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EQUITY RESEARCH
Company Report

January 4, 2017

Evoke Pharma (EVOK - $ 2.63)

Healthcare/Biotechnology

Ticker:	**EVOK**
Rating:	**Neutral**
Price Target:	

Gimoti in Moderate/Severe Diabetic Gastroparesis Patients Clinical Data Showed Significant Symptom Improvements

This morning, EVOK provided additional data highlighting statistically significant improvements in gastroparesis symptoms in Gimoti-treated moderate to severe diabetic gastroparesis (DG) patients from its METO IN-003 Phase III study.

- **Details.** The analysis demonstrated that 4 weeks of treatment with Gimoti vs. placebo provided statistically significant improvement in mean daily gastroparesis symptom assessment (GSA) scores up to 3 weeks in the intent-to-treat (ITT) population (n=52) and up to 4 weeks in per protocol population (n=38) (Table 1). The analysis is based on approx. half (105/205) of total enrolled patients who are with moderate to severe symptoms. Additionally, statistically significant improvements in nausea and upper abdominal pain scores were observed in the same patient population (based on ITT) throughout the 4 weeks of treatment. The FDA's draft guidance on the clinical evaluation of drugs for the treatment of gastroparesis issued in July 2015 suggested clinical trials should enroll patients with greater symptom severity in order to demonstrate treatment effect. Given the METO IN-003 study had already started enrolling female DG patients with a broad range of symptom severity for more than a year at that point, this could therefore potentially explain why the trial failed to meet the primary endpoint possibly due to the drug not exhibiting sufficient symptom improvement in patients with mild symptoms. In 2017, EVOK could potentially conduct a Gimoti PK trial to show equivalent exposure to Reglan (10 mg tablet) in healthy volunteers and, if positive, might file an NDA thereafter.
- **Implications.** We are encouraged by today's data as EVK-001 demonstrated statistically significant symptom improvement in moderate/severe DG patients up to 3 weeks (in ITT). It might be important especially since this is the same patient population that the FDA considered as meaningful to receive relief of symptoms. We will look forward to more updates from management regarding the future path forward and timeline for Gimoti development. Should NDA filing occur in 2017, we estimate FDA decisions could potentially occur in 2018.
- **Action.** We reiterate our neutral rating. We still view EVK-001 could have potential as a viable diabetic gastroparesis treatment to fulfill the unmet need and with large market potential; and we would further reassess the outlook once more information is available.

Trading Data:

Last Price (01/04/2017)	$ 2.63
52–Week High (7/13/2016)	$ 11.11
52–Week Low (11/10/2016)	$ 1.35
Market Cap. (MM)	$ 32
Shares Out. (MM)	12

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.20	-0.18	-0.20	-0.18	-0.76	NM
FY-16E	-0.45A	-0.41A	-0.29A	-0.21	-1.36	NM
FY-15A	-0.58	-0.52	-0.42	-0.37	-1.87	NM
FY-14A	-0.49	-0.59	-0.63	-0.48	-2.20	NM

Source: Laidlaw & Company estimates

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Table 1: Phase III estimated mean change from baseline in mean daily GSA total scores in moderate to severe study populations

Population	Time Period	Placebo[1]	Gimoti[1]	*p*-value[2]
		(N = 53)	**(N = 52)**	
Intent-to-Treat	Week 1	-0.387	-0.588	**0.036**
	Week 2	-0.614	-0.950	**0.025**
	Week 3	-0.749	-1.096	**0.039**
	Week 4	-0.856	-1.220	0.085*
		(N = 40)	**(N = 38)**	
Per Protocol	Week 1	-0.362	-0.623	**0.019**
	Week 2	-0.625	-1.040	**0.015**
	Week 3	-0.714	-1.286	**0.003**
	Week 4	-0.841	-1.373	**0.014**

[1] LSMean from ANCOVA

[2] *p*-value is obtained from an ANCOVA model with fixed effect for treatment group and the baseline value as a covariate. If the normality assumption was not met, the *p*-value was obtained from a rank ANCOVA test and denoted with an *.

