

Flamel Technologies (FLML - \$23.92)

Healthcare/Biotechnology

The most exciting development pipeline in our coverage space

While it's usually better for a company to not miss the quarter on both the top & bottom line, primarily driven by confusion on the proper accounting for "deferred" revenues, the fact that management reiterated their full year guidance of \$170M-\$185M in product revenues gives comfort that the fundamental underlying story remains intact. That, plus the fact that FLML's lead product Bloxiverz continues to command ~70% market share even a few months after Fresenius' competing neostigmine launched into the market. Equally as important the deep pipeline at FLML – perhaps the deepest in our coverage space – continues to track in-line with expectations. The next key catalysts include the initiation of the Phase 3 trial for the Micropump sodium oxybate and the Phase 1 data for the Medusa GLP-1 agonist for Type 2 diabetes, both in 4Q15, and a potential licensing agreement on the LiquiTime OTC pain & respiratory compounds in early 2016. We reiterate Buy rating, \$30 PT.

Ticker: **FLML**
Rating: **Buy**
Price Target: **\$ 30.00**

Trading Data:

Last Price (07/31/2015)	\$ 23.92
52-Week High (7/23/2015)	\$26.09
52-Week Low (1/14/2015)	\$9.30
Market Cap. (MM)	\$962.9
Shares Out. (MM)	40.75

- **Miss mostly due to accounting artifact of high deferrals in 1Q15.** The high reported "deferred" revenues from 1Q15 (due to the dramatic price increase in the Q) skewed consensus & our sales estimates. Positively, management reiterated FY15 guidance, and we expect normalized revenue in 2H15.
- **Pipeline remains on-track with expectations.** Perhaps most importantly FLML reiterated that the development pipeline is on track. (See page 3 of this report for our projected clinical trials timeline.) With the third Eclat program NDA filed, a Phase 3 trial for sodium oxybate starting in 4Q15, and a potential partnership on 2 OTC products in late '15/early '16, we continue to see FLML as the most promising pipeline story in our coverage space.
- **Could JAZZ be interested in FLML?** JAZZ's Xyrem (sodium oxybate) is facing multiple generic challenges, including an inter-partes review (IPR) of Xyrem's distribution patents. FLML's next generation sodium oxybate (eliminating the middle-of-the-night dose) could extend JAZZ's Xyrem portfolio should the Phase 3 trials prove successful (starting 4Q15).
- **Next Eclat product could launch 2H16.** Filed in the 2Q15, we expect a 3Q15 NDA acceptance and a 10-month review, with a 3Q16 launch. Targeting a market similar to Bloxiverz (\$75M-\$80M) there could be upside if FLML has similar pricing power with Eclat #3 as they did with Bloxiverz.
- **Reiterate Buy rating, \$30 price target.** Our price target is based on a sum-of-the-parts analysis: Eclat \$16/share, pipeline \$11/share, and cash \$3/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	0.27	0.29	0.19	0.25	1.00	23.9x
FY-15E	0.27A	0.34A	0.20	0.17	0.80	29.9x
FY-14A	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM
FY-13A	(0.35)	(1.29)	(0.27)	0.20	(0.63)	NM

James Molloy

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

Source: Company data and Laidlaw & Company estimates

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FLML miss on revenues & EPS, accounting artifact given high amount of deferrals in 1Q15. FLML missed 2Q15 with revenues of \$49.8MM vs. consensus: \$64.1MM & Laidlaw \$64MM as confusion on the accounting for 1Q15 deferrals appeared to drive the miss. Bloxiverz sales were well below estimates but it was a nice positive to see Vazculep sales of \$3.6MM, ahead of our estimate of \$2.2MM. Positively, FLML reiterated their FY15 product sales guidance of \$170MM-\$185MM (Bloxiverz & Vazculep). 2Q15 adjusted EPS of \$0.34 was closer to our \$0.38 estimate (but well below consensus: \$0.43) mainly due to significantly lower COGS. Operating expenses were roughly in-line.

Figure 1: Quarterly variance analysis

Flamel Technologies					
Quarterly variance analysis					
(\$000 except per share)	2Q14A	2Q15A	2Q15E	Variance	% Y/Y
Bloxiverz (neostigmine)	\$2,200	\$45,500	\$61,680	(16,180)	1968.2%
Vazculep		3,600	2,250	1,350	NM
1x milestones (license deals)	1,683	30	50	(20)	-98.2%
Total Revenue	\$8,081	\$49,795	\$63,980	(14,185)	516.2%
COGS	1,636	2,756	7,102	(4,346)	68.5%
Gross Profit	6,445	47,039	56,878	(9,839)	629.9%
SG&A Expense	4,732	5,873	4,500	1,373	24.1%
R&D Expense	6,742	7,204	6,250	954	6.9%
Operating Inc (loss)	(5,029)	33,962	46,128	(12,166)	-775.3%
Interest inc (exp)	94	312	25	287	231.9%
FOREX gain (loss)	292	480	0	480	64.4%
Other inc (exp)	30	(2)	50	(52)	-106.7%
Pretax Income	(4,613)	24,103	33,044	(8,941)	-622.5%
Income Taxes (benefit)	273	10,242	16,522	(6,280)	3651.6%
Net Income as reported	(4,886)	13,861	16,522	(2,661)	-383.7%
1x & non cash exp	16,187	31,261	0	31,261	93.1%
Adj Net income	(21,073)	(17,400)	16,522	(33,922)	-17.4%
Shares out (000)	38,438	40,353	40,507	(154)	5.0%
Fully diluted shares (000)	42,038	40,748	43,507	(2,759)	-3.1%
EPS as reported	(\$0.55)	(\$0.43)	N/A	N/A	-21.3%
Adj EPS ex-1x & non cash	(\$0.13)	\$0.34	\$0.38	(\$0.04)	-367.6%

