

Flamel Technologies (FLML - \$10.24)

FLML Looking for Additional FSC Acquisitions in 2016

Flamel recently reported 4Q16 missing top line but beating EPS on better operating expense control. FLML should start recording significant FSC contributions in 2Q16 with the acquisition expected to be neutral in 2016 and accretive to 2017 and beyond. More importantly FLML will look for additional products to bring in to run across the FSC 45 person sales force. FLML's pipeline continues on-track with their Micropump sodium oxybate (Xyrem) product expected to start Phase 3 in 2Q16 following the receipt of a Special Protocol Assessment (SPA) from the FDA. The next key catalyst for FLML remains the April 30th PDUFA date for Eclat #3, expected to target a \$75M-\$100M market opportunity upon approval. We are reiterating our Buy rating and \$25 price target.

- **Eclat still delivering near term cash flow.** FLML noted that the FDA appears to have walked back from their written policy of requiring unapproved generics to exit the market upon an FDA approved product launching. It took the FDA a full year to require the unapproved neostigmines to exit the market, and now FLML guides for Eclat #3 to only have 20%-30% market share in 2016, as opposed to 100%. So while there appear to be some holes in FLML's Eclat strategy of getting exclusivity for getting FDA approved products to the market, overall the strategy has succeeded in getting FLML cash-flow positive until their internal pipeline can get to market.
- **4Q15 EPS beat on lower expenses.** FLML reported 4Q15 with top line revenues slightly below our estimates (\$43.4M vs \$46M) but delays in R&D expenses allowed them to significantly beat bottom line with adjusted EPS of \$0.32 vs our estimated \$0.18. Similarly, FY15 top line was somewhat lower than expected (\$173.2M vs \$175.9M) but offset by smaller R&D expenses enabling an adjusted EPS beat of \$0.99 vs our estimated \$0.90.
- **Maintain our BUY rating, \$25 price target.** Our PT is based on a sum-of-the-parts analysis with the Eclat portfolio worth \$10/share, the pipeline, royalties & tech value worth \$12/share, and cash (end '16E) worth \$3/share.

Healthcare/Biotechnology

Ticker:	FLML
Rating:	Buy
Price Target:	\$25.00

Trading Data:

Last Price (03/14/2016)	\$10.24
52-Week High (07/23/2015)	\$26.09
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$414.7
Shares Out. (MM)	40.50

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	0.08	0.15	0.16	0.20	0.60	17.1x
FY-16E	0.18	0.11	0.05	0.02	0.35	29.3x
FY-15A	0.27	0.34	0.27	0.32	0.99	10.3x
FY-14A	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM

James Molloy

Managing Director /
Specialty Pharmaceutical &
Biotechnology Analyst
(857) 317-5061
jmolloy@laidlawltd.com

Source: Company data and Laidlaw & Company estimates

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: Variance analysis

Flamel Technologies										
Quarterly variance analysis										
(\$000 except per share)	4Q14A	4Q15A	4Q15E	Variance	% Y/Y	FY14A	FY15A	FY15E	Variance	% Y/Y
Bloxiverz (neostigmine)	\$2,230	\$34,860	\$40,223	(5,363)	1463.2%	\$10,470	\$150,778	\$156,141	(5,363)	1340.1%
Vazculep		7,394	5,750	1,644	NM		20,151	18,461	1,690	NM
1x milestones (license deals)	29	721	50	671	2386.2%	5,114	721	139	582	-85.9%
Total Revenue	\$2,966	\$43,368	\$46,023	(2,655)	1362.2%	\$27,250	\$173,209	\$175,882	(2,673)	535.6%
COGS	1,396	2,448	2,069	379	75.4%	5,775	10,921	10,542	379	89.1%
Gross Profit	1,570	40,920	43,954	(3,034)	2506.4%	21,475	162,288	165,340	(3,052)	655.7%
SG&A Expense	4,093	6,808	5,500	1,308	66.3%	16,485	21,712	20,404	1,308	31.7%
R&D Expense	5,636	5,161	14,500	(9,339)	-8.4%	26,500	25,608	34,947	(9,339)	-3.4%
Operating Inc (loss)	(8,159)	28,951	23,954	4,997	NM	(21,510)	114,968	109,989	4,979	NM
Interest inc (exp)	543	934	70	864	72.0%	(1,450)	2,651	1,114	1,537	-282.8%
FOREX gain (loss)	0	1,651	0	1,651	NM	(149)	1,500	2,936	(1,436)	NM
Other inc (exp)	(188)	(32)	50	(82)	-83.0%	(35)	0	(754)	754	-100.0%
Pretax Income	(7,804)	23,488	14,611	8,877	NM	(23,144)	78,268	77,138	1,130	NM
Income Taxes/(benefit)	(1,272)	9,613	6,575	3,038	NM	(1,487)	35,167	39,308	(4,141)	NM
Adj Net income/(loss)	(6,532)	13,875	8,036	5,839	NM	(21,657)	43,101	37,830	5,271	NM
1x & non cash exp	20,617	(62,222)	6,500	(68,722)	-401.8%	63,249	2,442	71,733	(69,291)	-96.1%
NI/(loss) as reported	(27,149)	76,097	1,536	74,561	NM	(84,906)	40,659	(33,903)	74,562	NM
Shares out (000)	39,208	41,125	40,925	200	4.9%	36,211	40,580	40,528	53	12.1%
Fully diluted shares (000)	42,808	43,430	43,675	(245)	1.5%	40,531	43,619	42,070	1,549	7.6%
EPS as reported	(\$0.69)	\$1.75	\$0.04	\$1.72	NM	(\$2.34)	\$0.93	(\$0.84)	\$1.77	NM
Adj EPS ex-1x & non cash	(\$0.17)	\$0.32	\$0.18	\$0.14	NM	(\$0.60)	\$0.99	\$0.90	\$0.09	NM

