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EQUITY RESEARCH
Company Report

November 8, 2016

OPKO Health, Inc. (OPK - $ 9.73)

Healthcare/Biotechnology

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

3Q16: Rayaldee Launch and Reporting of Several Top-line Clinical Data Are Near-Term Catalysts

OPK reported 3Q16 financial results yesterday after the market close with a loss of ($15MM) vs. the estimates of ($6.3MM) of Laidlaw and ($14.7MM) of the Street. Loss per share was ($0.03) vs. ($0.01) for Laidlaw and ($0.03) for the Street. OPK ended 3Q16 with cash of ~$145MM.

- **Rayaldee is ready for launch in November.** OPK indicated the Rayaldee commercialization organization is in place with 10 telemarketing reps, 35 regional reps and 11 regional scientific liaisons. OPK plans to launch Rayaldee in late November after introducing the product at the ASN meeting. Reps headcount could eventually reach 80 by mid-2017. OPK guided the average net price of Rayaldee of $550 per unit, which is the equivalent of 55% to 65% of the WAC. Our model conservatively assumes each patient takes 10 units per year on average given potential incomplete compliance by patient. Management suggested that script trends and other metrics could be better measured in 2H17 since Rayaldee is OPK's first major drug launched in the U.S. European MAA filing by Vifor Fresenius could occur in 1H17; and a global pivotal trial for Rayaldee in ESRD patients could begin in 2H17.
- **Novitas 4Kscore test reimbursement decisions in next February.** OPK is waiting for the local coverage decision (LCD) for Medicare reimbursement approval by Novitas to occur in their 2017 February review cycle; and is optimistic for a positive outcome. OPK also has communicated with Palmetto by providing more recently published documents hoping for potential reversal of prior non-coverage decision.
- **Multiple clinical data releases in next 6 months.** OPK updated investors for several clinical data releases and developments over the next 6 months. hGH-CTP (MOD-4023) in adult GHD Phase III top-line results and the start of a pediatric Phase III trial all are expected in late 4Q16. Factor VIIa-CTP (IV) in hemophilia A/B patients developing FVIII or FIX inhibitors Phase IIa (n=24) interim safety results (first 3 dose cohorts) will be available in 1Q17 with full data to be reported in 2H17. A subcutaneous (s.c.) FVIIa-CTP Phase I study is scheduled to start in 4Q16.
- **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 (11/07/2016)	$ 9.73
52–Week High (3/22/2016)	$ 11.85
52–Week Low (1/20/2016)	$ 7.12
Market Cap. (MM)	$ 5,425050
Shares Out. (MM)	558

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.02A	0.03A	-0.03A	-0.03	-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
FY-13A	-0.11	-0.01	-0.17	-0.04	-0.32	NM

Source: Laidlaw & Company estimates

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- **4Kscore test growth in 3Q16.** OPK reported 16,000 4Kscore tests were performed in 3Q16 (9% Q/Q and 365% Y/Y growth) with majority (~60%) conducted by urologists.

- **Other updates.** OPK reported initial clinical plans for developing the two assets from the acquisition of Transition. For TT401, the drug has exhibited significantly superior in weight loss and is similar in HbA1c reduction compared to extended release exenatide. OPK plans to develop TT401 in type II diabetes and obesity with Phase IIb dose escalation optimization study to start in 2H17. TT701 is a once daily oral selective androgen receptor modulator (SARM) with potential as androgen deficiency therapy. OPK is planning a Phase II study to explore TT701's potential in reducing prostate hypertrophy and providing anabolic therapeutic effects in aging males. The study is potentially to start in mid-2017.

