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EQUITY RESEARCH
Company Report

May 17, 2018

MEI Pharma (MEIP - $3.40)

Healthcare/Biotechnology

Ticker:	**MEIP**
Rating:	**Buy**
Price Target:	**$7.00**

The ASCO Abstracts Boost Our Confidence in ME-401 in R/R FL and CLL/SLL Outlook

ASCO yesterday afternoon released abstracts to be presented during June 1 – 5 including two of MEIP's developments: ME-401 in r/r FL and CLL/SLL Phase Ib study (Abstract No: 7519), and ME-344 for the abrogation of resistance against bevacizumab in early HER2-negative breast cancer (HERNEBC) (Abstract No: 2552).

- **Details.** ME-401 in r/r FL development is the current major focus for investors. The abstract reported results from 29 patients that response can be evaluated (20 FL, 9 CLL/SLL). All were treatment experienced [without prior PI3K therapy and no prior progression of disease (POD) on BTK therapy]. 60 mg (12), 120 mg (12) and 180 mg (6) ME-401 were tested. ME-401 was given once daily on days 1-28 of 28-day cycle until POD or unacceptable toxicity. The overall ORR was 83% (24/29), with 75% (15/20) in FL and 100% (9/9) in CLL/SLL. Most (20/24) responders occurred by cycle 2. On the safety side, no DLTs were reported. Most common AEs (all grades/grade $\geq$3 in %) were diarrhea (32/16), fatigue (29/0), cough (29/0), nasal congestion (26/0) and rash (29/10). All SAEs were reported in cycle 3 or later. Five patients discontinued MEI-401 due to AEs: rash (3), colitis (1), and cardiomyopathy (1), and 2 for personal reasons. In summary, ME-401 was well tolerated with high early response. An alternative dosing (dosed days 1-7 of 28-day cycle starting with cycle 3), and lower dose (45 and 60 mg) ME-401 combined with rituximab is being evaluated. The ME-401 in r/r FL pivotal trial could start in 4Q18.
- **Implications.** We view the rapid and high ORR very encouraging suggesting ME-401 could be a very potent PI3Kδ inhibitor (prior reported >50% at all doses, and ORR of Zydelig and Aliqopa is 54% and 59%, respectively with the caveat of comparing different trials). Safety could be on par with other PI3Kδ inhibitors and we believe better efficacy is the major priority for 3rd-line therapy. MEIP expects to report more matured data at the ASCO presentation. We anticipate combo data available in 4Q18. Further, we believe most of the recent share value increase after financing was just to match up the cash value of MEIP. Going forward, we anticipate much greater upside exists based on successful clinical advancements of ME-401 and other pipeline products.
- **Action.** We are reiterating our Buy rating and $7 target price to reflect that the company will have two products at or approaching late clinical development stage, and multiple catalysts over the next 18 months. Our valuation is based on probability adjusted DCF, NPV-driven sum-of-the-parts and peer comparable analyses.

Trading Data:

Last Price (5/16/2018)	$3.40
52–Week High (5/15/2018)	$3.47
52–Week Low (5/19/2017)	$1.58
Market Cap. (MM)	$122
Shares Out. (MM)	36.94

Earnings Estimates: (per share)

(**June**)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.24A	-0.16A	-0.16A	-0.16	-0.71	NM
FY-17A	-0.12	0.32	-0.02	-0.12	0.07	NM
FY-16A	-0.13	-0.15	-0.16	-0.17	-0.62	NM
FY-15A	-0.42	-0.39	-0.27	-0.40	-1.16	NM

Source: Laidlaw & Company estimates

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Following are the abstracts to be presented at ASCO.

- **Initial results of a dose escalation study of a selective and structurally differentiated PI3Kδ inhibitor, ME-401, in relapsed/refractory (R/R) follicular lymphoma (FL) and chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) --** Abstract No: 7519
Poster Section: Monday, June 4, 2018, 8:00 AM -11:30 AM, Location: Hall A; Poster Discussion Session: Monday June 4, 1:15 PM to 2:30 PM, Location: E450 (Board #156)

  Sub-category: Non-Hodgkin Lymphoma; Category: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia

  Jacob Drobnyk Soumerai, John M. Pagel, Deepa Jagadeesh, Huda S. Salman, Vaishalee Padgaonkar Kenkre, Adam Steven Asch, Anastasios Stathis, Nishitha M. Reddy, Alexia Iasonos, Richard Ghalie, Andrew David Zelenetz; *Massachusetts General Hospital, Boston, MA; Swedish Cancer Institute, Seattle, WA; Cleveland Clinic, Cleveland, OH; Stony Brook University School of Medicine, Stony Brook, NY; University of Wisconsin, Madison, WI; University of Oklahoma Stephenson Cancer Center, Oklahoma City, OK; IOSI - Oncology Institute of Southern Switzerland, Bellinzona, Switzerland; Vanderbilt University Ingram Cancer Center, Nashville, TN; Memorial Sloan Kettering Cancer Center, New York, NY; MEI Pharma, Inc., San Diego, CA*

  Background: ME-401, an oral tyrosine kinase inhibitor highly selective for PI3Kδ was studied in a phase 1b trial for patients (pts) with R/R FL or CLL/SLL. The starting dose was based on pharmacokinetic and pharmacodynamic data from a study in healthy volunteers.

  Methods: Eligible adult pts had ECOG ≤2, no prior PI3K therapy, and no prior progression of disease (POD) on BTK therapy. ME-401 was given once daily on days 1-28 of 28-day cycle until POD or unacceptable toxicity. All pts received PJP prophylaxis and CMV monitoring was mandatory. At least 6 evaluable pts were treated at each dose level, with option to expand to 12 pts for efficacy assessment. Dose limiting toxicities (DLT) were assessed up to Day 56. Response was assessed after Cycles 2 and 6.

  Results: 31 pts (21 FL, 10 CLL/SLL) received ME-401 and 30 were evaluable for DLT: 12 at 60 mg, 12 at 120 mg, and 6 at 180 mg. Median age was 65 (range: 47-79), 14/30 (47%) pts received ≥2 prior therapies, and 9/21 (43%) pts with FL had POD < 24 months after initial chemoimmunotherapy (POD24). Of 29 pts evaluable for response, the overall objective response rate was 83% (24/29), with 75% (15/20) in FL, including 9/9 (100%) with POD24, and 100% (9/9) in CLL/SLL, occurring by Cycle 2 in 20/24 responders. No DLTs were reported and escalation above 180 mg was closed given frequent responses across lower dose levels. With a median follow-up of 20 weeks (range: 2-53 weeks) 3 pts had POD at 8, 14 and 17 weeks after starting therapy. Five pts discontinued MEI-401 due to adverse events (AEs): rash (n = 3), colitis (n = 1), and cardiomyopathy (n = 1), and 2 pts discontinued for personal reasons. Most common AEs (all grades/grade ≥3) were diarrhea (32%/16%), fatigue (29%/0%), cough (29%/0%), rash (29%/10%), and nasal congestion (26%/0%). All grade ≥3 AEs were reported in Cycle 3 or later.

  Conclusions: ME-401 was well tolerated with high early response rates among R/R FL and CLL/SLL pts. No DLTs were reported. An alternative dosing (ME-401 days 1-7 of 28-day cycle starting with Cycle 3) is being evaluated, including dosing ME-401 at 45 mg and at 60 mg in combination with rituximab.

  Clinical trial information: NCT02914938.

- **Abrogation of resistance against bevacizumab (Bev) by mitochondrial inhibition: A phase 0 randomized trial of Bev plus ME344 or placebo in early HER2-negative breast cancer (HERNEBC) --** Abstract No: 2552
Poster Section: Monday, June 4, 2018, 8:00 AM -11:30 AM, Location: Hall A (Board #378)

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Sub-category: Other Novel Agents; Category: Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics

Miguel Quintela-Fandino, Juan V Apala, Alfonso Cortes Salgado, Silvana Andrea Mouron, Juan Antonio Guerra, Mana Gion Cortes, Manuel Morente, Luis Manso; *CNIO - Spanish National Cancer Research Center, Madrid, Spain; CNIO, Madrid, Spain; Hospital Ramón y Cajal, Madrid, Spain; Breast Cancer Clinical Research Unit, Spanish National Cancer Research (CNIO), Madrid, Spain; Hospital de Fuenlabrada, Madrid, Spain; Hospital Ramon y Cajal, Madrid, Spain; Hospital 12 de Octubre, Madrid, ES*

Background: Our preclinical data show that one mechanism of acquired resistance to anti-angiogenic therapy involves hypoxia correction, measured by decreased SUV (↓ SUV) on FDG-PET followed by mitochondrial up-regulation. ME344 is a potent inhibitor of mitochondrial respiration. The aims of this study were to assess 1) the fraction of HERNEBC patients that show ↓ SUV in response to single dose Bev and 2) if adding ME344 to Bev inhibits cell proliferation as determined by Ki67% decrease, a surrogate marker of efficacy in neoadjuvant breast cancer.

