24%	13%	43%	10%	14%	10%	16%	4%	4%
SG&A	99%	5%	239%	150%	7%	9%	5%	3%	6%	-6%	2%	2%	9%	2%	9%	8%
Operating income (loss)	114%	83%	-32%	-26%	51%	-194%	147%	205%	282%	77%	172%	25%	-51%	5%	-20%	-11%
Total Other Income, net	-15001%	3%	57%	-99%	-325%	-30%	-19%	-54%	-1427%	-22%	-169%	-24%	50%	-72%	4%	0%
Net Income	267%	49%	-82%	-16%	158%	-213%	210%	1468%	1130%	133%	350%	78%	-65%	0%	-23%	-11%
EPS	206%	26%	-85%	-26%	156%	-210%	206%	1578%	1114%	128%	346%	77%	-66%	-1%	-23%	-12%

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

## DISCLOSURES:

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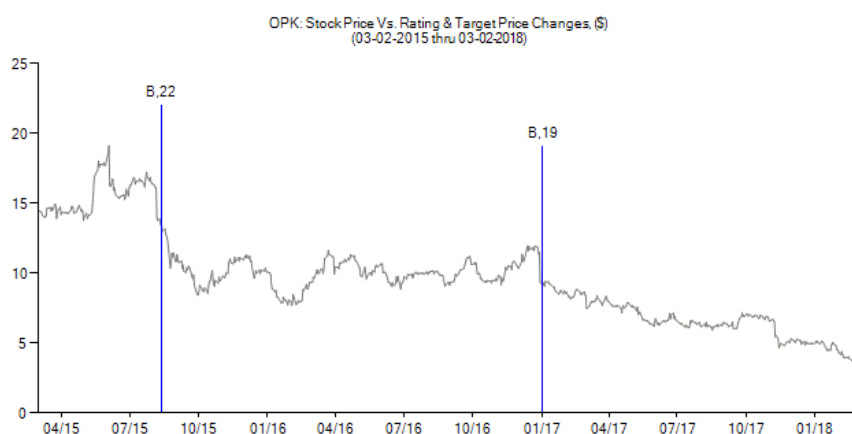
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*Additional information available upon request.*

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#### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
08/12/...	Buy (B)	13.45

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
08/12/...	22.00	13.45
01/03/...	19.00	9.09

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.	65.38%	26.92%	3.85%
<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%

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Tesaro (TSRO – Not Rated)

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