

Flamel Technologies (FLML - \$10.30)

Earlier Generics Hit Eclat Sales, Pipeline Remains the Story

We recently spent time with FLML senior management and we continue to remain optimistic about the opportunity for FLML's internally developed pipeline here. We are adjusting down our top & bottom line and lowering our price target to account for the earlier entrance of additional generics to Bloxiverz (in 1H16), and to Vazculep (now expected in mid-2016), but the main reason to own FLML remains the internally developed pipeline. The Eclat portfolio has always been a short term cash-infusion strategy to bridge to the pipeline; and some products are just a bit shorter duration than initially expected. We continue to anticipate approval of Eclat #4 on its April 30th PDUFA date, with this product expected to target a \$75M-\$80M market. While the product remains undisclosed for competitive reasons, management recently commented that this product has taken a price increase that could increase the potential market opportunity for Eclat #4. We have lowered our PT from \$30 to \$25 and reiterate our Buy rating.

- **Micropump seeking an SPA designation.** FLML will ask the FDA for an SPA for their sodium oxybate (Xyrem-like) compound in 1Q16, with the pivotal trial expected to start 2Q16, top line data still expected in early 2017 which is in-line with our expectations for top line data.
- **Guidance lowered following 3rd neostigmine entrant.** The 1Q16 launch of West-Ward's generic neostigmine ~6 months ahead of expectations drives a year over year decline in top-line revenues. We estimate this 3rd entrant will lower FLML's share of the neostigmine market from ~60% currently to 30-40% over 2016, with Merck's Bridion (sugammadex) expected to haircut the entire neostigmine market ~10%.
- **Eclat still delivering cash flow.** Vazculep is now anticipated to have another generic phenylephrine in mid-16, ~6 months ahead of our expectations. Eclat #3's remains on track for a 4/30/16 PDUFA and targeting a \$75M-\$80M market. With these changes FLML established new 2016 top line guidance of \$100M-\$120M in 2016, below our prior estimate of \$186.7M.
- **Lowering PT to \$25, reiterate Buy rating.** We have adjusted our 2016E-2018E eps estimates from \$1.00, \$1.60, and \$2.00 respectively to \$0.35, \$1.35, and \$1.45 respectively. Our PT is based on a sum-of-the-parts analysis with the Eclat portfolio worth \$10/share, the pipeline & royalties worth \$12/share, and cash (end '16E).

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	0.19	0.11	0.04	0.00	0.35	29.4x
FY-15E	0.27A	0.34A	0.28A	0.18	0.90	11.4x
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:	↓ \$ 25.00

Trading Data:

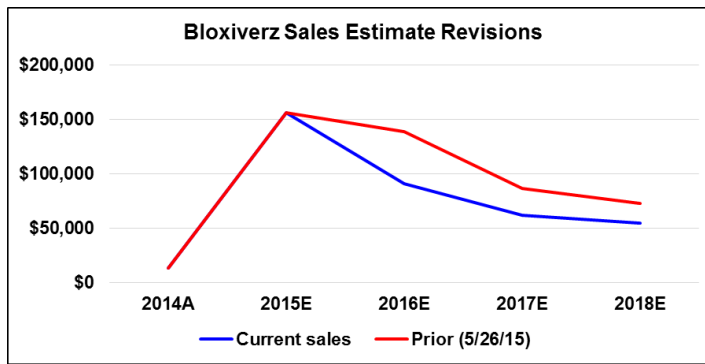
Last Price (1/21/2016)	\$10.30
52-Week High (07/23/2015)	\$26.09
52-Week Low (01/14/2016)	\$9.61
Market Cap. (MM)	\$417.1
Shares Out. (MM)	40.5

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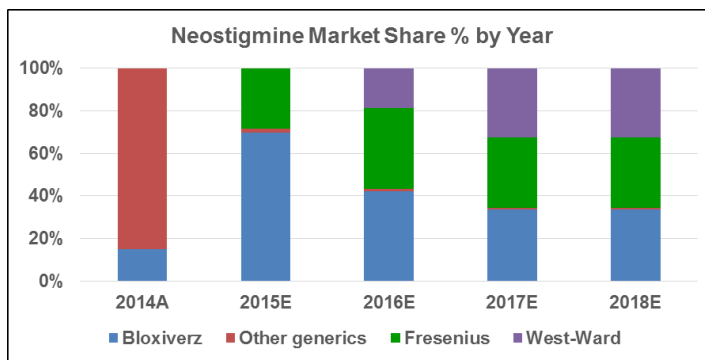
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Figure 1: Revised Bloxiverz sales projections



Source: Company reports & Laidlaw & Company estimates

Figure 2: Bloxiverz market share projections



Source: Company reports & Laidlaw & Company estimates.

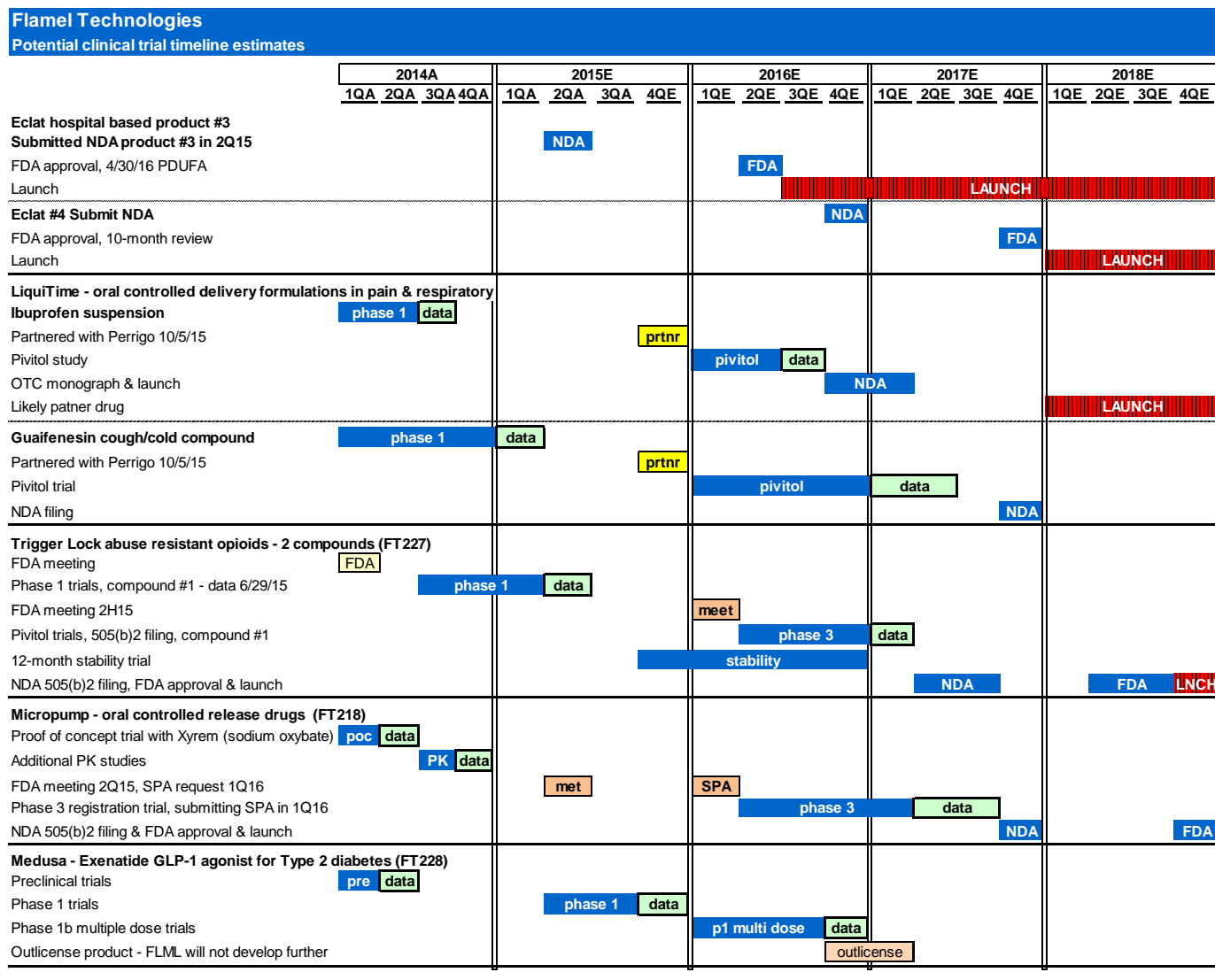
Figure 3: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Pipeline, royalties & tech value	\$551,945	\$12.00
Eclat products	\$444,868	\$10.00
Cash (end of '16E)	\$122,062	\$3.00
	\$1,118,874	\$25.00
2016 fully diluted shares out		44,675

Source: Laidlaw & Company estimates.

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Figure 4: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

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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										
Bloxiverz (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	5,750	18,461
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	\$46,023	\$175,882
Expenses										
Cost of Goods Sold	1,249	1,636	1,494	1,396	5,775	3,630	2,756	2,087	2,069	10,542
Gross Margin	7,926	6,445	5,534	1,570	21,475	29,096	47,039	45,251	43,954	165,340
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	5,500	20,404
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	20,000	55,351
Income (loss) from Ops	(2,723)	(5,029)	(5,599)	(8,159)	(21,510)	18,611	33,962	33,462	23,954	109,989
Royalty payments - Eclat					0	(5,796)	(10,649)	(10,239)	(9,463)	(36,147)
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
1x milestones										
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	14,611	77,138
Income tax exp/(benefit)	(459)	273	(29)	(1,272)	(1,487)	10,473	10,242	12,018	6,575	39,308
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	8,036	37,830
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)	\$0.04	(\$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%	32%	20%
SG&A	39%	59%	58%	138%	60%	14%	12%	10%	12%	12%
Operating margin	-30%	-62%	-80%	-275%	-79%	57%	68%	71%	52%	63%
Taxes	-10%	6%	0%	16%	6%	70%	42%	51%	45%	51%
Net margin	-46%	-60%	-86%	-220%	-79%	13%	28%	24%	17%	22%
Year-over-year change										
Net revenue	79%	46%	30%	-52%	21%	257%	516%	574%	1452%	545%
COGS	26%	28%	0%	317%	33%	191%	68%	40%	48%	83%
Gross margin	91%	51%	42%	-73%	19%	267%	630%	718%	2700%	670%
R&D	-17%	-8%	13%	35%	-1%	-15%	7%	3%	157%	32%
SG&A	43%	75%	29%	-29%	14%	26%	24%	11%	34%	24%
Operating income	-72%	-13%	1%	98%	-7%	-783%	-775%	-698%	-394%	-611%
Net income	-52%	10%	9%	11162%	35%	-205%	-384%	-291%	-223%	-275%

Specialty Pharmaceuticals

Source: Company reports and Laidlaw estimates

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

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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	\$91,295	\$61,942	\$54,897	WestWard entry 1Q16
Vazculep (phenylephrine hci)		18,461	23,750	20,000	18,500	Generics 2H16
Eclat products #3 & #4			2,650	119,225	145,000	~\$80M & \$30M-\$40M peak each
LiquiTime royalty				0	10,200	Licensed to Perrigo
1x milestones (license deals)	5,114	139	200	50,200	200	Partnership milestones here
Total Revenues	\$27,250	\$175,882	\$117,895	\$251,367	\$228,797	2016 Guide: \$100M-\$120M revs
Expenses						
Cost of Goods Sold	5,775	10,542	5,296	9,656	10,483	
Gross Margin	21,475	165,340	112,599	241,711	218,314	
R&D	26,500	34,947	42,000	45,500	46,000	2016 Guide: \$35-\$50M
SG&A	16,485	20,404	20,250	24,000	24,500	
Total Operating Expenses	42,985	55,351	62,250	69,500	70,500	
Income (loss) from Ops	(21,510)	109,989	50,349	172,211	147,814	
Royalty payments - Eclat	0	(36,147)	(24,226)	(41,408)	(44,955)	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)	77,138	27,923	103,578	106,509	
Taxes	(1,487)	39,308	12,431	41,431	37,278	Domicile structure drives taxes
Adj Net income/(loss)	(21,657)	37,830	15,492	62,147	69,231	
1x & non-cash items	63,249	71,733	0	(30,000)	0	non-cash item
Net inc/(loss) as reported	(84,906)	(33,903)	0	92,147	0	
EPS - adjusted	(\$0.60)	\$0.90	\$0.35	\$1.35	\$1.45	~20% EPS CAGR through 2018 1x milestone in 2017
EPS as reported	(\$2.34)	(\$0.84)		\$2.00		
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%	4%	5%	
R&D	97%	20%	36%	18%	20%	
SG&A	60%	12%	17%	10%	11%	
Operating margin	-79%	63%	43%	69%	65%	
Taxes	6%	51%	45%	40%	35%	
Net margin	-79%	22%	13%	25%	30%	
Year-over-year change						
Net revenue	21%	545%	-33%	113%	-9%	
COGS	33%	83%	-50%	82%	9%	
Gross margin	19%	670%	-32%	115%	-10%	
R&D	-1%	32%	20%	8%	1%	
SG&A	14%	24%	-1%	19%	2%	
Operating income	-7%	-611%	-54%	242%	-14%	
Net income	35%	-275%	-59%	301%	11%	

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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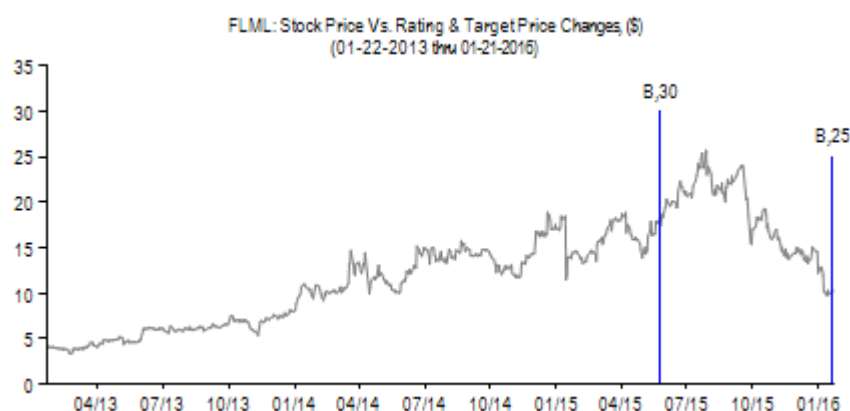
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Rating and Price Target Change History



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	10.30*

* Previous Close 1/20/2016

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.	64.71%	26.47%	2.94%
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

Merck (MRK – Not Rated)

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