

OPKO Health, Inc. (OPK - \$ 9.30)

hGH-CTP in Adult GHD Phase III Trial Failed But Pediatric Phase III Trial Moves Forward

OPK announced last Friday that the hGH-CTP in adult growth hormone deficiency (GHD) Phase III trial failed to meet the primary endpoint. The company also initiated an hGH-CTP in children GHD Phase III trial since OPK believes there is sufficient supporting evidence that hGH-CTP could be effective in treating pediatric GHD.

- Details.** The adult GHD Phase III trial did not meet its primary endpoint of change in trunk fat mass (TFM) from baseline to 26 weeks between treatment and placebo. After un-blinding the study, OPKO identified one or more outliers (which we believe could be greater than expected TFM reduction in the placebo group) that may have affected the primary outcome. OPKO therefore decided to undertake further review of the study population in order to better assess the outcome. OPK also initiated an hGH-CTP in children GHD Phase III trial based on evidence suggesting the drug could be effective in treating pediatric GHD. Specifically, the prior Phase II pediatric GHD trial has demonstrated a positive outcome; and in the just reported Phase III trial a greater percentage of treated patients exhibited normalized serum insulin-like growth factor-I (a downstream bio-marker that affords ~2/3 of growth effects of growth hormone) vs. placebo. The pediatric Phase III study plans to recruit ~220 patients and compare annual height velocity between hGH-CTP and Genotropin after one year of treatment. We estimate top-line results could be available in 1H19.
- Implications.** We are disappointed with the Phase III outcome given prior encouraging trial results, and hence believe clinical risks of this program have increased. Given that the pediatric Phase III study is underway and support from OPK and partner Pfizer; we view the news could just be a hiccup instead of an impediment that could derail the advancement of the program. OPK will discuss with the FDA to gain feedback for the pathway forward and we believe additional read out from the adult Phase III trial could be important. For adult GHD approval, we believe additional studies might be needed. As a reminder, pediatric GHD accounts for more than 50% of growth hormone market.
- Action.** We are reiterating our Buy rating and reducing our target price to \$19 from \$22 to reflect increased risks for the hGH-CTP development. We remain bullish on progress in OPK's multiple drivers in place, especially the 4Kscore test, Rayaldee, VARUBI (rolapitant) and hGH-CTP. Our valuation is based on our DCF analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.02A	0.03A	-0.03A	-0.03	-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
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: ↓ lower **\$ 19.00**

Trading Data:

Last Price (12/30/2016)	\$ 9.30
52-Week High (12/15/2016)	\$ 12.15
52-Week Low (1/20/2016)	\$ 7.12
Market Cap. (MM)	\$ 5,185050
Shares Out. (MM)	558

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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	****
		Potential EMEA filing	1H17	***
		Potential EU approval	1H18	****
	SHPT in ESRD patients	Start Phase III study	2H17	***
Rolapitant (VARUBI)	Chemotherapy -induced nausea and vomiting (CINV)	Potential approval of the IV version (PDUFA date)	Jan. 2017	****
hGH-CTP (MOD-4023)	hGH deficiency	Report of Phase III pediatric study top-line results	1H19	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	Feb. 2017	****
		Potential private payer reimbursement decision	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	1H17	***
		Potential approval	2018	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	1H17	****
		Potential approval	2018	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study tinterim results	1Q17	***
		Potentially report Phase I/IIa study top-line results	2H17	****
		Potentially start Phase II/III study	2017	***
MOD-5014 (s.c)	Hemophilia A/B with inhibitors	Potentially report Phase II/III study results	2018	****
		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	1Q17	***
TT401	Obesity	Start Phase IIb study	2H17	***
TT701	Prostate hypertrophy reduction in elder males	Start Phase II study	Mid-2017	***

**** / ***** 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	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	19.9	22.8	20.6	34.2	97.6	207.3	321.5	555.4	718.8
Revenue from services (Diagnostics)	11.7	8.7	329.7	252.5	266.0	259.0	268.1	1,045.6	1,209.7	1,401.4	1,630.5	1,868.3
Revenue from transfer of intellectual property	16.7	5.5	81.9	18.6	68.3	18.4	17.9	123.2	124.5	125.7	127.0	128.2
Total revenue	96.5	91.1	491.7	291.0	357.1	298.0	320.2	1,266.4	1,541.5	1,848.6	2,312.8	2,715.4
Costs of revenues	48.9	48.0	260.0	147.5	153.4	151.2	157.7	609.8	752.3	891.0	1,062.5	1,231.0
Gross Incomes	47.7	43.1	231.7	143.5	203.7	146.9	162.5	656.6	789.3	957.6	1,250.4	1,484.3
Selling, general and administrative	55.3	57.9	196.6	128.0	117.5	124.8	127.3	497.7	534.2	609.4	694.4	791.0
Research and development	53.9	83.6	99.5	27.8	31.3	24.4	25.4	109.0	116.6	122.5	127.4	132.4
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	1.8	10.8	3.1	3.3	18.9	18.9	18.9	18.9	18.9
Amortization of intangible assets	11.1	10.9	28.0	13.4	15.8	18.1	18.1	65.5	65.5	65.5	65.5	65.5
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	170.5	174.2	691.1	735.2	816.2	906.2	1,007.8
Total costs and expenses	176.2	236.9	615.0	318.6	328.8	321.7	331.9	1,300.8	1,487.5	1,707.2	1,968.6	2,238.8
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(27.5)	28.3	(23.6)	(11.7)	(34.4)	54.1	141.4	344.2	476.5
Interest income	0.4	0.8	0.3	0.0	0.1	0.2	0.2	0.5	0.6	0.7	0.7	0.7
Interest expense	(13.8)	(12.3)	(8.4)	(1.8)	(2.2)	(2.0)	(2.7)	(8.7)	(8.7)	(8.7)	(8.7)	(8.7)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	(1.4)	1.2	(5.7)	(4.0)	(9.9)	(6.0)	(6.0)	(6.0)	(6.0)
Other income (expense), net	34.8	(3.1)	7.7	0.5	6.0	(3.0)	3.0	6.5	29.0	29.0	29.0	29.0
Total Other Income, net	<u>(24.6)</u>	<u>(25.2)</u>	<u>(39.5)</u>	<u>(2.6)</u>	<u>5.1</u>	<u>(10.5)</u>	<u>(3.5)</u>	<u>(11.5)</u>	<u>14.9</u>	<u>14.9</u>	<u>15.0</u>	<u>15.0</u>
Income before tax	(104.2)	(171.0)	(138.0)	(30.2)	33.4	(34.2)	(15.2)	(46.0)	68.9	156.3	359.2	491.5
Tax	(1.7)	(0.0)	113.7	20.5	(15.9)	20.0	0.0	24.6	(25.5)	(57.8)	(132.9)	(181.9)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(9.6)	17.5	(14.2)	(15.2)	(21.3)	43.4	98.5	226.3	309.7
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(2.4)	(2.0)	(0.8)	(0.8)	(6.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(12.0)	15.5	(15.0)	(16.0)	(27.3)	40.4	95.5	223.3	306.7
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	(0.8)	-	-	0.0	0.0	(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	(15.0)	(16.0)	(27.3)	43.4	98.5	226.3	309.7
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.32)	(\$0.41)	(\$0.06)	(\$0.02)	\$0.03	(\$0.03)	(\$0.03)	(\$0.05)	\$0.09	\$0.18	\$0.45	\$0.55
Shares outstanding—basic	355.1	422.0	488.1	545.8	547.6	552.2	556.2	550.5	496.1	558.5	504.1	566.5
Shares outstanding—diluted	355.1	422.0	488.1	545.8	557.0	552.2	556.2	552.8	496.1	560.8	504.1	568.8
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	54%	53%	54%	52%	53%	53%	52%	49%	48%
Gross margin	39%	44%	37%	46%	47%	46%	48%	47%	47%	48%	51%	52%
R&D	56%	92%	20%	10%	9%	8%	8%	9%	8%	7%	6%	5%
MG&A	57%	64%	40%	44%	33%	42%	40%	39%	35%	33%	30%	29%
Operating Income (loss)	-82%	-160%	-20%	-9%	8%	-8%	-4%	-3%	4%	8%	15%	18%
Net Income	-119%	-188%	-6%	-4%	4%	-5%	-5%	-2%	3%	5%	10%	11%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	28%	0%	-1%	63%	22%	112%	55%	73%	29%
Revenue from services (Diagnostics)	567%	-26%	3705%	12104%	13842%	149%	21%	217%	16%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	49%	286%	0%	-46%	51%	1%	1%	1%	1%
Total Revenue	105%	-6%	440%	867%	742%	108%	16%	158%	22%	20%	25%	17%
R&D	176%	55%	19%	9%	6%	29%	0%	10%	7%	5%	4%	4%
SG&A	99%	5%	239%	634%	461%	126%	24%	153%	9%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-52%	-211%	187%	48%	-65%	-257%	161%	143%	38%
Total Other Income, net	-15001%	3%	57%	-95%	-131%	-122%	-78%	-71%	-229%	0%	0%	0%
Net Income	267%	49%	-82%	-90%	-136%	-112%	-1105%	-9%	-259%	127%	130%	37%
EPS	206%	26%	-85%	-92%	-130%	-111%	-1091%	-19%	-276%	101%	155%	22%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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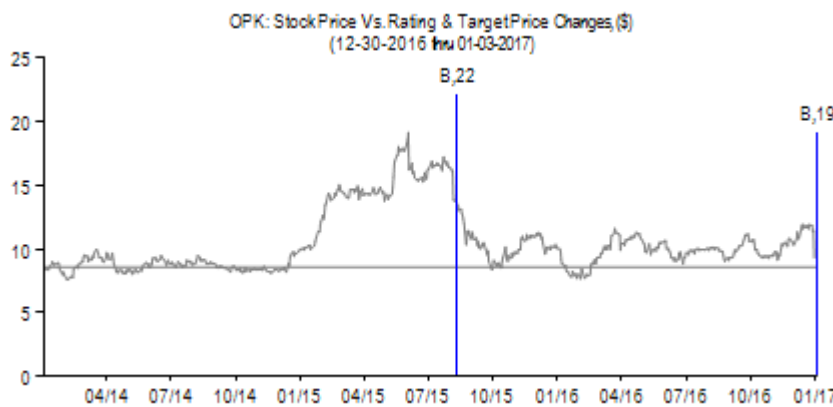
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3 Year Rating Change History

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	8.58*

* Previous Close 1/3/2014

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.50%	2.50%	0.00%
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Pfizer (PFE – Not Rated)

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