

Evoked Pharma (EVOK - \$ 6.98)

Takeaways from KOL Call on Gastroparesis Treatment

We recently hosted a KOL call with an academic-based gastroenterologist and investors focusing on gastroparesis treatment. We walked away with positive outlook on EVK-001 commercially if the drug receives approval. In addition to treating patients, he is also a professor and director of a GI motility research laboratory at a medical school. Key takeaways from the call include:

- **Even if approved in diabetic gastroparesis only, the drug would be used for treating gastroparesis of all etiologies.** The KOL indicated that physicians will use the drug to treat gastroparesis of all different etiologies even if it is only approved specifically in diabetic gastroparesis. As a reminder, diabetic gastroparesis accounts for ~30% of all gastroparesis cases.
- **FDA recently suggested endpoints for gastroparesis drug development are logical.** He concurred with the merit of the recent FDA draft guidance, which suggests using patient-reported outcome (PRO) instrument to assess gastroparesis symptoms is an ideal primary efficacy assessment tool. He believes PROs could exhibit the totality of clinical benefits by evaluating the full spectrum of symptoms (a total of five). This contrasts with earlier thoughts which were focused on certain aspects, like delayed gastric emptying, which has demonstrated poor correlation to symptom improvements. As a reminder, the primary endpoint of the METO IN-003 study, gastroparesis symptom assessment (GSA), is a PRO.
- **Potential use of nasal delivered metoclopramide (EVK-001).** Based on the assumption that EVK-001 is approved, he speculated that at least in the near term, oral metoclopramide could still be used as a first line therapy given patients' preference for oral drugs and the low generic drug price. EVK-001 initially could be used as a next line therapy for inadequately treated patients because of insufficient absorption caused by delayed gastric emptying. In addition, certain gastroparesis patients who already suffer from severe vomiting and nausea or severe delayed gastric emptying could also potentially benefit from using EVK-001 as initial treatment without using oral metoclopramide first.
- **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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.45A	-0.46	-0.20	-0.17	-1.19	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
FY-13A	-0.44	-0.21	-0.40	-0.27	-1.20	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (06/29/2016)	\$ 6.98
52-Week High (8/18/2015)	\$ 7.17
52-Week Low (1/20/2016)	\$ 2.37
Market Cap. (MM)	\$ 51
Shares Out. (MM)	7

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- **Metoclopramide-based treatment still is the mainstay of gastroparesis therapy.** Clinical studies have suggested that metoclopramide has multiple therapeutic effects, which include acceleration of gastric emptying and reduction of vomiting (occurred in 50% of gastroparesis patients) and nausea. Despite carrying a black box warning regarding the long term and high dose use, oral metoclopramide currently remains a gold standard for gastroparesis therapy due to its effectiveness. With potentially better efficacy by delivering the drug directly to systemic circulation without passing through the GI tract, a nasally delivered metoclopramide could potentially be a preferable treatment option going forward and the drug could have potential for reduce the need for dose escalations.
- **METO IN-003 trial top-line results to come shortly.** EVOK is expected to report the Phase III (METO IN-003) trial results in early 3Q16 (we estimate in July and possibly early August). Should the data be positive, EVOK would request a pre-NDA meeting shorter thereafter prior to 505(b)(2) filing, which could potentially occur in late 2H16 or early 1Q17, in our estimate. EVK-001 could potentially reach market in late 2017 or 2018

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	Early 3Q16	*****
		Potentially filing via 505(b)(2) pathway for approval	late 2H16	***
		Potential approval	2H17	*****

**** / ***** 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 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

Evoked Pharma – Income Statement											
(\$'000)	2014	2015	1Q16	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue											
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	2,015	2,257	1,038	623	5,933	1,246	1,184	1,219	1,256
General and administrative	3,158	3,664	1,138	1,092	1,049	1,090	4,369	4,762	5,191	5,658	6,111
Marketing and sales		0					0	22,000	23,100	24,486	25,710
Total Operating Expenses	13,150	11,818	3,153	3,349	2,087	1,713	10,302	29,930	34,472	39,872	46,421
Operating Incomes (losses)	(13,150)	(11,818)	(3,153)	(3,349)	(2,087)	(1,713)	(10,302)	(8,576)	21,061	54,672	101,845
Other expense			(73)				(73)				
Interest income	10	5		0	0	0	0	0	0	0	0
Interest expense	(108)	(307)		0	0	0	0	0	0	0	0
Change in fair value of warrant liability	0	0	0	0	0	0	0	0	0	0	0
Total Other Income, net	(98)	(302)	(73)	0	0	0	(73)	0	0	0	0
Income before tax	(13,248)	(12,120)	(3,225)	(3,349)	(2,087)	(1,713)	(10,375)	(8,576)	21,061	54,672	101,845
Tax Rate									32%	32%	32%
Tax	0	0	0	0	0	0	0	0	(6,739)	(17,495)	(32,590)
Net Income (Loss)	(13,248)	(12,120)	(3,225)	(3,349)	(2,087)	(1,713)	(10,375)	(8,576)	14,321	37,177	69,254
Net Income (Loss) Applicable to Common Shareholders	(13,248)	(12,120)	(3,225)	(3,349)	(2,087)	(1,713)	(10,375)	(8,576)	14,321	37,177	69,254
Net Earnings (Losses) Per Share—Basic and Diluted	(\$2.20)	(\$1.87)	(\$0.45)	(\$0.46)	(\$0.20)	(\$0.17)	(\$1.19)	(\$0.73)	\$1.13	\$2.71	\$4.71
Shares outstanding—basic and diluted	6,032	6,486	7,168	7,218	10,218	10,268	8,718	11,718	12,718	13,718	14,718
	6,032	6,486	7,168	7,218	10,218	10,268	8,718	11,718	12,718	13,718	14,718
Margin Analysis (% of Sales/Revenue)											
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	21%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	69%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	47%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	57%
R&D	944%	-18%	-80%	3%	-44%	-64%	-27%	-79%	-5%	3%	3%
SG&A	92%	16%	-64%	12%	28%	29%	19%	9%	9%	9%	8%
Marketing and sales		NA					NA	200%	5%	6%	5%
Operating Loss	405%	-10%	-76%	6%	-21%	-33%	-13%	-17%	-346%	160%	86%
Total Other Income, net	-58%	209%	-26%	-100%	-100%	-100%	-76%	-100%	N.A.	N.A.	N.A.
Pretax Income	367%	-9%	-76%	3%	-24%	-35%	-14%	-17%	-346%	160%	86%
Net Income	367%	-9%	-76%	3%	-24%	-35%	-14%	-17%	-267%	160%	86%
EPS	83%	-15%	-80%	-11%	-51%	-55%	-36%	-38%	-254%	141%	74%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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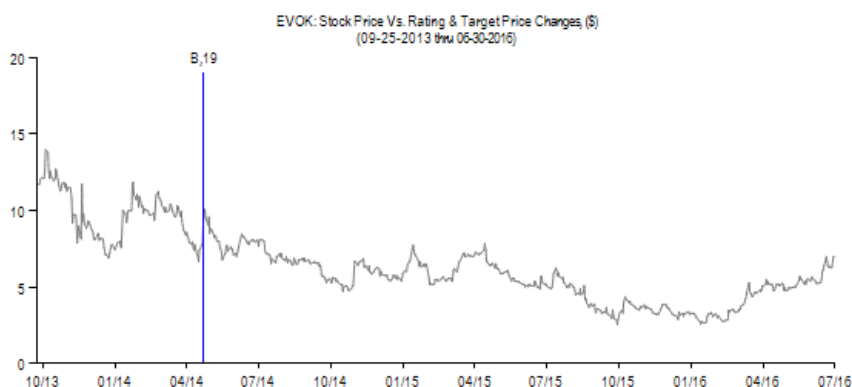
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3 Year Rating Change History

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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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