

## Flamel Technologies (FLML - \$10.68)

### Eclat is Portfolio Resilient with Significant 2017 Upside Potential

We recently spent time with the senior management of Flamel Technologies and we are increasingly confident on the prospects for 2017 earnings potentially coming in well ahead of expectations. This is on the strength of Akovaz & Vazculep, as well as the very real potential that the FDA could remove Akovaz competitor Akorn's unapproved ephedrine sulfate from the market in 2017. This could give FLML sole possession of the 7M vial, ~\$50/vial market (\$350M US market) ephedrine sulphate opportunity. FLML is building inventory now to show the FDA that they can supply the entire 7M vial US market, and when they have completed the inventory build in 1Q17 they expect to ask the FDA to remove AKRX's unapproved ephedrine. Vazculep continues to see no additional competition too. So 2017 could be a year of significant upside from the Eclat portfolio as we await the outcome of the ongoing sodium oxybate Phase 3 trial. We are reiterating our Buy rating, \$25 price target.

- **Akovaz franchise could have surprising – and significant - upside.** If the FDA removes AKRX's ephedrine sulfate, and if no other manufacturers enter the market (ENDP is another possible ephedrine entrant in 1Q17) there could be significant upside for FLML in this space. AKRX's "approved" ephedrine sulfate NDA is unlikely to be approved until the 483 warning letter on their Decatur IL manufacturing facility is removed. This could be sooner rather than later given the 12/5-9/16 FDA re-inspection of the facility which found no new 483 observations.
- **No Vazculep generics seen to date, also potential real upside.** FLML has 100% share in the 5ml & 10ml markets, and 40% share in the primary 1ml market (with WestWard). We had modeled in additional entrants and declining sales in 2017+, but to date this hasn't been seen, nor is it apparently likely.
- **Sodium oxybate enrolling on track, chance for faster enrollment.** The first patient is enrolled (but not yet dosed). There is a chance FLML could enroll the trial faster than the one year they have guided to the Street (mid-2018 top line).
- **Maintain our BUY rating, \$25 price target.** Our price target is based on a sum-of-the-parts analysis with sodium oxybate at \$11.50/share, the Eclat portfolio at \$8/share, the pipeline, royalties & tech value worth \$13/share, and cash (end '17E) worth \$3/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	0.01	0.09	0.12	0.18	0.40	26.7x
<b>FY-16E</b>	0.03A	(0.02)A	(0.08)A	(0.03)	(0.10)	NM
<b>FY-15A</b>	0.10	0.34	0.27	0.32	0.99	10.8x
<b>FY-14A</b>	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM

Source: Company data and Laidlaw & Company estimates

#### Healthcare/Biotechnology

Ticker:	<b>FLML</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$25.00</b>

#### Trading Data:

Last Price (12/09/2016)	\$10.68
52-Week High (12/23/2015)	\$15.54
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$440.5
Shares Out. (MM)	41.24

