

Flamel Technologies (FLML - \$12.99)

Healthcare/Biotechnology

Eclat Continues to Fund FLML's Deep Development Pipeline

Flamel reported 2Q earnings yesterday before the open beating top line on better than anticipated Bloxiverz revenue, but missing EPS on significantly higher than anticipated taxes. Tax expense is driven by FLML's Europe-development/US-sales structure. That said, the company did generate \$15M in cash from operations in the quarter, and ended 2Q16 with \$155M in cash. With the Eclat portfolio FLML notes that price and market share has remained somewhat steady from 1Q16 for Bloxiverz, suggesting that all the other entrants (and FLML) are behaving rationally and that Merck's Sugammadex is having minimal impact on the neostigmine market. Vazculep posted good sales in the quarter, beating our projections and we anticipate a 3Q16 launch of Akovaz (ephedrine sulfate injection). In a slight change in strategy, FLML plans to shift their pipeline focus to emphasize the development of Micropump sodium oxybate (no middle of the night dosed Xyrem) and LiquiTime (liquid oral guaifenesin for cough/cold) programs while looking to partner/sell/out-license the Trigger Lock (abuse-resistant opioids) and Medusa (GLP-1 agonist for diabetes) programs. We like the strategy of narrowing the development focus, given the limited size of FLML overall and the relative cost/benefit of the various programs. Timing is always a challenge when partnering, and is unlikely to occur before 2017 at the earliest. We reiterate our Buy rating, \$25 price target.

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

Trading Data:

Last Price (08/08/2016)	\$12.99
52-Week High (09/17/2015)	\$24.95
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$530.1
Shares Out. (MM)	41.24

- **Eclat portfolio showing surprising resilience.** Management notes that Bloxiverz has remained resilient in the low 40% market share range, with price sticking between \$45-\$50/vial. The Eclat strategy looks increasingly like it may have a longer "tail" post-generics than initially expected, which is a positive.
- **Unique tax structure continues to crush EPS.** Unfortunately the tax effects of holding IP & expenses in the EU and selling everything in the US continues to vex FLML's tax line. We anticipate this abnormally high tax rate will continue likely until (or if) the Micropump sodium oxybate can post meaningful sales from FLML's soon to be Irish domicile. We anticipate this could start in 2019.
- **Re-aligning development priorities makes sense.** FLML is de-emphasizing Trigger Lock (opioids) and Medusa (diabetes) to focus on nearer term (and cheaper to develop) Micropump and LiquiTime. FLML will look to sell or partner these assets over the 2H16-2017 timeframe.
- **Maintain our BUY rating, \$25 price target.** Our price target is based on a sum-of-the-parts analysis with the Eclat portfolio worth \$9/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
FY-17E	(0.02)	0.03	0.07	0.12	0.20	65.0x
FY-16E	0.04A	(0.02)	(0.04)	(0.12)	(0.14)	NM
FY-15A	0.27	0.34	0.27	0.32	0.99	13.1x
FY-14A	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM

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Source: Company data and Laidlaw & Company estimates

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Figure 1: Variance analysis

Flamel Technologies					
Quarterly variance analysis					
(\$000 except per share)	2Q15A	2Q16A	2Q16E	Variance	% Y/Y
Bloxiverz (neostigmine)	\$44,283	\$25,620	\$24,803	\$817	-42.1%
Vazculep		10,421	6,500	3,921	NM
FSC products		2,124	1,500	624	NM
1x milestones (license deals)	30	693	50	643	NM
Total Revenue	\$49,795	\$38,858	\$33,853	\$5,005	-22.0%
COGS	2,756	3,145	3,230	(85)	14.1%
Gross Profit	47,039	35,713	30,622	5,091	-24.1%
SG&A Expense	5,873	11,290	9,000	2,290	92.2%
R&D Expense	7,204	7,604	9,000	(1,396)	5.6%
Operating Inc (loss)	33,962	16,819	12,622	4,197	-50%
Interest inc (exp)	312	127	500	(373)	-59.3%
FOREX gain (loss)	480	0	0	0	NM
Other inc (exp)	(2)	0	100	(100)	-100.0%
Pretax Income	24,103	9,013	6,573	2,440	-62.6%
Income Taxes/(benefit)	10,242	9,998	3,944	6,054	-2.4%
Adj Net income/(loss)	13,861	(985)	2,629	(3,614)	NM
1x & non cash exp	31,261	18,973	0	18,973	-39.3%
NI/(loss) as reported	(17,400)	(19,958)	0	(19,958)	NM
Shares out (000)	40,353	41,241	41,541	(300)	2.2%
Fully diluted shares (000)	40,748	44,241	44,541	(300)	8.6%
Adj EPS ex-1x & non cash	\$0.34	(\$0.02)	\$0.06	(\$0.08)	NM
EPS as reported	(\$0.43)	(\$0.48)			

