

Evoked Pharma (EVOK - \$2.48)

Upgrading Stock Based on Improved Outlook on Gimoti in Moderate/Severe Diabetic Gastroparesis Potential Approval

The Gimoti approval outlook has improved after recent developments, including positive clinical results from the modest/severe diabetic gastroparesis (DG) sub-population of Phase III trial, and the FDA's suggestion that only additional positive PK study (vs. 10 mg Reglan tablet) results would be needed for an NDA filing. We are upgrading EVOK to Buy from Neutral, with an \$8.00 target price.

- Details.** After four weeks of treatment vs. placebo, Gimoti exhibited statistically significant improvements in mean daily gastroparesis symptom assessment (GSA) scores (up to 3 weeks) and in the mean daily nausea and upper abdominal pain score. The analysis is based on approx. half (105/205) of total enrolled patients who were moderate to severe. In 2015 the FDA issued draft guidance on clinical evaluation of drugs for the treatment of gastroparesis, suggesting clinical trials should enroll patients with greater symptom severity in order to demonstrate treatment effect. We believe EVOK could start a PK study in mid-2017 and plan to submit an NDA in 4Q17. For both safety and efficacy, the PK study intends to show ranges of Gimoti doses that should be considered equivalent and comparable to 10 mg Reglan.
- Implications.** Although a failed pivotal trial usually spells trouble for a clinical asset, we believe the situation with Gimoti is not typical. Given that: 1) Gimoti could be active in treating a patient population the FDA deems to require treatment since it showed statistically significant improvements of GSA, daily nausea and upper abdominal pain scores from a dataset with much smaller patient size; 2) the active ingredient metoclopramide is a well-established DG treatment for several decades; and 3) it only required a PK study before filing; we believe the chance for a positive regulatory outcome has improved. As such, we believe meaningful upside exists for EVOK shares from the current low valuation.
- Action.** We are upgrading EVOK shares to Buy from Neutral, and assigning 12-month target price of \$8.00, based on our NPV analysis with 30% discount rate and 2x terminal value multiple. We assume a Gimoti launch in 2019 with peak annual sales reaching \$300MM+ by 2024. Gimoti, in our opinion, could be an important treatment option for moderate/severe diabetic gastroparesis fulfilling the unmet need.

Healthcare/Biotechnology

Ticker:		EVOK
Rating:	↑ raise	Buy
Price Target:	↑ raise	\$8.00

Trading Data:

Last Price (1/27/2017)	\$2.48
52-Week High (7/13/2016)	\$11.11
52-Week Low (11/10/2016)	\$1.35
Market Cap. (MM)	\$30
Shares Out. (MM)	6.486

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.18	-0.14	-0.16	-0.15	-0.63	NM
FY-16E	-0.45A	-0.41A	-0.29A	-0.20	-1.34	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

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Source: Laidlaw & Company estimates

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Anticipated Milestones in 2017 and Beyond

Product	Indication	Event	Timing	Importance
Gimoti (EVK-100)	Diabetic gastroparesis	Start Phase I PK study vs. Reglan (10 mg tablet)	Mid-2017	***
		Complete Phase I PK study	2H17	***
		Potential NDA filing	Year-end 2017	****
		Potential FDA approval decision	2H18	*****

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

Source: Laidlaw & Company and company presentation

Major Risks

Failures of upcoming clinical studies. Although Gimoti has demonstrated promising efficacy and a satisfactory safety profile from parts of the Phase III study in diabetic gastroparesis; there is no assurance that the upcoming PK clinical study can demonstrate efficacy and safety profiles satisfactory enough along with part of the Phase III study results for gaining clinical approval. Given the clinical study successes are the biggest near-term hurdle to be overcome before Gimoti 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 Gimoti are more modest relative to Phase III studies of other biotech companies.

Gimoti may not reach anticipated sales. Assuming Gimoti receives approval and is commercialized, the sales potential could fall short of our forecasts. It is difficult to project accurately the sales potential of Gimoti in gastroparesis given that the market is relatively mature and is dominated by generic products. The assumption is that Gimoti 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 Gimoti vs. oral metoclopramide with a superior outcome could also slow down the initial market penetration.

Lack of diversified product portfolio increases risk if Gimoti 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 Gimoti 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 Gimoti 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.

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)	(\$0.20)	(\$1.34)	(\$0.63)	(\$0.31)	(\$0.47)	\$0.76
Shares outstanding—basic and diluted	6,032	6,486	7,168	7,218	10,615	11,665	9,166	12,837	14,837	15,837	16,837
	6,032	6,486	7,168	7,218	10,615	11,665	9,166	12,837	14,837	15,837	16,837
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%	-47%	-28%	-53%	-51%	50%	-263%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Date	Rating	Closing Price (\$)
04/22/2014	Buy (B)	9.29
07/19/2016	Hold (H)	2.47
01/30/2017	Buy (B)	2.48*

Date	Target Price (\$)	Closing Price, (\$)
04/22/2014	19.00	9.29
07/19/2016		2.47
01/30/2017	8.00	2.48*

* Previous Close 1/27/2017

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.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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