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EQUITY RESEARCH
Company Report

March 16, 2017

Evoke Pharma (EVOK - $3.02)

Healthcare/Biotechnology

4Q16: Gimoti Makes a Comeback and is On Track for Potential 505(b)(2) Submission by Year End 2017

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

Yesterday after the market close, EVOK reported 4Q16 financial results with a net loss of ($1.5MM), vs. the estimates of Laidlaw ($2.3MM) and the Street ($2.6MM). Net loss/share was ($0.12) vs. ($0.20) and ($0.18) for Laidlaw and the Street, respectively. EVOK currently has cash of ~$16MM (pro forma), enough for operations into 2Q18, in our opinion.

- **Gimoti PK study preparations underway.** During the conference call, management indicated that the company is focusing on trial material preparation and CRO assessment. This is because the Gimoti in female diabetic gastroparesis regulatory path would not need additional Human Factors (HF) validation study; and the bio-equivalency PK study (vs. oral metoclopramide or 10mg Reglan tablet) is the major requirement before filing for 505(b)(2) approval. EVOK guided for starting and completing the Phase I PK trial in healthy volunteers in 2H17 and we believe the trial likely to start in early 2H17. Should the PK study be positive and EVOK files for approval in late 2017 or 1Q18; we believe a potential approval decision by the FDA could slate to late 2018. EVOK plans to report the PK study outcome later in 2H17.
- **Potential differentiation from oral metoclopramide.** Based on the outcome of the bio-equivalency PK study, the dose of the final version of Gimoti to be submitted for approval could be slightly different from that used in the Phase III (METO IN-003) clinical study. In addition, some of the information gained from the Phase III trial, in our opinion, could be incorporated into the final package. Possible examples could include QT/QTc safety data, female patient or modest/severe patient. As such, Gimoti could potentially exhibit certain differentiations from generic oral metoclopramide.
- **Increase exposure at the Digestive Disease Week (DDW) meeting.** Management indicated that the company will attend the DDW conference this May 6-9, potentially to present data and equally important, to discuss with KOLs and participants from industry and clinical community to increase the exposure of Gimoti.
- **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 the unmet need.

Trading Data:

Last Price (3/15/2017)	$3.02
52–Week High (7/13/2016)	$11.11
52–Week Low (11/10/2016)	$1.35
Market Cap. (MM)	$49
Shares Out. (MM)	9.338

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.17	-0.16	-0.20	-0.25	-0.79	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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- **Changing regulatory path could be novel but not a strategy unheard of.** Although some investors might be uncertain regarding the validity and risk of changing the regulatory path after the completion of a Phase III trial for potential approval; such a strategy is uncommon but not unheard of. For instance, the regulatory filing path of Horizant for restless legs syndrome has changed from an NDA to 505(b)(2) after receiving a CR letter in 4Q10. XenoPort and GSK later submitted additional data and Horizant subsequently received approval in 2Q11. Although we recognize the circumstances of Gimoti and Horizant are not identical, changing filing strategy (path) by taking advantage of favorable aspects, in our opinion, is a valid approach. In the case of Gimoti and given metoclopramide has been approved for gastroparesis treatment for several decades, EVOK has adjusted the regulatory pathway accordingly and is seeking approval. In addition, the PK bio-equivalency study is of relatively low risk, in our assessment.

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Anticipated Milestones in 2017 and Beyond

Product	Indication	Event	Timing	Importance
Gimoti (EVK-100)	Diabetic gastroparesis	Start Phase I PK study vs. Reglan (10 mg tablet)	**Mid-2017**	***
		Complete Phase I PK study	**2H17**	***
		Report PK study results	**2H17**	***
		Potential NDA filing	**4Q17/1Q18**	****
		Potential FDA approval decision	**2H18**	*****

***** / ***** 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	1Q16	2Q16	3Q16	4Q16	2016	1Q17E	2Q17E	3Q17E	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	2,015	2,095	1,339	1,502	6,952	1,577	1,719	2,097	3,041	8,435	7,169	7,241	6,662	4,996	3,248
General and administrative	3,664	1,138	803	830	822	3,593	855	864	898	943	3,561	3,881	4,230	4,569	4,889	5,231
Marketing and sales	0					0	0	0	0	0	0	0	23,100	24,255	24,983	25,732
Total Operating Expenses	11,818	3,153	2,898	2,169	2,324	10,544	2,432	2,583	2,996	3,984	11,995	11,050	35,970	38,377	39,473	41,946
Operating Incomes (losses)	(11,818)	(3,153)	(2,898)	(2,169)	(2,324)	(10,544)	(2,432)	(2,583)	(2,996)	(3,984)	(11,995)	(11,050)	(20,434)	(6,248)	11,699	44,008
Other expense		(73)	(73)	-	-	(145)	-	-	-	-	0	0	0	0	0	0
Interest income	5	-	-	-	-	0	-	-	-	-	0	0	0	0	0	0
Interest expense	(307)	-	-	(123)	-	(123)	-	-	-	-	0	0	0	0	0	0
Financing costs related to warrant liability		-	-	(534)	-	(534)	-	-	-	-	0	0	0	0	0	0
Change in fair value of warrant liability	0	-	-	(199)	797	598	(100)	100	(100)	101	1	100	100	100	100	100
Total Other Income, net	(302)	(73)	(73)	(856)	797	(205)	(100)	100	(100)	101	1	100	100	100	100	100
Income before tax	(12,120)	(3,225)	(2,970)	(3,025)	(1,528)	(10,749)	(2,532)	(2,483)	(3,096)	(3,883)	(11,994)	(10,950)	(20,334)	(6,148)	11,799	44,108
Tax Rate												32%	32%	32%	35%	35%
Tax	0	-	-	-	-	0	-	-	-	-	0	3,504	6,507	1,967	(4,130)	(15,438)
Net Income (Loss)	(12,120)	(3,225)	(2,970)	(3,025)	(1,528)	(10,749)	(2,532)	(2,483)	(3,096)	(3,883)	(11,994)	(7,446)	(13,827)	(4,181)	7,669	28,670
Net Income (Loss) Applicable to Common Shareholders	(12,120)	(3,225)	(2,970)	(3,025)	(1,528)	(10,749)	(2,532)	(2,483)	(3,096)	(3,883)	(11,994)	(7,446)	(13,827)	(4,181)	7,669	28,670
Net Earnings (Losses) Per Share—Basic and Diluted	($1.87)	($0.45)	($0.41)	($0.29)	($0.12)	($1.15)	($0.17)	($0.16)	($0.20)	($0.25)	($0.79)	($0.43)	($0.76)	($0.22)	$0.39	$1.42
Shares outstanding—basic and diluted	6,486	7,168	7,218	10,615	12,305	9,338	15,080	15,130	15,180	15,230	15,155	17,155	18,155	19,155	19,655	20,155
	6,486	7,168	7,218	10,615	12,305	9,338	15,080	15,130	15,180	15,230	15,155	17,155	18,155	19,155	19,655	20,155
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	NA	NA	NA	NA	21%	10%	4%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	90%	58%	36%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-19%	23%	51%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-13%	15%	33%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	107%	59%	68%
R&D	-18%	-80%	-4%	-27%	-12%	-15%	-81%	-18%	57%	102%	21%	-15%	1%	-8%	-25%	-35%
SG&A	16%	-64%	-18%	1%	-2%	-2%	-77%	8%	8%	15%	-1%	9%	9%	8%	7%	7%
Marketing and sales	NA					NA					NA	5%	6%	5%	3%	3%
Operating Loss	-10%	-76%	-8%	-18%	-9%	-11%	-79%	-11%	38%	71%	14%	-8%	85%	-69%	-287%	276%
Total Other Income, net	209%	-26%	-5%	1017%	-1190%	-32%	-67%	-238%	-88%	-87%	-100%	9900%	0%	0%	0%	0%
Pretax Income	-9%	-76%	-8%	11%	-42%	-11%	-79%	-16%	2%	154%	12%	-9%	86%	-70%	-292%	274%
Net Income	-9%	-76%	-8%	11%	-42%	-11%	-79%	-16%	2%	154%	12%	-38%	86%	-70%	-283%	274%
EPS	-15%	-80%	-21%	-32%	-66%	-38%	-91%	-60%	-28%	105%	-31%	-45%	75%	-71%	-279%	265%

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

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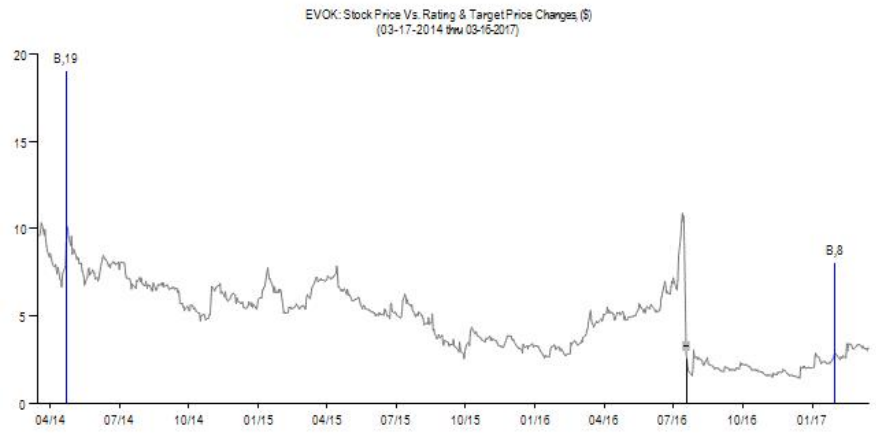
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/22/2...	Buy (B)	9.29
07/19/2...	Hold (H)	2.47
01/30/2...	Buy (B)	2.85

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/22/2...	19.00	9.29
07/19/2...		2.47
01/30/2...	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.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

XenoPort (XNPT – Not Rated)
GlaxoSmithKline (GSK – Not Rated)

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