Source: Company presentation

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Anticipated Milestones in 2017 and Beyond

Product	Indication	Event	Timing	Importance
EVK-100	Diabetic gastroparesis	Potential additional PK study and next step for METO IN-003 regulatory developments	**2017**	*****

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

Source: Laidlaw & Company and company presentation

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Major Risks

Failures of upcoming clinical studies. Although EVK-001 has demonstrated promising efficacy and a satisfactory safety profile from prior Phase II studies in diabetic gastroparesis; there is no assurance that the upcoming Phase III clinical study can demonstrate efficacy and safety profiles satisfactory enough for gaining clinical approval. Given the clinical study successes are the biggest near-term hurdle to be overcome before EVK-001 can be advanced into commercialization, clinical study failure could significantly impair the value of the company's assets and shareholder value. Overall, we view clinical risks of EVK-001 are more modest relative to Phase III studies of other biotech companies.

EVK-001 may not reach anticipated sales. Assuming EVK-001 receives approval and is commercialized, the sales potential could fall short of our forecasts. It is difficult to project accurately the sales potential of EVK-001 in gastroparesis given that the market is relatively mature and is dominated by generic products. The assumption is that EVK-001 could afford more effective drug availability and bypass the hurdle of slow gastric emptying and vomiting. However, the actual clinical performance from the Phase III study could influence physician acceptance for the drug as well as the company's flexibility to price the drug. The lack of a large size comparative clinical study for EVK-001 vs. oral metoclopramide with a superior outcome could also slow down the initial market penetration.

Lack of diversified product portfolio increases risk if EVK-100 fails. Since Evoke only has only one product in development and without other prospects on their pipeline, EVOK has very limited options to hedge its risk of product failure. As such, any mishap or failure of EVK-001 development could significantly reduce the value of EVOK shareholders.

Additional financing could dilute shareholder value. Regardless of whether or not the company forges additional collaborations with partners to generate non-dilutive revenue to support operations, it is likely that Evoke may need to raise additional cash from investors to fund its operations, especially if the company needs to commercialize EVK-001 by themselves. As such, the share value for existing investors could be diluted. Further, if the company cannot raise equity capital at favorable terms, the share value of current shareholders could be further impaired.

Limited trading liquidity limits shareholder options. Daily trading volume and name recognition of EVOK shares are relatively modest. Some investors may be hesitant to own the shares due to illiquid trading volume. This could impose constraints if they want to increase or reduce their positions in a volatile stock market.

