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EQUITY RESEARCH
Company Report

August 9, 2016

OPKO Health, Inc. (OPK - $ 10.11)

Healthcare/Biotechnology

2Q16: Rayaldee Launch in November and Several Top-line Clinical Data to be Reported in Next Six Months

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

OPK reported 2Q16 financial results yesterday with earnings of $15MM vs. the net loss estimates of ($20MM) of Laidlaw and earnings of $3MM of the Street. Earnings per share were $0.02 vs. ($0.04) for Laidlaw and $0.02 for the Street. The major discrepancy is the additional one time $50MM revenue of Rayaldee license fees from VFMCRP. OPK ended 2Q16 with cash of ~$172MM.

- **Rayaldee launch in November.** OPK indicated pre-launch marketing activities are in high gear with expansion of the commercialization team underway, which includes 5 regional business managers, 10 internal, and 35 regional reps. Headcount of the sales force could eventually reach 70–80. OPK plans to launch Rayaldee in November 2016. For pricing, the company is contemplating either the specialty tier or other options. For formulary, OPK has filed applications for 9 U.S. compendiums for consistent and favorable listings. OPK will not learn whether it has gained a more favorable decision before they load a price, which OPK expects to occur two weeks prior to launch in November. Potential public comments by the United States Pharmacopeia (USP) (before Oct. 1st 2016) could provide an early read regarding its prospects.
- **Multiple clinical data releases in next 6 months.** In addition to Rayaldee and the 4Kscore test, we believe several clinical data releases in next 6 months offer a very significant set of catalysts for OPK shares. In late 4Q16, results of 3 studies, hGH-CTP (MOD-4023) in adult GHD Phase III, Factor VIIa-CTP (IV) in hemophilia A/B patients developing FVIII or FIX inhibitors Phase IIa (n=24) and MOD-6031Phase I would be available. MOD-4023 (subcutaneous or s.c.) in pediatric GHD Phase III studies (1 global and 1 Japanese study) to start in 3Q16. We estimate peak MOD-4023 sales could reach $1.2 billion and OPK will participate in profit sharing (including Genotropin) with Pfizer once the pediatric GHD indication is launched. For FVIIa-CTP Phase I/II trial, we view good PK and safety results are critical given OPK is scheduled to initiate a Phase IIa trial later using s.c. FVIIa-CTP – a more preferable form as prophylactics. OPK indicated that no additional bridging study is needed given the formulation of the IV and s.c. is similar.
- **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 (08/08/2016)	$ 10.11
52–Week High (8/10/2015)	$ 14.33
52–Week Low (1/20/2016)	$ 7.12
Market Cap. (MM)	$ 5,564050
Shares Out. (MM)	550

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.02A	0.03A	-0.01	-0.02	-0.02	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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- **MAC reimbursement decisions for 4Kscore test in next two months.** OPK indicated it has submitted complete packages to the two MACs (Novitas and Palmetto) for Medicare reimbursement approval. The decision from Palmetto could be available in September; while a much more critical decision by Novitas (the only MAC decision required for reimbursement) is scheduled in October. We anticipate positive Novitas decision is very likely given the robust clinical and other data; and a good probability of approval decision by Palmetto. We view positive MAC along with more private payer decisions key for significant 4Kscore test revenue ramp-up going forward.

- **Other updates.** OPK is scheduled to close the Transition acquisition in 3Q16 (September) and expects to report more details for the clinical developments of TT401 and TT701. TT401 has exhibited significantly superior in weight loss and is similar in HbA1c reduction comparing to extended release exenatide. We believe OPK is likely to develop TT401 and another in-house developed oxyntomodulin program (MOD-6031) in obesity to determine the potential utility of each program. TT701 is a once daily oral selective androgen receptor modulator (SARM) with potential as androgen deficiency therapy. The specific indications for further clinical advancements have not been revealed. Management suggested, if clinically successful, TT701 could potentially become an important element of a urology franchise, which also includes 4Kscore test and others. OPK updated that more than 5,000 physicians have prescribed 4Kscore tests and ~5,300 procedures were conducted in June alone (4,600 in April).

Table 1: Estimated and reported 2Q16 results

2Q16 Estimates and Reported Results			
($ MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$319.0**	**$357.1**	**$324.2**
Total op. profit (loss)	**($24.7)**	**$28.3**	**$4.7**
R&D	$29.8	$31.3	
SG&A	$132.2	$117.5	
EPS	**($0.04)**	**$0.03**	**$0.02**
Net income (loss)	($20.2)	$15.5	$2.6

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	**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**	***
		Potential commencement of pediatric Phase III study	**3Q16**	***
		Report of Phase III pediatric study top-line results	**2018/2019**	****
4Kscore test	Prostate cancer diagnostics	CMS reimbursement decisions	**2H16**	****
		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.

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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	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue												
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
Total revenue	96.5	91.1	491.7	291.0	357.1	328.8	357.0	1,336.3	1,621.7	1,940.0	2,417.2	2,834.5
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
Total Operating Expenses	127.3	188.9	355.0	171.0	175.4	176.0	185.2	707.5	744.0	825.9	916.6	1,019.1
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
Income before tax	(104.2)	(171.0)	(138.0)	(30.2)	33.4	(6.5)	(9.7)	(10.6)	96.1	187.8	395.8	534.2
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)
Net income (loss)	(117.3)	(174.6)	(31.4)	(12.0)	15.5	(7.1)	(10.5)	(11.7)	57.5	115.3	246.4	333.5
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)
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(30.0)	(12.0)	15.5	(6.3)	(9.7)	(10.3)	60.5	118.3	249.4	336.5
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
Margin Analysis (% of Sales/Revenue)												
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%
Financial Indicator Growth Analysis (YoY%)												
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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Additional information available upon request.

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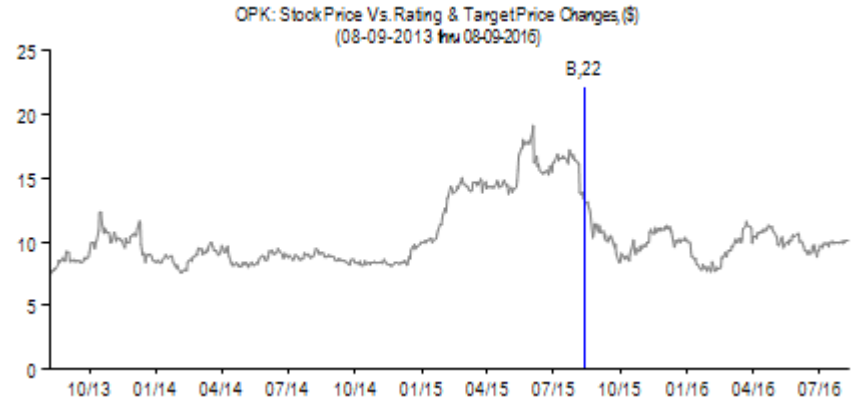
RATINGS INFORMATION

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	62.16%	27.03%	2.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.70%	0.00%	0.00%

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Pfizer (PFE – Not Rated)

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NOTES: