

# **Merrimack Pharmaceuticals**

# Outperform (1)

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# MM-398's Pivotal Trial Readout Mid-2013; MM-111 Enters Phase II

**Conclusion:** Merrimack reported Q3 results in line with our expectations. MACK entered a \$40MM loan facility in Q4, which with cash on hand (\$87MM at end Q3), is expected to fund operations into 2014. The broad pipeline continues to progress, with data from multiple trials expected in 2013, including MM-398's pivotal Phase III in pancreatic cancer. MACK also revealed MM-111's Phase II program, targeting underserved segments of the HER2 market. We expect steady newsflow to drive outperformance vs. the market over the next year.

- **Financials In Line, Loan Extends Runway.** MACK reported \$11.3MM in revenue from the research collaboration with Sanofi. Q3 net loss was (\$23.2MM) vs. our (\$22.4MM) estimate. MACK bolstered its cash in Q4 with a \$40MM loan agreement (\$25MM drawn Nov 8, \$15MM available before Dec 15 at MACK's option; interest rate appx. 12%).
- MM-398's Pivotal Pancreatic Data In Mid-2013. The NAPOLI-1 trial in second line pancreatic cancer was amended in July to add a third arm. The trial is now testing MM-398 (liposomal irinotecan) alone, a 5-FU/leucovorin control, and the new arm, a combination regimen of MM-398 + 5-FU/LV. MACK announced today that despite the amendment, the trial should still be completed by mid:13, as originally planned, because an increased pace of recruitment has offset delays caused by the trial amendment.
- MM-111 Targets Underserved Patients. MACK described MM-111's (bispecific HER2/ErbB3) active-controlled Phase II program, currently starting up. The initial trial will test '111 in two patient segments: (1) HER2+/FISH+ ('111 plus Herceptin vs. Herceptin alone); and (2) HER2+/FISH- ('111 vs. paclitaxel). MACK anticipates synergistic efficacy to Herceptin in group 1, and hopes '111 will be the first drug to work well in group 2, for whom no agents are approved. The initial trial will enroll up to 180 second-line gastric cancer patients, and trials in other cancers are planned.

MACK (11/15)	\$6.80	Reve	enue \$MM						
Mkt cap	\$637.2MM	FY	<u> 2011</u>	<u>2012E</u>		<u>201</u>	<u>3E</u>	<u>2014E</u>	2015E
Dil shares out	93.7MM	Dec	Actual	Prior	Current	Prior	Current	Current	Current
Avg daily vol	406.8K	Q1	0.0	_	11.3A	_	9.2	_	_
52-wk range	\$5.7-11.1	Q2	0.0	_	12.1A	_	8.9	_	_
Dividend	Nil	Q3	0.0	_	11.3A	_	8.6	_	_
Dividend yield	Nil	Q4	0.0		10.0		8.4	_	
BV/sh	\$0.35	Year	34.2	43.5	44.7	_	35.0	25.0	47.0
Net cash/sh	\$0.92	EV/S	_	_	12.5x	_	16.0x	22.4x	11.9x
Debt/cap	NA								
ROE (LTM)	NA								
5-yr fwd EPS	NA	EPS \$							
growth (Norm)		FY	<u>2011</u>	<u>201</u> 2	<u>2E</u>	<u>201</u>		<u>2014E</u>	<u> 2015E</u>
		Dec	Actual	Prior	Current	Prior	Current	Current	Current
		Q1	_	_	(2.14)A	_	(0.31)	_	_
		Q2	_	_	(0.22)A	_	(0.30)	_	_
		Q3	_	_	(0.25)A	_	(0.30)	_	_
S&P 500	1351.7	Q4	_	(0.25)	(0.27)		(0.31)	_	
		Year	(1.05)	(1.25)	(1.26)	(0.90)	(1.20)	(1.10)	(1.10)
		P/E	_	_	_	_	_	_	_



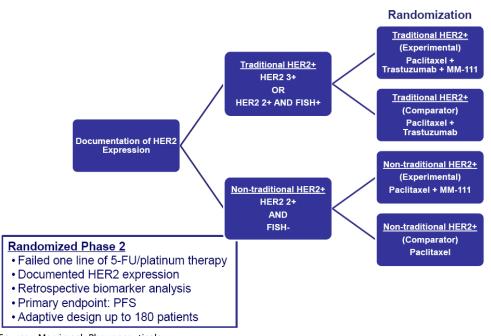
## **Investment Summary**

Merrimack Pharmaceuticals is developing therapeutics and companion diagnostics for oncology utilizing a novel Network biology-based approach. A deep understanding of signaling networks (as opposed to single gene defects) has enabled Merrimack to identify targets with broad application in oncology. Merrimack has a pipeline of eight biologic and nanoparticle-based drug candidates, five of which are in the clinic. Three of the most advanced include MM-121, MM-111, and MM-398. MM-121 is an antibody that blocks ErbB3's ability to co-stimulate signaling through the EGFR and HER2 receptors. In partnership with Sanofi, Merrimack has shown that MM-121 is active in a variety of tumor types (breast, ovarian, lung), and multiple Phase II trials are underway. MM-111 is a bi-specific antibody directed at blocking the HER2/ErbB3 interaction and overcoming resistance to Herceptin/Tykerb. This candidate is now entering Phase II in secondline gastric cancer. MM-398 is a liposomal formulation of irinotecan designed to enable selective uptake in tumors. A 405-patient Phase III trial in second line pancreatic cancer began recruiting patients to three treatment arms in July 2012 and is expected to read out in mid-2013. In addition, promising data from a Phase I trial of MM-398 in second-line colorectal cancer support an ongoing Phase II trial. With the exception of MM-121, Merrimack retains full ownership of this pipeline. Moreover, companion diagnostics for each candidate should facilitate smarter, more personalized clinical trial design. Merrimack believes it is funded into 2014, even assuming no new business development activity.

### MM-111's Phase II Trial Design



# MM-111 in HER2+ Gastric, GEJ and Esophageal Cancer Open-label, Randomized Phase 2 Study Design



Source: Merrimack Pharmaceuticals



# **Merrimack Pharmaceuticals Upcoming Milestones**

Milestone	Timing			
Begin first Phase I trial of MM-141	Q4:12			
Begin MM-111 Phase II program in gastric cancer	Q4:12			
Data from MM-302's Phase I trial in HER2(+) breast cancer at SABCS	Dec 4-8			
Begin Phase I trial of MM-DX-929 nanotherapeutic imaging diagnostic	H1:13			
Data from MM-121's Phase II ER+/PR+ breast cancer trial	H1:13			
Data from MM-121's Phase II NSCLC trial (patient group with mutant EGFR and EGFR inhibitor resistance)	H1:13			
Begin first Phase I trial of MM-301	H1:13			
Data from MM-398's Phase II colorectal cancer trial	Mid:13			
Data from MM-398's Phase III trial in gemcitabine-refractory pancreatic cancer	Mid:13			
Data from MM-121's Phase II neoadjuvant HER2(-) breast cancer trial	H2:13			
Data from MM-151's Phase I trial	H2:13			
Data from MM-141's Phase I trial	H2:13			
Begin first Phase I trial of MM-131				

Source: Cowen and Company



# **Merrimack Pharmaceuticals Quarterly P&L Model**

	2011A	Q1:12A	Q2:12A	Q3:12A	Q4:12E	2012E	Q1:13E	Q2:13E	Q3:13E	Q4:13E	2013E
MM-398 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MM-121 Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
U.S. MM-121 End-User Revenue											
Ex-U.S. MM-121 End-User Revenue											
MM-111 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MM-302 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MM-151 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Research and Development Revenues	34.2	11.3	12.1	11.3	10.0	44.7	9.2	8.9	8.6	8.4	35.0
MM-121 Cost Reimbursement	25.1	8.1	9.2	8.6	8.0	33.9	7.0	6.5	6.0	5.5	25.0
MM-121 Upfront Amort.	5.0	1.3	1.3	1.3	1.3	5.0	1.3	1.3	1.3	1.3	5.0
MM-121 Milestones	2.6	1.4	0.5	0.5	0.6	3.0	0.8	1.0	1.2	1.5	4.5
Other	1.6	0.5	1.1	1.0	0.2	2.8	0.1	0.1	0.1	0.1	0.5
Total Revenue	34.2	11.3	12.1	11.3	10.0	44.7	9.2	8.9	8.6	8.4	35.0
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross margin											
R&D	100.6	31.7	28.8	30.9	31.0	122.3	31.5	32.0	32.5	33.0	129.0
R&D as a % of sales											
SG&A	14.5	3.7	3.6	4.3	4.0	15.7	4.0	4.1	4.2	4.3	16.6
SG&A as a % of sales											
Contingent Consideration	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Expenses	115.1	35.4	32.4	35.2	35.0	137.9	35.5	36.1	36.7	37.3	145.6
Operating Income/Loss	(80.9)	(24.1)	(20.3)	(23.9)	(25.0)	(93.2)	(26.3)	(27.2)	(28.1)	(28.9)	(110.6)
Interest Income	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest Expense	(0.0)	(0.0)	0.0	0.0	(0.3)	(0.3)	(1.0)	(1.0)	(1.0)	(1.0)	(4.0)
Other Income (Expense)	1.2	0.6	0.2	0.6	0.0	1.3	0.0	0.0	0.0	0.0	0.0
Attributable to non-controlling interest	(0.5)	(0.1)	(0.1)	(0.1)	(0.2)	(0.5)	(0.1)	(0.1)	(0.1)	(0.1)	(0.5)
Pre-tax Income/Loss	(79.2)	(23.3)	(20.0)	(23.2)	(25.1)	(91.6)	(27.2)	(28.1)	(29.0)	(29.8)	(114.1)
Tax rate (%)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Provision for (Benefit from) income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(79.2)	(23.3)	(20.0)	(23.2)	(25.1)	(91.6)	(27.2)	(28.1)	(29.0)	(29.8)	(114.1)
GAAP EPS, Basic	(\$1.05)	(\$2.14)	(\$0.22)	(\$0.25)	(\$0.27)	(\$1.26)	(\$0.31)	(\$0.30)	(\$0.30)	(\$0.31)	(\$1.20)
Basic Shares Outstanding	75.3	11.8	90.6	93.7	94.0	72.5	94.5	95.0	95.5	96.0	95.3
Diluted Shares Outstanding	75.3	11.8	110.6	113.7	114.0	87.5	114.5	115.0	115.5	116.0	115.3

Source: Cowen and Company



# **Merrimack Pharmaceuticals Annual P&L Model**

	2011A	2012E	2013E	2014E	2015E	2016E	2017E
MM-398 Revenue	0.0	0.0	0.0	0.0	25.0	125.0	250.0
MM-121 Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0
U.S. MM-121 End-User Revenue							
Ex-U.S. MM-121 End-User Revenue							
MM-111 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MM-302 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MM-151 Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Research and Development Revenues	34.2	44.7	35.0	25.0	22.0	25.0	25.0
MM-121 Cost Reimbursement	25.1	33.9	25.0	12.0	5.0	3.0	1.0
MM-121 Upfront Amort.	5.0	5.0	5.0	5.0	5.0	5.0	5.0
MM-121 Milestones	2.6	3.0	4.5	7.5	11.5	16.5	18.5
Other	1.6	2.8	0.5	0.5	0.5	0.5	0.5
Total Revenue	34.2	44.7	35.0	25.0	47.0	150.0	275.0
Y/Y growth					90%	90%	90%
COGS	0.0	0.0	0.0	0.0	2.5	12.5	25.0
Gross margin						112%	59%
R&D	100.6	122.3	129.0	130.0	135.0	140.0	148.0
R&D as a % of sales						57%	31%
SG&A	14.5	15.7	16.6	18.0	50.0	71.0	78.0
SG&A as a % of sales						0%	0%
Contingent Consideration	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Expenses	115.1	137.9	145.6	148.0	187.5	223.5	251.0
Operating Income/Loss	(80.9)	(93.2)	(110.6)	(123.0)	(140.5)	(73.5)	24.0
Interest Income	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Interest Expense	(0.0)	(0.3)	(4.0)	(4.0)	(4.0)	(4.0)	0.0
Other Income (Expense)	1.2	1.3	0.0	(1.0)	(1.0)	(1.0)	1.0
Attributable to non-controlling interest	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Pre-tax Income/Loss	(79.2)	(91.6)	(114.1)	(127.5)	(145.0)	(78.0)	25.5
Tax rate (%)	0%	0%	0%	0%	0%	0%	3%
Provision for (Benefit from) income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.8
Net Income (Loss)	(79.2)	(91.6)	(114.1)	(127.5)	(145.0)	(78.0)	24.7
GAAP EPS, Basic	(\$1.05)	(\$1.26)	(\$1.20)	(\$1.10)	(\$1.10)	(\$0.55)	\$0.15
Basic Shares Outstanding	75.3	72.5	95.3	116.0	132.0	143.0	144.0
Diluted Shares Outstanding	75.3	87.5	115.3	136.0	152.0	163.0	164.0

Source: Cowen and Company



## **Addendum**

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Ticker	Company Name
MACK	Merrimack Pharmaceuticals

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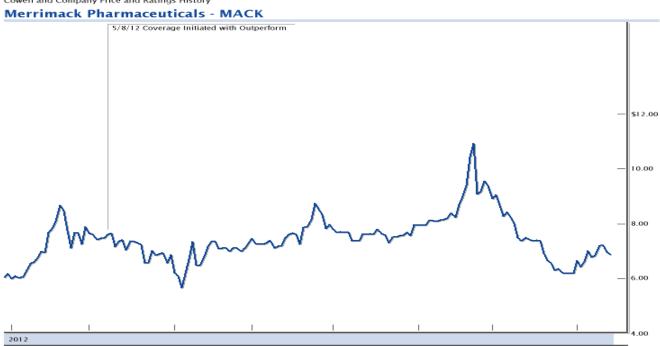
(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

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