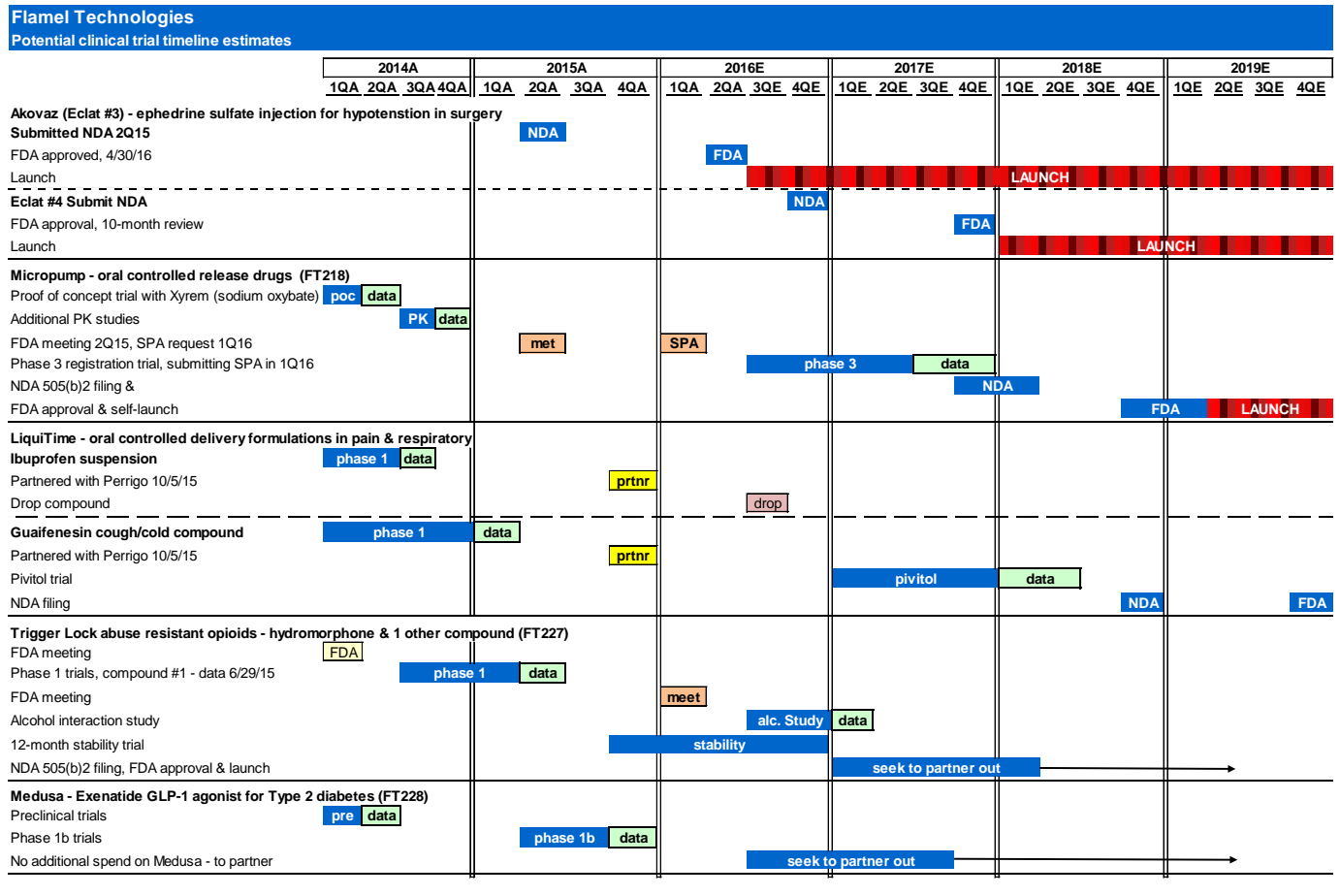
Source: Company reports & Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Pipeline, royalties & tech value	\$621,408	\$13.00
Eclat products	\$425,167	\$9.00
Cash (end of '17E)	\$130,286	\$3.00
	\$1,176,861	\$25.00
2017 fully diluted shares out		45,841

Source: Laidlaw & Company estimates.

Figure 3: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 4: 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	3QE	4QE	
Revenues										
Bloxivierz (neostigmine)	\$28,642	\$44,283	\$41,218	\$34,860	\$149,003	\$24,747	\$25,620	\$18,821	\$15,998	\$85,186
Vazculep (phenylephrine hci)	3,524	3,627	5,600	7,394	20,151	9,406	10,421	6,000	5,000	30,827
FSC products						1,200	2,124	2,750	3,550	9,624
License & research						863				
Product sales & service	(38)	662	514	393	2,054					
1x, other, (licenses deals)	53	30	6	721	721		693	50	50	793
Total Revenues	\$32,726	\$49,795	\$47,338	\$43,368	\$173,209	\$36,216	\$38,858	\$31,871	\$33,098	\$140,043
Expenses										
Cost of Goods Sold	3,630	2,756	2,087	2,448	10,921	3,392	3,145	3,154	3,201	12,892
Gross Margin	29,096	47,039	45,251	40,920	162,288	32,824	35,713	28,717	29,897	127,151
R&D	6,022	7,204	7,221	5,161	25,608	5,388	7,604	8,500	12,500	33,992
SG&A	4,463	5,873	4,568	6,808	21,712	9,461	11,290	8,938	9,188	38,876
Acq. liab. remeasurement					0					0
Impairment of assets					0					0
Total Operating Expenses	10,485	13,077	11,789	11,969	47,320	14,849	18,894	17,438	21,688	72,868
Income (loss) from Ops	18,611	33,962	33,462	28,951	114,968	17,975	16,819	11,279	8,210	54,283
Royalty payments - Eclat	(5,796)	(10,649)	(10,239)	(8,016)	(40,851)	(7,240)	(7,933)	(5,984)	(6,072)	(27,229)
Interest income/(exp)	657	312	75	934	2,651	200	127	200	200	727
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	100	25
Pretax Income (Loss)	14,884	24,103	23,540	23,488	78,268	10,760	9,013	5,595	2,438	27,806
Income tax exp/(benefit)	10,473	10,242	12,018	9,613	35,167	9,210	9,998	7,100	7,250	33,558
NI from discontinued ops										
Adj Net income/(loss)	4,411	13,861	11,522	13,875	43,101	1,550	(985)	(1,505)	(4,812)	(5,752)
EPS - adjusted	\$0.10	\$0.34	\$0.27	\$0.32	\$0.99	\$0.04	(\$0.02)	(\$0.04)	(\$0.12)	(\$0.14)
EPS as reported	\$0.27	(\$0.43)	(\$0.73)	\$1.75	\$0.93	(\$0.15)	(\$0.48)			(\$0.79)
Shares out (000)	40,207	40,353	40,625	41,125	40,580	41,241	41,241	41,541	41,841	41,466
Fully diluted shares (000)	42,834	40,748	42,875	43,430	43,619	44,241	44,241	44,541	44,841	44,466
Margin & expense analysis										
COGS	11%	6%	4%	6%	6%	9%	8%	10%	10%	9%
R&D	18%	14%	15%	12%	15%	15%	20%	27%	38%	24%
SG&A	14%	12%	10%	16%	13%	26%	29%	28%	28%	28%
Operating margin	57%	68%	71%	67%	66%	50%	43%	35%	25%	39%
Taxes	70%	42%	51%	41%	45%	86%	111%	127%	297%	121%
Net margin	13%	28%	24%	32%	25%	4%	-3%	-5%	-15%	-4%
Year-over-year change										
Net revenue	257%	516%	574%	1362%	536%	11%	-22%	-33%	-24%	-19%
COGS	191%	68%	40%	75%	89%	-7%	14%	51%	31%	18%
Gross margin	267%	630%	718%	2506%	656%	13%	-24%	-37%	-27%	-22%
R&D	-15%	7%	3%	-8%	-3%	-11%	6%	18%	142%	33%
SG&A	26%	24%	11%	66%	32%	112%	92%	96%	35%	79%
Operating income	-783%	-775%	-698%	-455%	-634%	-3%	-50%	-66%	-72%	-53%
Net income	-205%	-384%	-291%	-312%	-299%	-65%	-107%	-113%	-135%	-113%