Methods: Treatment-naïve HERNEBC patients (T > 1 cm, any N, M0) received 15 mg/kg Bev on d0 and were then randomized 1:1 to ME344 10 mg/kg IV d8, 15 and 21 (arm A) or placebo (arm B) followed by physician's choice of definitive therapy. FDG-PET was performed on d0 and d7 and tumor biopsy on day 0 and 28. The primary endpoint was Ki67% relative reduction from d0 to 28. A 40 patient sample size was powered to detect a 30% relative difference in Ki67% between arm A and B (alpha 0.05, beta 0.2). Threshold for hypoxia correction by PET was 10% ↓ SUV. A predefined interim analysis was planned when 20 patients had completed treatment.

Results: 19 patients were randomized (arm A/B: 7/7 LumA, 2/2 LumB, 1/0 TNBC). Baseline characteristics: Ki67 by IHC: mean 10.3% (1%-48%), age: mean 56 (44-75), T (8 T1, 10 T2, 1 T3), N (14 N0, 5 N1) and G (4 G1, 12 G2, 3 G3) were balanced between arms. 31% of patients experienced ↓ SUV > 10%. Mean absolute (relative) Ki67 decreases were 5.13 (29%) and 1.2 (9%) in arms A and B (P = 0.06). Patients with ↓ SUV > 10% experienced an absolute average Ki67 decrease of 16.6 vs. 2.3 in arms A and B (P = 0.19). Two G3 adverse events (high blood pressure) were reported (1 per arm) and deemed related to Bev.

Conclusions: ME344 results in significant Ki67 reduction compared to placebo in HERNEBC patients exposed to single-dose Bev. This effect may be greater in those patients with Bev induced hypoxia correction. These clinical results are consistent with preclinical data suggesting that ME-344 can reverse resistance to anti-angiogenic therapy and warrant further studies to assess clinical efficacy of the combination.

Clinical trial information: NCT02806817.

Source: 2018 ASCO website

Anticipated milestones in 2018 and beyond

Program	Indication	Event	Timing	Importance
Pracinostat	Acute myeloid leukemia (AML)	Potentially complete Phase III study patient enrollment	**Late 2019**	***
		Potentially report Phase III study top-line results	**Late 2020/2012**	****
	Myelodysplastic syndrome (MDS)	Potentially report stage 1 results of the Phase II dose-optimization trial	**2Q18**	***
ME-401	CLL and follicular lymphoma	Potentially report results of the Phase Ib dose-optimization trial at ASCO meeting	**June 1-5, 2018**	****
		Potentially report results of the umbralisib Phase IIII (UNITY-CLL) trial	**2Q18**	**
		Potential FDA meeting discussing pivotal study	**2H18**	***
		Potentially more Phase Ib trial update at ASH meeting	**4Q18**	****
		Potentially start single agent registration trial in r/r FL patients	**4Q18**	***
		Potential FDA approval decision on duvelisib in CLL	**1Q19**	**
		Potentially report results of the umbralisib Phase IIII (UNITY-NHL) trial - FL	**Mid-2019**	***
Voruciclib	B-cell malignancies	Potentially start Phase I trial in r/r patients	**2Q18**	***
		Initial data readout of the Phase I trial	**2019**	****
ME-344	Breast cancer (HER-2¯)	Potentially report results of Avastin combination trial	**2Q18**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major risks

Clinical study failure could have a major impact on MEIP share value. Despite the robust Phase II study results of pracinostat in AML, it remains difficult to fully handicap the outcome of the Phase III study given the differences in study design. In addition, it would be difficult to further assess the potential outcome of the proposed pivotal trial of ME-401 in follicular lymphoma due to limited earlier clinical data. Should any of these studies fail to successfully meet the primary endpoint of their respective clinical study, MEIP share value could be substantially impacted. Failures in clinical development of other pipeline products could have similar negative impact on share price as well.

Failure or substantial delay of regulatory approval could have a major negative impact on MEIP share value. Even if MEIP's pipeline products complete clinical studies successfully, risks remain as whether the regulatory agencies could approve the regulatory filing. If unsuccessful or with substantial delaying due to various factors, such as requirement for additional studies, the MEIP shareholder value could also be significantly impaired.

Commercial risks remain difficult to handicap. Despite MEIP's drugs could be approved, it may be difficult to more precisely forecast the commercial value of the drug due to various reasons. Multiple factors that could affect the future sales of a drug include: 1) change of competitive landscape, possibly due to entrance of new and better drugs of the same drug class; 2) the pace of physician adoption for the drug use; 3) pricing flexibility; 4) level or acceptance of reimbursement by third party insurers, and 5) potential change of the treatment paradigm and render some drug obsolete. In short, if the company's sales substantially fall short, we believe shareholder disappointment could negatively impact the company's valuation.

Additional financings could dilute shareholder value. The company currently has ~$100MM total cash (pro forma). As such, MEIP would most likely need more financial resources going forward if they want to conduct more later stage clinical studies and potentially participate in the commercialization of approved drug. Unless the company can successfully explore non-dilutive financial sources, the value of current shareholder might be reduced with additional equity offerings, unless the share price increase if the upsides created due to greater financial source could offset the dilution of current shareholders.

Limited trading liquidity limits shareholder options. Given daily trading volume of MEIP shares are relatively modest, some investor could be hesitating to own the shares as relatively illiquid trading volume could face constraints if they want to increase or reduce their positions in a volatile stock market.

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Figure 1: Income Statement

MEI Pharma, Inc. – Income Statement

('000 $)	2015	2016	2017	1Q18	2Q18	3Q18	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	2Q15	2Q16		3Q17	4Q17	1Q18	2Q18			2Q20	2Q21	2Q21	2Q22	2Q23	3Q24
Revenues															
Product revenues	0	0	0	-	-	-	-	0	0	0	19,332	103,347	209,503	297,800	392,027
ME-401 revenue											19,332	98,818	196,275	274,428	358,988
Pracinostat royalties												4,529	13,228	23,372	33,039
License revenue	0	0	20,880	-	-	-	-	0	0	0	0	0	0	0	0
Research and development revenue	0	0	2,369	283	358	433	360	1,434	1,280	1,318	1,358	1,399	1,441	1,484	1,528
Total Revenue	0	0	23,249	283	358	433	360	1,434	1,280	1,318	20,690	104,746	210,944	299,284	393,555
COGS											1,933	9,882	19,628	27,443	35,899
Cost of research and development revenue	0	0	5,000	618	728	930	756	3,032	2,688	2,769	2,852	2,937	3,025	3,116	3,210
Research and development	23,823	13,403	7,237	6,064	3,444	3,071	3,100	15,679	18,853	21,493	21,707	22,576	23,479	24,418	25,395
General and administrative	8,948	7,601	8,628	2,488	2,358	2,486	2,561	9,893	10,501	11,026	11,467	11,857	12,260	12,677	13,108
Marketing and sales	0	0		-	-						18,000	21,600	22,248	22,915	23,603
Operaing expense	32,771	21,004	20,865	9,170	6,530	6,487	6,417	28,604	32,042	35,287	54,026	58,970	61,012	63,126	65,315
Operating income	(32,771)	(21,004)	2,384	(8,887)	(6,172)	(6,054)	(6,057)	(27,170)	(30,762)	(33,969)	(35,269)	35,894	130,304	208,714	292,341
Interest and dividend income	77	142	286	100	93	106	99	398	401	440	461	470	450	550	620
Income (loss) before taxes	(32,694)	(20,862)	2,670	(8,787)	(6,079)	(5,948)	(5,958)	(26,772)	(30,361)	(33,529)	(34,808)	36,364	130,754	209,264	292,961
Income tax expense	-	-	-	(1)	-	-	-	(1)	-	-	-	(12,728)	(45,764)	(73,243)	(102,536)
Net income	(32,694)	(20,862)	2,670	(8,788)	(6,079)	(5,948)	(5,958)	(26,773)	(27,673)	(33,529)	(34,808)	23,637	84,990	136,022	190,425
Net income attributable to common shareholders	($32,694)	($21,523)	$2,670	($8,788)	($6,079)	($5,948)	($5,958)	($26,773)	($27,673)	($33,529)	($34,808)	$23,637	$84,990	$136,022	$190,425
Net Earnings (Losses) Per Share—Basic	($1.16)	($0.62)	$0.07	($0.24)	($0.16)	($0.16)	($0.16)	($0.71)	($0.60)	($0.66)	($0.63)	$0.43	$1.52	$2.41	$3.34
Net Earnings (Losses) Per Share—Diluted	($1.16)	($0.62)	$0.07	($0.24)	($0.16)	($0.16)	($0.16)	($0.71)	($0.60)	($0.66)	($0.63)	$0.43	$1.52	$2.41	$3.34
Shares outstanding—basic	28,204	34,400	36,813	37,245	37,414	37,449	38,249	37,589	45,949	50,949	54,949	55,449	55,949	56,449	56,949
Shares outstanding—diluted	28,204	34,400	36,938	37,245	37,414	37,449	38,249	37,589	45,949	50,949	54,949	55,449	55,949	56,449	56,949
Margin Analysis (% of Sales/Revenue)															
COGS											10%	10%	10%	10%	10%
Costs of R&D	NA	NA	211%	218%	203%	210%	210%	211%	210%	210%	210%	210%	210%	210%	210%
R&D	NA	NA	31%	2143%	962%	709%	861%	1093%	1473%	1630%	105%	22%	11%	8%	6%
G&A	NA	NA	37%	879%	659%	574%	711%	690%	820%	836%	55%	11%	6%	4%	3%
Operating Income (loss)	NA	NA	10%	-3140%	-1724%	-1398%	-1682%	-1895%	-2403%	-2577%	-170%	34%	62%	70%	74%
Pretax	NA	NA	11%	-3105%	-1698%	-1374%	-1655%	-1867%	-2372%	-2543%	-168%	35%	62%	70%	74%
Tax Rate	NA	NA	98790%	NA	NA	NA	NA	NA	NA	NA	NA	35%	35%	35%	35%
Net Income	NA	NA	11%	-3105%	-1698%	-1374%	-1655%	-1867%	-2162%	-2543%	-168%	23%	40%	45%	48%
Financial Indicator Growth Analysis (YoY%)															
Total Revenue	N.A.	N.A.	N.A.	-74%	-98%	-90%	-20%	-94%	-11%	3%	1469%	406%	101%	42%	31%
Costs of R&D	N.A.	N.A.	N.A.	-44%	-59%	-19%	-23%	-39%	-11%	3%	3%	3%	3%	3%	3%
R&D expenses	N.A.	-44%	-46%	268%	110%	64%	50%	117%	20%	14%	1%	4%	4%	4%	4%
General and administrative	N.A.	-15%	14%	-7%	20%	16%	40%	15%	6%	5%	4%	3%	3%	3%	3%
Sales and marketing												20%	3%	3%	3%
Operaing expense	N.A.	-36%	-1%	69%	21%	25%	31%	37%	12%	10%	53%	9%	3%	3%	3%
Operating Incomes (Losses)	N.A.	-36%	-111%	106%	-152%	804%	36%	-1240%	13%	10%	4%	-202%	263%	60%	40%
Pretax Income	N.A.	-36%	-113%	106%	-151%	888%	37%	-1103%	13%	10%	4%	-204%	260%	60%	40%
Net Income	N.A.	-36%	-113%	106%	-151%	888%	37%	-1103%	3%	21%	4%	-168%	260%	60%	40%
EPS - Basic	N.A.	-47%	-112%	98%	-151%	881%	33%	-1082%	-15%	9%	-4%	-167%	256%	59%	39%
EPS - Diluted	N.A.	-47%	-112%	98%	-151%	881%	35%	-1085%	-15%	9%	-4%	-167%	256%	59%	39%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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DISCLOSURES:

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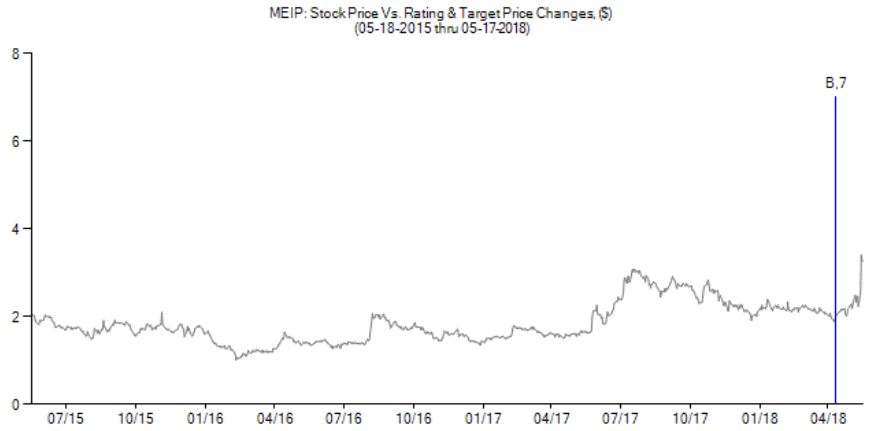
Additional information available upon request.

#Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/12/...	Buy (B)	2.05

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/12/...	7.00	2.05

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	25.93%	3.70%
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

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