Source: Company reports & Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Pipeline, royalties & tech value	\$553,349	\$12.00
Eclat products	\$427,894	\$10.00
Cash (end of '16E)	\$127,588	\$3.00
	\$1,108,831	\$25.00
2016 fully diluted shares out		44,875

Source: Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

Flamel Technologies Quarterly income statement										
(\$000's except per share)	2014A				2014A Year	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
Bloxiverz (neostigmine)	\$3,840	\$2,200	\$2,200	\$2,230	\$10,470	\$29,200	\$45,500	\$41,218	\$34,860	\$150,778
Vazculep (phenylephrine hci)						3,511	3,600	5,600	7,394	20,151
FSC products										
License & research	1,433	2,270	681	29	4,413					
Product sales & service	2,100	1,928	2,547	677	7,252	(38)	600	514	393	2,054
1x, other, milestones (license de	1,802	1,683	1,600	29	5,114	53	30	6	721	721
Total Revenues	\$9,175	\$8,081	\$7,028	\$2,966	\$27,250	\$32,726	\$49,795	\$47,338	\$43,368	\$173,209
Expenses										
Cost of Goods Sold	1,249	1,636	1,494	1,396	5,775	3,630	2,756	2,087	2,448	10,921
Gross Margin	7,926	6,445	5,534	1,570	21,475	29,096	47,039	45,251	40,920	162,288
R&D	7,094	6,742	7,028	5,636	26,500	6,022	7,204	7,221	5,161	25,608
SG&A	3,555	4,732	4,105	4,093	16,485	4,463	5,873	4,568	6,808	21,712
Acq. liab. remeasurement					0					0
Impairment of assets										0
Total Operating Expenses	10,649	11,474	11,133	9,729	42,985	10,485	13,077	11,789	11,969	47,320
Income (loss) from Ops	(2,723)	(5,029)	(5,599)	(8,159)	(21,510)	18,611	33,962	33,462	28,951	114,968
Royalty payments - Eclat					0	(5,796)	(10,649)	(10,239)	(8,016)	(40,851)
Interest income/(exp)	(2,173)	94	86	543	(1,450)	657	312	75	934	2,651
FOREX gain/(loss)	179	292	(620)		(149)	2,264	480	192	1,651	1,500
1x milestones										
Other income/(loss)	52	30	71	(188)	(35)	(852)	(2)	50	(32)	
Pretax Income (Loss)	(4,665)	(4,613)	(6,062)	(7,804)	(23,144)	14,884	24,103	23,540	23,488	78,268
Income tax exp/(benefit)	(459)	273	(29)	(1,272)	(1,487)	10,473	10,242	12,018	9,613	35,167
NI from discontinued ops				4,735						
Adj Net income/(loss)	(4,206)	(4,886)	(6,033)	(6,532)	(21,657)	4,411	13,861	11,522	13,875	43,101
EPS - adjusted	(\$0.15)	(\$0.13)	(\$0.16)	(\$0.17)	(\$0.60)	\$0.10	\$0.34	\$0.27	\$0.32	\$0.99
EPS as reported	(\$0.94)	(\$0.55)	(\$0.26)	(\$0.69)	(\$2.34)	\$0.27	(\$0.43)	(\$0.73)	\$1.75	\$0.93
Shares out (000)	28,312	38,438	38,767	39,208	36,211	40,207	40,353	40,625	41,125	40,580
Fully diluted shares (000)	34,912	42,038	42,367	42,808	40,531	42,834	40,748	42,875	43,430	43,619
Margin & expense analysis										
COGS	14%	20%	21%	47%	21%	11%	6%	4%	6%	6%
R&D	77%	83%	100%	190%	97%	18%	14%	15%	12%	15%
SG&A	39%	59%	58%	138%	60%	14%	12%	10%	16%	13%
Operating margin	-30%	-62%	-80%	-275%	-79%	57%	68%	71%	67%	66%
Taxes	-10%	6%	0%	16%	6%	70%	42%	51%	41%	45%
Net margin	-46%	-60%	-86%	-220%	-79%	13%	28%	24%	32%	25%
Year-over-year change										
Net revenue	79%	46%	30%	-52%	21%	257%	516%	574%	1362%	536%
COGS	26%	28%	0%	317%	33%	191%	68%	40%	75%	89%
Gross margin	91%	51%	42%	-73%	19%	267%	630%	718%	2506%	656%
R&D	-17%	-8%	13%	35%	-1%	-15%	7%	3%	-8%	-3%
SG&A	43%	75%	29%	-29%	14%	26%	24%	11%	66%	32%
Operating income	-72%	-13%	1%	98%	-7%	-783%	-775%	-698%	-455%	-634%
Net income	-52%	10%	9%	11162%	35%	-205%	-384%	-291%	-312%	-299%

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

Figure 5: Annual Income Statement

Flamel Technologies						
Annual income statement						
(\$000's except per share)	2014A	2015A	2016E	2017E	2018E	Comments
Revenues						
Bloxiverz (neostigmine)	\$10,470	\$150,778	\$89,096	\$61,942	\$60,997	WestWard entry 1Q16
Vazculep (phenylephrine hci)		20,151	23,750	20,000	18,500	Generics 2H16
Eclat products #3 & #4			2,650	77,225	125,000	~\$80M & \$30M-\$40M peak each
LiquiTime royalty				0	7,500	Licensed to Perrigo
1x milestones (license deals)	5,114	721	200	50,200	200	Partnership milestones here
Total Revenues	\$27,250	\$173,209	\$124,246	\$219,367	\$223,447	2016 Guide: \$110M-\$130M revs
Expenses						
Cost of Goods Sold	5,775	10,921	5,197	7,163	9,202	
Gross Margin	21,475	162,288	119,049	212,204	214,245	
R&D	26,500	25,608	40,000	45,250	46,000	2016 Guide: \$35-\$50M
SG&A	16,485	21,712	29,425	41,000	41,000	FSC reps & SG&A here
Total Operating Expenses	42,985	47,320	69,425	86,250	87,000	
Income (loss) from Ops	(21,510)	114,968	49,624	125,954	127,245	
Royalty payments - Eclat	0	(40,851)	(23,774)	(32,763)	(42,094)	Deerfield & Broadfin payments
Interest income	(1,450)	2,651	2,250	2,375	3,250	
FOREX gain/(loss)	(149)	1,500	0	0	0	non-cash item
Other income/(loss)	(35)	0	400	400	400	
Pretax Income (Loss)	(23,144)	78,268	28,500	45,966	88,801	
Taxes	(1,487)	35,167	12,629	18,387	31,080	Domicile structure drives taxes
Adj Net income/(loss)	(21,657)	43,101	15,870	27,580	57,721	
1x & non-cash items	63,249	2,442	0	(50,000)	0	non-cash item
Net inc/(loss) as reported	(84,906)	40,659	0	77,580	0	
EPS - adjusted	(\$0.60)	\$0.99	\$0.35	\$0.60	\$1.20	~20% EPS CAGR through 2018 1x milestone in 2017
EPS as reported	(\$2.34)	\$0.93		\$1.67		
Shares out (000)	36,211	40,580	41,875	43,075	44,275	
Fully diluted shares (000)	40,531	43,619	44,875	46,325	48,025	
Margin & expense analysis						
COGS	21%	6%	4%	3%	4%	
R&D	97%	15%	32%	21%	21%	
SG&A	60%	13%	24%	19%	18%	
Operating margin	-79%	66%	40%	57%	57%	
Taxes	6%	45%	44%	40%	35%	
Net margin	-79%	25%	13%	13%	26%	
Year-over-year change						
Net revenue	21%	536%	-28%	77%	2%	
COGS	33%	89%	-52%	38%	28%	
Gross margin	19%	656%	-27%	78%	1%	
R&D	-1%	-3%	56%	13%	2%	
SG&A	14%	32%	36%	39%	0%	
Operating income	-7%	-634%	-57%	154%	1%	
Net income	35%	-299%	-63%	74%	109%	

Source: Bloomberg LP; Company reports; Laidlaw & 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

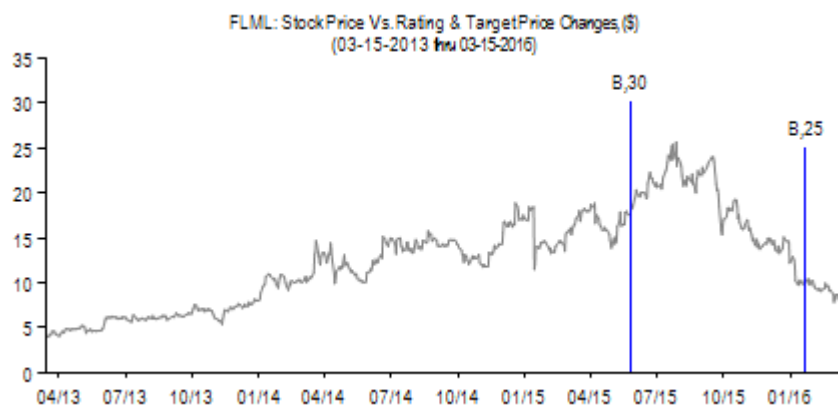
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell 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
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.	65.71%	25.71%	2.86%
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

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.

© 2016 Laidlaw & Co. (UK), Ltd.

NOTES: