

OPKO Health (OPK - \$6.81)

Royaldee Japan Tobacco Deal Supplies an Important Piece for Its Global Commercial Reach

Via their subsidiary EirGen Pharma, OPK this morning announced an exclusive agreement with Japan Tobacco (JT) for the development and commercialization of Royaldee in Japan as a treatment of secondary hyperparathyroidism (SHPT) in non-dialysis and dialysis patients with chronic kidney disease (CKD).

- Details.** Under the terms of the agreement, OPK will receive a \$6MM upfront payment and \$6MM upon initiation of the upcoming Royaldee in ESRD Phase II study (possibly in 4Q17). OPKO is also eligible for up to \$31MM regulatory- and \$75MM sales-based milestones. The sales-based royalties are tiered, starting from double digits to 20+%. JT will be responsible for all regulatory approvals and commercial activities in Japan. JT estimates currently there are 13.3MM CKD and 300K+ dialysis patients in Japan.
- Implications.** We view today's news a positive development for Royaldee global development after the U.S. launch and the EU partnership with Vifor Fresenius in 2Q16. We believe in Japan, majority of the SHPT treatment are for dialysis (ESRD) patients. As such, we believe the success of the upcoming Royaldee in ESRD clinical studies are important for the success of the Japanese market. Similar to many other drug developments in Japan, we also anticipate an additional clinical trial conducted in Japan is needed for potential approval in that country. We recently have also examined the script trends of Royaldee based on information gathered by Bloomberg and noticed that TRx and NRx all have a healthy month/month growth in 2017 with slightly greater increase between July and August. Although we do not have the readout of September, we view this overall trend bodes well for the ramp up of Royaldee by patients and physicians. Our discussion with management indicated that OPK has completed sales force expansion (n=70) in early October. As such, we anticipate Royaldee sales could start a more significant growth in 2018. In addition, we anticipate the next near-term catalyst for OPK shares could be a positive FDA PDUFA date decision for the potential approval of IV Varubi developed by TSRO. IV drugs account for the vast majority of CINV therapies in the U.S. and we estimate OPK to receive a mid-teen Varubi sales royalty.
- Action.** We are reiterating our Buy rating and \$19 target price to reflect our bullish view on progress in OPK's multiple drivers in place, especially the 4Kscore test, Royaldee, 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-17E	-0.06A	-0.03A	-0.05	-0.04	-0.18	NM
FY-16A	-0.02	0.03	-0.03	-0.02	-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

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	OPK
Rating:	Buy
Price Target:	\$19.00

Trading Data:

Last Price (10/11/2017)	\$6.81
52-Week High (12/15/2016)	\$12.15
52-Week Low (8/17/2017)	\$5.85
Market Cap. (MM)	\$3,838
Shares Out. (MM)	550.847

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Potential include in for formulary of healthcare plans	2017/2018	****
		Potential EMEA filing	2H17	***
		Potential EU approval	1H18	****
	SHPT in ESRD patients	Start Phase II study	4Q17	***
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	PDUFA date of IV VARUBI	Oct. 25, 2017	****
hGH-CTP (MOD-4023)	hGH deficiency	FDA feedback and additional adult GHD Phase III data analysis	2H17	***
		Potential file BLA for adult GHD	2H17	****
		Potentially report of ACP-001 pediatric Phase III study top-line results by Ascendis	1H19	***
		Report of Phase III pediatric study top-line results	1H19	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	2017	****
		Potential more private payer reimbursement decision	2017	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	2H17	***
		Potential approval	2018	****
Claros 1 PSA test	POC PSA test	Modular PMA filing	3Q17	***
		Potential approval	2018	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	2H17	****
		Potential approval	2018	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study top-line results	2H17	****
		Potentially start Phase II/III study	2018	***
		Potentially report Phase II/III study results	2020	****
MOD-5014 (s.c)		Potentially report Phase I study results	2H17	****
		Potentially start Phase II/III study	2018	***
		Potentially report Phase II/III study results	2020	***
NK-1 inhibitor (OPK88002)	Pruritus	Potentially start Phase IIa study	2H17	***
OPK88004	Obesity	Start Phase IIb study	4Q17	***
OPK88003	Benign prostate hypertrophy	Start Phase II study	4Q17	***
		Potentially report Phase II study results	Mid-2018	****
OPK88001	Dravet Syndrome	Potentially start Phase I/II trial	4Q17	***

**** / ***** 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 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.

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	2016	1Q17	2Q17	3Q17E	4Q17E	2017E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	83.5	22.2	29.0	31.8	41.3	123.5	222.3	399.6	520.8
Revenue from services (Diagnostics)	11.7	8.7	329.7	1,012.1	255.3	256.7	278.0	270.7	1,059.1	1,231.0	1,425.9	1,645.1
Revenue from transfer of intellectual property	16.7	5.5	81.9	126.0	18.6	28.5	17.5	22.9	87.5	88.3	89.2	90.1
Total revenue	96.5	91.1	491.9	1,221.7	296.1	314.2	327.3	334.8	1,270.1	1,541.6	1,914.7	2,256.0
Costs of revenues	48.9	48.0	260.0	611.4	154.8	157.4	169.5	167.5	647.4	781.6	922.8	1,080.1
Gross Incomes	47.7	43.1	231.9	610.2	141.3	156.8	157.7	167.4	623.2	760.0	991.9	1,175.9
Selling, general and administrative	55.3	57.9	196.6	490.9	136.7	128.3	129.5	132.0	526.5	599.0	682.9	778.1
Research and development	53.9	83.6	99.5	111.2	26.0	32.6	38.1	40.0	136.8	143.6	149.4	155.4
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	17.0	2.4	4.4	1.9	1.8	10.5	10.5	10.5	10.5
Amortization of intangible assets	11.1	10.9	28.0	64.4	17.9	18.0	18.0	19.0	72.9	72.9	72.9	72.9
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	683.5	183.0	183.3	187.5	192.9	746.7	826.1	915.7	1,016.9
Total costs and expenses	176.2	236.9	615.0	1,294.9	337.8	340.7	357.0	360.4	1,394.1	1,607.7	1,838.5	2,097.0
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(73.3)	(41.7)	(26.5)	(29.8)	(25.5)	(124.0)	(66.0)	76.2	159.0
Interest income	0.4	0.8	0.3	0.5	-	-	0.1	0.1	0.3	0.3	0.3	0.3
Interest expense	(13.8)	(12.3)	(8.4)	(7.4)	-	-	(2.3)	(2.3)	(4.6)	(4.6)	(4.6)	(4.6)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	2.8	-	-	(4.4)	1.8	(2.6)	(2.6)	(2.6)	(2.6)
Other income (expense), net	34.8	(3.1)	7.7	3.9	5.9	3.6	(4.5)	3.0	8.0	8.0	8.0	8.0
Total Other Income, net	<u>(24.6)</u>	<u>(25.2)</u>	<u>(39.5)</u>	<u>(0.3)</u>	<u>5.9</u>	<u>3.6</u>	<u>(11.1)</u>	<u>2.6</u>	<u>1.1</u>	<u>1.1</u>	<u>1.1</u>	<u>1.1</u>
Income before tax	(104.2)	(171.0)	(138.0)	(73.5)	(35.8)	(22.9)	(40.8)	(22.9)	(123.0)	(64.9)	77.4	160.1
Tax	(1.7)	(0.0)	113.7	56.1	6.9	11.0	16.2	0.0	34.1	25.0	(28.6)	(59.2)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(17.4)	(28.9)	(11.9)	(24.6)	(22.9)	(88.3)	(39.9)	48.7	100.9
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(7.7)	(2.1)	(5.6)	(0.9)	(2.0)	(10.6)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(25.1)	(31.0)	(17.5)	(25.5)	(24.9)	(98.9)	(42.9)	45.7	97.9
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	0.0	-	-	0.0	-	0.0	0.0	0.0	0.0
Net Income (Loss) Applicable to Common Shareholders	(114.8)	(171.7)	(30.0)	(25.1)	(31.0)	(17.5)	(25.5)	(24.9)	(98.9)	(42.9)	45.7	97.9
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.32)	(\$0.41)	(\$0.06)	(\$0.05)	(\$0.06)	(\$0.03)	(\$0.05)	(\$0.04)	(\$0.18)	(\$0.08)	\$0.08	\$0.17
Shares outstanding—basic	355.1	422.0	488.1	550.8	550.0	559.3	563.3	567.3	560.0	558.8	568.0	566.8
Shares outstanding—diluted	355.1	422.0	488.1	550.8	550.0	564.2	568.2	572.2	563.6	558.8	571.6	566.8
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	56%	56%	55%	55%	54%	55%	54%	51%	50%
Gross margin	39%	44%	37%	44%	44%	45%	45%	46%	45%	46%	49%	50%
R&D	56%	92%	20%	9%	9%	10%	12%	12%	11%	9%	8%	7%
MG&A	57%	64%	40%	40%	46%	41%	40%	39%	41%	39%	36%	34%
Operating Income (loss)	-82%	-160%	-20%	-6%	-14%	-8%	-9%	-8%	-10%	-4%	4%	7%
Net Income	-119%	-188%	-6%	-2%	-10%	-6%	-8%	-7%	-8%	-3%	2%	4%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	4%	12%	27%	55%	104%	48%	80%	80%	30%
Revenue from services (Diagnostics)	567%	-26%	3705%	207%	1%	-4%	7%	15%	5%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	54%	0%	-58%	-5%	11%	-31%	1%	1%	1%
Total Revenue	105%	-6%	440%	148%	2%	-12%	10%	22%	4%	21%	24%	18%
R&D	176%	55%	19%	12%	37%	4%	56%	45%	23%	5%	4%	4%
SG&A	99%	5%	239%	150%	7%	9%	4%	10%	7%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-26%	51%	-194%	26%	-49%	69%	-47%	-215%	109%
Total Other Income, net	-15001%	3%	57%	-99%	-325%	-30%	5%	-66%	-499%	3%	3%	0%
Net Income	267%	49%	-82%	-16%	158%	-213%	71%	82%	294%	-57%	-207%	114%
EPS	206%	26%	-85%	-26%	156%	-210%	67%	94%	288%	-57%	-205%	114%

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

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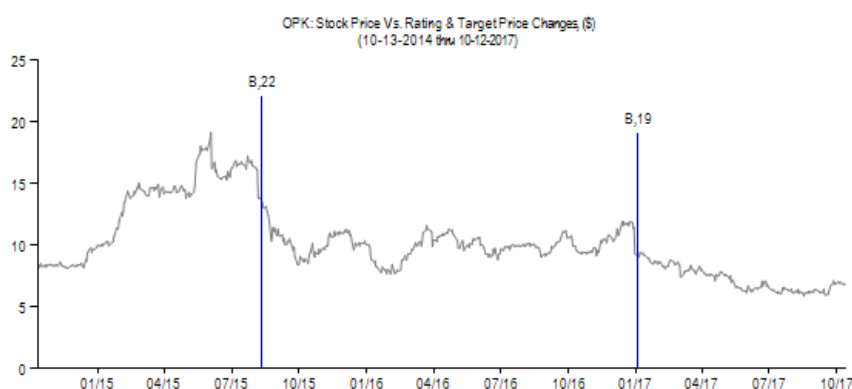
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3 Year Rating Change History

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
01/03/2017	19.00	9.09

Source: Laidlaw & Company

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ADDITIONAL COMPANIES MENTIONED

Japan Tobacco (TYO:2914 – Not Rated)
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