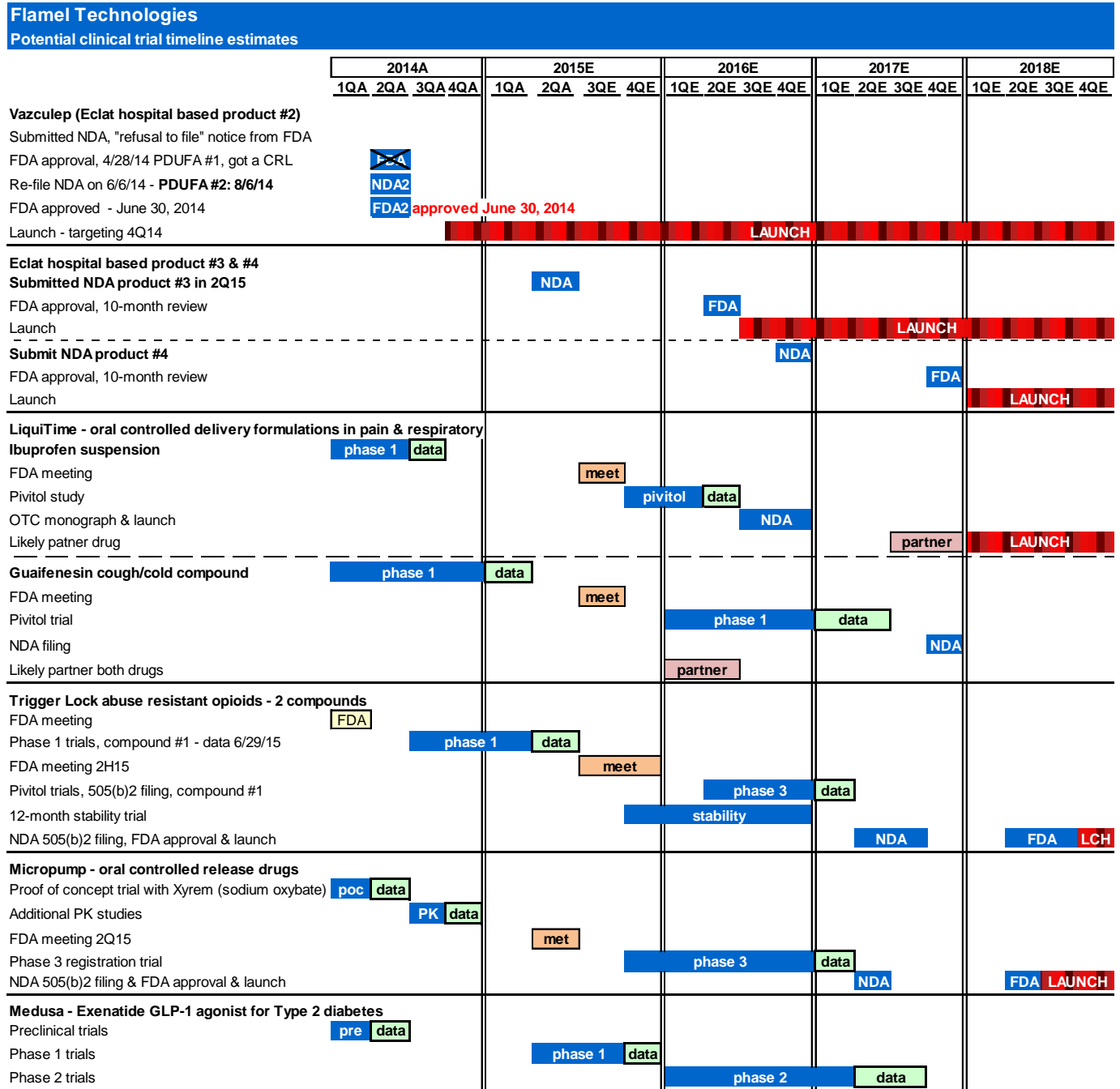
Source: Company reports & Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation: FLML		
Segment	Valuation (000's)	Per share value
Eclat products	\$753,831	\$16.00
Pipeline & royalties value	\$520,695	\$11.00
Cash (end of '16E)	\$147,841	\$3.00
	\$1,422,367	\$30.00
2016 fully diluted shares out		44,703

