

Flamel Technologies (FLML - \$9.40)

Healthcare/Biotechnology

REST-ON Underway On-Track, Eclat Continues to Perform

Flamel reported 3Q16 yesterday before the open with top and bottom line roughly in line with our estimates due to the resiliency of Bloxiverz and Vazculep and an impressive launch of Akovaz (ephedrine sulfate injection) that sold \$5.6M vs. our estimated \$4.3M. While Bloxiverz posted lower sales of \$15.6M vs. our anticipated \$18.8M, it still retains a solid ~40% market share in the face of four other products on the market. We view this post-generics “tail” as a strong positive for FLML as they develop their internal pipeline. With the Special Protocol Assessment (SPA) for Micropump finally resolved, FLML has initiated their Phase 3 pivotal trial for FT218 (a “Xyrem-like” sodium oxybate that eliminates the middle of the night dosing) in Europe and Canada and expect to have all trial participants on drug by 2H17. We reiterate our Buy rating, \$25 price target.

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

Trading Data:

Last Price (11/07/2016)	\$9.40
52-Week High (11/09/2015)	\$16.50
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$387.7
Shares Out. (MM)	41.24

- **Top and bottom line roughly in-line, FY16 guidance raised.** Lower Bloxiverz sales were off-set by strong Vazculep sales of \$9.3M vs. LL: \$6M and an impressive Akovaz launch at \$5.6M vs. LL: \$4.3M. FSC continues to woefully underperform, and isn’t likely to come anywhere near FLML’s \$10M-\$15M top line projections, but fortunately the Akovaz/Vazculep outperformance is more than offsetting FSC weakness leading FLML to raise FY16 guidance to \$133M-\$143M from \$125M-\$140M previously.
- **REST-ON Phase 3 on-track, R&D expense guidance reiterated.** FLML finally received their SPA from the FDA on 10/6/16 and the pivotal Phase 3 trial of FT218 (Micropump sodium oxybate) in Europe and Canada is underway. Management is guiding to all study participants being on drug by 2H17 with data read-out in 1H18 (see our Clinical Trials timeline later in this report).
- **Peculiar Tax structure still an issue, Akovaz helping the cause.** Although tax effects of holding IP and expenses in EU persist, Akovaz sales out of Ireland are alleviating some of the previously seen pressure on EPS. We still believe FT218 sales should help fix this issue starting in 2019.
- **Maintain our BUY rating, \$25 price target.** Our price target is based on a sum-of-the-parts analysis with the FT218 at \$10/share, the Eclat portfolio at \$7/share, and cash (end ’17) & tech value at \$8/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	(0.06)	0.01	0.01	0.06	0.01	65.0x
FY-16E	0.03A	(0.02A)	(0.08)A	(0.09)	(0.17)	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)	3Q15A	3Q16A	3Q16E	Variance	% Y/Y
Bloxiverz (neostigmine)	\$41,243	\$15,591	\$18,821	(\$3,230)	-62.2%
Vazculep		9,340	6,000	3,340	NM
Akovaz		5,568	4,250	1,318	NM
FSC products		841	2,750	(1,909)	NM
1x milestones (license deals)	6	747	50	697	NM
Total Revenue	\$47,338	\$32,087	\$31,871	\$216	-32.2%
COGS	2,087	2,844	3,154	(310)	36.3%
Gross Profit	45,251	29,243	28,717	526	-35.4%
SG&A Expense	4,568	12,740	8,938	3,803	178.9%
R&D Expense	7,221	8,143	8,500	(357)	12.8%
Operating Inc (loss)	33,462	8,360	11,279	(2,919)	-75%
Interest inc (exp)	75	226	200	26	201.3%
Other inc (exp)	50	0	100	(100)	-100.0%
Pretax Income	23,540	1,917	5,595	(3,678)	-91.9%
Income Taxes/(benefit)	12,018	5,416	7,100	(1,684)	-54.9%
Adj Net income/(loss)	11,522	(3,499)	(1,505)	(1,994)	NM
1x & non cash exp	41,207	25,796		25,796	-37.4%
NI/(loss) as reported	(29,685)	(22,297)		(22,297)	NM
Shares out (000)	40,625	41,241	41,541	(300)	1.5%
Fully diluted shares (000)	42,875	47,741	44,541	3,200	11.3%
Adj EPS ex-1x & non cash	\$0.27	(\$0.08)	(\$0.04)	(\$0.05)	NM
EPS as reported	(\$0.73)	(\$0.54)			

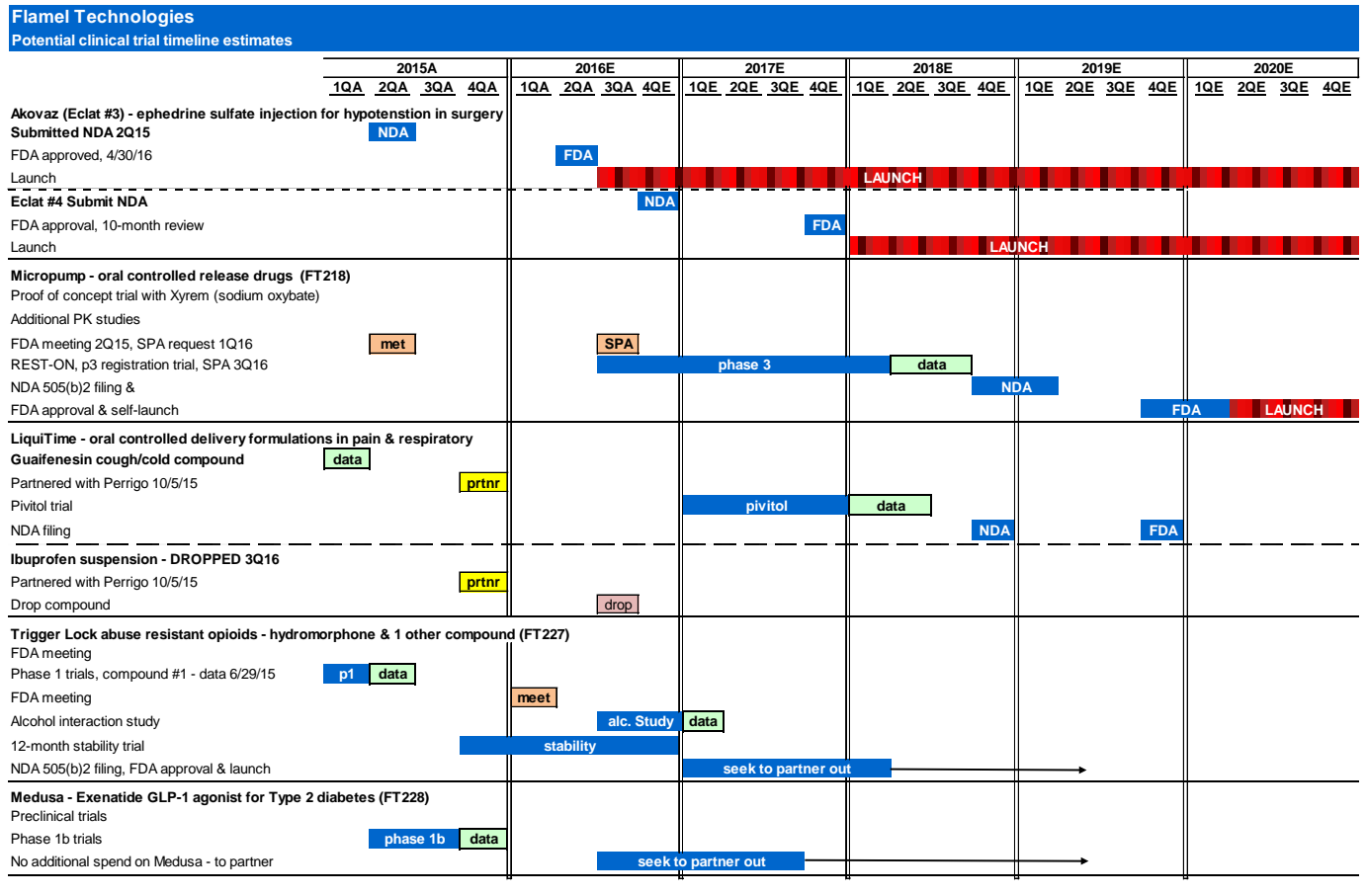
Source: Company reports & Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Sodium Oxybate (FT 218)	\$500,284	\$10.00
Eclat products	\$339,854	\$7.00
Cash (end of '17E) & tech value	\$404,978	\$8.00
	\$1,245,115	\$25.00
2017 fully diluted shares out		48,791

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	3QA	4QE	
Revenues										
Bloxiverz (neostigmine)	\$28,642	\$44,283	\$41,243	\$34,860	\$149,028	\$24,747	\$25,620	\$15,591	\$14,116	\$80,074
Vazculep (phenylephrine hci)	3,524	3,627	5,605	7,394	20,151	9,406	10,421	9,340	9,750	38,917
FSC products						1,200	2,124	841	1,250	5,415
License & research						863				
Product sales & service	(38)	662	465	393	2,054					
1x, other, (licenses deals)	53	30	6	721	721		693	747	50	1,490
Total Revenues	\$32,726	\$49,795	\$47,338	\$43,368	\$173,209	\$36,216	\$38,858	\$32,087	\$33,666	\$140,827
Expenses										
Cost of Goods Sold	3,630	2,756	2,087	2,448	10,921	3,392	3,145	2,844	3,010	12,391
Gross Margin	29,096	47,039	45,251	40,920	162,288	32,824	35,713	29,243	30,656	128,436
R&D	6,022	7,204	7,221	5,161	25,608	5,388	7,604	8,143	8,250	29,385
SG&A	4,463	5,873	4,568	6,808	21,712	9,461	11,290	12,740	12,688	46,179
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	20,883	20,938	75,564
Income (loss) from Ops	18,611	33,962	33,462	28,951	114,968	17,975	16,819	8,360	9,719	52,873
Royalty payments - Eclat	(5,796)	(10,649)	(10,239)	(8,016)	(40,851)	(7,240)	(7,933)	(6,669)	(6,662)	(28,504)
Interest income/(exp)	657	312	75	934	2,651	200	127	226	200	753
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	(75)
Pretax Income (Loss)	14,884	24,103	23,540	23,488	78,268	10,760	9,013	1,917	3,356	25,046
Income tax exp/(benefit)	10,473	10,242	12,018	9,613	35,167	9,210	9,998	5,416	7,250	31,874
NI from discontinued ops										
Adj Net income/(loss)	4,411	13,861	11,522	13,875	43,101	1,550	(985)	(3,499)	(3,894)	(6,828)
EPS - adjusted	\$0.10	\$0.34	\$0.27	\$0.32	\$0.99	\$0.03	(\$0.02)	(\$0.08)	(\$0.09)	(\$0.17)
EPS as reported	\$0.27	(\$0.43)	(\$0.73)	\$1.75	\$0.93	(\$0.15)	(\$0.48)	(\$0.54)	(\$0.09)	(\$1.44)
Shares out (000)	40,207	40,353	40,625	41,125	40,580	41,241	41,241	41,241	41,541	41,316
Fully diluted shares (000)	42,879	40,748	42,875	43,430	43,619	47,838	47,837	47,741	48,041	47,864
Margin & expense analysis										
COGS	11%	6%	4%	6%	6%	9%	8%	9%	9%	9%
R&D	18%	14%	15%	12%	15%	15%	20%	25%	25%	21%
SG&A	14%	12%	10%	16%	13%	26%	29%	40%	38%	33%
Operating margin	57%	68%	71%	67%	66%	50%	43%	26%	29%	38%
Taxes	70%	42%	51%	41%	45%	86%	111%	283%	216%	127%
Net margin	13%	28%	24%	32%	25%	4%	-3%	-11%	-12%	-5%
Year-over-year change										
Net revenue	257%	516%	574%	1362%	536%	11%	-22%	-32%	-22%	-19%
COGS	191%	68%	40%	75%	89%	-7%	14%	36%	23%	13%
Gross margin	267%	630%	718%	2506%	656%	13%	-24%	-35%	-25%	-21%
R&D	-15%	7%	3%	-8%	-3%	-11%	6%	13%	60%	15%
SG&A	26%	24%	11%	66%	32%	112%	92%	179%	86%	113%
Operating income	-783%	-775%	-698%	-455%	-634%	-3%	-50%	-75%	-66%	-54%
Net income	-205%	-384%	-291%	-312%	-299%	-65%	-107%	-130%	-128%	-116%

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							
Bloxivert (neostigmine)	\$149,028	\$80,074	\$56,161	\$53,657	\$54,968	\$57,081	WestWard entry 1Q16
Vazculep (phenylephrine hci)	20,151	38,917	29,000	19,750	18,000	15,000	Generics 2H16
FSC products		5,415	5,000	8,500	10,000	11,500	FSC underperforming
Akovaz & Eclat #4		14,068	77,225	125,000	135,000	115,000	Akovaz ~\$350M mkt (7M vials)
LiquiTime royalty				0	0	750	Licensed to Perrigo
Sodium Oxybate (Xyrem-like)						75,000	Eliminates middle night dosing
1x milestones (license deals)	721	1,490	200	200	0	200	
Total Revenues	\$173,209	\$140,827	\$167,586	\$207,107	\$217,968	\$274,531	2016 Guide: \$133M-\$143M revs
Expenses							
Cost of Goods Sold	10,921	12,391	14,940	18,253	18,717	22,087	
Gross Margin	162,288	128,436	152,647	188,854	199,251	252,444	
R&D	25,608	29,385	29,250	21,750	20,000	20,000	2016 Guide: \$30M-\$40M
SG&A	21,712	46,179	49,750	50,688	52,000	52,000	FSC reps & SG&A here
Total Operating Expenses	47,320	75,564	79,000	72,438	72,000	72,000	
Income (loss) from Ops	114,968	52,873	73,647	116,416	127,251	180,444	
Royalty payments - Eclat	(40,851)	(28,504)	(33,426)	(40,840)	(42,808)	(38,509)	Deerfield & Broadfin payments
Interest income	2,651	753	1,000	1,200	1,500	2,000	
FOREX gain/(loss)	1,500	0	0	0	0	0	non-cash item
Other income/(loss)	0	(75)	400	400	402	404	
Pretax Income (Loss)	78,268	25,046	41,621	77,176	86,345	144,339	
Taxes	35,167	31,874	41,250	54,500	50,500	36,085	Domicile structure drives tax rate
Adj Net income/(loss)	43,101	(6,828)	371	22,676	35,845	108,254	
Non cash & 1x-items	2,442	52,695					
Net inc/(loss) as reported	40,659	(59,523)					
EPS - adjusted	\$0.99	(\$0.17)	\$0.01	\$0.45	\$0.70	\$2.10	+15% CAGR 2015-2020
EPS as reported	\$0.93	(\$1.44)					
Shares out (000)	40,580	41,316	42,291	43,491	44,243	44,845	
Fully diluted shares (000)	43,619	47,864	48,791	50,241	50,993	51,595	
Margin & expense analysis							
COGS	6%	9%	9%	9%	9%	8%	
R&D	15%	21%	17%	11%	9%	7%	
SG&A	13%	33%	30%	24%	24%	19%	
Operating margin	66%	38%	44%	56%	58%	66%	
Taxes	45%	127%	99%	71%	58%	25%	
Net margin	25%	-5%	0%	11%	16%	39%	
Year-over-year change							
Net revenue	536%	-19%	19%	24%	5%	26%	
COGS	89%	13%	21%	22%	3%	18%	
Gross margin	656%	-21%	19%	24%	6%	27%	
R&D	-3%	15%	0%	-26%	-8%	0%	
SG&A	32%	113%	8%	2%	3%	0%	
Operating income	-634%	-54%	39%	58%	9%	42%	
Net income	-299%	-116%	-105%	6007%	58%	202%	

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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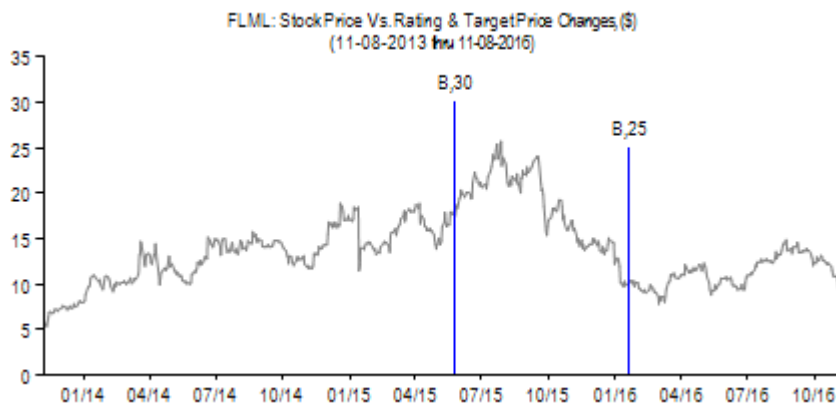
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Rating and Price Target Change History



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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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Merck (MRK – Not Rated)

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