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EQUITY RESEARCH
Company Report

March 2, 2017

OPKO Health (OPK - $8.39)

Healthcare/Biotechnology

4Q16: Multiple Drugs in Development with Greater Visibility on Revenue Growth Particular to Certain Products Later in 2017

Ticker:	**OPK**
Rating:	**Buy**
Price Target:	**$19.00**

OPK reported 4Q16 financial results yesterday after the market close with a loss of ($13.6MM) vs. the estimates of ($19.4MM) for Laidlaw and ($12.2MM) for the Street. Loss per share was ($0.02) vs. ($0.03) for Laidlaw and ($0.04) for the Street. OPK ended 4Q16 with cash of ~$169MM.

- **Rayaldee launch and coverage status updates.** Since the November launch, Rayaldee has already obtained formulary access covering ~60% of U.S. eligible patients, of which ~50% don't need prior authorization. OPK expects to increase coverage to 75-80% by year end 2017. Although the initial Rayaldee TRx were not robust, management believes it remains in the early stage of launch; and that Rayaldee is substantially different from other existing treatments and might need more education for physicians. Additionally, updated guidance from the Kidney Disease Improving Global Outcomes (KDIGO), possibly available in 2Q17, may suggest that the current treatments are either ineffective (nutritional vitamin) or have risk of increased calcification (vitamin D receptor activators or VDRAs). We believe such evidence-based information could potentially help the buy-in by doctors. Together, we anticipate more visibility on Rayaldee sales and its future trajectory in 2H17. Additionally, OPK indicated the net price of Rayaldee is ~$550 per low dose unit, which is between 55% to 65% of the WAC of $920 (the long-term price is likely on the lower end of the price range).
- **4Kscore test reimbursement updates.** OPK indicated that the local coverage decision (LCD) for Medicare reimbursement by Novitas is still being processed, while the majority of 4Kscore tests performed continue to be reimbursed for by Novitas. Approx. 18,000 4Kscore tests were performed in 4Q16 (12% Q/Q), which is a modest increase. With level 1 CPT code and CMS pricing established, OPK is working with additional commercial payers to potentially obtain coverage and favorable pricing for reimbursement. In our opinion, adding more commercial payers for reimbursement will be a significant factor to grow 4Kscore test revenue.
- **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 4Kscore test, Rayaldee, VARUBI (rolapitant) and hGH-CTP (MOD-4023). Our valuation is based on our DCF analyses.

Trading Data:

Last Price (3/1/2017)	$8.39
52–Week High (12/15/2016)	$12.15
52–Week Low (2/8/2017)	$7.99
Market Cap. (MM)	$4,672
Shares Out. (MM)	502

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.02	-0.02	-0.02	-0.01	-0.08	NM
FY-16A	-0.02	0.03	-0.03	-0.02	-0.05	NM
FY-15A	-0.26	-0.09	0.26	0.00	-0.06	NM
FY-14A	-0.11	-0.06	-0.11	-0.12	-0.41	NM

Source: Laidlaw & Company estimates

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- **Claros POC tests updates.** For the Claros point of care (POC) PSA test, the clinical study is underway and OPK remains on track to submit the PMA filing in 1H17 with the potential for approval in 2018. Additionally, OPK intends to commence a study of Claros 1 testosterone test in 2017 with 510(k) filing shortly thereafter, which could potentially gain approval in 2018. Further, management indicated a revamp Bio-Reference's billing system in Oct. 2016 which could potentially improve its financial performance going forward.

- **hGH-CTP and Factor VIIa-CTP development updates.** For hGH-CTP (MOD-4023) in adult GHD development, OPK indicated that a statistical outlier analysis of the Phase III data is underway, and Pfizer is preparing a potential BLA resubmission. We estimate this could occur before year-end 2017. The hGH-CTP in pediatric GHD Phase III study is underway and we anticipate top-line results could be available 1H19. Factor VIIa-CTP (IV) in hemophilic A/B patients with inhibitors to FVIII or FIX Phase IIa study is completing and we estimate safety data could be available in 1H17, potentially with more details in 2H17. The Phase I study of subcutaneous (s.c.) FVIIa-CTP is underway with top-line results potentially available in 2H17. OPK intends to develop both formulations with the IV product intended for on-demand treatment (surgery and rescue) and the s.c. product intended for prophylactic use. Following the s.c. FVIIa-CTP Phase I study, we anticipate OPK could meet with the FDA in 2H17 to determine the subsequent development pathway. Should the company advance to Phase II/III trials in 2018, and should these trials be positive, we estimate product launch could occur in 2021.