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Figure 1: Income Statement

Evoke Pharma – Income Statement

($'000)	2014	2015	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue											
EVK-001 sales		0					0	0	0	21,354	55,533
Product royalty revenue	0	0	-	-	-	-	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	0	21,354	55,533
Costs of goods		0					0	0	0	1,922	4,998
Research and development	9,992	8,154	2,015	2,095	1,339	804	6,253	3,086	2,623	2,649	2,676
General and administrative	3,158	3,664	1,138	803	830	863	3,634	3,315	3,613	3,938	4,253
Marketing and sales		0					0	0	0	23,100	24,255
Total Operating Expenses	13,150	11,818	3,153	2,898	2,169	1,667	9,887	6,401	6,236	31,609	36,182
Operating Incomes (losses)	(13,150)	(11,818)	(3,153)	(2,898)	(2,169)	(1,667)	(9,887)	(6,401)	(6,236)	(10,256)	19,351
Other expense			(73)	(73)	0	0	(145)	0	0	0	0
Interest income	10	5		0	0	0	0	0	0	0	0
Interest expense	(108)	(307)		0	(123)	(123)	(246)	(492)	(541)	(595)	(595)
Financing costs related to warrant liability					(534)	(300)	(834)	(1,200)			
Change in fair value of warrant liability	0	0	0	0	(199)	(199)	(398)	0	0	0	0
Total Other Income, net	(98)	(302)	(73)	(73)	(856)	(622)	(1,623)	(1,692)	(541)	(595)	(595)
Income before tax	(13,248)	(12,120)	(3,225)	(2,970)	(3,025)	(2,289)	(11,510)	(8,093)	(6,777)	(10,851)	18,756
Tax Rate									32%	32%	32%
Tax	0	0	0	0	0	0	0	0	2,169	3,472	(6,002)
Net Income (Loss)	(13,248)	(12,120)	(3,225)	(2,970)	(3,025)	(2,289)	(11,510)	(8,093)	(4,609)	(7,379)	12,754
Net Income (Loss) Applicable to Common Shareholders	(13,248)	(12,120)	(3,225)	(2,970)	(3,025)	(2,289)	(11,510)	(8,093)	(4,609)	(7,379)	12,754
Net Earnings (Losses) Per Share—Basic and Diluted	($2.20)	($1.87)	($0.45)	($0.41)	($0.29)	($0.21)	($1.36)	($0.76)	($0.39)	($0.58)	$0.93
Shares outstanding—basic and diluted	6,032	6,486	7,168	7,218	10,615	10,665	8,916	10,690	11,690	12,690	13,690
	6,032	6,486	7,168	7,218	10,615	10,665	8,916	10,690	11,690	12,690	13,690
Margin Analysis (% of Sales/Revenue)											
Costs of goods								9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	5%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	51%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	35%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	23%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	160%
R&D	944%	-18%	-80%	-4%	-27%	-53%	-23%	-51%	-15%	1%	1%
SG&A	92%	16%	-64%	-18%	1%	2%	-1%	-9%	9%	9%	8%
Marketing and sales		NA					NA	NA	5%	6%	5%
Operating Loss	405%	-10%	-76%	-8%	-18%	-35%	-16%	-35%	-3%	64%	-289%
Total Other Income, net	-58%	209%	-26%	-5%	1017%	751%	438%	4%	-68%	10%	0%
Pretax Income	367%	-9%	-76%	-8%	11%	-13%	-5%	-30%	-16%	60%	-273%
Net Income	367%	-9%	-76%	-8%	11%	-13%	-5%	-30%	-43%	60%	-273%
EPS	83%	-15%	-80%	-21%	-32%	-42%	-27%	-44%	-48%	47%	-260%

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

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Additional information available upon request.

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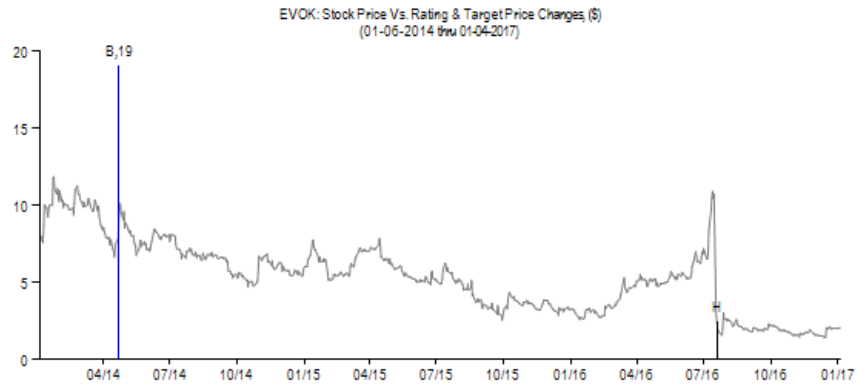
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/22/2014	Buy (B)	9.29
07/19/2016	Hold (H)	2.47

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/22/2014	19.00	9.29
07/19/2016		2.47

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.	2.50%	2.50%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	57.50%	27.50%	2.50%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	5.00%	0.00%	0.00%

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