

Flamel Technologies (FLML - \$14.19)

Multiple upcoming catalysts augur well for FLML in 2016

Flamel recently reported 3Q15, missing consensus but beating our top & bottom line estimates as Bloxiverz and Vazculep continue to be the short-term cash generating machines they have always intended to be. Bloxiverz was slightly below our estimates in the 3Q, but Vazculep was nearly double our number, more than covering the Bloxiverz miss to beat our sales estimate. More importantly the extensive pipeline at FLML remains on track for all their programs; which is remarkable in itself for a company with this deep and varied a pipeline. Eclat #3 remains on-track for an April 30, 2016 PDUFA date, and it appears that Eclat #4 is still possible for a 2016 NDA too. Recall that the Eclat programs are (and always have been) a short-term cash generating opportunity while FLML's pipeline matures, and are expected to be genericized in the near term, so we are relatively unconcerned about the decline in Bloxiverz sales as we have generics entering that market in 2H16 anyway. We continue to like FLML here as they have multiple significant pipeline opportunities ahead and on track. We are reiterating our Buy rating and our \$30 PT.

- **FLML beats revenues & EPS, Vazculep sales exceed expectations.** FLML reported 3Q15 with top line revenues of \$47.3M vs our estimate \$46.8M and as Bloxiverz maintained ~60% market share and Vazculep exceeded our expectations with \$5.6M in sales vs our estimated \$3.6M. Lower than expected R&D cost lead to EPS beat of \$0.28 vs our estimated \$0.20.
- **Eclat #3 could launch 2H16.** Eclat #3 has a 4/30/16 PDUFA date with a potential 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.
- **Robust pipeline still on-track with multiple near-term catalysts.** Most importantly, in our opinion, FLML reiterated that their pipeline remains on track. With a Phase 3 trial for sodium oxybate starting this quarter, LiquiTime licensed to Perrigo in 4Q15, Trigger Lock to start Phase 3 in 1H16, and Medusa data in 4Q15 we see a raft of catalysts upcoming for FLML in the next two quarters.
- **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	0.28	0.19	0.25	1.00	14.2x
FY-15E	0.27A	0.34A	0.28A	0.18	0.90	15.8x
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

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (11/13/2015)	\$14.19
52-Week High (07/23/2015)	\$26.09
52-Week Low (01/14/2015)	\$9.30
Market Cap. (MM)	\$571.2
Shares Out. (MM)	40.3

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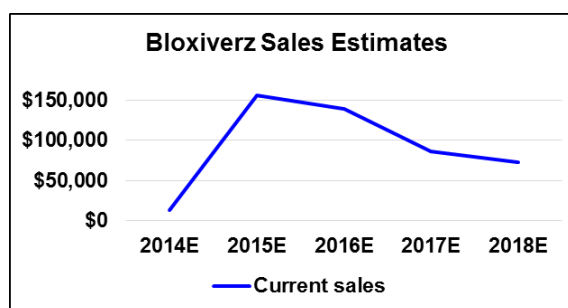
Could JAZZ be interested in FLML? JAZZ's Xyrem (sodium oxybate) is facing multiple generic challenges, including an inter-partes review (IPR) of Xyrem's distribution patents. FLML's next generation sodium oxybate (eliminating the middle-of-the-night dose) could extend JAZZ's Xyrem portfolio should the Phase 3 trials prove successful (starting 4Q15).

Figure 1: Quarterly variance analysis

Flamel Technologies					
Quarterly variance analysis					
(\$000 except per share)	3Q14A	3Q15A	3Q15E	Variance	% Y/Y
Bloxivertz (neostigmine)	\$2,200	\$41,218	\$43,178	(1,960)	1773.5%
Vazculep		5,600	3,600	2,000	NM
1x milestones (license deals)	1,600	6	50	(44)	-99.6%
Total Revenue	\$7,028	\$47,338	\$46,828	511	573.6%
COGS	1,494	2,087	2,807	(720)	39.7%
Gross Profit	5,534	45,251	44,021	1,230	717.7%
SG&A Expense	4,105	5,779	6,000	(221)	40.8%
R&D Expense	7,028	7,221	12,750	(5,529)	2.7%
Operating Inc (loss)	(5,599)	32,251	25,271	6,980	NM
Interest inc (exp)	86	75	75	0	-12.8%
FOREX gain (loss)	(620)	192	0	192	NM
Other inc (exp)	71	50	50	0	-29.6%
Pretax Income	(6,062)	23,540	15,767	7,773	NM
Income Taxes/(benefit)	(29)	12,018	7,253	4,765	NM
Adj Net income/(loss)	(6,033)	11,522	8,514	3,008	NM
1x & non cash exp	4,013	41,207	5,000	36,207	926.8%
NI/(loss) as reported	(10,046)	(29,685)	3,514	(33,199)	NM
Shares out (000)	38,767	40,625	40,653	(28)	4.8%
Fully diluted shares (000)	42,367	41,025	43,403	(2,378)	-3.2%
EPS as reported	(\$0.26)	(\$0.73)	\$0.08	(\$0.81)	NM
Adj EPS ex-1x & non cash	(\$0.16)	\$0.28	\$0.20	\$0.08	NM

Source: Company reports & Laidlaw & Company estimates

Figure 2: Bloxivertz Sales projections



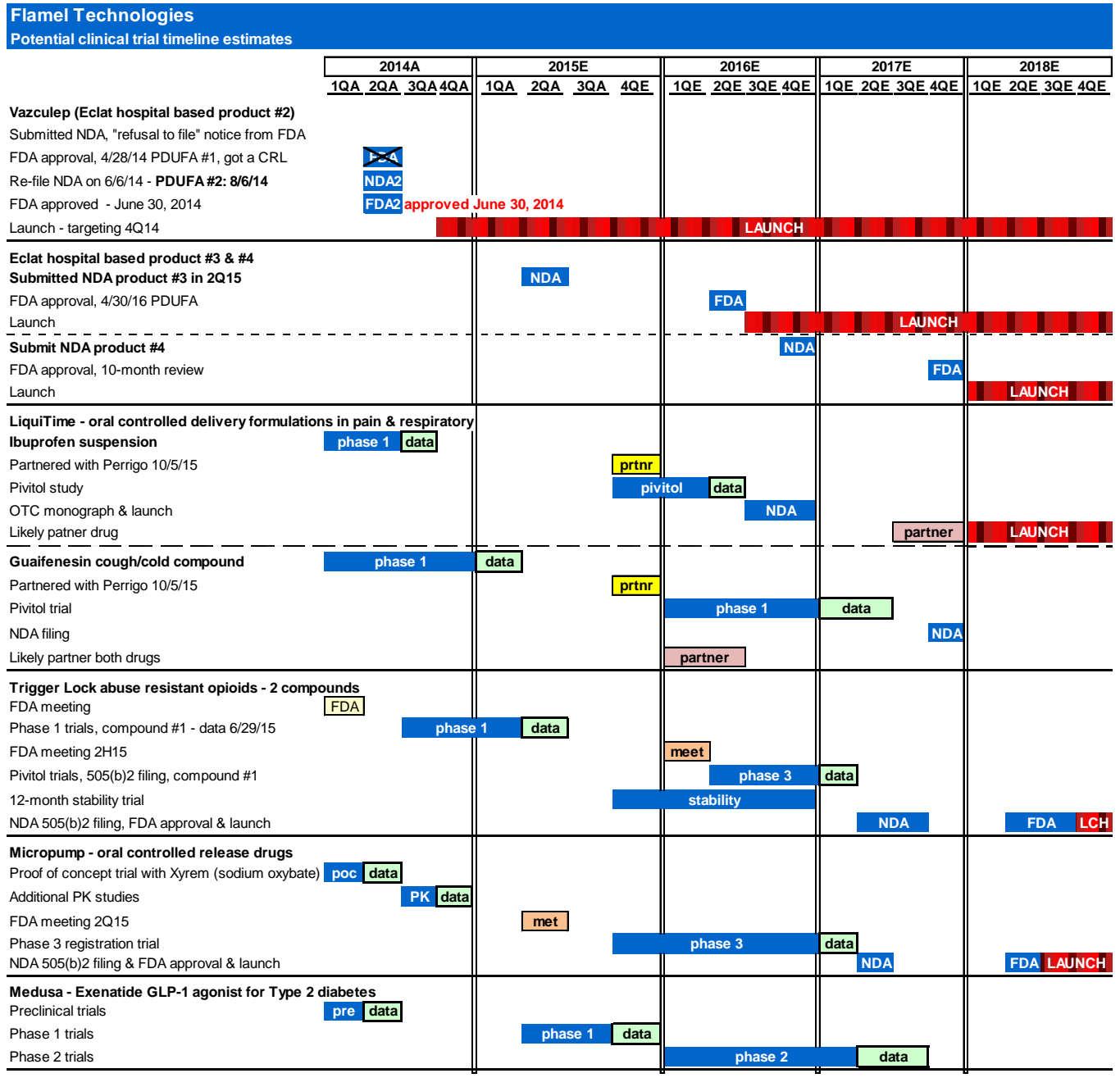
Source: Bloomberg LP.

Figure 3: Valuation

Sum-of-the-parts valuation: FLML		
Segment	Valuation (000's)	Per share value
Eclat products	\$696,846	\$16.00
Pipeline & royalties value	\$506,310	\$11.00
Cash (end of '16E)	\$150,998	\$3.00
	\$1,354,155	\$30.00
2016 fully diluted shares out		44,675

Source: Bloomberg LP.

Figure 4: Clinical trials timeline



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	3QA	4QE	
Revenues										
Bloxivierz (neostigmine)	\$3,840	\$2,200	\$2,200	\$2,907	\$11,147	\$29,200	\$45,500	\$41,218	\$40,223	\$156,141
Vazculep (phenylephrine hci)						3,511	3,600	5,600	6,250	18,961
License & research	1,433	2,270	681	30	4,414	(38)				
Product sales & service	2,100	1,928	2,547		6,575		600	514		
1x, other, milestones (license)	1,802	1,683	1,600	29	5,114	53	30	6	50	139
Total Revenues	\$9,175	\$8,081	\$7,028	\$2,966	\$27,250	\$32,726	\$49,795	\$47,338	\$46,523	\$176,382
Expenses										
Cost of Goods Sold	1,249	1,636	1,494	1,396	5,775	3,630	2,756	2,087	2,091	10,564
Gross Margin	7,926	6,445	5,534	1,570	21,475	29,096	47,039	45,251	44,432	165,818
R&D	7,094	6,742	7,028	5,636	26,500	6,022	7,204	7,221	14,500	34,947
SG&A	3,555	4,732	4,105	4,093	16,485	4,463	5,873	4,568	6,000	20,904
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	20,500	55,851
Income (loss) from Ops	(2,723)	(5,029)	(5,599)	(8,159)	(21,510)	18,611	33,962	33,462	23,932	109,967
Royalty payments - Eclat					0	(5,796)	(10,649)	(10,239)	(9,566)	(36,250)
Interest income/(exp)	(2,173)	94	86	543	(1,450)	657	312	75	70	1,114
FOREX gain/(loss)	179	292	(620)		(149)	2,264	480	192		2,936
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	23,540	14,486	77,013
Income tax exp/(benefit)	(459)	273	(29)	(1,272)	(1,487)	10,473	10,242	12,018	6,519	39,252
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	7,967	37,761
EPS - adjusted	(\$0.15)	(\$0.13)	(\$0.16)	(\$0.17)	(\$0.60)	\$0.10	\$0.34	\$0.28	\$0.18	\$0.90
EPS as reported	(\$0.94)	(\$0.55)	(\$0.26)	(\$0.69)	(\$2.34)	\$0.27	(\$0.43)	(\$0.73)	\$0.03	(\$0.84)
Shares out (000)	28,312	38,438	38,767	39,208	36,211	40,207	40,353	40,625	40,925	40,528
Fully diluted shares (000)	34,912	42,038	42,367	42,808	40,531	42,834	40,748	41,025	43,675	42,070
Margin & expense analysis										
COGS	14%	20%	21%	47%	21%	11%	6%	4%	4%	6%
R&D	77%	83%	100%	190%	97%	18%	14%	15%	31%	20%
SG&A	39%	59%	58%	138%	60%	14%	12%	10%	13%	12%
Operating margin	-30%	-62%	-80%	-275%	-79%	57%	68%	71%	51%	62%
Taxes	-10%	6%	0%	16%	6%	70%	42%	51%	45%	51%
Net margin	-46%	-60%	-86%	-220%	-79%	13%	28%	24%	17%	21%
Year-over-year change										
Net revenue	79%	46%	30%	-52%	21%	257%	516%	574%	1469%	547%
COGS	26%	28%	0%	317%	33%	191%	68%	40%	50%	83%
Gross margin	91%	51%	42%	-73%	19%	267%	630%	718%	2730%	672%
R&D	-17%	-8%	13%	35%	-1%	-15%	7%	3%	157%	32%
SG&A	43%	75%	29%	-29%	14%	26%	24%	11%	47%	27%
Operating income	-72%	-13%	1%	98%	-7%	-783%	-775%	-698%	-393%	-611%
Net income	-52%	10%	9%	11162%	35%	-205%	-384%	-291%	-222%	-274%

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	\$156,141	\$138,632	\$86,545	\$72,972	~60% share 3Q15
Vazculep (phenylephrine hci)		18,961	41,250	47,750	30,000	100% share in 10mL/5mL sizes
Eclat products #3 & #4			6,650	117,225	170,000	~\$80M & \$30M-\$40M peak each
LiquiTime royalty				0	10,200	Licensed to Perrigo
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	139	200	200	0	Partnership milestones here
Total Revenues	\$27,250	\$176,382	\$186,732	\$251,720	\$283,172	2015 Guide: \$170M-\$185M product revs
Expenses						
Cost of Goods Sold	5,775	10,564	8,394	12,073	13,103	
Gross Margin	21,475	165,818	178,338	239,647	270,070	
R&D	26,500	34,947	40,250	43,250	43,750	Deep pipeline entering clinic
SG&A	16,485	20,904	23,000	24,750	26,500	
Total Operating Expenses	42,985	55,851	63,250	68,000	70,250	
Income (loss) from Ops	(21,510)	109,967	115,088	171,647	199,820	
Royalty payments - Eclat	0	(36,250)	(38,396)	(51,773)	(56,189)	Deerfield & Broadfin payments
Interest income	(1,450)	1,114	1,400	2,375	3,250	
FOREX gain/(loss)	(149)	2,936	0	0	0	non-cash item
Other income/(loss)	(35)	(754)	400	400	400	
Pretax Income (Loss)	(23,144)	77,013	78,492	122,649	147,281	
Taxes	(1,487)	39,252	33,995	49,060	51,548	NOLs limit taxes
Adj Net income/(loss)	(21,657)	37,761	44,497	73,590	95,733	
1x & non-cash items	63,249	71,733	0	0	0	non-cash item
Net inc/(loss) as reported	(84,906)	(33,972)	0	0	0	
EPS - adjusted	(\$0.60)	\$0.90	\$1.00	\$1.60	\$2.00	30% EPS CAGR through 2018
EPS as reported	(\$2.34)	(\$0.84)				
Shares out (000)	36,211	40,528	41,675	42,875	44,075	
Fully diluted shares (000)	40,531	42,070	44,675	46,125	47,825	
Margin & expense analysis						
COGS	21%	6%	4%	5%	5%	
R&D	97%	20%	22%	17%	15%	
SG&A	60%	12%	12%	10%	9%	
Operating margin	-79%	62%	62%	68%	71%	
Taxes	6%	51%	43%	40%	35%	
Net margin	-79%	21%	24%	29%	34%	
Year-over-year change						
Net revenue	21%	547%	6%	35%	12%	
COGS	33%	83%	-21%	44%	9%	
Gross margin	19%	672%	8%	34%	13%	
R&D	-1%	32%	15%	7%	1%	
SG&A	14%	27%	10%	8%	7%	
Operating income	-7%	-611%	5%	49%	16%	
Net income	35%	-274%	18%	65%	30%	

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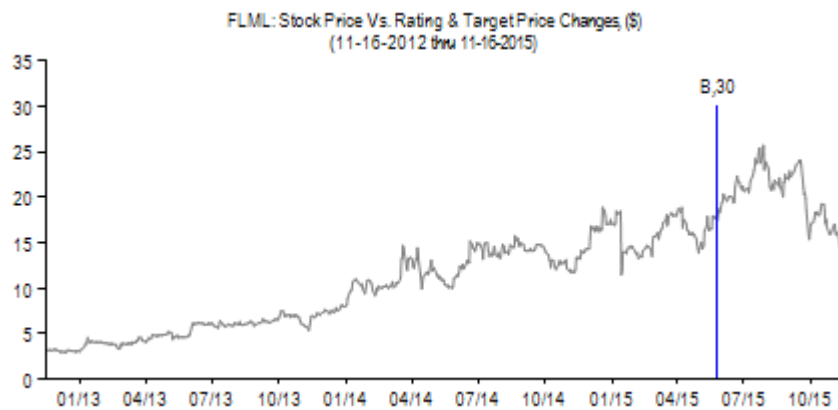
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Date	Rating	Closing Price (\$)
05/26/2015	Buy (B)	17.48

3 Year Price Change History

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

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%
Buy (B)	Expected to outperform the sector average over 12 months.	71.88%	25.00%	6.25%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.13%	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

Perrigo Company plc (PRGO – Not Rated)
Jazz Pharmaceuticals (JAZZ – Not Rated)

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