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

Figure 5: Annual Income Statement

Flamel Technologies							
Annual income statement							
(\$000's except per share)	2015A	2016E	2017E	2018E	2019E	2020E	Comments
Revenues							
Bloxiverz (neostigmine)	\$149,003	\$85,186	\$62,095	\$61,148	\$60,176	\$59,978	WestWard entry 1Q16
Vazculep (phenylephrine hc)	20,151	30,827	20,000	18,500	18,000	15,000	Generics 2H16
FSC		9,624	10,000	11,250	12,500	14,000	~\$80M & \$30M-\$40M peak each
Akovaz (ephedrine sulfate inj) & Eclat #4		12,750	77,225	125,000	125,000	115,000	~\$80M & \$30M-\$40M peak each
LiquiTime royalty				1,500	7,050	12,750	Licensed to Perrigo
MicroPump (Xyrem-like)					75,000	175,000	Eliminates middle night dosing
1x milestones (license deal)	721	793	200	200	0	200	Partnership milestones here
Total Revenues	\$173,209	\$140,043	\$169,520	\$217,598	\$301,476	\$399,428	2016 Guide: \$125M-\$140M revs
Expenses							
Cost of Goods Sold	10,921	12,892	15,932	20,465	27,818	32,998	
Gross Margin	162,288	127,151	153,588	197,133	273,658	366,430	
R&D	25,608	33,992	33,750	30,000	35,000	38,000	2016 Guide: \$30M-\$40M
SG&A	21,712	38,876	38,250	37,188	48,750	65,000	FSC reps & SG&A here
Total Operating Expense:	47,320	72,868	72,000	67,188	83,750	103,000	
Income (loss) from Ops	114,968	54,283	81,588	129,946	189,908	263,430	
Royalty payments - Eclat	(40,851)	(27,229)	(32,794)	(42,125)	(41,822)	(39,105)	Deerfield & Broadfin payments
Interest income	2,651	727	1,200	1,950	3,252	3,254	
FOREX gain/(loss)	1,500	0	0	0	0	0	non-cash item
Other income/(loss)	0	25	400	400	402	404	
Pretax Income (Loss)	78,268	27,806	50,394	90,171	151,741	227,983	
Taxes	35,167	33,558	41,250	54,500	50,500	56,996	Domicile structure drives tax rate
Adj Net income/(loss)	43,101	(5,752)	9,144	35,671	101,241	170,987	
Non cash & 1x-items	2,442	26,899					
Net inc/(loss) as reported	40,659	(32,651)					
EPS - adjusted	\$0.99	(\$0.14)	\$0.20	\$0.75	\$2.10	\$3.50	30% CAGR 2015-2020
EPS as reported	\$0.93	(\$0.79)					
Shares out (000)	40,580	41,466	42,591	43,791	44,543	45,145	
Fully diluted shares (000)	43,619	44,466	45,841	47,541	48,295	48,899	
Margin & expense analysis							
COGS	6%	9%	9%	9%	9%	8%	
R&D	15%	24%	20%	14%	12%	10%	
SG&A	13%	28%	23%	17%	16%	16%	
Operating margin	66%	39%	48%	60%	63%	66%	
Taxes	45%	121%	82%	60%	33%	25%	
Net margin	25%	-4%	5%	16%	34%	43%	
Year-over-year change							
Net revenue	536%	-19%	21%	28%	39%	32%	
COGS	89%	18%	24%	28%	36%	19%	
Gross margin	656%	-22%	21%	28%	39%	34%	
R&D	-3%	33%	-1%	-11%	17%	9%	
SG&A	32%	79%	-2%	-3%	31%	33%	
Operating income	-634%	-53%	50%	59%	46%	39%	
Net income	-299%	-113%	-259%	290%	184%	69%	

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.

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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.

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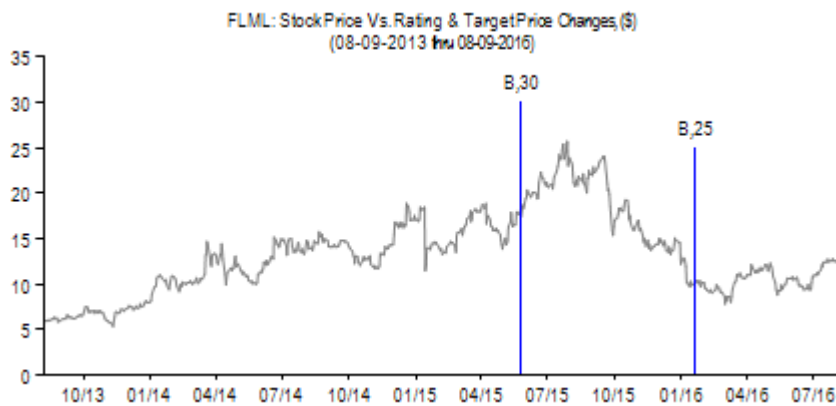
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Rating and Price Target Change History



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	10.25

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.	62.16%	27.03%	2.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.70%	0.00%	0.00%

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Merck (MRK – Not Rated)

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