LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

April 27, 2016

OPKO Health, Inc. (OPK - $ 10.99)

Healthcare/Biotechnology

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

Rayaldee NDA Resubmitted and Has Been Accepted by the FDA with New PDUFA Date of Oct. 22, 2016

This afternoon, OPK announced that the FDA has accepted the NDA resubmitted by OPK for Rayaldee in secondary hyperparathyroidism (SHPT) in patients with stage 3/4 CKD and vitamin D insufficiency and assigned a PDUFA date of Oct. 22, 2016.

- **Details.** As a reminder, the FDA issued a CRL on March 30 regarding the Rayaldee NDA as the agency discovered seemingly routine in nature deficiencies during its facility inspection of third party manufacturer Catalent's plant in St. Petersburg, FL. The CRL did not request additional clinical studies prior to FDA approval, nor did it cite any safety, efficacy, or labeling issues. OPK also indicated then that Catalent would likely submit an action plan to ameliorate the problems by or before April 15. OPK indicated that once the issues were resolved that the company would resubmit an NDA for approval with either a Class I resubmission (with two months review period) or Class II resubmission (with six months review period). Today's news indicated that the NDA is under a Class II submission. For the Class II submission, the plant will need to be re-inspected by the FDA before potential approval. Further, OPK indicated on March 30 that the agency and the company reached an agreement for Rayaldee's potentially approvable package insert and labeling, and OPK is continuing its commercialization activities.
- **Implications.** We view today's news as a positive as Rayaldee's NDA filing is advancing with only a very minor delay. We do not believe the fundamentals of the Rayaldee outlook have been altered for its likely approval and product launch. We estimate the Rayaldee approval could slate to 4Q16 with potential product launch in 1Q17.
- **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.

Trading Data:

Last Price (04/27/2016)	$ 10.99
52–Week High (6/3/2015)	$ 19.20
52–Week Low (1/20/2016)	$ 7.12
Market Cap. (MM)	$ 5,999
Shares Out. (MM)	546

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

Yale Jen, Ph.D.
Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

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)	Hemophilia A/B with inhibitors	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)		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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Figure 1: Income Statement

OPKO Health – Income Statement

($'MM)	2013	2014	2015	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
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%

Yale Jen, Ph.D. 212-953-4978

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

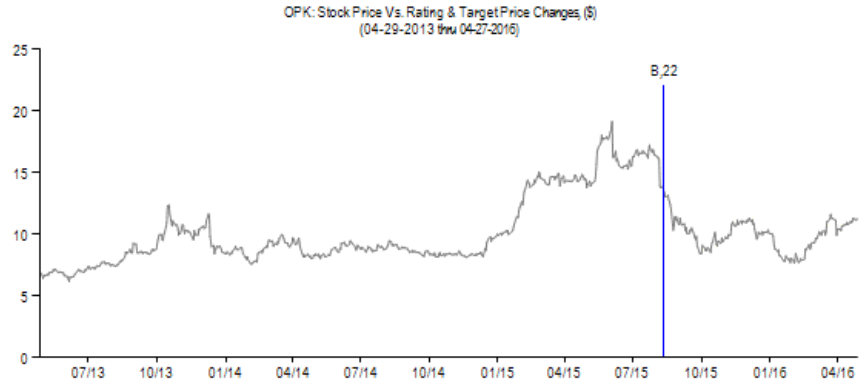
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

Rating and Price Target Change History



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 **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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

Catalent Inc. (CTLT – NYSE; Not Rated)

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices. market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.Laidlawltd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

NOTES: