

OPKO Health (OPK - \$3.28)

1Q18: A First Step for Potential Turn-Around with BR Revenue Improvements and More Clinical Trials Underway

OPK reported 1Q18 financial results yesterday after the market close with a loss of (\$43MM) vs. the estimates of (\$72MM) for Laidlaw and (\$73MM) for the Street. Loss per share was (\$0.08) vs. (\$0.13) for Laidlaw and (\$0.14) of the Street. OPK ended 1Q18 with cash of ~\$100MM.

- A better quarter for Bio-Reference (BR) and overall OPK operations.** BR 1Q17 revenue was \$255MM, including BR revenue of \$211.3MM (with 3% business volume reduction) and product (pharma) revenue of ~\$28MM (\$3.7MM from Rayaldee, 763 prescribers, 29% Q/Q increase). Operating expenses (R&D+SG&A) in the mid-\$120MM, was lower than the prior several quarters of ~\$160MM. Management guided that the 2Q18 revenue of service (\$205MM-\$225MM), product (\$25MM-\$30MM which include \$4-5MM from Rayaldee) and transfer of intellectual property (\$15MM-\$20MM). With the new general manager, Geoff Monk in place, we believe the diagnostic business is taking the first step to reinvigorate and recover their operations under a still challenging diagnostic sector macro-environment. The differences in 1Q18 adjusted revenue, although lower than 1Q17, were smaller (\$255 vs. \$266 instead of the initial stated \$291MM). Together, we project a more conservative \$1.07 billion and \$550MM total revenue and operating expense, respectively, in 2018. Since the pharmaceutical pipeline is not mature enough to report clinical data, in our opinion, the continued improvement of the diagnostic operation will be a critical driver for OPK share value.
- Pipeline product clinical trial updates:** 1) The hGH-CTP in pediatric GHD global and Japan Phase III studies are underway, patient recruitment completion and top-line results could be in 4Q18 and 1H20, respectively. OPK is expecting feedback from the FDA on the adult hGH-CTP post-hoc sensitivity analyses; 2) OPK88004 (oral selective androgen receptor modulator or SARM) in BPH Phase IIb (n=125) dose ranging study is ongoing with topline readout possibly in 2019; 3) Readout from the OPK88003 (GLP-1 glucagon dual agonist) Phase IIb dose escalation trial also likely in 2019; and 4) High dose Rayaldee in ESRD and vitamin D insufficiency Phase II trial could start in mid-2018.
- 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 Rayaldee, hGH-CTP (MOD-4023) and several other in development products. Our valuation is based on our DCF analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.08A	-0.10	-0.11	-0.10	-0.35	NM
FY-17A	-0.06	-0.03	-0.08	-0.38	-0.55	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

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (5/8/2018)	\$3.28
52-Week High (5/9/2017)	\$7.53
52-Week Low (3/2/2018)	\$2.66
Market Cap. (MM)	\$1,802
Shares Out. (MM)	559.161

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Table 1: Estimated and reported 1Q18 results

1Q18 Estimates and Reported Results			
(\$ MM)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$242.8	\$254.9	\$237.0
Total op. profit (loss)	(\$74.0)	(\$42.6)	(\$70.2)
R&D	\$34.9	\$32.9	
SG&A	\$128.3	\$91.5	
EPS	(\$0.13)	(\$0.08)	(\$0.14)
Net income (loss)	(\$72.4)	(\$43.1)	(\$73.3)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Potential include in for formulary of healthcare plans	2018	****
		Potential EU filing for approval	2Q18	***
	SHPT in ESRD patients	Start Phase II study	3Q18	***
hGH-CTP (MOD-4023)	hGH deficiency	FDA feedback and additional adult GHD Phase III data analysis	2018	***
		Potential file BLA for adult GHD	2018	****
		Potentially report of ACP-001 pediatric Phase III study top-line results by Ascendis	1H19	***
		Report of Phase III pediatric study top-line results	1H20	****
4Kscore test	Prostate cancer diagnostics	Novitas reimbursement decisions	2018	****
		Potential more private payer reimbursement decision	2018	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	2H18	***
		Potential approval	2018/2019	****
Claros 1 PSA test	POC PSA test	Potential approval	2H18	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	2018	****
		Potential approval	2018	****
NK-1 inhibitor (OPK88002)	Pruritus	Potentially start Phase IIa study	2Q18	***
OPK88003	Obesity	Potentially report Phase II study results	2019	***
OPK88004	Benign prostate hypertrophy	Potentially report Phase II study results	2019	****
OPK88001	Dravet Syndrome	Potentially start Phase I/II trial	1H18	***

**** / ***** 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	2016	2017	1Q18	2Q18E	3Q18E	4Q18E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	83.5	107.8	27.9	29.3	31.7	32.5	121.3	256.0	337.4
Revenue from services (Diagnostics)	11.7	8.7	329.7	1,012.1	889.1	211.3	220.2	224.0	219.9	875.4	994.5	1,132.0
Revenue from transfer of intellectual property	16.7	5.5	81.9	126.0	70.6	15.7	18.0	17.0	19.0	69.7	70.4	71.1
Total revenue	96.5	91.1	491.9	1,221.7	1,067.5	254.9	267.5	272.7	271.4	1,066.4	1,320.9	1,540.5
Costs of revenues	48.9	48.0	260.0	611.4	620.1	154.1	161.2	163.5	160.2	622.2	620.5	711.2
Gross Incomes	47.7	43.1	231.9	610.2	447.4	100.8	106.3	109.2	111.2	444.2	700.4	829.3
Selling, general and administrative	55.3	57.9	196.6	490.9	521.0	91.5	99.7	103.7	105.8	400.8	653.1	744.9
Research and development	53.9	83.6	99.5	111.2	125.1	32.9	38.2	39.1	40.1	150.2	156.2	162.5
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	(3.3)	1.7	2.3	2.7	4.0	10.7	10.7	10.7
Amortization of intangible assets	11.1	10.9	28.0	64.4	84.7	17.3	18.0	18.0	18.0	71.3	71.3	71.3
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	727.5	143.4	158.2	163.5	167.9	633.0	891.3	989.4
Total costs and expenses	176.2	236.9	615.0	1,294.9	1,347.6	297.5	319.4	327.0	328.0	1,255.2	1,511.8	1,700.5
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(73.3)	(280.1)	(42.6)	(51.9)	(54.3)	(56.6)	(188.7)	(190.8)	(160.0)
Total Other Income, net	(24.6)	(25.2)	(39.5)	(0.3)	3.6	1.0	(2.5)	(6.5)	5.4	1.0	1.0	1.0
Income before tax	(104.2)	(171.0)	(138.0)	(73.5)	(276.5)	(41.6)	(54.4)	(60.8)	(51.2)	(187.7)	(189.8)	(159.0)
Tax	(1.7)	(0.0)	113.7	56.1	(18.9)	1.0	1.0	0.0	0.0	2.0	0.0	0.0
Loss before investment losses	(105.9)	(171.1)	(24.3)	(17.4)	(294.4)	(40.6)	(53.4)	(60.8)	(51.2)	(185.7)	(189.8)	(159.0)
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(7.7)	(14.4)	(2.5)	(3.0)	(3.1)	(3.4)	(12.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(25.1)	(308.8)	(43.1)	(56.4)	(63.9)	(54.6)	(197.7)	(192.8)	(162.0)
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)	(308.8)	(43.1)	(56.4)	(63.9)	(54.6)	(197.7)	(192.8)	(162.0)
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.32)	(\$0.41)	(\$0.06)	(\$0.05)	(\$0.55)	(\$0.08)	(\$0.10)	(\$0.11)	(\$0.10)	(\$0.35)	(\$0.34)	(\$0.29)
Shares outstanding—basic	355.1	422.0	488.1	550.8	558.0	559.5	559.6	559.7	559.8	559.6	566.0	567.6
Shares outstanding—diluted	355.1	422.0	488.1	550.8	559.2	559.5	559.6	559.7	559.8	559.6	567.2	567.6
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	56%	62%	64%	65%	64%	63%	62%	50%	48%
Gross margin	39%	44%	37%	44%	38%	36%	35%	36%	37%	38%	50%	52%
R&D	56%	92%	20%	44%	12%	13%	14%	14%	15%	14%	12%	11%
MG&A	57%	64%	40%	40%	49%	36%	37%	38%	39%	38%	49%	48%
Operating Income (loss)	-82%	-160%	-20%	-6%	-26%	-17%	-19%	-20%	-21%	-18%	-14%	-10%
Net Income	-119%	-188%	-6%	-2%	-29%	-17%	-21%	-23%	-20%	-19%	-15%	-11%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	4%	29%	26%	1%	39%	-4%	13%	111%	32%
Revenue from services (Diagnostics)	567%	-26%	3705%	207%	-12%	-17%	-14%	-2%	49%	-2%	14%	14%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	54%	-44%	-16%	-37%	45%	61%	-1%	1%	1%
Total Revenue	105%	-6%	440%	148%	-13%	-14%	-15%	3%	40%	0%	24%	17%
R&D	176%	55%	19%	12%	13%	35%	17%	21%	17%	20%	4%	4%
SG&A	99%	5%	239%	150%	6%	-33%	-22%	-21%	-15%	-23%	9%	8%
Operating income (loss)	114%	83%	-32%	-26%	282%	2%	96%	-7%	-63%	-33%	1%	-16%
Total Other Income, net	-15001%	3%	57%	-99%	-1427%	-83%	-169%	-24%	50%	-72%	4%	0%
Net Income	267%	49%	-82%	-16%	1130%	39%	222%	38%	-74%	-36%	-2%	-16%
EPS	206%	26%	-85%	-26%	1114%	37%	222%	38%	-74%	-36%	-4%	-16%

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

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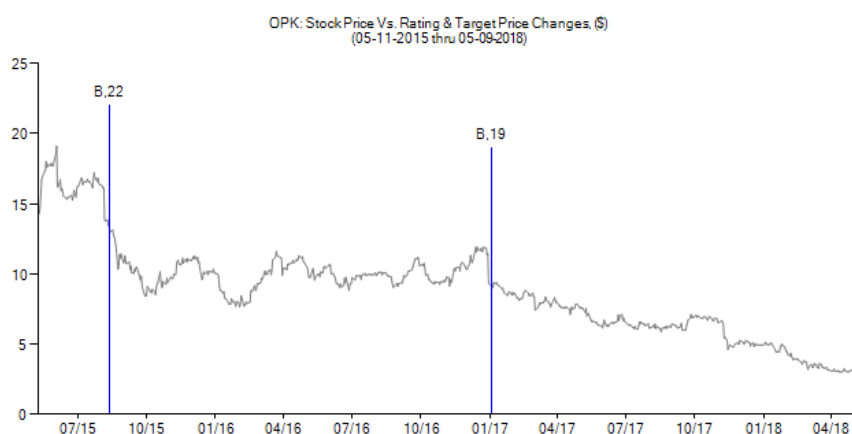
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
08/12/...	Buy (B)	13.45

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
08/12/...	22.00	13.45
01/03/...	19.00	9.09

Source: Laidlaw & Company

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Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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