Source: Bloomberg LP & Laidlaw & Company estimates

Figure 3: Clinical trials timeline



Specialty Pharmaceuticals

Source: Company reports and Laidlaw estimates

Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

Flamel Technologies Quarterly income statement										
(\$000's except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
Revenues										
Bloxiverz (neostigmine)	\$3,840	\$2,200	\$2,200	\$2,907	\$11,147	\$29,200	\$45,500	\$43,178	\$45,450	\$163,328
Vazculep (phenylephrine hci)						3,511	3,600	3,600	3,750	14,461
License & research	1,433	2,270	681	30	4,414	(38)				
Product sales & service	2,100	1,928	2,547		6,575		600			
1x, other, milestones (license)	1,802	1,683	1,600	29	5,114	53	30	50	50	183
Total Revenues	\$9,175	\$8,081	\$7,028	\$2,966	\$27,250	\$32,726	\$49,795	\$46,828	\$49,250	\$178,599
Expenses										
Cost of Goods Sold	1,249	1,636	1,494	1,396	5,775	3,630	2,756	2,807	3,444	12,637
Gross Margin	7,926	6,445	5,534	1,570	21,475	29,096	47,039	44,021	45,806	165,962
R&D	7,094	6,742	7,028	5,636	26,500	6,022	7,204	12,750	15,750	41,726
SG&A	3,555	4,732	4,105	4,093	16,485	4,463	5,873	6,000	6,500	22,836
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	18,750	22,250	64,562
Income (loss) from Ops	(2,723)	(5,029)	(5,599)	(8,159)	(21,510)	18,611	33,962	25,271	23,556	101,400
Royalty payments - Eclat					0	(5,796)	(10,649)	(9,629)	(10,127)	(36,201)
Net interest inc/(exp) from BS	(2,173)	94	86	543	(1,450)	657	312	75	70	1,114
FOREX gain/(loss)	179	292	(620)		(149)	2,264	480			2,744
Other income/(loss)	52	30	71	(188)	(35)	(852)	(2)	50	50	(754)
Pretax Income (Loss)	(4,665)	(4,613)	(6,062)	(7,804)	(23,144)	14,884	24,103	15,767	13,549	68,303
Income tax exp/(benefit)	(459)	273	(29)	(1,272)	(1,487)	10,473	10,242	7,253	6,097	34,065
NI from discontinued ops				4,735						
Adj Net income/(loss)	(4,206)	(4,886)	(6,033)	(6,532)	(21,657)	4,411	13,861	8,514	7,452	34,238
EPS - adjusted	(\$0.15)	(\$0.13)	(\$0.16)	(\$0.17)	(\$0.60)	\$0.10	\$0.34	\$0.20	\$0.17	\$0.80
EPS as reported	(\$0.94)	(\$0.55)	(\$0.26)	(\$0.69)	(\$2.34)	\$0.27	(\$0.43)	\$0.08	\$0.02	(\$0.03)
Shares out (000)	28,312	38,438	38,767	39,208	36,211	40,207	40,353	40,653	40,953	40,542
Fully diluted shares (000)	34,912	42,038	42,367	42,808	40,531	42,834	40,748	43,403	43,703	42,672
Margin & expense analysis										
COGS	14%	20%	21%	47%	21%	11%	6%	6%	7%	7%
R&D	77%	83%	100%	190%	97%	18%	14%	27%	32%	23%
SG&A	39%	59%	58%	138%	60%	14%	12%	13%	13%	13%
Operating margin	-30%	-62%	-80%	-275%	-79%	57%	68%	54%	48%	57%
Taxes	-10%	6%	0%	16%	6%	70%	42%	46%	45%	50%
Net margin	-46%	-60%	-86%	-220%	-79%	13%	28%	18%	15%	19%
Year-over-year change										
Net revenue	79%	46%	30%	-52%	21%	257%	516%	566%	1560%	555%
COGS	26%	28%	0%	317%	33%	191%	68%	88%	147%	119%
Gross margin	91%	51%	42%	-73%	19%	267%	630%	695%	2818%	673%
R&D	-17%	-8%	13%	35%	-1%	-15%	7%	81%	179%	57%
SG&A	43%	75%	29%	-29%	14%	26%	24%	46%	59%	39%
Operating income	-72%	-13%	1%	98%	-7%	-783%	-775%	-551%	-389%	-571%
Net income	-52%	10%	9%	11162%	35%	-205%	-384%	-241%	-214%	-258%

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

Figure 5: Annual Income Statement

Flamel Technologies						
Annual income statement						
(\$000's except per share)	2014A	2015E	2016E	2017E	2018E	Comments
Revenues						
Bloxiverz (neostigmine)	\$11,147	\$163,328	\$154,928	\$86,545	\$72,972	~\$500M mkt oppty; 100% share 2Q15
Vazculep (phenylephrine hci)		14,461	39,250	47,750	30,000	\$80M-\$90M market opportunity
Eclat products #3 & #4			6,650	117,225	195,000	~\$75M & \$30M-\$40M peak each
LiquiTime royalty				0	10,200	oral ibuprofen & guarifenesin
TriggerLock royalty					0	Less abusable opioids
License & research	4,414	0	0	0	0	Sold to Recipharm AB 12/1/14
Product sales & service	6,575	0	0	0	0	Sold to Recipharm AB 12/1/14
1x milestones (license deals)	5,114	183	200	200	0	Partnership milestones here
Total Revenues	\$27,250	\$178,599	\$201,028	\$251,720	\$308,172	2015 Guide: \$170M-\$185M product revs
Expenses						
Cost of Goods Sold	5,775	12,637	16,066	22,637	26,818	
Gross Margin	21,475	165,962	184,961	229,083	281,355	
R&D	26,500	41,726	43,250	47,000	42,000	Deep pipeline entering clinic
SG&A	16,485	22,836	23,000	25,500	34,500	
Total Operating Expenses	42,985	64,562	66,250	72,500	76,500	
Income (loss) from Ops	(21,510)	101,400	118,711	156,583	204,855	
Royalty payments - Eclat	0	(36,201)	(41,338)	(51,773)	(61,335)	Deerfield & Broadfin payments
Interest income	(1,450)	1,114	1,400	2,375	3,250	
FOREX gain/(loss)	(149)	2,744	0	0	0	non-cash item
Other income/(loss)	(35)	(754)	400	400	400	
Pretax Income (Loss)	(23,144)	68,303	79,173	107,586	147,170	
Taxes	(1,487)	34,065	34,310	43,034	51,510	NOLs limit taxes
Adj Net income/(loss)	(21,657)	34,238	44,863	64,551	95,661	
1x & non-cash items	63,249	35,526	0	0	0	non-cash item
Net inc/(loss) as reported	(84,906)	(1,288)	0	0	0	
EPS - adjusted	(\$0.60)	\$0.80	\$1.00	\$1.40	\$2.00	
EPS as reported	(\$2.34)	(\$0.03)				
Shares out (000)	36,211	40,542	41,703	42,903	44,103	
Fully diluted shares (000)	40,531	42,672	44,703	46,153	47,853	
Margin & expense analysis						
COGS	21%	7%	8%	9%	9%	
R&D	97%	23%	22%	19%	14%	
SG&A	60%	13%	11%	10%	11%	
Operating margin	-79%	57%	59%	62%	66%	
Taxes	6%	50%	43%	40%	35%	
Net margin	-79%	19%	22%	26%	31%	
Year-over-year change						
Net revenue	21%	555%	13%	25%	22%	
COGS	33%	119%	27%	41%	18%	
Gross margin	19%	673%	11%	24%	23%	
R&D	-1%	57%	4%	9%	-11%	
SG&A	14%	39%	1%	11%	35%	
Operating income	-7%	-571%	17%	32%	31%	
Net income	35%	-258%	31%	44%	48%	

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.

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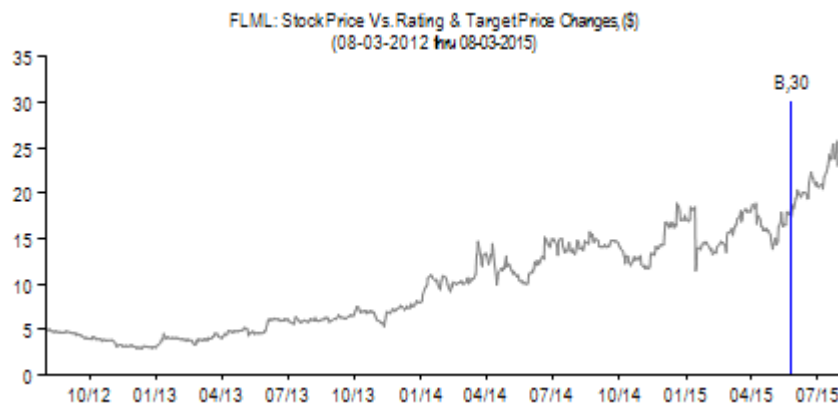
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Rating and Price Target Change History



Date	Rating	Closing Price (\$)
05/26/2015	Buy (B)	17.48

Date	Target Price (\$)	Closing Price, (\$)
05/26/2015	30.00	17.48

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.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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

Fresenius Medical Care (FMS – Not Rated)
Jazz Pharmaceuticals (JAZZ – Not Rated)

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