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EQUITY RESEARCH
Company Report

February 15, 2018

Evoke Pharma (EVOK - $2.43)

Healthcare/Biotechnology

Ticker:	**EVOK**
Rating:	**Buy**
Price Target:	**$8.00**

Gimoti NDA Filing Will Be Pushed to 2Q18 With More Gender Specific PK Data to Be Included

This morning, EVOK reported the discovery of additional information regarding the different PK exposure of Gimoti between males and females. With the additional discussions with the FDA, the company plans to incorporate the recent discovery into their NDA filing, which could occur in 2Q18.

- **Details.** During the comparative PK analysis between Gimoti and the reference drug, Reglan tablets, for the 505(b)(2) NDA submission, EVOK met the bioequivalence requirement between the two drugs. In addition, they have also discovered that the area under the curve (AUC) of men is lower with statistical significance compared to that of women. These differences are not correlated with individual's body mass index (BMI) or weight. In addition, from retrospective analysis of data from earlier PK studies, EVOK also identified the existence of the PK discrepancies between gender of oral metoclopramide. In addition, the tested Gimoti dose for women of an independent analysis also met bioequivalence criteria for $AUC_{0\text{-}inf}$ and $AUC_{0\text{-}t}$ to the oral drug. As such, EVOK will propose such dose for the upcoming NDA submission with an indication of female-only gastroparesis. EVOK also has filed new patent applications related to the discovery. Concurrently, EVOK has conducted another pre-NDA meeting with the FDA due to the new discovery and has gained more clarity about the agency's expectation. By incorporating the FDA's feedback and recent discoveries, EVOK anticipates filing the Gimoti NDA in 2Q18.
- **Implications.** Overall, we believe the news should be positive for EVOK shares as the potential 505(b)(2) NDA filing could have resolved any gender-related PK issue and became a more supportive package; even though the filing time has been pushed out for several months. It has been known for a while that the inhaled metoclopramide is less effective in males compared to females, and we view the lower AUC in men could be one of the factors. With more evidence-supported clinical information, we believe Gimoti potentially has a stronger position heading into its NDA filing.
- **Action.** We are reiterating our Buy rating and $8 target price based on our peer comparable, cash driven NPV and forward price/sales analyses. Gimoti, in our opinion, could be an important treatment option for modest/severe diabetic gastroparesis, fulfilling an unmet need.

Trading Data:

Last Price (2/14/2018)	$2.43
52–Week High (2/15/2017)	$4.55
52–Week Low (8/14/2017)	$2.19
Market Cap. (MM)	$35
Shares Out. (MM)	9.338

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.37A	-0.11A	-0.34A	-0.24	-1.05	NM
FY-16A	-0.45	-0.41	-0.29	-0.12	-1.15	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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Anticipated Milestones in 2018 and Beyond

Product	Indication	Event	Timing	Importance
Gimoti (EVK-001)	Diabetic gastroparesis	Potential NDA filing	**2Q18**	****
		Potential FDA approval decision	**1H19**	*****

***** / ***** 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 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.

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Figure 1: Income Statement

Evoke Pharma – Income Statement

($'000)	2015	2016	1Q17	2Q17	3Q17	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E
Revenue												
EVK-001 sales	0	0	-	-	-	-	0	0	15,536	32,129	51,172	85,954
Product royalty revenue	0	0	-	-	-	-	0	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	15,536	32,129	51,172	85,954
Costs of goods	0	0					0	0	1,398	2,892	4,605	7,736
Research and development	8,154	6,952	771	2,018	2,718	2,854	8,360	7,106	7,177	6,603	4,952	3,219
General and administrative	3,664	3,593	1,210	872	984	999	4,064	4,430	4,829	5,215	5,580	5,971
Marketing and sales	0	0	0	0	0	0	0	0	23,100	24,255	24,983	25,732
Total Operating Expenses	11,818	10,544	1,980	2,890	3,702	3,852	12,424	11,536	36,504	38,964	40,120	42,658
Operating Incomes (losses)	(11,818)	(10,544)	(1,980)	(2,890)	(3,702)	(3,852)	(12,424)	(11,536)	(20,968)	(6,835)	11,052	43,297
Other expense		(145)	-	-	-	-	0	0	0	0	0	0
Interest income	5	0	1	2	3	2	7	8	9	10	11	12
Interest expense	(307)	(123)	-	-	-	-	0	0	0	0	0	0
Financing costs related to warrant liability		(534)	-	-	-	-	0	0	0	0	0	0
Change in fair value of warrant liability	0	598	(3,073)	1,262	(1,544)	101	(3,254)	100	100	100	100	100
Total Other Income, net	(302)	(205)	(3,072)	1,264	(1,541)	103	(3,247)	108	109	110	111	112
Income before tax	(12,120)	(10,749)	(5,052)	(1,626)	(5,243)	(3,749)	(15,670)	(11,428)	(20,859)	(6,725)	11,162	43,409
Tax	0	0	-	-	-	-	0	0	0	0	(3,907)	(15,193)
Net Income (Loss)	(12,120)	(10,749)	(5,052)	(1,626)	(5,243)	(3,749)	(15,670)	(11,428)	(20,859)	(6,725)	7,256	28,216
Net Income (Loss) Applicable to Common Shareholders	(12,120)	(10,749)	(5,052)	(1,626)	(5,243)	(3,749)	(15,670)	(11,428)	(20,859)	(6,725)	7,256	28,216
Net Earnings (Losses) Per Share—Basic and Diluted	($1.87)	($1.15)	($0.37)	($0.11)	($0.34)	($0.24)	($1.05)	($0.66)	($1.13)	($0.35)	$0.36	$1.38
Shares outstanding—basic and diluted	6,486	9,338	13,528	15,343	15,351	15,401	14,906	17,401	18,401	19,401	19,901	20,401
	6,486	9,338	13,528	15,421	15,351	15,401	14,925	17,401	18,401	19,401	19,901	20,401
Margin Analysis (% of Sales/Revenue)												
Costs of goods							9%	9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	21%	10%	4%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	92%	60%	37%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-21%	22%	50%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-21%	14%	33%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	107%	59%	68%
R&D	-18%	-15%	-91%	-4%	103%	90%	20%	-15%	1%	-8%	-25%	-35%
SG&A	16%	-2%	-67%	9%	19%	21%	13%	9%	9%	8%	7%	7%
Marketing and sales	NA	NA					NA	5%	6%	5%	3%	3%
Operating Loss	-10%	-11%	-83%	0%	71%	66%	18%	-7%	82%	-67%	-262%	292%
Total Other Income, net	209%	-32%	918%	-1838%	80%	-87%	1487%	-103%	1%	1%	1%	1%
Pretax Income	-9%	-11%	-58%	-45%	73%	145%	46%	-27%	83%	-68%	-266%	289%
Net Income	-9%	-11%	-58%	-45%	73%	145%	46%	-27%	83%	-68%	-208%	289%
EPS	-15%	-38%	-80%	-74%	20%	96%	-9%	-38%	73%	-69%	-205%	279%

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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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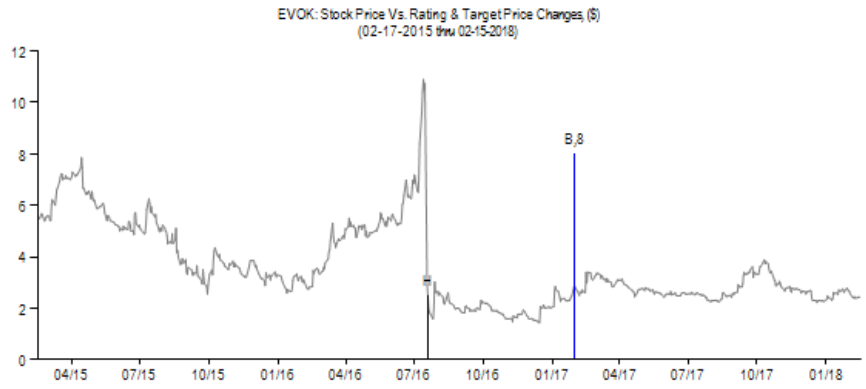
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
07/19/2016	Hold (H)	2.47
01/30/2017	Buy (B)	2.85

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
07/19/2016		2.47
01/30/2017	8.00	2.85

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.	66.67%	29.41%	1.96%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.96%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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