

## Evoked Pharma (EVOK - \$ 4.84)

### EVK-001 in Diabetic Gastroparesis Pivotal Trial (METO IN-003) Top-line Results Expected in Early 3Q16

This morning, EVOK announced that it expects to provide top-line data from its Phase III pivotal trial of EVK-001 (a nasal delivery formulation of metoclopramide) in women with diabetic gastroparesis in early 3Q16. This guidance is in-line with our prior projection.

- Details.** As a reminder, the study is a randomized, double-blind, placebo-controlled Phase III trial that evaluates the efficacy, safety and population pharmacokinetics of EVK-001 in female diabetic gastroparesis patients. EVOK reported that 205 patients (initially targeted for 200) have been recruited for the study. The primary endpoint is the symptom score changes at week four vs. the baseline determined by a proprietary Patient Report Outcome (PRO) instrument. In addition to the company's completion of other supportive work, including the safety analysis which illustrated that higher doses of EVK-001 did not prolong the cardiac QT intervals (QTc) in healthy volunteers; and the completion of CMC related large commercial scale manufacturing of EVK-001, EVOK has also assembled a team and begun preparation for an NDA.
- Implications.** Today's announcement confirmed and narrowed our prior projection (potentially June-August) that the topline results could be available within a July to possibly early August timeframe. We view the reporting of the METO IN-003 study results as the most critical binary event for EVOK share value. If the data are positive, for which we remain bullish, EVOK would conduct a pre-NDA meeting prior to a 505(b)(2) filing, by year end 2016 in our estimate. Given EVK-001 is one of the clinically most advanced treatments in development in the gastroparesis space; should the drug get approved and marketed, EVOK could enjoy a first mover advantage in the market place.
- Action.** We reiterate our Buy rating and \$19 target price based on our peer comparable, cash driven NPV and forward price/sales analyses. Our recommendation is based on potential success of the METO IN-003 study and the positive commercial outlook of EVK-001 in gastroparesis treatment.

*Healthcare/Biotechnology*

Ticker: **EVOK**  
Rating: **Buy**  
Price Target: **\$ 19.00**

#### Trading Data:

Last Price (05/03/2016)	\$ 4.84
52-Week High (8/18/2015)	\$ 7.17
52-Week Low (1/20/2016)	\$ 2.37
Market Cap. (MM)	\$ 35
Shares Out. (MM)	7

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.39	-0.41	-0.18	-0.14	-1.04	NM
<b>FY-15A</b>	-0.58	-0.52	-0.42	-0.37	-1.87	NM
<b>FY-14A</b>	-0.49	-0.59	-0.63	-0.48	-2.20	NM
<b>FY-13A</b>	-0.44	-0.21	-0.40	-0.27	-1.20	NM

#### Yale Jen, Ph.D.

Managing Director/Senior  
Biotechnology Analyst  
(212) 953-4978  
yjen@laidlawltd.com

Source: Laidlaw & Company estimates

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## Anticipated Milestones in 2016 and Beyond

Product	Indication	Event	Timing	Importance
EVK-100	Diabetic gastroparesis	Potentially report top-line METO IN-003 Phase III trial results	<b>Early 3Q16</b>	<b>*****</b>
		Potentially filing via 505(b)(2) pathway for approval	<b>late 2H16</b>	<b>***</b>
		Potential approval	<b>2H17</b>	<b>*****</b>

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

Source: Laidlaw & Company and company presentation

## Major Risks

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**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.

Figure 1: Income Statement

<b>Evoke Pharma – Income Statement</b>											
(\$'000)	2014	2015	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
<b>Revenue</b>											
EVK-001 sales		0					0	21,354	55,533	94,545	148,265
Product royalty revenue	0	0	-	-	-	-	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	21,354	55,533	94,545	148,265
Costs of goods		0					0	1,922	4,998	8,509	13,344
Research and development	9,992	8,154	1,913	2,143	986	591	5,633	1,183	1,124	1,158	1,192
General and administrative	3,158	3,664	809	777	746	775	3,107	3,386	3,691	4,023	4,345
Marketing and sales		0					0	22,000	23,100	24,486	25,710
<b>Total Operating Expenses</b>	<b>13,150</b>	<b>11,818</b>	<b>2,722</b>	<b>2,920</b>	<b>1,731</b>	<b>1,367</b>	<b>8,740</b>	<b>28,491</b>	<b>32,913</b>	<b>38,176</b>	<b>44,592</b>
Operating Incomes (losses)	(13,150)	(11,818)	(2,722)	(2,920)	(1,731)	(1,367)	(8,740)	(7,138)	22,620	56,369	103,674
Interest income	10	5	1	1	1	1	5	5	5	6	7
Interest expense	(108)	(307)	(74)	(74)	(74)	(74)	(297)	(326)	(359)	(395)	(395)
Change in fair value of warrant liability	0	0	0	0	0	0	0	0	24	(27)	(27)
Total Other Income, net	(98)	(302)	(73)	(73)	(73)	(73)	(292)	(322)	(330)	(416)	(415)
<b>Income before tax</b>	<b>(13,248)</b>	<b>(12,120)</b>	<b>(2,795)</b>	<b>(2,993)</b>	<b>(1,804)</b>	<b>(1,440)</b>	<b>(9,033)</b>	<b>(7,459)</b>	<b>22,290</b>	<b>55,953</b>	<b>103,258</b>
Tax Rate									32%	32%	32%
Tax	0	0	0	0	0	0	0	0	(7,133)	(17,905)	(33,043)
<b>Net Income (Loss)</b>	<b>(13,248)</b>	<b>(12,120)</b>	<b>(2,795)</b>	<b>(2,993)</b>	<b>(1,804)</b>	<b>(1,440)</b>	<b>(9,033)</b>	<b>(7,459)</b>	<b>15,157</b>	<b>38,048</b>	<b>70,216</b>
Net Income (Loss) Applicable to Common Shareholders	(13,248)	(12,120)	(2,795)	(2,993)	(1,804)	(1,440)	(9,033)	(7,459)	15,157	38,048	70,216
Net Earnings (Losses) Per Share—Basic and Diluted	(\$2.20)	(\$1.87)	(\$0.39)	(\$0.41)	(\$0.18)	(\$0.14)	(\$1.04)	(\$0.64)	\$1.19	\$2.77	\$4.77
Shares outstanding—basic and diluted	6,032	6,486	7,173	7,223	10,223	10,273	8,723	11,723	12,723	13,723	14,723
	6,032	6,486	7,173	7,223	10,223	10,273	8,723	11,723	12,723	13,723	14,723
<b>Margin Analysis (% of Sales/Revenue)</b>											
Costs of goods								9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	20%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	70%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	47%
<b>Financial Indicator Growth Analysis (YoY%)</b>											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	57%
R&D	944%	-18%	-81%	-2%	-46%	-65%	-31%	-79%	-5%	3%	3%
SG&A	92%	16%	-74%	-20%	-9%	-8%	-15%	9%	9%	9%	8%
Marketing and sales		NA					NA	200%	5%	6%	5%
Operating Loss	405%	-10%	-79%	-8%	-35%	-46%	-26%	-18%	-417%	149%	84%
Total Other Income, net	-58%	209%	-25%	-5%	-5%	0%	-3%	10%	3%	26%	0%
Pretax Income	367%	-9%	-79%	-8%	-34%	-45%	-25%	-17%	-399%	151%	85%
Net Income	367%	-9%	-79%	-8%	-34%	-45%	-25%	-17%	-303%	151%	85%
EPS	83%	-15%	-82%	-21%	-58%	-62%	-45%	-39%	-287%	133%	72%
Yale Jen, Ph.D. 212-953-4978											

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

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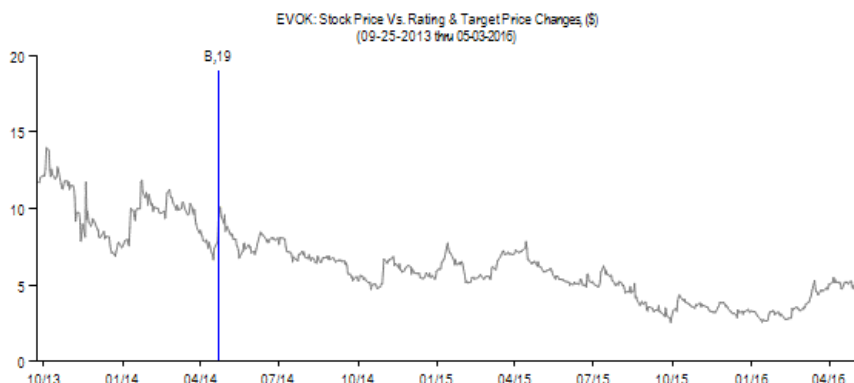
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#### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/22/2014	Buy (B)	9.29

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/22/2014	19.00	9.29

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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