#### Analysts

**Jim Molloy**/Spec Pharma & Biotech  
(857) 317-5061  
jmolloy@laidlawltd.com

**Francois Brisebois**,  
MSc/Associate (857)317-5362  
fbrisebois@laidlawltd.com

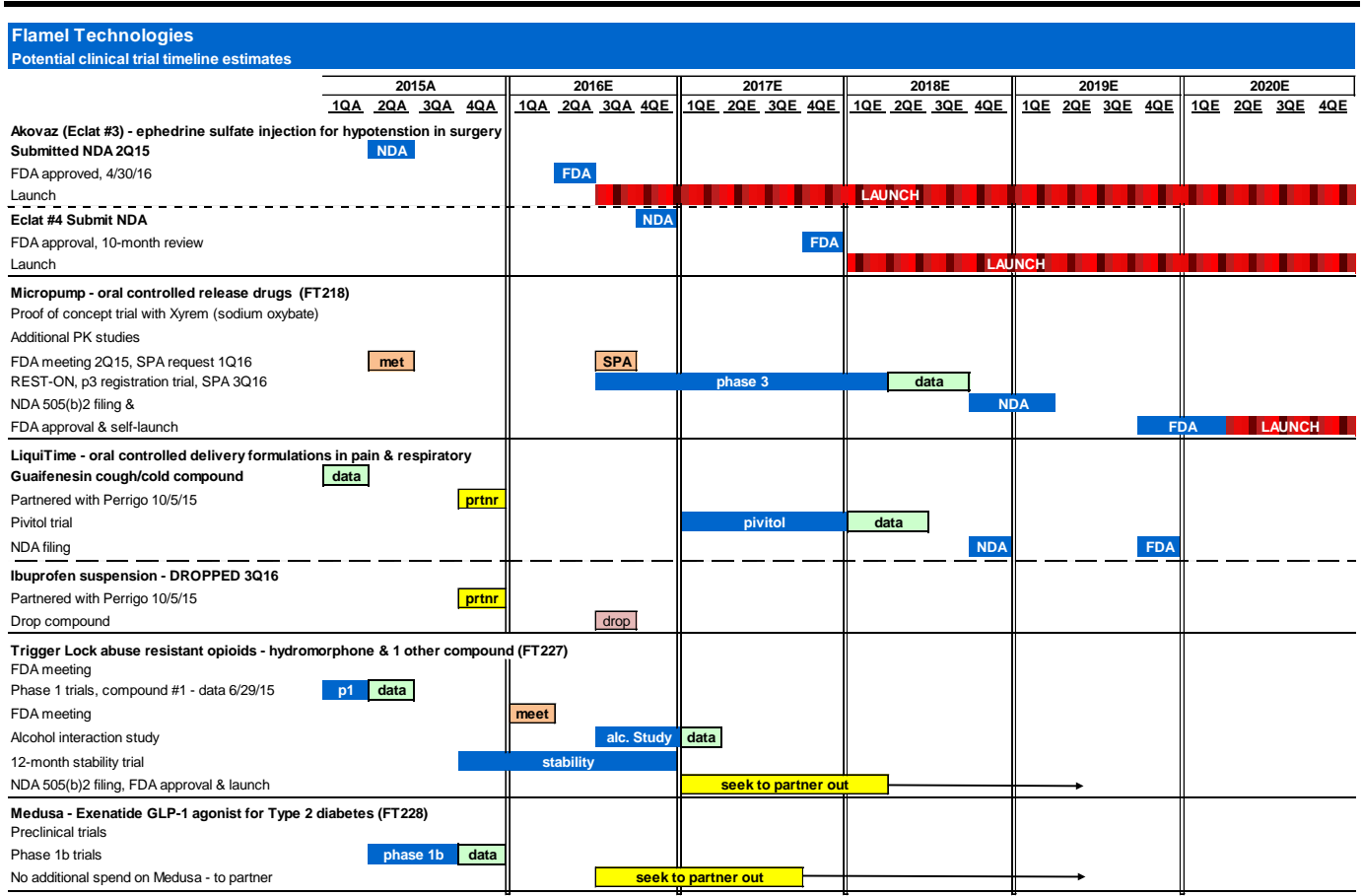
FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

Figure 1: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Sodium Oxybate (FT 218)	\$556,078	\$11.50
Eclat products	\$425,314	\$8.00
Cash (end of '17E) & tech value	\$312,536	\$5.50
	\$1,293,929	<b>\$25.00</b>
2017 fully diluted shares out		48,791

Source: Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 3: Quarterly Income Statement

