Evoke Pharma (EVOK - $ 8.60)

Healthcare/Biotechnology

Commencement of Phase III (METO IN-003) Study

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

Shortly after our coverage initiation this morning, EVOK announced the commencement of its Phase III (METO IN-003) clinical trial evaluating EVK-001 in female diabetic gastroparesis (DG) patients.

- **Details.** The METO IN-003 study (ClinicalTrials.gov Identifier: NCT02025725) is a double-blind, placebo controlled, parallel group trial evaluating the safety and population PK in female diabetic gastroparesis patients. The study is scheduled to enroll 200 patients equally randomized into placebo and 10 mg EVK-001. Patients will be dosed four times a day (QID) for treatment duration of four weeks. A total of 60 clinical sites are expected to engage in the study, with many having already participated in the prior Phase IIb study. The primary endpoint is change in the average Gastroparesis Symptom Assessment (GSA) total score for baseline vs. four weeks of treatment. Secondary endpoints include population PK.

- **Implications.** As the company is on-track to start the Phase III study, we estimate top-line results will potentially be available in mid-2015 (possibly in 3Q15 in our estimate), which we believe could be a major catalyst for EVOK shares. Should the outcome be positive, as we believe is likely, the company could file for approval possibly via a 505(b)(2) pathway in late 2H15. We estimate a potential approval could slate in late 2016 with possible product launch shortly afterward. We also anticipate the company to start another Phase III study (METO IN-004) with similar trial design evaluating EVK-001 in male DG patients, but regulatory filing for approval does not require the submission of METO IN-004 study outcome.

- **Action.** As the company has started its most critical pivotal study to advance EVK-001 and given EVOK shares remain under-exposed and under-valued, we believe substantial upside exist as developments further mature. As such, we are reiterating our $19 12-month target price, which is supported by our peer comparable, cash driven NPV and forward price/sales analyses

Trading Data:

Last Price (04/22/2014)	$8.60
52–Week High (10/7/2013)	$ 14.25
52–Week Low (4/15/2014)	$ 6.48
Market Cap. (MM)	$ 52
Shares Out. (MM)	6

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.33	-0.58	-0.72	-0.79	-2.46	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
FY-11A	NA	NA	NA	NA	-2.18	NM

Source: Laidlaw & Company estimates

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Anticipated Milestones in 2014 and Beyond

Product	Indication	Event	Timing	Importance
EVK-100	Diabetic gastroparesis	Commencement of METO IN-004 (male only) Phase III trial	**2Q14**	**
		Commencement of QT cardiac safety clinical study	**3Q14**	**
		Potentially report top-line QT cardiac safety clinical study results	**1H15**	***
		Potentially report top-line METO IN-003 Phase III trial results	**3Q15**	*****
		Potentially filing via 505(b)(2) pathway for approval	**Late 15 / early '16**	***
		Potential approval	**Late '16**	*****

***** / ***** 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 asset and shareholder value. Overall, we view clinical risks of EVK-001 is more modest comparing to Phase III studies of other biotech companies.

EVK-001 may not reach anticipated sales. Although EVK-001 has illustrated promising efficacy and safety profiles, the sales potential could fall short of our forecasts. It is difficult to project more accurately the sales potential of EVK-001 in gastroparesis given the market is relatively mature and is dominated by generic products. Although the assumption that EVK-001 could bypass the hurdle of slow gastric emptying and vomiting to afford more effective drug availability, the actual clinical performance from Phase III study could potentially determine 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 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 shareholder has very limited option to hedge their risk of owning the stock. 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 operation, it is likely that Evoke may need to provide offerings to raise 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 more favorable terms, the share value of current shareholder could be further impaired.

Limited trading liquidity limits shareholder options. Given daily trading volume and name recognition of EVOK shares are relatively modest, some investors could be hesitate to own the shares as relatively illiquid trading volume 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)	2011	2012	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue														
EVK-001 sales										3,989	25,670	64,013	112,205	166,655
Product royalty revenue			0		-	-	-	0	0	0	0	0	0	0
Total revenue	0	0	0		-	-	-	0	0	3,989	25,670	64,013	112,205	166,655
Costs of goods										359	2,310	5,761	10,098	14,999
Research and development	1,844	1,166	957	955	2,520	3,402	3,913	10,790	9,711	4,953	4,210	3,999	4,119	4,243
General and administrative	571	837	1,645	1,067	1,195	1,279	1,381	4,922	5,168	5,685	6,197	6,755	7,363	7,952
Marketing and sales									1,000	15,500	46,500	48,825	51,755	54,342
Total Operating Expenses	2,415	2,002	2,602	2,022	3,715	4,681	5,294	15,712	15,879	26,497	59,217	65,340	73,335	81,535
Operating Incomes (losses)	(2,415)	(2,002)	(2,602)	(2,022)	(3,715)	(4,681)	(5,294)	(15,712)	(15,879)	(22,508)	(33,547)	(1,327)	38,870	85,120
Interest income	11	2	7	3	3	3	3	12	13	15	16	18	19	21
Interest expense	(3)	(24)	(80)	(40)	(40)	(40)	(40)	(161)	(177)	(195)	(215)	(236)	(260)	(260)
Change in fair value of warrant liability	6	7	(82)	(10)	25	(27)	(14)	(26)	(30)	15	(20)	24	(27)	(27)
Total Other Income, net	13	(15)	(235)	(47)	(12)	(64)	(51)	(175)	(194)	(166)	(219)	(195)	(267)	(265)
Income before tax	(2,401)	(2,018)	(2,836)	(2,069)	(3,728)	(4,745)	(5,345)	(15,887)	(16,073)	(22,674)	(33,766)	(1,521)	38,603	84,854
Tax Rate	0	0										32%	32%	32%
Tax	0	0	0	0	-	-	-	0	0	0	0	487	(12,353)	(27,153)
Net Income (Loss)	(2,401)	(2,018)	(2,836)	(2,069)	(3,728)	(4,745)	(5,345)	(15,887)	(16,073)	(22,674)	(33,766)	(1,035)	26,250	57,701
Net Income (Loss) Applicable to Common Shareholders	($2,401)	(2,018)	(2,836)	(2,069)	(3,728)	(4,745)	(5,345)	(15,887)	(16,073)	(22,674)	(33,766)	(1,035)	26,250	57,701
Net Earnings (Losses) Per Share—Basic and Diluted	($2.18)	($1.79)	($1.20)	($0.34)	($0.59)	($0.72)	($0.79)	($2.46)	($1.37)	($1.78)	($2.45)	($0.07)	$1.66	$3.44
Shares outstanding—basic and diluted	1,103	1,124	2,368	6,171	6,371	6,571	6,771	6,471	11,771	12,771	13,771	14,771	15,771	16,771
	1,103	1,124	2,368	6,171	6,371	6,571	6,771	6,471	11,771	12,771	13,771	14,771	15,771	16,771

Margin Analysis (% of Sales/Revenue)	2011	2012	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Costs of goods										9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	124%	16%	6%	4%	3%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	531%	205%	87%	53%	37%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-564%	-131%	-2%	35%	51%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-568%	-132%	-2%	23%	35%

Financial Indicator Growth Analysis (YoY%)	2011	2012	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total Revenue		NA	NA	NA	NA	NA	NA	NA	NA	NA	544%	149%	75%	49%
R&D		-37%	-18%	430%	942%	4221%	515%	1027%	-10%	-49%	-15%	-5%	3%	3%
SG&A		47%	97%	459%	307%	214%	46%	199%	5%	10%	9%	9%	9%	8%
Marketing and sales										1450%	200%	5%	6%	5%
Operating Loss		-17%	30%	445%	594%	864%	235%	504%	1%	42%	49%	-96%	-3030%	119%
Total Other Income, net		-213%	1454%	-62%	-94%	20580%	43%	-25%	11%	-15%	32%	-11%	37%	-1%
Pretax Income			41%	319%	408%	877%	231%	460%	1%	41%	49%	-95%	-2637%	120%
Net Income		-16%	41%	319%	1454%	889%	231%	460%	1%	41%	49%	-97%	-2637%	120%
EPS		-18%	-33%	-23%	177%	79%	192%	105%	-44%	30%	38%	-97%	-2476%	107%

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

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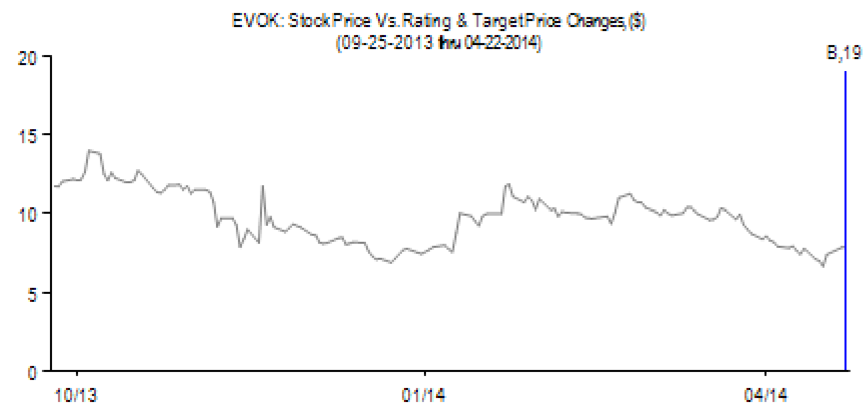
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/22/2014	Buy (B)	7.86*

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/22/2014	19.00	7.86*

** Previous Close4/21/2014*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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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%
Buy (B)	Expected to outperform the sector average over 12 months.	87.50%	31.25%	12.50%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.25%	0.00%	0.00%
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