- **Three Phase II clinical trial initiations over the next 12 months.** In addition to current development, OPK plans to start three Phase II clinical trials in 2H17 and 1Q18. Together with Vifor Fresenius, OPK plans to commence a Phase II study of Rayaldee for ESRD patients with SHPT undergoing dialysis in 2H17. In addition, TT701 (oral SARM) in benign prostate hypertrophy (BPH) Phase IIb dose-ranging trial could start in 2H17. A stepwise dose increasing TT401 (oxyntomodulin dual GLP1/Glucagon agonist) in type II diabetes and obesity Phase IIb study is planned to start in early 2018. Obesity could be the major focus. Lastly, A Phase IIa trial that evaluates NK-1 inhibitor in treating pruritus (itching), which is common in CKD patients, would be commenced in 2017 in collaboration with Fresenius.

Table 1: Estimated and reported 4Q16 results

4Q16 Estimates and Reported Results			
($ MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$315.7**	**$275.5**	**$310.8**
Total op. profit (loss)	**($15.1)**	**($50.4)**	**($24.9)**
R&D	$25.4	$27.6	
SG&A	$127.3	$120.5	
EPS	**($0.03)**	**($0.02)**	**($0.04)**
Net income (loss)	($19.4)	($13.6)	($12.2)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Potential include in for formulary of healthcare plans	**2017/2018**	****
		Potential EMEA filing	**1H17**	***
		Potential EU approval	**1H18**	****
	SHPT in ESRD patients	Start Phase III study	**2H17**	***
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	Potential approval of the IV version	**2H17**	****
hGH-CTP (MOD-4023)	hGH deficiency	FDA feedback and additional adult GHD Phase III data analysis	**2017**	***
		Report of Versartis' Somavaratan in pediatric GHD Phase III study top-line results	**3Q17**	***
		Potential file BLA for adult GHD	**2H17**	****
		Report of Phase III pediatric study top-line results	**1H19**	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	**2017**	****
		Potential private payer reimbursement decision	**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	**1H17**	***
		Potential approval	**2018**	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	**1H17**	****
		Potential approval	**2018**	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study tinterim results	**1H17**	***
		Potentially report Phase I/IIa study top-line results	**2H17**	****
		Potentially start Phase II/III study	**2018**	***
		Potentially report Phase II/III study results	**2020**	****
MOD-5014 (s.c)		Potentially report Phase I study results	**2H17**	****
		Potentially start Phase II/III study	**2018**	***
		Potentially report Phase II/III study results	**2020**	***
NK-1 inhibitor	Pruritus	Potentially start Phase IIa study	**2017**	***
MOD-6031	Obesity	Potentially report Phase I study top-line results	**1Q17**	***
TT401	Obesity	Start Phase IIb study	**1Q18**	***
TT701	Benign prostate hypertrophy	Start Phase II study	**Mid-2017**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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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.

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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.

