

OPKO Health, Inc. (OPK - \$ 10.25)

EU and Selected ROW Rayaldee Commercialization Agreement with Vifor Fresenius

This morning, OPK announced a collaboration and license agreement with Vifor Fresenius Medical Care Renal Pharma (VFMCRP), a joint venture between Vifor Pharma (part of Galenica Group) and Fresenius Medical Care, for the ex-U.S. commercialization of Rayaldee valued at \$282MM for the treatment of SHPT in CKD and vitamin D insufficiency.

- Details.** Under the agreement, OPK is entitled to receive a \$50MM upfront payment, regulatory and launch milestones payments up to \$52MM, and sales-based milestones up to \$180MM, plus tiered, double-digit product sales-based royalties from VFMCRP. VFMCRP will commercialize Rayaldee in Europe, Canada, Mexico, Australia, South Korea, and other ex-U.S. markets for treatment of SHPT in patients with CKD and vitamin D insufficiency. OPK still retains all rights in the U.S., Latin America (excluding Mexico), Russia, China, Taiwan and Japan. Together, OPK and VFMCRP will also prepare the MAA submission to the EMA. Additionally, the agreement also entails the co-development and commercialization of Rayaldee for the treatment of SHPT in dialysis patients with the option for VFMCRP to acquire rights to the U.S. market for treatment of dialysis patients. Should VFMCRP exercise this option, OPK would be entitled to additional commercial-based milestones and double-digit royalties. As a reminder, OPK recently resubmitted its NDA following the FDA's March 29 CRL citing deficiencies at OPK's third party manufacturer. The new PDUFA date is scheduled for October 22, 2016.
- Implications.** We view today's news as very encouraging for the ex-U.S. commercial outlook for OPK's Rayaldee given VFMCRP could be a good ex-U.S. sales and marketing partner based on its strong product portfolio, global sales reach, and impressive track record. Vifor Pharma generated ~\$970MM sales in 2015. It operates three franchises: iron, VFMCRP and infectious diseases. The company has a strong presence in the nephrology CKD space with major products in iron replacement, like Ferinject (\$258MM) and EPO drug Mircera (\$213MM).
- 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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.07	-0.04	-0.03	-0.05	-0.20	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

Healthcare/Biotechnology

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

Trading Data:

Last Price (05/09/2016)	\$ 10.25
52-Week High (6/3/2015)	\$ 19.20
52-Week Low (1/20/2016)	\$ 7.12
Market Cap. (MM)	\$ 5,595
Shares Out. (MM)	546

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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	***
		FDA PDUFA date	Oct. 22, 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)		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)	Hemophilia A/B with inhibitors	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	***
MOD-6031	Obesity	Potentially report Phase I study top-line results	2H16	
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.

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 successful 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.

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.

Figure 1: Income Statement

OPKO Health – Income Statement												
(\$'MM)	2013	2014	2015					2016E	2017E	2018E	2019E	2020E
				1Q16E	2Q16E	3Q16E	4Q16E					
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	21.9	23.7	25.5	34.2	105.4	215.3	331.0	566.8	732.5
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	275.2	292.1	1,088.2	1,346.5	1,634.5	2,077.4	2,455.8
Costs of revenues	48.9	48.0	260.0	128.9	136.3	140.5	147.3	553.1	676.0	804.6	964.6	1,120.1
Gross Incomes	47.7	43.1	231.7	125.2	130.5	134.6	144.8	535.2	670.5	830.0	1,112.8	1,335.6
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	297.2	312.8	1,187.4	1,395.2	1,605.1	1,855.3	2,112.8
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(28.1)	(28.4)	(22.0)	(20.7)	(99.2)	(48.7)	29.5	222.0	342.9
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)	(16.5)	(28.2)	(108.2)	(35.6)	42.6	235.3	356.2
Tax	(1.7)	(0.0)	113.7	0.0	0.0	0.0	0.0	0.0	0.0	(15.8)	(87.1)	(131.8)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(39.6)	(23.9)	(16.5)	(28.2)	(108.2)	(35.6)	26.9	148.2	224.4
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)	(17.1)	(29.0)	(111.2)	(38.6)	23.9	145.2	221.4
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)	(16.3)	(28.2)	(109.8)	(35.6)	26.9	148.2	224.4
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.32)	(\$0.41)	(\$0.06)	(\$0.07)	(\$0.04)	(\$0.03)	(\$0.05)	(\$0.20)	(\$0.07)	\$0.05	\$0.29	\$0.39
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%	54%	54%	54%	53%	51%	48%	47%
Gross margin	39%	44%	37%	46%	46%	46%	46%	46%	47%	49%	52%	53%
R&D	56%	92%	20%	10%	11%	11%	11%	11%	9%	8%	7%	6%
MG&A	57%	64%	40%	43%	43%	42%	40%	42%	40%	37%	33%	32%
Operating Income (loss)	-82%	-160%	-20%	-11%	-11%	-8%	-7%	-9%	-4%	2%	11%	14%
Net Income	-119%	-188%	-6%	-16%	-9%	-6%	-10%	-10%	-3%	2%	7%	9%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	42%	4%	23%	63%	31%	104%	54%	71%	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%	92%	6%	121%	24%	21%	27%	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%	168%	162%	1%	-51%	-160%	654%	54%
Total Other Income, net	-15001%	3%	57%	-79%	-127%	-88%	-53%	-77%	-245%	1%	1%	0%
Net Income	267%	49%	-82%	-66%	-44%	-113%	-1868%	265%	-68%	-175%	452%	51%
EPS	206%	26%	-85%	-73%	-54%	-111%	-1821%	220%	-64%	-166%	520%	33%

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

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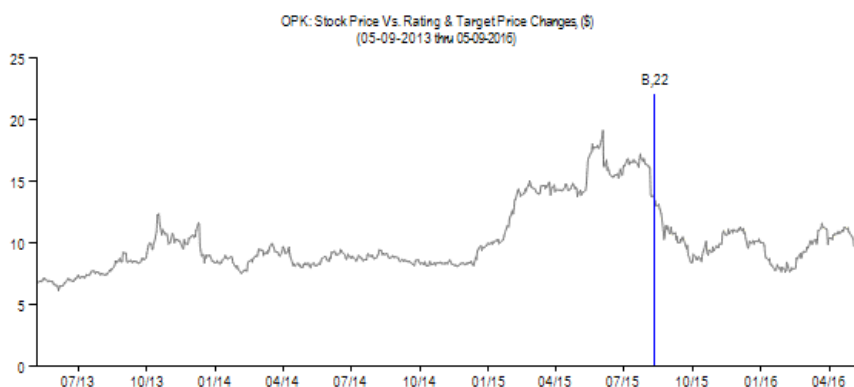
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3 Year Rating Change History

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

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			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.	66.67%	27.78%	2.78%
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%

ADDITIONAL COMPANIES MENTIONED

Fresenius Medical Care (FMS – Not Rated)

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