

Flamel Technologies (FLML - \$9.42)

Eclat Continues to Throw Off Cash in the First Quarter As Pipeline Progresses

Flamel reported 1Q16 recently hitting our top-line expectations but missing EPS on lower than expected gross margins and FLML's higher taxes. That said, FLML did generate \$22.5M in cash from operations in the quarter (no cash taxes paid in the quarter however), showing that FLML's near term strategy of utilizing the Eclat portfolio to generate cash flow has been successful. Bloxiverz and Vazculep continue to maintain solid market share and management maintains its full year revenues guidance of \$110M-\$130M. FLML's pipeline remains on-track with the Micropump sodium oxybate (improved Xyrem) product starting its Phase 3 trial in 2Q16 (we expect data mid-2017) following the Special Protocol Assessment (SPA) submission to the FDA in 1Q16. Eclat product #3, Akovaz (ephedrine sulfate injection), was recently approved and is expected to launch in 3Q16. We see Akovaz as targeting a \$75M-\$100M market opportunity. We are reiterating our Buy rating and \$25 price target.

- **Micropump sodium oxybate (Xyrem), most valuable asset on-track.** The SPA was submitted to the FDA for the once nightly version of Micropump sodium oxybate at the end of 1Q16. We expect the pivotal Phase 3 trial to start 2Q16 with data to read out mid-2017.
- **Akovaz approved and ready to launch 3Q16.** On 4/29/16, FLML received FDA approval for Eclat #3, Akovaz, which is their formulation of ephedrine sulfate injection for hypotension during surgery. With launch in 3Q16, we believe this represents another stream of cash flow that could be used for more growth and acquisitions such as the FSC acquisition in 1Q16. Competitor Akorn has an NDA on file for a branded ephedrine too so it's unlikely that FLML will get market exclusivity in this product. Timing remains uncertain for the potential approval of Akorn's ephedrine sulfate.
- **Strong top line in line with expectations, bottom line miss.** Bloxiverz sales were \$24.7M, a little below our expectations of \$29.5M but balanced by stronger than expected sales of Vazculep at \$9.4M (vs \$6.2M). Bottom line adjusted-EPS of \$0.04 (vs us at \$0.18) was due to higher COGS due to the lower margin FSC products in the mix. FSC also drove a slightly higher SG&A expense in the Q.
- **Maintain our BUY rating, \$25 price target.** Our price target 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

Earnings Estimates: (per share)

\$3/share.

Healthcare/Biotechnology

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

Trading Data:

Last Price (05/10/2016)	\$9.42
52-Week High (07/23/2015)	\$26.09
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$381.5
Shares Out. (MM)	40.50

James Molloy

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(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	0.08	0.15	0.16	0.20	0.60	15.7x
FY-16E	0.04A	0.06	0.03	0.03	0.15	62.8x
FY-15A	0.27	0.34	0.27	0.32	0.99	9.5x
FY-14A	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM

Source: Company data and Laidlaw & Company estimates

Figure 1: Variance analysis

Flamel Technologies					
Quarterly variance analysis					
<i>(\$000 except per share)</i>	1Q15A	1Q16A	1Q16E	Variance	% Y/Y
Bloxiverz (neostigmine)	\$28,642	\$24,747	\$29,475	(4,728)	-13.6%
Vazculep		9,406	6,250	3,156	NM
1x milestones (license deals)	53	0	50	(50)	-100.0%
Total Revenue	\$32,726	\$36,216	\$36,525	(309)	10.7%
COGS	3,630	3,392	1,608	1,784	-6.6%
Gross Profit	29,096	32,824	34,917	(2,093)	12.8%
SG&A Expense	4,463	9,461	4,750	4,711	112.0%
R&D Expense	6,022	5,388	9,000	(3,612)	-10.5%
Operating Inc (loss)	18,611	17,975	21,167	(3,192)	NM
Interest inc (exp)	657	200	500	(300)	-69.6%
FOREX gain (loss)	2,264	0	0	0	NM
Other inc (exp)	(852)	(175)	100	(275)	-79.5%
Pretax Income	14,884	10,760	14,413	(3,653)	NM
Income Taxes/(benefit)	10,473	9,210	6,486	2,724	NM
Adj Net income/(loss)	4,411	1,550	7,927	(6,377)	NM
1x & non cash exp	(7,235)	7,926	0	7,926	-209.6%
NI/(loss) as reported	11,646	(6,376)	0	(6,376)	NM
Shares out (000)	40,207	41,241	41,425	(184)	2.6%
Fully diluted shares (000)	42,834	44,241	44,425	(184)	3.3%
EPS as reported	\$0.27	(\$0.15)	\$0.00	(\$0.15)	NM
Adj EPS ex-1x & non cash	\$0.10	\$0.04	\$0.18	(\$0.14)	NM

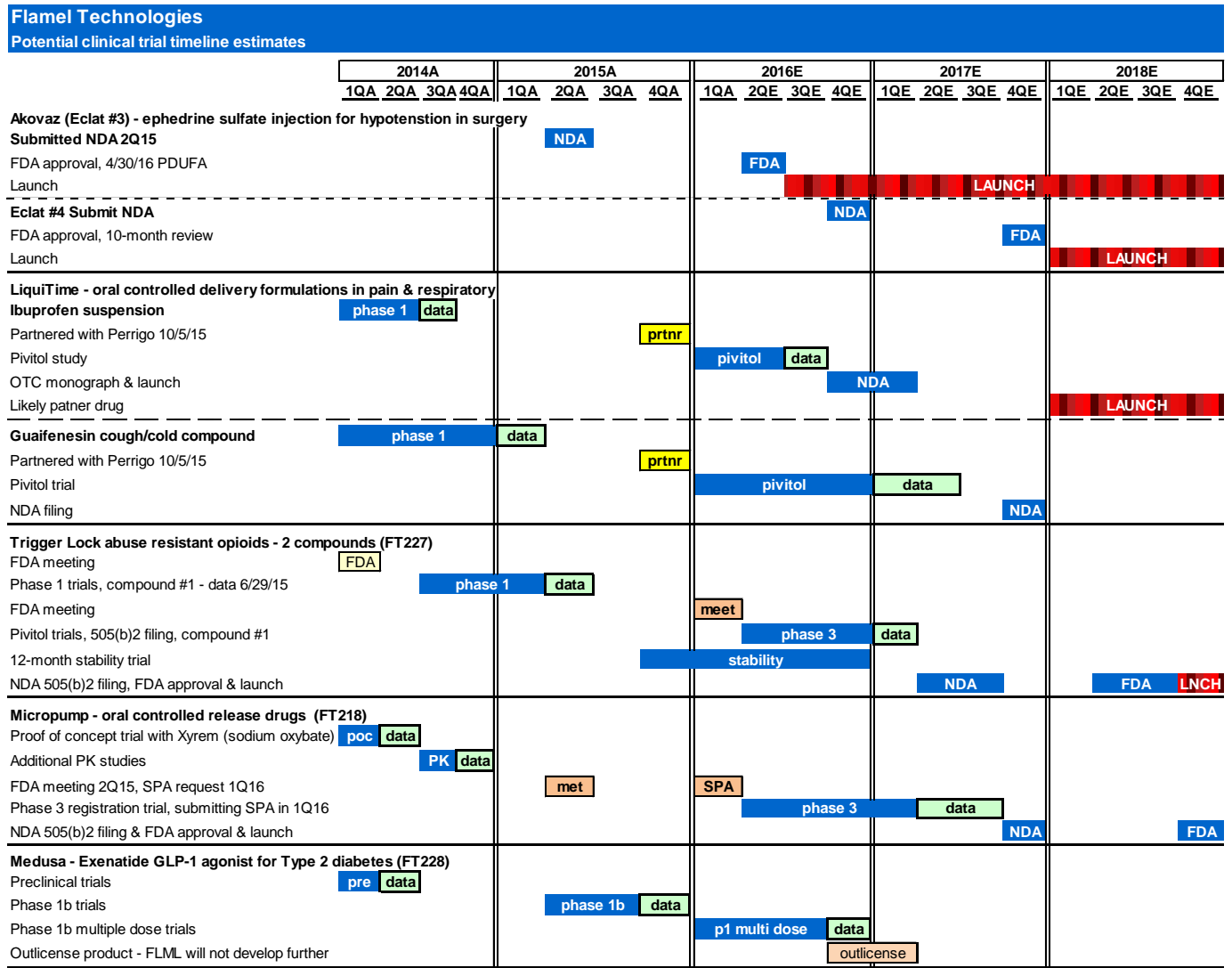
Source: Company reports & Laidlaw & Company estimates

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)	\$120,251	\$3.00
	\$1,101,494	\$25.00
2016 fully diluted shares out		44,691

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	2QE	3QE	4QE	
Revenues										
Bloxiverz (neostigmine)	\$28,642	\$45,500	\$41,218	\$34,860	\$150,220	\$24,747	\$24,803	\$18,821	\$15,998	\$84,368
Vazculep (phenylephrine hci)	3,524	3,600	5,600	7,394	20,151	9,406	6,500	6,000	5,000	26,906
FSC products						1,200	1,500	2,750	3,550	9,000
License & research						863				
Product sales & service	(38)	600	514	393	2,054					
1x, other, (licenses deals)	53	30	6	721	721		50	50	50	150
Total Revenues	\$32,726	\$49,795	\$47,338	\$43,368	\$173,209	\$36,216	\$33,853	\$31,871	\$33,098	\$135,037
Expenses										
Cost of Goods Sold	3,630	2,756	2,087	2,448	10,921	3,392	3,230	2,907	2,950	12,479
Gross Margin	29,096	47,039	45,251	40,920	162,288	32,824	30,622	28,964	30,148	122,558
R&D	6,022	7,204	7,221	5,161	25,608	5,388	9,000	11,000	12,500	37,888
SG&A	4,463	5,873	4,568	6,808	21,712	9,461	9,000	9,188	9,438	37,086
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	18,000	20,188	21,938	74,974
Income (loss) from Ops	18,611	33,962	33,462	28,951	114,968	17,975	12,622	8,776	8,210	47,584
Royalty payments - Eclat	(5,796)	(10,649)	(10,239)	(8,016)	(40,851)	(7,240)	(6,649)	(5,984)	(6,072)	(25,945)
Interest income/(exp)	657	312	75	934	2,651	200	500	500	750	1,950
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)	100	100	100	125
Pretax Income (Loss)	14,884	24,103	23,540	23,488	78,268	10,760	6,573	3,392	2,989	23,714
Income tax exp/(benefit)	10,473	10,242	12,018	9,613	35,167	9,210	3,944	2,035	1,793	16,983
NI from discontinued ops										
Adj Net income/(loss)	4,411	13,861	11,522	13,875	43,101	1,550	2,629	1,357	1,195	6,732
EPS - adjusted	\$0.10	\$0.34	\$0.27	\$0.32	\$0.99	\$0.04	\$0.06	\$0.03	\$0.03	\$0.15
EPS as reported	\$0.27	(\$0.43)	(\$0.73)	\$1.75	\$0.93	(\$0.15)				
Shares out (000)	40,207	40,353	40,625	41,125	40,580	41,241	41,541	41,841	42,141	41,691
Fully diluted shares (000)	42,834	40,748	42,875	43,430	43,619	44,241	44,541	44,841	45,141	44,691
Margin & expense analysis										
COGS	11%	6%	4%	6%	6%	9%	10%	9%	9%	9%
R&D	18%	14%	15%	12%	15%	15%	27%	35%	38%	28%
SG&A	14%	12%	10%	16%	13%	26%	27%	29%	29%	27%
Operating margin	57%	68%	71%	67%	66%	50%	37%	28%	25%	35%
Taxes	70%	42%	51%	41%	45%	86%	60%	60%	60%	72%
Net margin	13%	28%	24%	32%	25%	4%	8%	4%	4%	5%
Year-over-year change										
Net revenue	257%	516%	574%	1362%	536%	11%	-32%	-33%	-24%	-22%
COGS	191%	68%	40%	75%	89%	-7%	17%	39%	20%	14%
Gross margin	267%	630%	718%	2506%	656%	13%	-35%	-36%	-26%	-24%
R&D	-15%	7%	3%	-8%	-3%	-11%	25%	52%	142%	48%
SG&A	26%	24%	11%	66%	32%	112%	53%	101%	39%	71%
Operating income	-783%	-775%	-698%	-455%	-634%	-3%	-63%	-74%	-72%	-59%
Net income	-205%	-384%	-291%	-312%	-299%	-65%	-81%	-88%	-91%	-84%

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	\$150,220	\$84,368	\$61,942	\$60,997	WestWard entry 1Q16
Vazculep (phenylephrine hci)		20,151	26,906	20,000	18,500	Generics 2H16
Eclat products #3 & #4			13,750	77,225	125,000	~\$80M & \$30M-\$40M peak each
LiquiTime royalty				0	7,500	Licensed to Perrigo
1x milestones (license deals)	5,114	721	150	50,200	200	Partnership milestones here
Total Revenues	\$27,250	\$173,209	\$135,037	\$219,367	\$223,447	2016 Guide: \$110M-\$130M revs
Expenses						
Cost of Goods Sold	5,775	10,921	12,479	15,917	20,450	
Gross Margin	21,475	162,288	122,558	203,450	202,997	
R&D	26,500	25,608	37,888	39,000	40,000	2016 Guide: \$35-\$50M
SG&A	16,485	21,712	37,086	38,250	40,000	FSC reps & SG&A here
Total Operating Expenses	42,985	47,320	74,974	77,250	80,000	
Income (loss) from Ops	(21,510)	114,968	47,584	126,200	122,997	
Royalty payments - Eclat	0	(40,851)	(25,945)	(32,763)	(42,094)	Deerfield & Broadfin payments
Interest income	(1,450)	2,651	1,950	2,375	3,250	
FOREX gain/(loss)	(149)	1,500	0	0	0	non-cash item
Other income/(loss)	(35)	0	125	400	400	
Pretax Income (Loss)	(23,144)	78,268	23,714	46,212	84,554	
Taxes	(1,487)	35,167	16,983	18,485	29,594	Domicile structure drives taxes
Adj Net income/(loss)	(21,657)	43,101	6,732	27,727	54,960	
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	77,727	0	
EPS - adjusted	(\$0.60)	\$0.99	\$0.15	\$0.60	\$1.15	~20% EPS CAGR through 2018
EPS as reported	(\$2.34)	\$0.93		\$1.68		1x milestone in 2017
Shares out (000)	36,211	40,580	41,691	42,891	44,091	
Fully diluted shares (000)	40,531	43,619	44,691	46,141	47,841	
Margin & expense analysis						
COGS	21%	6%	9%	7%	9%	
R&D	97%	15%	28%	18%	18%	
SG&A	60%	13%	27%	17%	18%	
Operating margin	-79%	66%	35%	58%	55%	
Taxes	6%	45%	72%	40%	35%	
Net margin	-79%	25%	5%	13%	25%	
Year-over-year change						
Net revenue	21%	536%	-22%	62%	2%	
COGS	33%	89%	14%	28%	28%	
Gross margin	19%	656%	-24%	66%	0%	
R&D	-1%	-3%	48%	3%	3%	
SG&A	14%	32%	71%	3%	5%	
Operating income	-7%	-634%	-59%	165%	-3%	
Net income	35%	-299%	-84%	312%	98%	

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.

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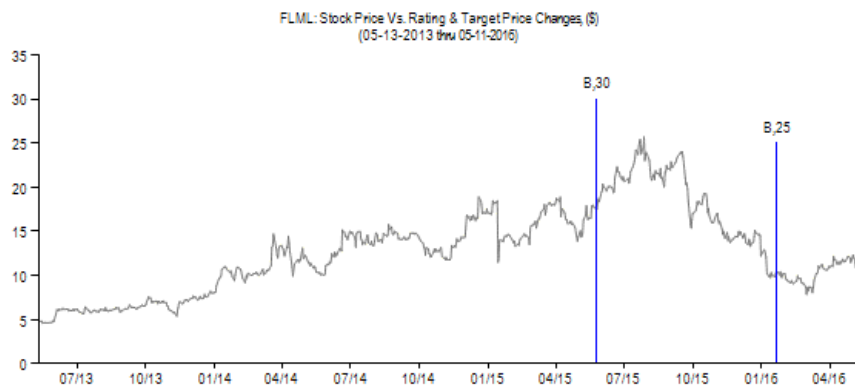
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Rating and Price Target Change History



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

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.	66.67%	27.78%	2.78%
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%

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Akorn (AKRX – Not Rated)

ADDITIONAL DISCLOSURES

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