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Figure 1: Income Statement

OPKO Health – Income Statement

($'MM)	2013	2014	2015	1Q16	2Q16	3Q16	4Q16	2016	1Q17E	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E
Revenue																
Products (Pharmaceuticals)	68.2	77.0	80.1	19.9	22.8	20.6	20.2	83.5	26.1	31.6	34.9	50.3	142.9	237.8	407.0	520.4
Revenue from services (Diagnostics)	11.7	8.7	329.7	252.5	266.0	259.0	234.6	1,012.1	246.1	264.4	278.0	270.7	1,059.1	1,231.0	1,425.9	1,645.1
Revenue from transfer of intellectual property	16.7	5.5	81.9	18.6	68.3	18.4	20.7	126.0	19.5	21.0	17.5	26.9	84.9	85.7	86.6	87.4
Total revenue	96.5	91.1	491.9	291.0	357.1	298.0	275.5	1,221.7	291.6	317.0	330.4	347.8	1,286.9	1,554.5	1,919.5	2,252.9
Costs of revenues	48.9	48.0	260.0	147.5	153.4	151.2	159.3	611.4	149.4	161.8	168.7	168.4	648.2	781.8	921.9	1,078.1
Gross Incomes	47.7	43.1	231.9	143.5	203.7	146.9	116.2	610.2	142.2	155.3	161.7	179.5	638.6	772.7	997.6	1,174.8
Selling, general and administrative	55.3	57.9	196.6	128.0	117.5	124.8	120.5	490.9	121.7	124.1	125.3	127.8	498.9	599.0	682.9	778.1
Research and development	53.9	83.6	99.5	27.8	31.3	24.4	27.6	111.2	26.9	30.1	35.2	37.0	129.1	135.6	141.0	146.6
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	3.1	1.4	17.0	3.3	3.4	1.9	1.8	10.4	10.4	10.4	10.4
Amortization of intangible assets	11.1	10.9	28.0	13.4	15.8	18.1	17.1	64.4	16.0	19.0	18.0	19.0	72.0	72.0	72.0	72.0
Grant repayment	0.0	0.0	25.9	-	-	-	-	0.0	-	-	-	-	0.0	0.0	0.0	0.0
Total Operating Expenses	127.3	188.9	355.0	171.0	175.4	170.5	166.6	683.5	167.9	176.6	180.4	185.5	710.4	817.0	906.3	1,007.2
Total costs and expenses	176.2	236.9	615.0	318.6	328.8	321.7	325.9	1,294.9	317.3	338.4	349.1	353.9	1,358.6	1,598.8	1,828.2	2,085.3
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(27.5)	28.3	(23.6)	(50.4)	(73.3)	(25.6)	(21.4)	(18.7)	(6.1)	(71.7)	(44.3)	91.3	167.7
Interest income	0.4	0.8	0.3	0.0	0.1	0.2	0.1	0.5	0.1	0.1	0.1	0.1	0.6	0.6	0.7	0.7
Interest expense	(13.8)	(12.3)	(8.4)	(1.8)	(2.2)	(2.0)	(1.4)	(7.4)	(2.3)	(2.3)	(2.3)	(2.3)	(9.2)	(9.2)	(9.2)	(9.2)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	(1.4)	1.2	(5.7)	8.7	2.8	(1.7)	3.0	(4.4)	1.8	(1.3)	(1.3)	(1.3)	(1.3)
Other income (expense), net	34.8	(3.1)	7.7	0.5	6.0	(3.0)	0.4	3.9	0.6	1.5	(4.5)	3.0	0.6	0.6	0.6	0.6
Total Other Income, net	(24.6)	(25.2)	(39.5)	(2.6)	5.1	(10.5)	7.8	(0.3)	(3.3)	2.3	(11.1)	2.6	(9.3)	(9.3)	(9.2)	(9.2)
Income before tax	(104.2)	(171.0)	(138.0)	(30.2)	33.4	(34.2)	(42.6)	(73.5)	(28.9)	(19.0)	(29.7)	(3.4)	(81.1)	(53.6)	82.1	158.4
Tax	(1.7)	(0.0)	113.7	20.5	(15.9)	20.0	31.5	56.1	15.0	7.0	16.2	0.0	38.2	25.0	(30.4)	(58.6)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(9.6)	17.5	(14.2)	(11.1)	(17.4)	(13.9)	(12.0)	(13.5)	(3.4)	(42.9)	(28.6)	51.7	99.8
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(2.4)	(2.0)	(0.8)	(2.5)	(7.7)	(1.2)	(1.0)	(0.9)	(2.0)	(5.1)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(12.0)	15.5	(15.0)	(13.6)	(25.1)	(15.1)	(13.0)	(14.4)	(5.4)	(48.0)	(31.6)	48.7	96.8
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	(0.8)	-	-	-	0.0	0.0	-	-	-	0.0	0.0	0.0	0.0
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(30.0)	(12.0)	15.5	(15.0)	(13.6)	(25.1)	(15.1)	(13.0)	(14.4)	(5.4)	(48.0)	(31.6)	48.7	96.8
Net Earnings (Losses) Per Share—Basic and Diluted	($0.32)	($0.41)	($0.06)	($0.02)	$0.03	($0.03)	($0.02)	($0.05)	($0.02)	($0.02)	($0.02)	($0.01)	($0.08)	($0.06)	$0.08	$0.17
Shares outstanding—basic	355.1	422.0	488.1	545.8	547.6	552.2	603.0	550.8	607.0	611.0	615.0	619.0	613.0	558.8	621.0	566.8
Shares outstanding—diluted	355.1	422.0	488.1	545.8	557.0	552.2	579.8	550.8	583.8	587.8	591.8	595.8	589.8	558.8	597.8	566.8
Margin Analysis (% of Sales/Revenue)																
Costs of goods	61%	56%	63%	54%	53%	54%	63%	56%	55%	55%	54%	52%	54%	53%	50%	50%
Gross margin	39%	44%	37%	46%	47%	46%	37%	44%	45%	45%	46%	48%	46%	47%	50%	50%
R&D	56%	92%	20%	10%	9%	8%	10%	9%	9%	9%	11%	11%	10%	9%	7%	7%
MG&A	57%	64%	40%	44%	33%	42%	44%	40%	42%	39%	38%	37%	39%	39%	36%	35%
Operating Income (loss)	-82%	-160%	-20%	-9%	8%	-8%	-18%	-6%	-9%	-7%	-6%	-2%	-6%	-3%	5%	7%
Net Income	-119%	-188%	-6%	-4%	4%	-5%	-5%	-2%	-5%	-4%	-4%	-2%	-4%	-2%	3%	4%
Financial Indicator Growth Analysis (YoY%)																
Products (Pharmaceuticals)	50%	13%	4%	28%	0%	-1%	-4%	4%	31%	39%	70%	149%	71%	66%	71%	28%
Revenue from services (Diagnostics)	567%	-26%	3705%	12104%	13842%	149%	6%	207%	-3%	-1%	7%	15%	5%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	49%	286%	0%	-38%	54%	5%	-69%	-5%	30%	-33%	1%	1%	1%
Total Revenue	105%	-6%	440%	867%	742%	108%	0%	148%	0%	-11%	11%	26%	5%	21%	23%	17%
R&D	176%	55%	19%	9%	6%	29%	8%	12%	42%	-4%	44%	34%	16%	5%	4%	4%
SG&A	99%	5%	239%	634%	461%	126%	17%	150%	-5%	6%	0%	6%	2%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-52%	-211%	187%	534%	-26%	-7%	-176%	-21%	-88%	-2%	-38%	-306%	84%
Total Other Income, net	-15001%	3%	57%	-95%	-131%	-122%	-149%	-99%	24%	-54%	5%	-66%	3346%	-1%	-1%	0%
Net Income	267%	49%	-82%	-90%	-136%	-112%	-986%	-16%	26%	-184%	-4%	-60%	91%	-34%	-254%	99%
EPS	206%	26%	-85%	-92%	-130%	-111%	-906%	-26%	13%	-175%	-14%	-61%	72%	-28%	-239%	118%

