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EQUITY RESEARCH
Company Report

November 9, 2017

OPKO Health (OPK - $6.58)

Healthcare/Biotechnology

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

3Q17: Tough Quarter for BioReference Revenue but 4Q Might Turn the Other Way

OPK reported 3Q17 financial results yesterday after the market close with a loss of ($46.4MM) vs. the estimates of ($25.5MM) for Laidlaw and ($36.7MM) for the Street. Loss per share was ($0.08) vs. ($0.05) for Laidlaw and ($0.04) for the Street. OPK ended 3Q17 with cash of ~$100MM.

- **Bio-Reference (BR) operation updates.** BR 3Q17 revenue was the lowest over the last seven quarters and the total revenue was below consensus. During the call, management pointed out some of the headwinds BR faced as well as the organization is undergoing a re-energization effort, especially for its GeneDx business. The company guided that the BR 2017 full year sales would be similar to that of 2016. Given BR has generated ~$260 sales quarterly on average over the last year and half, we believe such goal is attainable. For the 4Kscore tests, OPK plans to start a DTC campaign, mainly on TV and digital media, in the Northeast U.S. region shortly given the seemly successful example of Cologuard by EXAS. OPK has completed a PMA filing for the Claros PSA test recently with potential approval in 2H18. The 510(k) filing and clinical trial for Claros testosterone will come in 2018.
- **Rayaldee sales updates.** OPK indicated that they have shipped ~$6.7MM Rayaldee YTD and we believe the company could start discussing Rayaldee sales projections by the 4Q17 conference call (in 1Q18). In addition, management also indicated that Rayaldee TRx for 3Q17 has grown 66% Q/Q.
- **Pipeline product clinical trial updates.** OPK updated investors on several clinical studies of its pipeline products. They include: 1) The hGH-CTP in pediatric GHD global and Japan Phase III studies are underway and we anticipate top-line results could be available 2019. A meeting with the FDA could occur in 1Q18 for discussing the clinical path for hGH-CTP in adult GHD. It is possible that an additional bridging study for the pen-version of hGH-CTP in adult is needed; and 2) the subcutaneous Factor VII-CTP Phase II dosing trials are underway and we anticipate topline results could be available in 1Q18. If positive, OPK could potentially advance the IV and subcutaneous programs into Phase II or II/III developments in 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 4Kscore test, Rayaldee, VARUBI (rolapitant) and hGH-CTP (MOD-4023). Our valuation is based on our DCF analyses.

Trading Data:

Last Price (11/8/2017)	$6.58
52–Week High (12/15/2016)	$12.15
52–Week Low (8/17/2017)	$5.85
Market Cap. (MM)	$3,608
Shares Out. (MM)	550.847

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.06A	-0.03A	-0.08A	-0.07	-0.24	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

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- **Existing pipeline product development updates.** OPK88004 (oral selective androgen receptor modulator or SARM) in BPH Phase IIb (n=125) dose ranging study is scheduled to start in 1Q18. This could be a study potentially confirm the positive outcomes from prior 350 patient studies. The upcoming trial will test two doses of OPK88004, and management expects the study could take ~ three quarters to complete (4.5 months for recruitment and four months of treatment duration). Management suggested that a reduction of 15-20% of prostate volume and 30-40% of PSA level would be a positive sign for potentially advancing the program into pivotal trials. Other endpoints, such as increased muscle mass and bone strength and decreased fat mass also will be measured. During the call, Dr. Frost also commented on the potential for a SARM for treating urinary incontinence. This, in our opinion, could be an interesting disorder to explore given GTx currently is developing Enobosarm (another SARM) in stress urinary incontinence with promising preliminary Phase II results.

Table 1: Estimated and reported 3Q17 results

3Q17 Estimates and Reported Results			
($ MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$327.3**	**$263.5**	**$319.7**
Total op. profit (loss)	**($29.8)**	**($58.3)**	**($31.3)**
R&D	$38.1	$32.3	
SG&A	$129.5	$131.4	
EPS	**($0.05)**	**($0.08)**	**($0.04)**
Net income (loss)	($25.5)	($46.4)	($36.6)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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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**	***
hGH-CTP (MOD-4023)	hGH deficiency	FDA feedback and additional adult GHD Phase III data analysis	**1Q18**	***
		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	**1H19**	****
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	**1Q18**	***
		Potential approval	**2018**	****
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**	****
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 II study results	**1Q18**	****
		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	**1Q18**	***
OPK88003	Obesity	Start Phase IIb study	**1Q18**	***
OPK88004	Benign prostate hypertrophy	Start Phase II study	**4Q17**	***
		Potentially report Phase II study results	**2H18**	****
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.

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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)	2013	2014	2015	2016	1Q17	2Q17	3Q17	4Q17E	2017E	2018E	2019E	2020E
Revenue												
Products (Pharmaceuticals)	68.2	77.0	80.1	83.5	22.2	29.0	22.8	35.3	117.5	222.3	399.6	520.8
Revenue from services (Diagnostics)	11.7	8.7	329.7	1,012.1	255.3	256.7	229.0	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	11.7	12.2	71.0	71.7	72.4	73.2
Total revenue	96.5	91.1	491.9	1,221.7	296.1	314.2	263.5	318.1	1,247.7	1,525.0	1,897.9	2,239.0
Costs of revenues	48.9	48.0	260.0	611.4	154.8	157.4	151.3	166.9	646.8	781.6	922.8	1,080.1
Gross Incomes	47.7	43.1	231.9	610.2	141.3	156.8	112.2	151.3	561.6	743.4	975.1	1,158.9
Selling, general and administrative	55.3	57.9	196.6	490.9	136.7	128.3	131.4	134.0	530.4	599.0	682.9	778.1
Research and development	53.9	83.6	99.5	111.2	26.0	32.6	32.3	33.9	124.8	131.1	136.3	141.7
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	(11.2)	1.8	(2.6)	(2.6)	(2.6)	(2.6)
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	170.5	188.7	725.5	800.4	889.5	990.2
Total costs and expenses	176.2	236.9	615.0	1,294.9	337.8	340.7	321.8	355.6	1,372.4	1,582.0	1,812.3	2,070.3
Operating Incomes (losses)	(79.6)	(145.8)	(98.5)	(73.3)	(41.7)	(26.5)	(58.3)	(37.5)	(124.7)	(57.0)	85.6	168.7
Interest income	0.4	0.8	0.3	0.5			0.2	0.1	0.4	0.4	0.5	0.5
Interest expense	(13.8)	(12.3)	(8.4)	(7.4)			(1.8)	(2.3)	(4.1)	(4.1)	(4.1)	(4.1)
Fair value changes of derivative instruments, net	(45.9)	(10.6)	(39.1)	2.8			(7.6)	1.8	(5.8)	(5.8)	(5.8)	(5.8)
Other income (expense), net	34.8	(3.1)	7.7	3.9	5.9	3.6	0.6	3.0	13.1	13.1	13.1	13.1
Total Other Income, net	(24.6)	(25.2)	(39.5)	(0.3)	5.9	3.6	(8.5)	2.6	3.6	3.6	3.7	3.7
Income before tax	(104.2)	(171.0)	(138.0)	(73.5)	(35.8)	(22.9)	(66.8)	(34.8)	(121.1)	(53.3)	89.3	172.4
Tax	(1.7)	(0.0)	113.7	56.1	6.9	11.0	24.4	0.0	42.3	25.0	(33.0)	(63.8)
Loss before investment losses	(105.9)	(171.1)	(24.3)	(17.4)	(28.9)	(11.9)	(42.4)	(34.8)	(118.1)	(28.3)	56.3	108.6
Loss from investments in investees	(11.5)	(3.6)	(7.1)	(7.7)	(2.1)	(5.6)	(4.0)	(2.0)	(13.7)	(3.0)	(3.0)	(3.0)
Net income (loss)	(117.3)	(174.6)	(31.4)	(25.1)	(31.0)	(17.5)	(46.4)	(36.8)	(131.8)	(31.3)	53.3	105.6
Net loss attributable to noncontrolling interests	(2.9)	(3.0)	(1.4)	0.0	-	-	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)	(46.4)	(36.8)	(131.8)	(31.3)	53.3	105.6
Net Earnings (Losses) Per Share—Basic and Diluted	($0.32)	($0.41)	($0.06)	($0.05)	($0.06)	($0.03)	($0.08)	($0.07)	($0.24)	($0.06)	$0.09	$0.19
Shares outstanding—basic	355.1	422.0	488.1	550.8	550.0	559.3	559.4	563.4	558.0	558.8	566.0	566.8
Shares outstanding—diluted	355.1	422.0	488.1	550.8	550.0	564.2	559.4	563.4	559.2	558.8	567.2	566.8
Margin Analysis (% of Sales/Revenue)												
Costs of goods	61%	56%	63%	56%	56%	55%	60%	55%	55%	54%	51%	50%
Gross margin	39%	44%	37%	44%	44%	45%	40%	45%	45%	46%	49%	50%
R&D	56%	92%	20%	9%	9%	10%	12%	11%	10%	9%	7%	6%
MG&A	57%	64%	40%	40%	46%	41%	50%	42%	43%	39%	36%	35%
Operating Income (loss)	-82%	-160%	-20%	-6%	-14%	-8%	-22%	-12%	-10%	-4%	5%	8%
Net Income	-119%	-188%	-6%	-2%	-10%	-6%	-18%	-12%	-11%	-2%	3%	5%
Financial Indicator Growth Analysis (YoY%)												
Products (Pharmaceuticals)	50%	13%	4%	4%	12%	27%	11%	75%	41%	89%	80%	30%
Revenue from services (Diagnostics)	567%	-26%	3705%	207%	1%	-4%	-12%	15%	5%	16%	16%	15%
Revenue from transfer of intellectual property	N.A.	-67%	1395%	54%	0%	-58%	-37%	-41%	-44%	1%	1%	1%
Total Revenue	105%	-6%	440%	148%	2%	-12%	-12%	15%	2%	22%	24%	18%
R&D	176%	55%	19%	12%	37%	4%	32%	23%	12%	5%	4%	4%
SG&A	99%	5%	239%	150%	7%	9%	5%	11%	8%	9%	9%	8%
Operating income (loss)	114%	83%	-32%	-26%	51%	-194%	147%	-26%	70%	-54%	-250%	97%
Total Other Income, net	-15001%	3%	57%	-99%	-325%	-30%	-19%	-66%	-1427%	1%	1%	0%
Net Income	267%	49%	-82%	-16%	158%	-213%	210%	170%	425%	-76%	-270%	98%
EPS	206%	26%	-85%	-26%	156%	-210%	206%	189%	418%	-76%	-268%	98%

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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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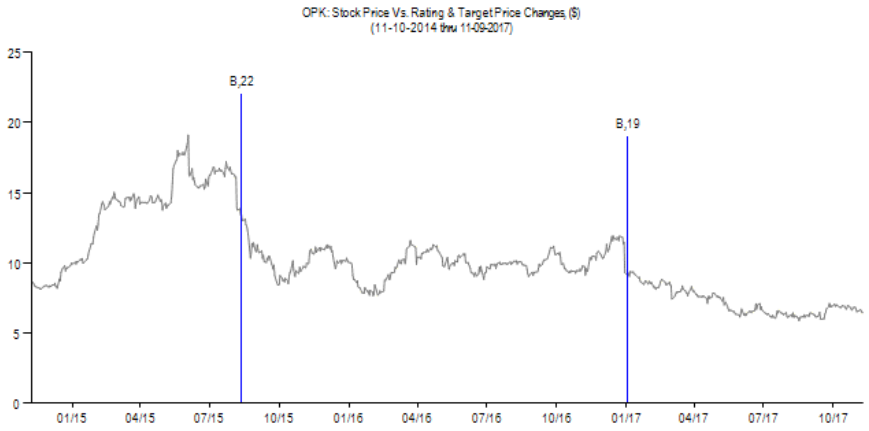
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/12/2...	Buy (B)	13.45

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/12/2...	22.00	13.45
01/03/2...	19.00	9.09

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.	0.00%	0.00%	0.00%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Exact Sciences (EXAS – Not Rated)
GTx (GTXI – Not Rated)

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