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EQUITY RESEARCH
Company Report

March 16, 2016

OPKO Health, Inc. (OPK - $ 10.15)

Healthcare/Biotechnology

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

MOD-6031 (Long-acting Oxyntomodulin) in Obesity and Type II Diabetes Phase I Study Started

This morning, OPK announced they have dosed the first healthy, overweight or obese volunteer for MOD-6031 in obesity and Type II diabetes Phase I trial. It is a dose escalation study for assessing the safety and PK.

- **Details.** The objective of the Phase I study is to evaluate PK, PD, safety and tolerability [measured by AEs, electrocardiograms (ECG) and others] of MOD-6031 in healthy, overweight or obese males volunteers (n=40). Subjects will be randomized 3:1 between the treatment and the placebo group within each dose cohort. Subjects will receive a single dose of MOD-6031 (20 mg, 50 mg, 100 mg, 150 mg, or 200 mg) or a placebo and monitored for 30 days. The trial will be conducted at the Tel Aviv Sourasky Medical Center in Israel. We estimate the top-line results could potentially be available 2H16. As a reminder, MOD-6031 is a long acting (via OPK's proprietarily reversible pegylation technology) oxyntomodulin (OXM). OXM is a glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist. It is a peptide hormone acting as a natural appetite suppressor, and was secreted from the L cells of the gut after the consumption of food. OXM is potentially more potent than GLP1 agonist for treating obesity while it could also improve glycemic control as a potential diabetes treatment. MOD-6031's potential benefit is it requires less frequent dosing and with improved PK and PD. Prior pre-clinical studies suggested that MOD-6031 is superior to that of native OXM and PEG-OXM based on weight loss, required reduced dose and ability for delivering the drug into brain. Additionally, OPK recently announced the appointment of Dr. Gregory Henderson as President of Bio-Reference Laboratories; while the European Association of Urology (EAU) Prostate Cancer Guidelines Panel has decided to include 4Kscore test in the 2016 EAU guidelines for prostate cancer.
- **Implications.** We view the kick off of the Phase I dosing study as an important step for advancing MOD-6031 clinically as a potential obesity treatment. We look forward to gaining greater visibility on the safety and efficacy signal from clinical studies, possibly in 2017, to further assess the potential of MOD-6031 as a novel treatment modality in obesity and diabetes.
- **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 (03/16/2016)	$ 10.15
52–Week High (6/3/2015)	$ 19.20
52–Week Low (1/20/2016)	$ 7.12
Market Cap. (MM)	$ 5,534
Shares Out. (MM)	546

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.07	-0.04	-0.01	-0.01	-0.14	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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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**	***
		PDUFA date	**March 29, 2016**	****
		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**	***
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.

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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	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	21.9	23.7	37.3	59.0	142.0	256.5	373.2	588.3	759.0
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
Total revenue	96.5	91.1	491.7	**254.1**	266.8	287.0	316.9	1,124.9	1,387.8	1,676.7	2,098.9	2,482.2
Costs of revenues	48.9	48.0	260.0	128.9	136.3	141.7	149.8	556.7	680.1	808.8	966.7	1,122.8
Gross Incomes	47.7	43.1	231.7	125.2	130.5	145.2	167.1	568.2	707.6	867.9	1,132.2	1,359.4
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
Total Operating Expenses	127.3	188.9	355.0	153.3	159.0	156.7	165.5	634.3	719.2	800.5	890.8	992.7
Total costs and expenses	176.2	236.9	615.0	282.1	295.3	298.4	315.3	1,191.0	1,399.3	1,609.3	1,857.5	2,115.5
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(28.1)	(28.4)	(11.4)	1.7	(66.2)	(11.5)	67.4	241.4	366.7
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
Total Other Income, net	(24.6)	(25.2)	(39.5)	(11.5)	4.5	5.5	(7.5)	(9.0)	13.1	13.2	13.3	13.3
Income before tax	(104.2)	(171.0)	(138.0)	(39.6)	(23.9)	(5.9)	(5.8)	(75.2)	1.6	80.6	254.7	380.0
Tax	(1.7)	(0.0)	113.7	0.0	0.0	0.0	0.0	0.0	(0.6)	(29.8)	(94.2)	(140.6)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(39.6)	(23.9)	(5.9)	(5.8)	(75.2)	1.0	50.8	160.5	239.4
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)
Net income (loss)	(117.3)	(174.6)	(31.4)	**(40.5)**	(24.6)	(6.5)	(6.6)	(78.2)	(2.0)	47.8	157.5	236.4
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)
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(30.0)	(39.7)	(23.9)	(5.7)	(5.8)	(76.8)	1.0	50.8	160.5	239.4
Net Earnings (Losses) Per Share—Basic and Diluted	($0.32)	($0.41)	($0.06)	($0.07)	($0.04)	($0.01)	($0.01)	($0.14)	$0.00	$0.09	$0.32	$0.42
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
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	54%	54%	52%	50%	53%	52%	50%	48%	47%
Gross margin	39%	44%	37%	46%	46%	48%	50%	47%	48%	50%	52%	53%
R&D	56%	92%	20%	10%	11%	10%	10%	10%	9%	8%	6%	6%
MG&A	57%	64%	40%	43%	43%	40%	37%	41%	38%	36%	33%	32%
Operating Income (loss)	-82%	-160%	-20%	-11%	-11%	-4%	1%	-6%	-1%	4%	12%	15%
Net Income	-119%	-188%	-6%	-16%	-9%	-2%	-2%	-7%	0%	3%	8%	10%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	42%	4%	80%	180%	77%	81%	45%	58%	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%	101%	15%	129%	23%	21%	25%	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%	39%	-121%	-33%	-83%	-685%	258%	52%
Total Other Income, net	-15001%	3%	57%	-79%	-127%	-88%	-53%	-77%	-245%	1%	1%	0%
Net Income	267%	49%	-82%	-66%	-44%	-104%	-467%	155%	-101%	5070%	216%	49%
EPS	206%	26%	-85%	-73%	-54%	-104%	-457%	124%	-101%	4434%	255%	31%

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

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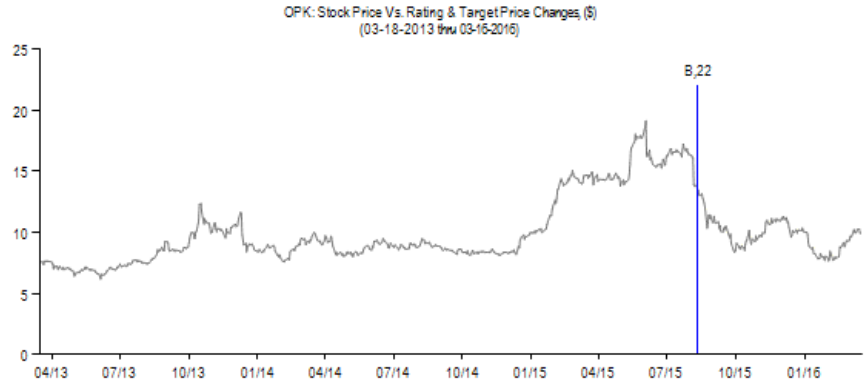

3 Year Rating Change History

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.	65.71%	25.71%	2.86%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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