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

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DISCLOSURES:

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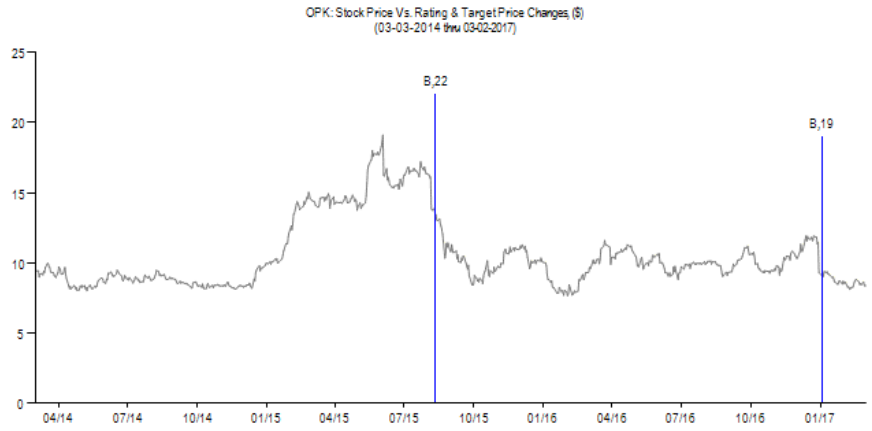
Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/12/2...	Buy (B)	13.45

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/12/2...	22.00	13.45
01/03/2...	19.00	9.09

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Fresenius (FMS – Not Rated)

ADDITIONAL DISCLOSURES

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