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EQUITY RESEARCH
Company Report

September 15, 2015

Evoke Pharma (EVOK - $ 4.17)

Healthcare/Biotechnology

METO IN-003 Study Design is Well In-Line With Recently Published FDA Recommendations

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

This morning EVOK reported that the study design of the company's ongoing EVK-001 in diabetic gastroparesis Phase III trial (METO IN-003) is consistent with the recently published FDA's recommendations from draft guidance entitled "Gastroparesis: Clinical Evaluation of Drugs for Treatment -- Guidance for Industry (Draft Guidance)".

- **Details.** The most relevant aspect of the FDA guidance as it relates to the METO IN-003 study is that the draft guidance suggests a patient-reported outcome (PRO) instrument to assess gastroparesis symptoms as an ideal primary efficacy assessment tool. The METO IN-003 study primary endpoint ─ gastroparesis symptom assessment (GSA) ─ is such a PRO; in line with the FDA guidance. In addition, the draft guidance indicated that "Patients with diabetic gastroparesis may experience further derangement of glucose control because of unpredictable gastric emptying and altered absorption of orally administered hypoglycemic drugs, which may in turn affect measurement of core signs and symptoms." Although the statement refers to an oral drug for treating diabetes, we also believe this could bode well for EVK-001 (a metoclopramide nasal spray) since the therapeutic impact of an oral gastroparesis treatment could also be negatively impacted from the same pathological condition.

- **Implications.** We view today's announcement a positive for EVOK shareholder value since it further de-risks trial design concerns of the METO IN-003 study. METO IN-003 Phase III study completion is expected in 1H16 with top-line results available shortly thereafter. Our investment thesis is that if the outcome of the METO IN-003 trial is positive, as we believe is likely, EVOK share value could be lifted significantly. EVOK is expected to file for EVK-001 approval via a 505(b)(2) pathway, possibly in 2H16.

- **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.

Trading Data:

Last Price (09/15/2015)	$ 4.17
52–Week High (1/13/2015)	$ 8.32
52–Week Low (8/24/2015)	$ 2.80
Market Cap. (MM)	$ 26
Shares Out. (MM)	6

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.58A	-0.52A	-0.53	-0.54	-2.17	NM
FY-14A	-0.49	-0.59	-0.63	-0.48	-2.20	NM
FY-13A	-0.44	-0.21	-0.40	-0.27	-1.20	NM
FY-12A	-0.45	-0.32	-0.43	-0.60	-1.79	NM

Source: Laidlaw & Company estimates

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Anticipated Milestones in 2015 and Beyond

Product	Indication	Event	Timing	Importance
EVK-100	Diabetic gastroparesis	Potentially report top-line METO IN-003 Phase III trial results	**1H16**	*****
		Potentially filing via 505(b)(2) pathway for approval	**2H16**	***
		Potential approval	**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)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
EVK-001 sales								0	0	23,227	64,013	112,205	166,655
Product royalty revenue		0	0	-	-	-	-	0	0	0	0	0	0
Total revenue	0	0	0	-	-	-	-	0	0	23,227	64,013	112,205	166,655
Costs of goods								0	0	2,090	5,761	10,098	14,999
Research and development	1,166	957	9,992	2,420	2,188	2,254	2,299	9,161	3,756	2,441	2,319	2,389	2,461
General and administrative	837	1,645	3,158	1,025	976	996	1,036	4,033	3,469	3,781	4,121	4,492	4,851
Marketing and sales							-	0	15,500	46,500	48,825	51,755	54,342
Total Operating Expenses	2,002	2,602	13,150	3,445	3,165	3,250	3,335	13,194	22,725	54,813	61,027	68,734	76,653
Operating Incomes (losses)	(2,002)	(2,602)	(13,150)	(3,445)	(3,165)	(3,250)	(3,335)	(13,194)	(22,725)	(31,586)	2,987	43,471	90,002
Interest income	2	7	10	2	1	1	1	5	5	6	7	7	8
Interest expense	(24)	(80)	(108)	(77)	(78)	(78)	(78)	(310)	(341)	(375)	(413)	(454)	(454)
Change in fair value of warrant liability	7	(82)	0	0	0	0	0	0	0	0	24	(27)	(27)
Total Other Income, net	(15)	(235)	(98)	(76)	(77)	(77)	(77)	(305)	(336)	(369)	(382)	(474)	(473)
Income before tax	(2,018)	(2,836)	(13,248)	(3,521)	(3,241)	(3,326)	(3,411)	(13,499)	(23,061)	(31,955)	2,604	42,997	89,529
Tax Rate	0										32%	32%	32%
Tax	0	0	0	0	0	0	-	0	0	0	(833)	(13,759)	(28,649)
Net Income (Loss)	(2,018)	(2,836)	(13,248)	(3,521)	(3,241)	(3,326)	(3,411)	(13,499)	(23,061)	(31,955)	1,771	29,238	60,879
Net Income (Loss) Applicable to Common Shareholders	(2,018)	(2,836)	(13,248)	(3,521)	(3,241)	(3,326)	(3,411)	(13,499)	(23,061)	(31,955)	1,771	29,238	60,879
Net Earnings (Losses) Per Share—Basic and Diluted	($1.79)	($1.20)	($2.20)	($0.58)	($0.52)	($0.53)	($0.54)	($2.17)	($2.24)	($2.82)	$0.14	$2.20	$4.25
Shares outstanding—basic and diluted	1,124	2,368	6,032	6,104	6,213	6,263	6,313	6,223	10,313	11,313	12,313	13,313	14,313
	1,124	2,368	6,032	6,104	6,213	6,263	6,313	6,223	10,313	11,313	12,313	13,313	14,313
Margin Analysis (% of Sales/Revenue)													
Costs of goods										9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	11%	4%	2%	1%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	216%	83%	50%	36%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-136%	5%	39%	54%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-138%	3%	26%	37%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	176%	75%	49%
R&D	-37%	-18%	944%	153%	-24%	-27%	6%	-8%	-59%	-35%	-5%	3%	3%
SG&A	47%	97%	92%	-38%	58%	36%	40%	28%	-14%	9%	9%	9%	8%
Marketing and sales								NA	1450%	200%	5%	6%	5%
Operating Loss	-17%	30%	405%	32%	-9%	-15%	14%	0%	72%	39%	-109%	1356%	107%
Total Other Income, net	-213%	1454%	-58%	-68%	39%	1732%	1318%	213%	10%	10%	4%	24%	0%
Pretax Income		41%	367%	24%	-9%	-13%	17%	2%	71%	39%	-108%	1551%	108%
Net Income	-16%	41%	367%	24%	-9%	-13%	17%	2%	71%	39%	-106%	1551%	108%
EPS	-18%	-33%	83%	-52%	-11%	-16%	12%	-1%	3%	26%	-105%	1427%	94%

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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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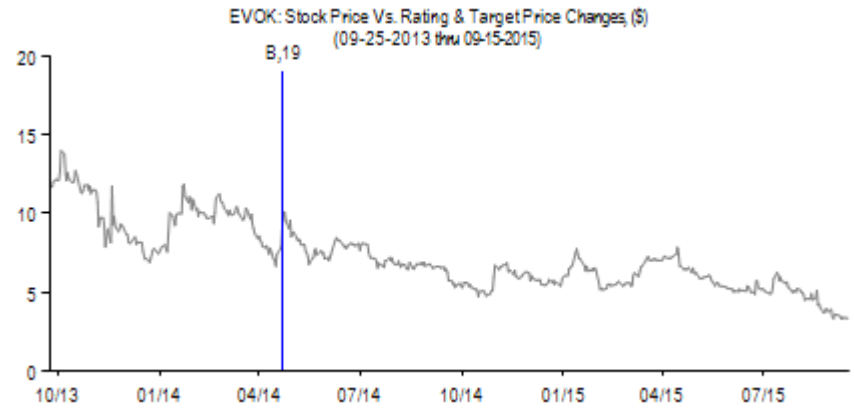
Rating and Price Target Change History



3 Year Rating Change History

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

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**

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.	77.42%	29.03%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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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