Table 1: Estimated and reported 3Q16 results

3Q16 Estimates and Reported Results			
($ MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$328.8**	**$298.0**	**$322.0**
Total op. profit (loss)	**($12.0)**	**($23.6)**	**($20.3)**
R&D	$32.9	$24.4	
SG&A	$129.3	$124.8	
EPS	**($0.01)**	**($0.03)**	**($0.03)**
Net income (loss)	($6.3)	($15.0)	($14.7)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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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	**Nov. 2016**	***
		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	**2H17**	***
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**	****
		Initiate pediatric Phase III study	**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	**Feb. 2017**	****
		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	**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	**1Q17**	***
		Potentially report Phase I/IIa study top-line results	**2H17**	****
		Potentially start Phase II/III study	**2017**	***
		Potentially report Phase II/III study results	**2018**	****
MOD-5014 (s.c)		Potentially start Phase I study	**4Q16**	***
		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	**1Q17**	***
TT401	Obesity	Start Phase IIb study	**2H17**	***
TT701	Prostate hypertrophy reduction in elder males	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	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	19.9	22.8	**20.6**	34.2	97.6	207.3	321.5	555.4	718.8
Revenue from services (Diagnostics)	11.7	8.7	329.7	252.5	266.0	**259.0**	268.1	1,045.6	1,209.7	1,401.4	1,630.5	1,868.3
Revenue from transfer of intellectual property	16.7	5.5	81.9	18.6	68.3	**18.4**	17.9	123.2	124.5	125.7	127.0	128.2
Total revenue	96.5	91.1	491.7	291.0	357.1	298.0	320.2	1,266.4	1,541.5	1,848.6	2,312.8	2,715.4
Costs of revenues	48.9	48.0	260.0	147.5	153.4	151.2	157.7	609.8	752.3	891.0	1,062.5	1,231.0
Gross Incomes	47.7	43.1	231.7	143.5	203.7	146.9	162.5	656.6	789.3	957.6	1,250.4	1,484.3
Selling, general and administrative	55.3	57.9	196.6	128.0	117.5	124.8	127.3	497.7	534.2	609.4	694.4	791.0
Research and development	53.9	83.6	99.5	27.8	31.3	24.4	25.4	109.0	116.6	122.5	127.4	132.4
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	1.8	10.8	3.1	3.3	18.9	18.9	18.9	18.9	18.9
Amortization of intangible assets	11.1	10.9	28.0	13.4	15.8	18.1	18.1	65.5	65.5	65.5	65.5	65.5
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	174.2	691.1	735.2	816.2	906.2	1,007.8
Total costs and expenses	176.2	236.9	615.0	318.6	328.8	321.7	331.9	1,300.8	1,487.5	1,707.2	1,968.6	2,238.8
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(27.5)	28.3	(23.6)	(11.7)	(34.4)	54.1	141.4	344.2	476.5
Interest income	0.4	0.8	0.3	0.0	0.1	0.2	0.2	0.5	0.6	0.7	0.7	0.7
Interest expense	(13.8)	(12.3)	(8.4)	(1.8)	(2.2)	(2.0)	(2.7)	(8.7)	(8.7)	(8.7)	(8.7)	(8.7)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	(1.4)	1.2	(5.7)	(4.0)	(9.9)	(6.0)	(6.0)	(6.0)	(6.0)
Other income (expense), net	34.8	(3.1)	7.7	0.5	6.0	(3.0)	3.0	6.5	29.0	29.0	29.0	29.0
Total Other Income, net	(24.6)	(25.2)	(39.5)	(2.6)	5.1	(10.5)	(3.5)	(11.5)	14.9	14.9	15.0	15.0
Income before tax	(104.2)	(171.0)	(138.0)	(30.2)	33.4	(34.2)	(15.2)	(46.0)	68.9	156.3	359.2	491.5
Tax	(1.7)	(0.0)	113.7	20.5	(15.9)	20.0	0.0	24.6	(25.5)	(57.8)	(132.9)	(181.9)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(9.6)	17.5	(14.2)	(15.2)	(21.3)	43.4	98.5	226.3	309.7
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(2.4)	(2.0)	(0.8)	(0.8)	(6.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(12.0)	15.5	(15.0)	(16.0)	(27.3)	40.4	95.5	223.3	306.7
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	(0.8)	-	-	0.0	0.0	(3.0)	(3.0)	(3.0)	(3.0)
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(30.0)	(12.0)	15.5	(15.0)	(16.0)	(27.3)	43.4	98.5	226.3	309.7
Net Earnings (Losses) Per Share—Basic and Diluted	($0.32)	($0.41)	($0.06)	($0.02)	$0.03	($0.03)	($0.03)	($0.05)	$0.09	$0.18	$0.45	$0.55
Shares outstanding—basic	355.1	422.0	488.1	545.8	547.6	552.2	556.2	550.5	496.1	558.5	504.1	566.5
Shares outstanding—diluted	355.1	422.0	488.1	545.8	557.0	552.2	556.2	552.8	496.1	560.8	504.1	568.8
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	54%	53%	54%	52%	53%	53%	52%	49%	48%
Gross margin	39%	44%	37%	46%	47%	46%	48%	47%	47%	48%	51%	52%
R&D	56%	92%	20%	10%	9%	8%	8%	9%	8%	7%	6%	5%
MG&A	57%	64%	40%	44%	33%	42%	40%	39%	35%	33%	30%	29%
Operating Income (loss)	-82%	-160%	-20%	-9%	8%	-8%	-4%	-3%	4%	8%	15%	18%
Net Income	-119%	-188%	-6%	-4%	4%	-5%	-5%	-2%	3%	5%	10%	11%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	28%	0%	-1%	63%	22%	112%	55%	73%	29%
Revenue from services (Diagnostics)	567%	-26%	3705%	12104%	13842%	149%	21%	217%	16%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	49%	286%	0%	-46%	51%	1%	1%	1%	1%
Total Revenue	105%	-6%	440%	867%	742%	108%	16%	158%	22%	20%	25%	17%
R&D	176%	55%	19%	9%	6%	29%	0%	10%	7%	5%	4%	4%
SG&A	99%	5%	239%	634%	461%	126%	24%	153%	9%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-52%	-211%	187%	48%	-65%	-257%	161%	143%	38%
Total Other Income, net	-15001%	3%	57%	-95%	-131%	-122%	-78%	-71%	-229%	0%	0%	0%
Net Income	267%	49%	-82%	-90%	-136%	-112%	-1105%	-9%	-259%	127%	130%	37%
EPS	206%	26%	-85%	-92%	-130%	-111%	-1091%	-19%	-276%	101%	155%	22%

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

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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.

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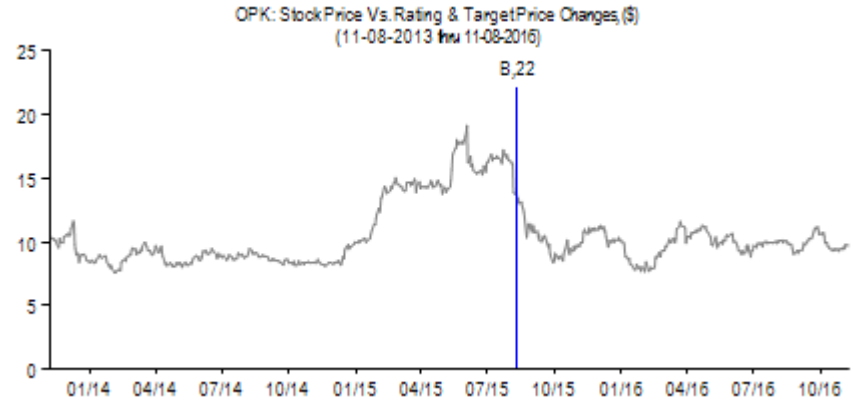
Rating and Price Target Change History



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 **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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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NOTES: