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EQUITY RESEARCH
Company Report

September 2, 2015

OPKO Health, Inc. (OPK - $ 11.18)

Healthcare/Biotechnology

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

Rolapitant (VARUBI) in Chemotherapy-Induced Nausea and Vomiting (CINV) Approved

This morning, Tesaro announced that the FDA approved rolapitant (VARUBI) to be used in combination with other antiemetic agents for the prevention of delayed chemotherapy-induced nausea and vomiting (CINV).

- **Details.** This morning, Tesaro announced that the FDA has approved rolapitant (VARUBI) to be used in combination with other antiemetic agents, mainly 5-hydroxytryptamine ($5\text{-}HT_3$) receptor antagonists and dexamethasone, for the prevention of delayed chemotherapy-induced nausea and vomiting (CINV). With the approval, OPK expects to receive up to $110MM milestone payments going forward with the first $15MM once TSRO starts the first commercial sales (we estimate in 4Q15). OPK also expects to receive double digit tiered royalties (which we estimated to be 14%) based on VARUBI sales.

- **Implication.** We view today's news an important positive for OPK shareholder value as VARUBI is OPK's first major drug approval, potentially followed by Rayaldee (PDUFA date: March 29, 2016) and hGH-CTP or MOD-4023 (2H17). TSRO is also developing an IV formulation of rolapitant with possible approval in late 2016. The approval of oral VARUBI today could significantly de-risk the probability of IV VARUBI approval. The majority of CINV prescriptions in the U.S. are from the IV formulation because of the high prior authorization required by insurance companies for oral CINV drugs. The potential success of the IV formulation could substantially improve the commercial outlook for VARUBI. We estimate the global annual peak sales of VARUBI could reach $400MM and OPK could receive $50+MM royalty payments each year. VARUBI is a substance P/neurokinin-1 (NK1) receptor antagonist and it would complete with Emend (current market leader developed by Merck) and Akynzeo (a fixed dose combination of netupitant and palonosetron developed by Eisai/Helsinn). We project VARUBI could have a strong competitive edge given the future Emend IV formulation patent expiry (expected in 2019) and Akynzeo IV formulation development is behind that of VARUBI.

- **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 4Kscore test, Rayaldee, VARUBI (rolapitant) and hGH-CTP (MOD-4023). Our valuation is based on our DCF analyses.

Trading Data:

Last Price (09/02/2015)	$ 11.18
52–Week High (6/3/2015)	$ 19.20
52–Week Low (10/13/2014)	$ 8.02
Market Cap. (MM)	$ 6,023
Shares Out. (MM)	540

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.26A	-0.09A	-0.08	0.03	-0.37	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
FY-12A	-0.03	-0.04	-0.03	-0.01	-0.11	NM

Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Start to build M&S organization	**2H15**	***
		PDUFA date	**March 29, 2016**	****
		Product launch	**Mid-2016**	***
		Potential include in for formulary of healthcare plans	**2017'**	****
Rolapitant	Chemotherapy -induced nausea and vomiting (CINV)	Potential product launch	**4Q15**	***
hGH-CTP (MOD-4023)	hGH deficiency	Report of Phase III study top-line results	**2H16**	****
		Potential product launch for adult hGH deficiency	**2H17**	***
		Report of Phase III pediatric study top-line results	**2018**	****
4Kscore test	Prostate cancer diagnostics	Category 1 CPT code approval decision	**4Q15/1Q16**	***
		CMS reimbursement decision	**2016**	****
		Potential private payer reimbursement decision	**2016 - 2017**	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	**1H16**	***
		Potential approval	**2017**	****
Claros 1 PSA test	POC PSA test	Modular PMA filing	**1H16**	***
		Potential approval	**2017**	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	**4Q16**	****
		Potential approval	**2017**	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study top-line results	**4Q16**	***
		Pontentially start Phase II/III study	**1Q17**	***
		Pontentially report Phase II/III study results	**2Q18**	****
MOD-5014 (s.c)		Pontentially start Phase I study	**1H16**	***
		Pontentially report Phase I study results	**1H16**	****
		Pontentially start Phase II study	**4Q16**	***
		Pontentially report Phase II study results	**4H17**	***
MOD-6031 (Oxyntomodulin)	obesity	Potentially start Phase I study	**1Q16**	***

***** / ***** 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)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Products (Pharmaceuticals)	45.3	68.2	77.0	15.5	22.8	20.3	23.6	82.2	140.8	255.1	371.4	586.2	756.4
Revenue from services (Diagnostics)	1.7	11.7	8.7	2.1	1.9	85.6	270.7	360.3	1,119.0	1,300.8	1,499.8	1,712.7	1,956.8
Revenue from transfer of intellectual property	0.0	16.7	5.5	12.5	17.7	17.5	17.5	65.3	65.9	66.6	67.2	67.9	68.6
Total revenue	47.0	96.5	91.1	30.1	42.4	123.4	311.8	507.7	1,325.7	1,622.5	1,938.4	2,366.9	2,781.8
Costs of revenues	27.9	48.9	48.0	10.3	14.4	57.7	161.0	243.5	624.7	720.3	826.4	944.5	1,077.8
Gross Incomes	19.2	47.7	43.1	19.8	28.0	65.7	150.7	264.2	701.0	902.1	1,112.0	1,422.3	1,704.0
Selling, general and administrative	27.8	55.3	57.9	17.4	20.9	48.3	106.1	192.8	471.8	544.2	620.5	706.9	804.9
Research and development	19.5	53.9	83.6	25.5	29.6	30.5	30.8	116.3	125.6	134.4	141.1	146.8	152.6
In process research and development	0.0	0.0	12.1	-	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0	0.0
Contingent consideration	0.8	6.9	24.4	5.2	(0.3)	4.0	4.0	12.8	12.8	12.8	12.8	12.8	12.8
Amortization of intangible assets	8.3	11.1	10.9	2.7	3.2	6.5	6.5	18.8	18.8	18.8	18.8	18.8	18.8
Grant repayment	0.0	0.0	0.0	25.9	0.0	0.0	-	25.9	0.0	0.0	0.0	0.0	0.0
Total Operating Expenses	56.4	127.3	188.9	76.7	53.4	89.2	147.3	366.6	629.0	710.2	793.3	885.3	989.2
Total costs and expenses	84.3	176.2	236.9	87.0	67.8	147.0	308.4	610.2	1,253.8	1,430.5	1,619.8	1,829.8	2,067.0
Operating Incomes (losses)	(37.3)	(79.6)	(145.8)	(56.9)	(25.4)	(23.5)	3.4	(102.4)	72.0	191.9	318.7	537.0	714.8
Interest income	0.2	0.4	0.8	0.0	0.1	0.1	0.1	0.2	0.8	0.9	1.0	1.1	1.1
Interest expense	(1.4)	(13.8)	(12.3)	(2.6)	(1.0)	(1.0)	(1.0)	(5.5)	(5.5)	(5.5)	(5.5)	(5.5)	(5.5)
Fair value changes of derivative instruments, net	1.2	(45.9)	(10.6)	(49.8)	(16.6)	(15.0)	18.0	(63.3)	(18.0)	(18.0)	(18.0)	(18.0)	(18.0)
Other income (expense), net	0.2	34.8	(3.1)	(1.5)	0.8	3.0	(1.7)	0.6	0.6	0.6	0.6	0.6	0.6
Total Other Income, net	0.2	(24.6)	(25.2)	(53.9)	(16.7)	(12.9)	15.4	(68.2)	(22.2)	(22.1)	(22.0)	(21.9)	(21.9)
Income before tax	(37.1)	(104.2)	(171.0)	(110.8)	(42.1)	(36.5)	18.8	(170.6)	49.8	169.8	296.7	515.1	692.9
Tax Rate									*37%*	*37%*	*37%*	*37%*	*37%*
Tax	9.6	(1.7)	(0.0)	(5.5)	(0.3)	(1.0)	(1.0)	(7.8)	(18.4)	(62.8)	(109.8)	(190.6)	(256.4)
Loss before investment losses	(27.5)	(105.9)	(171.1)	(116.3)	(42.4)	(37.5)	17.8	(178.3)	31.4	107.0	186.9	324.5	436.5
Loss from investments in investees	(2.1)	(11.5)	(3.6)	(1.8)	(0.8)	(1.2)	(1.4)	(5.2)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(29.5)	(117.3)	(174.6)	(118.0)	(43.2)	(38.7)	16.4	(183.5)	28.4	104.0	183.9	321.5	433.5
Net loss attributable to noncontrolling interests	(0.5)	(2.9)	(3.0)	(0.9)	(0.5)	(0.8)	(0.9)	(3.1)	(3.1)	(3.0)	(3.0)	(3.0)	(3.0)
Net Income (Loss) Applicable to Common Shareholders	(31.3)	(114.8)	(171.7)	(117.1)	(42.7)	(37.9)	17.3	(180.4)	31.5	107.0	186.9	324.5	436.5
Net Earnings (Losses) Per Share—Basic and Diluted	($0.11)	($0.32)	($0.41)	($0.26)	($0.09)	($0.08)	$0.03	($0.37)	$0.06	$0.22	$0.33	$0.65	$0.77
Shares outstanding—basic and diluted	295.8	355.1	422.0	446.5	456.5	482.1	543.3	482.1	551.3	490.1	559.3	498.1	567.3
	295.8	355.1	422.0	446.5	456.5	482.1	543.3	482.1	551.3	490.1	559.3	498.1	567.3
Margin Analysis (% of Sales/Revenue)													
Costs of goods	59%	61%	56%	59%	58%	58%	55%	55%	50%	46%	44%	41%	40%
Gross margin	41%	39%	44%	41%	42%	42%	45%	45%	50%	54%	56%	59%	60%
R&D	41%	56%	92%	85%	70%	25%	10%	23%	9%	8%	7%	6%	5%
MG&A	59%	57%	64%	58%	49%	39%	34%	38%	36%	34%	32%	30%	29%
Operating Income (loss)	-79%	-82%	-160%	-189%	-60%	-19%	1%	-20%	5%	12%	16%	23%	26%
Net Income	-67%	-119%	-188%	-389%	-101%	-31%	6%	-36%	2%	7%	10%	14%	16%
Financial Indicator Growth Analysis (YoY%)													
Products (Pharmaceuticals)	63%	50%	13%	-22%	7%	17%	27%	7%	71%	81%	46%	58%	29%
Revenue from services (Diagnostics)	1196%	567%	-26%	5%	-11%	3349%	13035%	4057%	211%	16%	15%	14%	14%
Revenue from transfer of intellectual property	N.A.	N.A.	-67%	2532%	N.A.	N.A.	251%	1092%	1%	1%	1%	1%	1%
Total Revenue	68%	105%	-6%	35%	80%	524%	1121%	457%	161%	22%	19%	22%	18%
Gross Profit	79%	149%	-10%	100%	155%	659%	1008%	513%	165%	29%	23%	28%	20%
Cost of Sales	62%	75%	-2%	-17%	15%	419%	1250%	407%	157%	15%	15%	14%	14%
R&D	72%	176%	55%	21%	82%	48%	19%	39%	8%	7%	5%	4%	4%
SG&A	45%	99%	5%	26%	41%	245%	596%	233%	3%	9%	9%	9%	8%
Contingent consideration	NA	785%	252%	98%	-118%	-80%	987%	-47%	0%	10%	5%	6%	5%
Operating income (loss)	61%	114%	83%	88%	-27%	-51%	-111%	-30%	-170%	167%	66%	69%	33%
Total Other Income, net	-116%	-15001%	3%	343%	-280%	775%	-174%	170%	-67%	0%	0%	0%	0%
Pretax Income	53%	181%	64%	161%	65%	-27%	-135%	0%	-129%	241%	75%	74%	35%
Net Income	754%	267%	49%	163%	68%	-22%	-133%	5%	-117%	240%	75%	74%	35%
EPS	711%	206%	26%	143%	52%	-31%	-126%	-8%	-115%	282%	53%	95%	18%

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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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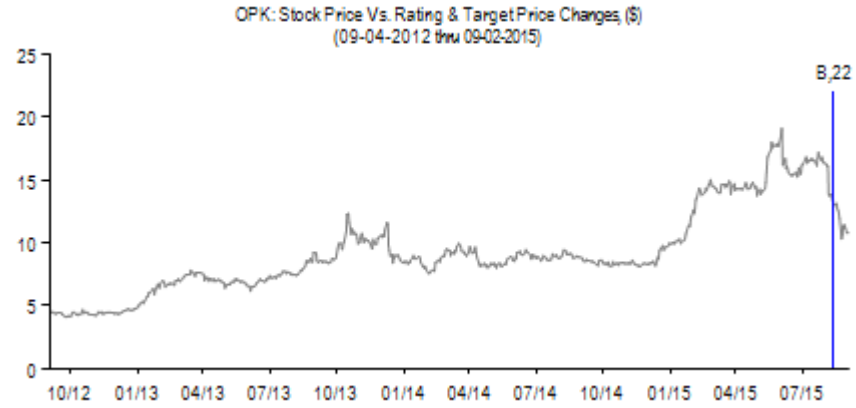
RATINGS INFORMATION

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.	77.42%	29.03%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Tesaro (TSRO – Not Rated)
Merck (MRK – Not Rated)
Eisai (TYO: 4523 – Not Rated)

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NOTES: