

Flamel Technologies (FLML - \$13.50)

FLML Investor/Analyst day, FT218 (Micropump sodium oxybate) takes center stage

We recently had the chance to attend the first official FLML Investor/Analyst day in NYC during which they mostly discussed their top pipeline asset FT218 (no middle of the night dosed Xyrem) for narcolepsy and its Phase 3 program, which is presently recruiting patients. The first KOL (Dr. Swick) elaborated on Narcolepsy and how it represents such an important underdiagnosed large unmet medical need as ~85% of patients suffering from narcolepsy aren't treated with the standard of care, Xyrem. The second KOL (Dr. Roth) gave more details on the study design and how its differentiated crossover design, allowance of stimulant use in placebo arm and larger inclusion criteria could help de-risk the outcome of the pivotal trial. We expect read-out on this in 2H17. Finally, FLML reassured investors that the SPA resolution should be imminent and that the delays are unrelated to endpoints or study design issues. We reiterate our Buy rating, \$25 price target.

- **Narcolepsy, a misunderstood underdiagnosed large unmet medical need.** While almost as common as MS, narcolepsy has only been correctly diagnosed in 25% of Americans due to inadequate education of sleep fellows. Dr. Swick estimates that 13-15% of currently diagnosed narcoleptics are currently treated with sodium oxybate, which means that ~85% of patients aren't treated with the standard of care. A summary of PK data also showed that in 40 healthy volunteers across two studies, results at 4.5g (lowest dose) showed an adequate consistent target product profile.
- **REST-ON trial, clever differentiated study design could de-risk read-out.** Dr. Roth believed including stimulants in the placebo arm (higher participation) and the cross-over design (fewer patients and fewer dropouts) represent "major victories". In most sites, 16-18 year olds will be allowed, which will speed up the process. FLML will also be screening and monitoring their subjects meticulously to carefully pick the right patients.
- **FT218' clear advantages over Xyrem, SPA update shortly while Trigger-Lock and Medusa de-emphasized.** With FT218 superior to Xyrem in terms of convenience (no disturbance of sleep for second dose) and greater safety, FLML reiterated that SPA resolution is imminent after delays unrelated to concerns with endpoints or study design. FLML reiterated de-emphasis on their Trigger-lock (opioids) and Medusa (diabetes) with the intent to sell or partner these in 2H16-2017.
- **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	67.5x
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	13.6x
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 (09/27/2016)	\$13.50
52-Week High (10/15/2015)	\$19.78
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$556.3
Shares Out. (MM)	41.2

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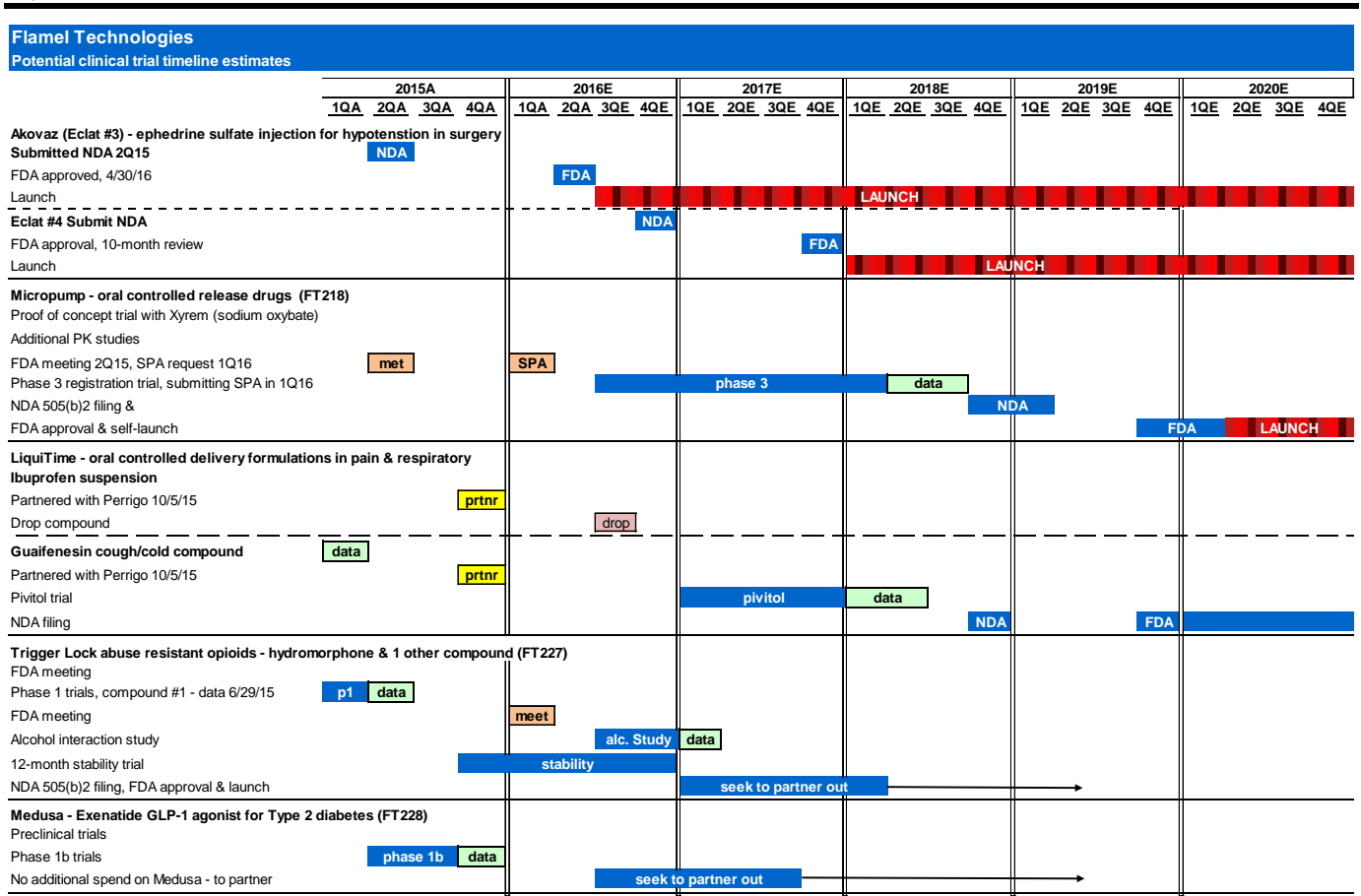
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Figure 1: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Sodium Oxybate (FT 218)	\$379,774	\$8.00
Eclat products	\$425,167	\$9.00
Pipeline, royalties & tech value	\$229,408	\$5.00
Cash (end of '17E)	\$130,286	\$3.00
	\$1,164,636	\$25.00
2017 fully diluted shares out		45,841

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	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 4: 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 hci)	20,151	30,827	20,000	18,500	18,000	15,000	Generics 2H16
FSC products		9,624	10,000	11,250	12,500	14,000	~\$80M & \$30M-\$40M peak each
Akovaz & 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
Sodium Oxybate (Xyrem-like)						75,000	Eliminates middle night dosing
1x milestones (license deals)	721	793	200	200	0	200	Partnership milestones here
Total Revenues	\$173,209	\$140,043	\$169,520	\$217,598	\$226,476	\$299,428	2016 Guide: \$125M-\$140M revs
Expenses							
Cost of Goods Sold	10,921	12,892	15,932	20,465	20,318	24,998	
Gross Margin	162,288	127,151	153,588	197,133	206,158	274,430	
R&D	25,608	33,992	33,750	30,000	31,000	32,000	2016 Guide: \$30M-\$40M
SG&A	21,712	38,876	38,250	37,188	38,000	43,750	FSC reps & SG&A here
Total Operating Expenses	47,320	72,868	72,000	67,188	69,000	75,750	
Income (loss) from Ops	114,968	54,283	81,588	129,946	137,158	198,680	
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	98,991	163,233	
Taxes	35,167	33,558	41,250	54,500	50,500	40,808	Domicile structure drives tax rate
Adj Net income/(loss)	43,101	(5,752)	9,144	35,671	48,491	122,425	
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	\$1.00	\$2.50	20% 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	46,264	45,841	47,541	48,295	48,899	
Margin & expense analysis							
COGS	6%	9%	9%	9%	9%	8%	
R&D	15%	24%	20%	14%	14%	11%	
SG&A	13%	28%	23%	17%	17%	15%	
Operating margin	66%	39%	48%	60%	61%	66%	
Taxes	45%	121%	82%	60%	51%	25%	
Net margin	25%	-4%	5%	16%	21%	41%	
Year-over-year change							
Net revenue	536%	-19%	21%	28%	4%	32%	
COGS	89%	18%	24%	28%	-1%	23%	
Gross margin	656%	-22%	21%	28%	5%	33%	
R&D	-3%	33%	-1%	-11%	3%	3%	
SG&A	32%	79%	-2%	-3%	2%	15%	
Operating income	-634%	-53%	50%	59%	6%	45%	
Net income	-299%	-113%	-259%	290%	36%	152%	

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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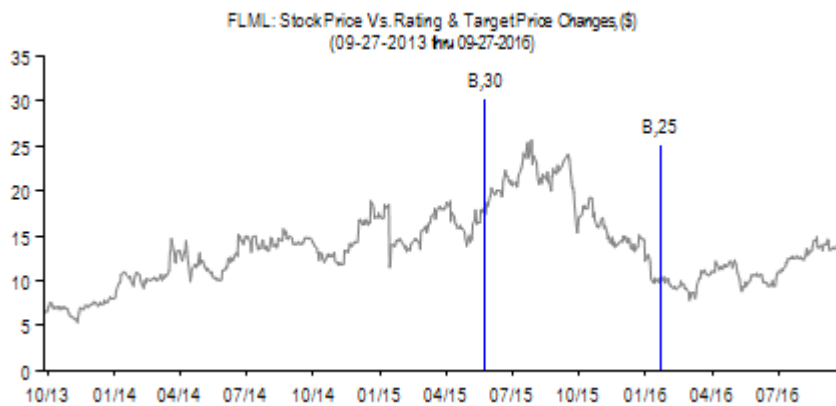
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Rating and Price Target Change History



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.	60.53%	28.95%	2.63%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.26%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.63%	0.00%	0.00%

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