

Flamel Technologies (FLML - \$9.83)

Management meetings highlight FLML opportunity

We recently spent time with the senior management of FLML and we continue to believe that FLML represents one of the most compelling names in our group at current levels. Key pipeline product sodium oxybate (Xyrem) remains on track for a 2Q16 initiation of the pivotal Phase 3 trial, and in fact clinicaltrials.gov has just posted the clinical trial details to their site. FLML is waiting for the FDA to approve their Special Protocol Assessment (SPA) request made at the end of 1Q16, which should happen any day. Management notes that Bloxiverz (neostigmine) continues on pace for similar sales to 1Q16 (\$24.7M) as they haven't yet seen an additional generic entrant and seem to be holding share at ~45% of the market. Newly approved Akovaz (ephedrine sulphate) remains on-track to launch in 3Q16, around when we anticipate competitor Akorn will launch their branded version of ephedrine sulfate (assuming approval on their mid-July PDUFA date). AKRX has already taken two ~10% price increases on their generic ephedrine so far this year, but the opportunity does exist for yet another before the product gets pulled – Generic Drugs Pricing Strategy 101 in our opinion. Additional highlights are below, we continue to rate FLML a Buy, with a \$25 price target.

- **SPA approval should help smooth trial process.** While the FDA isn't mandated to abide by an SPA, it does give some assurance to FLML (and to us) that the FDA at least agrees with FLML's clinical trial plan. This is important because this will be FLML's first "real" clinical trial. The Eclat approvals were "paper NDA's" where the company didn't have to generate any clinical data to file their NDA. Additionally FLML will be looking for approval for both cataplexy and excessive daytime sleepiness with one trial of ~250 people, where the original approval for Xyrem had an ~200 person trial for each indication.
- **Patent issues ahead for sodium Oxybate?** Management acknowledges that JAZZ is unlikely to allow FLML to walk in a take away their biggest selling product (assuming approval on the single dose regimen) and notes that Xyrem's possibly biggest patent picket fence is around their REMs and distribution channel. Management feels confident that if they show an improved dose schedule (and possibly eliminate the hangover effect in some patients) the FDA will find a way for FLML's product to get to market. In JAZZ's 10K even they acknowledge that that the FDA reserves the right to revisit JAZZ's REMs/distribution at the FDA's discretion.
- **Maintain our BUY rating, \$25 price target** based on a sum-of-the-parts Eclat: \$10/share, pipeline & royalties: \$12/share, and cash: \$3/share.

Adjusted Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	0.09	0.13	0.17	0.21	0.60	x
FY-16E	0.04A	0.06	0.03	0.03	0.15	x
FY-15A	0.10	0.34	0.27	0.32	0.99	x
FY-14A	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (05/20/2016)	\$9.83
52-Week High (07/23/2015)	\$26.09
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$405.4
Shares Out. (MM)	41.2

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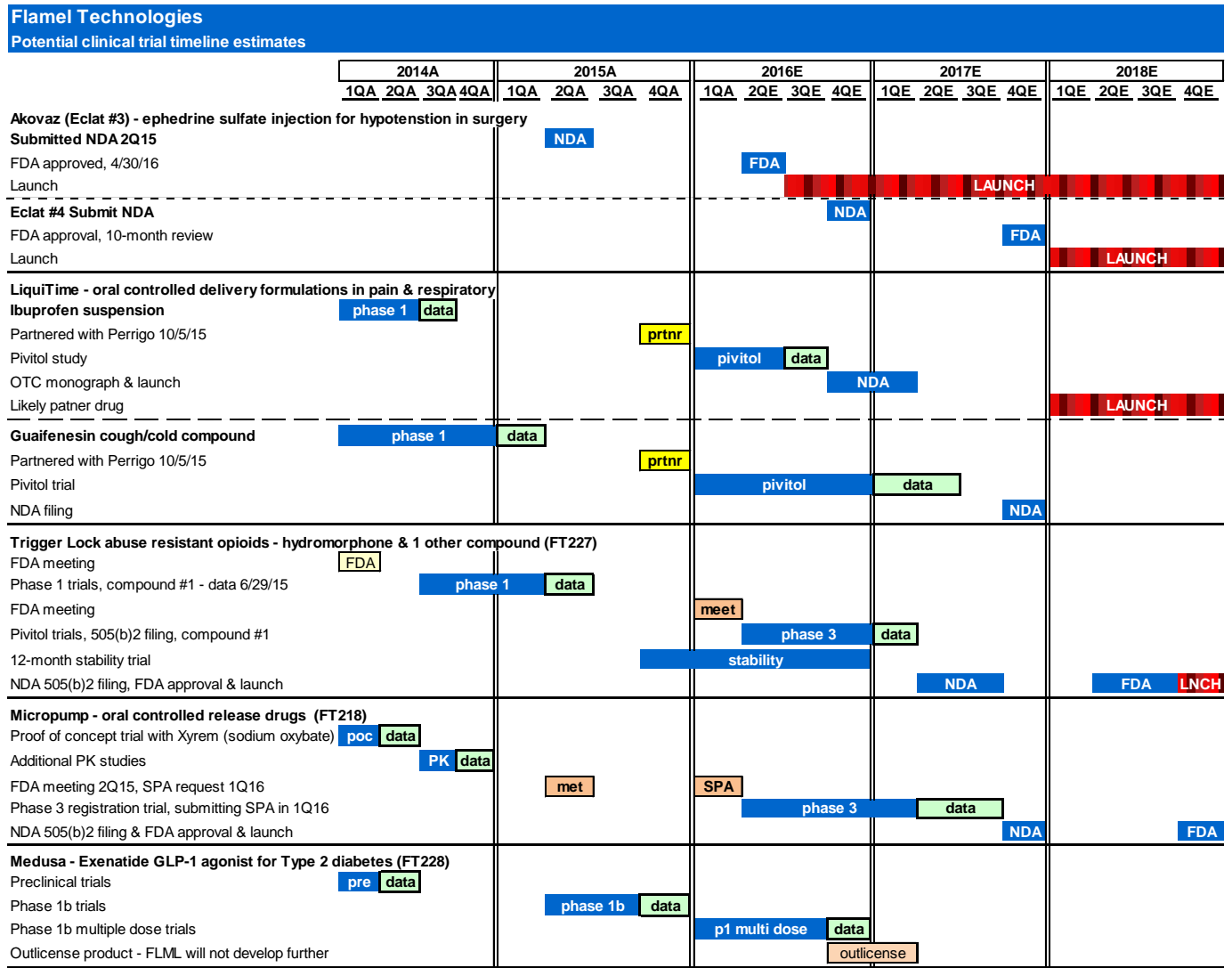
- **Death, taxes, and FLML's really high taxes.** Management reiterated that relief from their egregious tax rate – due to high profits in the US and high expenses ex-US – will continue to dog sales from the Eclat portfolio. Management is exploring re-domiciling from France to Ireland, and moving intellectual property there, so should any of FLML's pipeline bear fruit they ought to help dramatically cut FLML's tax rate.

Figure 1: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Pipeline, royalties & tech value	\$553,349	\$12.00
Eclat products	\$419,624	\$10.00
Cash (end of '16E)	\$121,876	\$3.00
	\$1,094,848	\$25.00
2016 fully diluted shares out		44,691

Source: Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 3: 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										
Bloxivertz (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)				(\$0.03)
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 4: 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
FSC			9,000	10,000	11,250	~\$80M & \$30M-\$40M peak each
Akovaz & Eclat #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	7,926	(50,000)	0	non-cash item
Net inc/(loss) as reported	(84,906)	40,659	(1,194)	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	(\$0.03)	\$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.

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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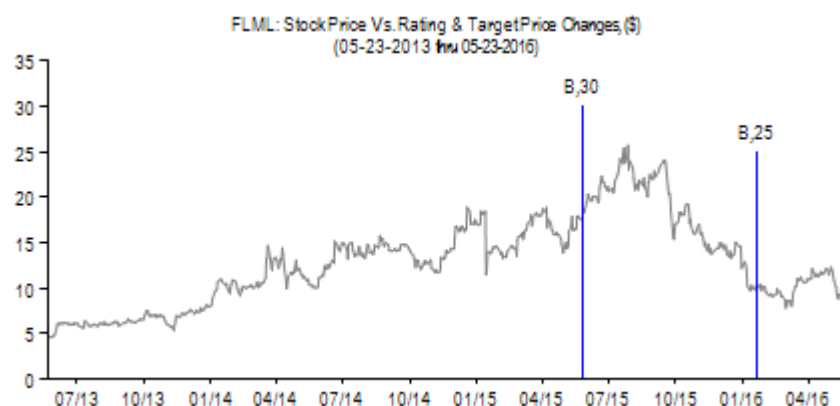
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Rating and Price Target Change History



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	10.25

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%

ADDITIONAL COMPANIES MENTIONED

Akorn (AKRX – Not Rated)

JAZZ Pharmaceuticals (JAZZ – Not Rated)

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