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Company Report

October 31, 2017

# Evoke Pharma (EVOK - $2.94)

*Healthcare/Biotechnology*

## Conference Call Provided More Perspective About the Gimoti Pharmacokinetic Study Results

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

This morning. EVOK hosted a conference call to provide more details regarding the just completed Gimoti PK study. The focus was on the use of bioequivalent area under the curve (AUC) of plasma concentration as key measurement, lower than referenced listed drug's (RLD) maximum plasma concentration ($C_{max}$) and what has been suggested by the FDA's CRF.

- **Details.** Given that the recent reporting of the Gimoti PK trial outcome created come confusions among investors, the goal of the conference call was to provide more clarity and the potential impact of the study outcome. As a reminder, the top-line data have shown that two of the three Gimoti doses tested met the selection criteria [90% confident for the plasma concentration measured by the area under the curve (AUC) within 80%-125% bioequivalence to that of the 10mg Reglan tablet]. The maximum observed plasma concentration ($C_{max}$) for Gimoti was slightly lower than that of the 80% bioequivalence range of RLD. EVOK indicated that during the second meeting with the FDA (Dec. 2016), they discussed such a possible lower $C_{max}$ outcome based on prior Gimoti PK study results and that Gimoti was delivered via a different route vs. oral. The discussion also suggested that similar systemic exposure of metoclopramide vs. RLD measured by AUC could be the basis for a potential 505(b)2 approval. Management also indicated that they might not provide the detail PK results soon, unless they have completed the assessment of IP benefits from the data. EVOK reiterated their intent to file an NDA via 505(b)(2) in 1Q18 with one recommended Gimoti dose.
- **Implications.** We view the conference call achieved EVOK's goal for providing greater clarity and perspective on the PK study outcomes. First, we believe the concerns over the lower $C_{max}$ readout have been overblown, since the impact of $C_{max}$ level is more limited given Gimoti will be given four times per day for multiple weeks instead of as a single administration. In addition, precedent exists for drug approval based on bioequivalent AUC and lower $C_{max}$, like Metozolv ODT. Further, with additional clinical study data as part of the NDA submission, the Gimoti product label, if approved, could potentially contain more information that might benefit prescribers and patients.
- **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 an unmet need.

**Trading Data:**

| | |
|---|---|
| Last Price (10/30/2017) | $2.94 |
| 52–Week High (2/15/2017) | $4.55 |
| 52–Week Low (11/10/2016) | $1.35 |
| Market Cap. (MM) | $45 |
| Shares Out. (MM) | 9.338 |

**Earnings Estimates:** (per share)

| (Dec) | 1Q | 2Q | 3Q | 4Q | FY | P/E |
|---|---|---|---|---|---|---|
| **FY-17E** | -0.37A | -0.11A | -0.26 | -0.32 | -1.04 | 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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## Anticipated Milestones in 2017 and Beyond

| Product | Indication | Event | Timing | Importance |
|---|---|---|---|---|
| Gimoti (EVK-001) | Diabetic gastroparesis | Potential NDA filing | **1Q18** | **** |
| | | Potential FDA approval decision | **4Q18/1Q19** | ***** |

***** / ***** 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 | 2016 | 1Q17 | 2Q17 | 3Q17E | 4Q17E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue** | | | | | | | | | | | | |
| EVK-001 sales | 0 | 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 | 6,952 | 771 | 2,018 | 3,026 | 4,086 | 9,900 | 8,415 | 8,499 | 7,819 | 5,865 | 3,812 |
| General and administrative | 3,664 | 3,593 | 1,210 | 872 | 889 | 903 | 3,874 | 4,222 | 4,602 | 4,971 | 5,319 | 5,691 |
| Marketing and sales | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 23,100 | 24,255 | 24,983 | 25,732 |
| **Total Operating Expenses** | 11,818 | 10,544 | 1,980 | 2,890 | 3,916 | 4,988 | 13,774 | 12,638 | 37,600 | 39,937 | 40,771 | 42,971 |
| Operating Incomes (losses) | (11,818) | (10,544) | (1,980) | (2,890) | (3,916) | (4,988) | (13,774) | (12,638) | (22,064) | (7,808) | 10,401 | 42,984 |
| Other expense | | (145) | - | - | - | - | 0 | 0 | 0 | 0 | 0 | 0 |
| Interest income | 5 | 0 | 1 | 2 | - | - | 3 | 3 | 3 | 4 | 4 | 4 |
| Interest expense | (307) | (123) | - | - | - | - | 0 | 0 | 0 | 0 | 0 | 0 |
| Financing costs related to warrant liability | | (534) | - | - | - | - | 0 | 0 | 0 | 0 | 0 | 0 |
| Change in fair value of warrant liability | 0 | 598 | (3,073) | 1,262 | (100) | 101 | (1,810) | 100 | 100 | 100 | 100 | 100 |
| Total Other Income, net | (302) | (205) | (3,072) | 1,264 | (100) | 101 | (1,807) | 103 | 103 | 104 | 104 | 104 |
| **Income before tax** | (12,120) | (10,749) | (5,052) | (1,626) | (4,016) | (4,887) | (15,581) | (12,535) | (21,961) | (7,704) | 10,505 | 43,088 |
| Tax | 0 | 0 | - | - | - | - | 0 | 4,011 | 7,028 | 2,465 | (3,677) | (15,081) |
| **Net Income (Loss)** | (12,120) | (10,749) | (5,052) | (1,626) | (4,016) | (4,887) | (15,581) | (8,524) | (14,934) | (5,239) | 6,828 | 28,007 |
| Net Income (Loss) Applicable to Common Shareholders | (12,120) | (10,749) | (5,052) | (1,626) | (4,016) | (4,887) | (15,581) | (8,524) | (14,934) | (5,239) | 6,828 | 28,007 |
| Net Earnings (Losses) Per Share—Basic and Diluted | ($1.87) | ($1.15) | ($0.37) | ($0.11) | ($0.26) | ($0.32) | ($1.04) | ($0.50) | ($0.83) | ($0.28) | $0.35 | $1.41 |
| Shares outstanding—basic and diluted | 6,486 | 9,338 | 13,528 | 15,343 | 15,393 | 15,443 | 14,927 | 16,927 | 17,927 | 18,927 | 19,427 | 19,927 |
| | 6,486 | 9,338 | 13,528 | 15,421 | 15,471 | 15,521 | 14,985 | 16,985 | 17,985 | 18,985 | 19,485 | 19,985 |
| **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 | 24% | 11% | 4% |
| MG&A | NA | NA | NA | NA | NA | NA | NA | NA | NA | 91% | 59% | 37% |
| Operating Income (loss) | NA | NA | NA | NA | NA | NA | NA | NA | NA | -24% | 20% | 50% |
| Net Income | NA | NA | NA | NA | NA | NA | NA | NA | NA | -16% | 13% | 33% |
| **Financial Indicator Growth Analysis (YoY%)** | | | | | | | | | | | | |
| Total Revenue | NA | NA | NA | NA | NA | NA | NA | NA | NA | 107% | 59% | 68% |
| R&D | -18% | -15% | -91% | -4% | 126% | 172% | 42% | -15% | 1% | -8% | -25% | -35% |
| SG&A | 16% | -2% | -67% | 9% | 7% | 10% | 8% | 9% | 9% | 8% | 7% | 7% |
| Marketing and sales | NA | NA | | | | | NA | 5% | 6% | 5% | 3% | 3% |
| Operating Loss | -10% | -11% | -83% | 0% | 80% | 115% | 31% | -8% | 75% | -65% | -233% | 313% |
| Total Other Income, net | 209% | -32% | 918% | -1838% | -88% | -87% | 783% | -106% | 0% | 0% | 0% | 0% |
| Pretax Income | -9% | -11% | -58% | -45% | 33% | 220% | 45% | -20% | 75% | -65% | -236% | 310% |
| Net Income | -9% | -11% | -58% | -45% | 33% | 220% | 45% | -45% | 75% | -65% | -230% | 310% |
| EPS | -15% | -38% | -80% | -74% | -8% | 155% | -9% | -52% | 65% | -67% | -227% | 300% |

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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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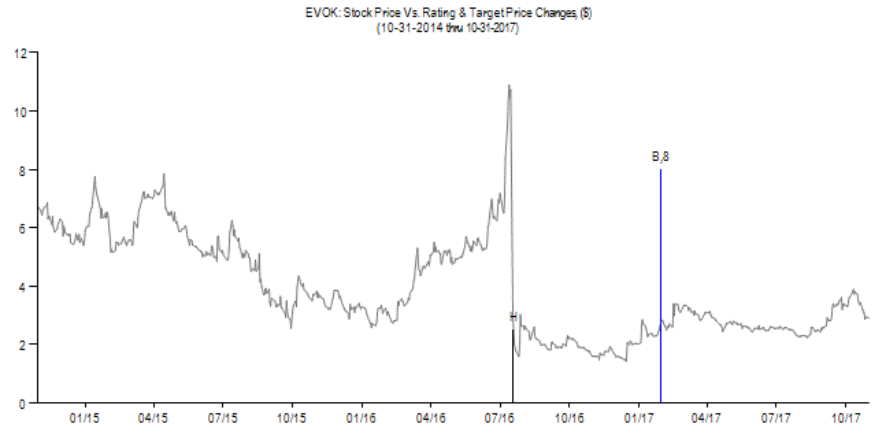


*3 Year Rating Change History*

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

*3 Year Price Change History*

| Date | Target Price ($) | Closing Price, ($) |
|---|---|---|
| 07/19/2... | | 2.47 |
| 01/30/2... | 8.00 | 2.85 |

**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. | 62.50% | 31.25% | 2.08% |
| **Hold (H)** | Expected returns to be in line with the sector average over 12 months. | 6.25% | 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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## ADDITIONAL DISCLOSURES

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