Flamel Technologies										
Quarterly income statement										
(\$000's except per share)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
Bloxivierz (neostigmine)	\$28,642	\$44,283	\$41,243	\$34,860	\$149,028	\$24,747	\$25,620	\$15,591	\$14,116	\$80,074
Vazculep (phenylephrine hci)	3,524	3,627	5,605	7,394	20,151	9,406	10,421	9,340	9,750	38,917
FSC products						1,200	2,124	841	1,250	5,415
Akovaz & Eclat #4							0	5,568	8,500	14,068
License & research						863				
Product sales & service	(38)	662	465	393	2,054					
1x, other, (licenses deals)	53	30	6	721	721		693	747	50	1,490
<b>Total Revenues</b>	<b>\$32,726</b>	<b>\$49,795</b>	<b>\$47,338</b>	<b>\$43,368</b>	<b>\$173,209</b>	<b>\$36,216</b>	<b>\$38,858</b>	<b>\$32,087</b>	<b>\$33,666</b>	<b>\$140,827</b>
<b>Expenses</b>										
Cost of Goods Sold	3,630	2,756	2,087	2,448	10,921	3,392	3,145	2,844	3,010	12,391
<b>Gross Margin</b>	<b>29,096</b>	<b>47,039</b>	<b>45,251</b>	<b>40,920</b>	<b>162,288</b>	<b>32,824</b>	<b>35,713</b>	<b>29,243</b>	<b>30,656</b>	<b>128,436</b>
R&D	6,022	7,204	7,221	5,161	25,608	5,388	7,604	8,143	9,750	30,885
SG&A	4,463	5,873	4,568	6,808	21,712	9,461	11,290	12,740	11,188	44,679
Acq. liab. remeasurement					0					0
Impairment of assets					0					0
<b>Total Operating Expenses</b>	<b>10,485</b>	<b>13,077</b>	<b>11,789</b>	<b>11,969</b>	<b>47,320</b>	<b>14,849</b>	<b>18,894</b>	<b>20,883</b>	<b>20,938</b>	<b>75,564</b>
<b>Income (loss) from Ops</b>	<b>18,611</b>	<b>33,962</b>	<b>33,462</b>	<b>28,951</b>	<b>114,968</b>	<b>17,975</b>	<b>16,819</b>	<b>8,360</b>	<b>9,719</b>	<b>52,873</b>
Royalty payments - Eclat	(5,796)	(10,649)	(10,239)	(8,016)	(40,851)	(7,240)	(7,933)	(6,669)	(6,662)	(28,504)
Interest income/(exp)	657	312	75	934	2,651	200	127	226	200	753
FOREX gain/(loss)	2,264	480	192	1,651	1,500					0
1x milestones						0	0	0	0	0
Other income/(loss)	(852)	(2)	50	(32)		(175)	0		100	(75)
<b>Pretax Income (Loss)</b>	<b>14,884</b>	<b>24,103</b>	<b>23,540</b>	<b>23,488</b>	<b>78,268</b>	<b>10,760</b>	<b>9,013</b>	<b>1,917</b>	<b>3,356</b>	<b>25,046</b>
Income tax exp/(benefit)	10,473	10,242	12,018	9,613	35,167	9,210	9,998	5,416	4,500	29,124
NI from discontinued ops										
<b>Adj Net income/(loss)</b>	<b>4,411</b>	<b>13,861</b>	<b>11,522</b>	<b>13,875</b>	<b>43,101</b>	<b>1,550</b>	<b>(985)</b>	<b>(3,499)</b>	<b>(1,144)</b>	<b>(4,078)</b>
<b>EPS - adjusted</b>	<b>\$0.10</b>	<b>\$0.34</b>	<b>\$0.27</b>	<b>\$0.32</b>	<b>\$0.99</b>	<b>\$0.03</b>	<b>(\$0.02)</b>	<b>(\$0.08)</b>	<b>(\$0.03)</b>	<b>(\$0.10)</b>
<b>EPS as reported</b>	<b>\$0.27</b>	<b>(\$0.43)</b>	<b>(\$0.73)</b>	<b>\$1.75</b>	<b>\$0.93</b>	<b>(\$0.15)</b>	<b>(\$0.48)</b>	<b>(\$0.54)</b>	<b>(\$0.54)</b>	<b>(\$1.85)</b>
Shares out (000)	40,207	40,353	40,625	41,125	40,580	41,241	41,241	41,241	41,541	41,316
Fully diluted shares (000)	42,879	40,748	42,875	43,430	43,619	47,838	47,837	47,741	48,041	47,864
<b>Margin &amp; expense analysis</b>										
COGS	11%	6%	4%	6%	6%	9%	8%	9%	9%	9%
R&D	18%	14%	15%	12%	15%	15%	20%	25%	29%	22%
SG&A	14%	12%	10%	16%	13%	26%	29%	40%	33%	32%
Operating margin	57%	68%	71%	67%	66%	50%	43%	26%	29%	38%
Taxes	70%	42%	51%	41%	45%	86%	111%	283%	134%	116%
Net margin	13%	28%	24%	32%	25%	4%	-3%	-11%	-3%	-3%
<b>Year-over-year change</b>										
Net revenue	257%	516%	574%	1362%	536%	11%	-22%	-32%	-22%	-19%
COGS	191%	68%	40%	75%	89%	-7%	14%	36%	23%	13%
Gross margin	267%	630%	718%	2506%	656%	13%	-24%	-35%	-25%	-21%
R&D	-15%	7%	3%	-8%	-3%	-11%	6%	13%	89%	21%
SG&A	26%	24%	11%	66%	32%	112%	92%	179%	64%	106%
Operating income	-783%	-775%	-698%	-455%	-634%	-3%	-50%	-75%	-66%	-54%
Net income	-205%	-384%	-291%	-312%	-299%	-65%	-107%	-130%	-108%	-109%

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

Figure 4: Annual Income Statement

<b>Flamel Technologies</b>							
<b>Annual income statement</b>							
(\$000's except per share)	<b>2015A</b>	<b>2016E</b>	<b>2017E</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>	<b>Comments</b>
<b>Revenues</b>							
Bloxivertz (neostigmine)	\$149,028	\$80,074	\$56,161	\$53,657	\$54,968	\$57,081	WestWard entry 1Q16
Vazculep (phenylephrine hci)	20,151	38,917	38,000	34,000	32,500	30,000	Generics 2H16
FSC products		5,415	5,000	8,500	10,000	11,500	FSC underperforming
Akovaz & Eclat #4		14,068	77,225	125,000	135,000	115,000	Akovaz ~\$350M mkt (7M vials)
LiquiTime royalty				0	0	750	Licensed to Perrigo
Sodium Oxybate (Xyrem-like)						75,000	Eliminates middle night dosing
1x milestones (license deals)	721	1,490	200	200	0	200	
<b>Total Revenues</b>	<b>\$173,209</b>	<b>\$140,827</b>	<b>\$176,586</b>	<b>\$221,357</b>	<b>\$232,468</b>	<b>\$289,531</b>	<b>2016 Guide: \$133M-\$143M revs</b>
<b>Expenses</b>							
Cost of Goods Sold	10,921	12,391	15,768	19,564	20,022	23,437	
<b>Gross Margin</b>	<b>162,288</b>	<b>128,436</b>	<b>160,819</b>	<b>201,793</b>	<b>212,446</b>	<b>266,094</b>	
R&D	25,608	30,885	29,250	24,000	24,000	24,000	2016 Guide: \$30M-\$35M
SG&A	21,712	44,679	48,250	54,688	54,000	54,250	2016 Guide: ~\$40M
<b>Total Operating Expenses</b>	<b>47,320</b>	<b>75,564</b>	<b>77,500</b>	<b>78,688</b>	<b>78,000</b>	<b>78,250</b>	
<b>Income (loss) from Ops</b>	<b>114,968</b>	<b>52,873</b>	<b>83,319</b>	<b>123,105</b>	<b>134,446</b>	<b>187,844</b>	
Royalty payments - Eclat	(40,851)	(28,504)	(35,278)	(43,773)	(45,793)	(41,596)	Deerfield & Broadfin payments
Interest income	2,651	753	1,000	1,200	1,500	2,000	
FOREX gain/(loss)	1,500	0	0	0	0	0	non-cash item
Other income/(loss)	0	(75)	400	400	402	404	
<b>Pretax Income (Loss)</b>	<b>78,268</b>	<b>25,046</b>	<b>49,441</b>	<b>80,932</b>	<b>90,555</b>	<b>148,652</b>	
Taxes	35,167	29,124	29,700	33,300	34,500	30,000	Domicile structure drives tax rate
<b>Adj Net income/(loss)</b>	<b>43,101</b>	<b>(4,078)</b>	<b>19,741</b>	<b>47,632</b>	<b>56,055</b>	<b>118,652</b>	
Non cash & 1x-items	2,442	72,445					
<b>Net inc/(loss) as reported</b>	<b>40,659</b>	<b>(76,523)</b>					
<b>EPS - adjusted</b>	<b>\$0.99</b>	<b>(\$0.10)</b>	<b>\$0.40</b>	<b>\$0.95</b>	<b>\$1.10</b>	<b>\$2.30</b>	+15% CAGR 2015-2020
<b>EPS as reported</b>	<b>\$0.93</b>	<b>(\$1.85)</b>					
Shares out (000)	40,580	41,316	42,291	43,491	44,243	44,845	
Fully diluted shares (000)	43,619	47,864	48,791	50,241	50,993	51,595	
<b>Margin &amp; expense analysis</b>							
COGS	6%	9%	9%	9%	9%	8%	
R&D	15%	22%	17%	11%	10%	8%	
SG&A	13%	32%	27%	25%	23%	19%	
Operating margin	66%	38%	47%	56%	58%	65%	
Taxes	45%	116%	60%	41%	38%	20%	Normalize w/Akovaz & Sod. Oxybate
Net margin	25%	-3%	11%	22%	24%	41%	
<b>Year-over-year change</b>							
Net revenue	536%	-19%	25%	25%	5%	25%	
COGS	89%	13%	27%	24%	2%	17%	
Gross margin	656%	-21%	25%	25%	5%	25%	
R&D	-3%	21%	-5%	-18%	0%	0%	
SG&A	32%	106%	8%	13%	-1%	0%	
Operating income	-634%	-54%	58%	48%	9%	40%	
Net income	-299%	-109%	-584%	141%	18%	112%	

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

## Major risks

---

**Exogenous events could impact our outlook.** We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

**Actual clinical results and the FDA's conclusions may deviate from expectations.** Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

**Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations.** Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

**Legal risks could lead to additional liabilities and revenue loss.** In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

## 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

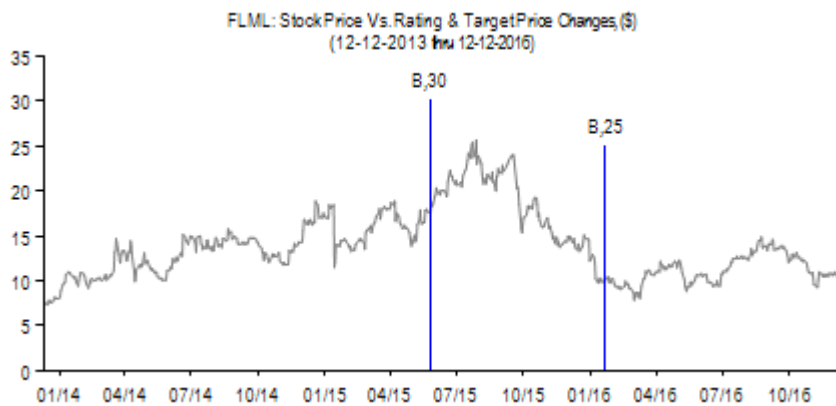
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell 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 (\$)
05/26/2015	Buy (B)	17.48

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
05/26/2015	30.00	17.48
01/21/2016	25.00	10.25

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	2.56%	2.56%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Akorn, Inc. (AKRX – Not Rated)  
Endo International (ENDP – 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](http://www.LaidlawLtd.com), or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2016 Laidlaw & Co. (UK), Ltd.

**NOTES:**