



AEGIS CAPITAL CORP

November 19, 2013

Key Metrics

EVOK - NASDAQ	\$8.15
Pricing Date	Nov 18 2013
Price Target	\$60.00
52-Week Range	\$14.25 - \$7.73
Shares Outstanding (mm)	5.8
Market Capitalization (\$mm)	\$47.3
3-Mo Average Daily Volume	89,203
Institutional Ownership	NA
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$(3.53)
Price/Book	(2.3)x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS (\$) FY: December

	2012A	Prior 2013E	Curr. 2013E	Prior 2014E	Curr. 2014E
1Q-Mar	--	--	--	--	(0.37)E
2Q-Jun	--	--	--	--	(0.53)E
3Q-Sep	--	--	(0.41)A	--	(0.69)E
4Q-Dec	--	--	(0.13)E	--	(0.70)E
FY	(1.79)	--	(0.55)E	--	(2.20)E
P/E	NM		NM		NM



Source: BigCharts.com

Company Description:

Evoke Pharma, Inc. (<http://www.evokepharma.com/>) is an emerging specialty pharmaceuticals firm headquartered in San Diego, CA.

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Initiating Coverage

Evoke Pharma, Inc.

Rating: Buy

Marching Metoclopramide Forward

Investment Highlights:

- Initiating Coverage.** We are initiating coverage on Evoke Pharma, Inc. with a Buy rating and an 18-month price target of \$60.00 per share. In our view, this firm represents one of the most risk-mitigated development-stage investment opportunities available in the healthcare sector. Evoke is preparing to start a pivotal Phase 3 trial with its sole product candidate, EVK-001. This agent is an intranasal formulation of metoclopramide, a drug that was originally approved in 1979 for diabetic gastroparesis, a disorder that involves disruption of the motility of the upper gastrointestinal (GI) tract. Evoke has obtained sanction from the FDA indicating that positive data from a single pivotal trial would be sufficient to support a regulatory filing and potentially obtain approval for the drug. Since the compound in question is already approved for the same indication in which Evoke is aiming to test it, this program seems a low-risk proposition. We expect the ~200-patient, randomized, placebo-controlled trial to begin enrollment early in 2014.
- Attractive Valuation.** Evoke Pharma went public in September 2013 at an enterprise value of ~\$50mm, raising \$25.2mm in gross proceeds from the sale of 2.1mm shares at \$12.00 per share. The IPO was underwritten by Aegis Capital Corp. as sole book runner. Total proceeds from the IPO following the exercise in full of the underwriters' over-allotment option were ~\$29mm. Currently, the stock trades at an enterprise value of under \$30mm. In our view, this is extremely cheap considering the fact that the firm is entering Phase 3 development with a proprietary formulation of an existing drug and could potentially generate pivotal data in mid-2015, file for approval in late 2015 / early 2016 and reach the market in late 2016. We believe that Evoke's intranasal metoclopramide formulation could generate over \$400mm in peak annual sales. This translates into a risk-adjusted Net Present Value (rNPV) of roughly \$480mm, assuming patent expiration in 2030.
- Solid Niche Market.** Investors should take note, in our view, of the fact that ~4mm metoclopramide prescriptions are written every year. The oral version of the drug is generically available, but is associated with various side effects, including tardive dyskinesia (TD), a form of involuntary movement. Evoke believes that its intranasal formulation could show superiority over the product profile of the orally-bioavailable generic competitors.

Investment Thesis

Evoke Pharma, Inc. is a specialty pharmaceuticals firm developing a novel intranasal formulation of metoclopramide for diabetic gastroparesis. The company is developing a novel, intranasally-administered form of metoclopramide, a drug that has been used for several decades in oral form as the only FDA-approved therapy for diabetic gastroparesis – a debilitating and painful paralytic condition of the upper gastrointestinal (GI) tract that is a co-morbidity of both Type 1 and Type 2 diabetes. In earlier trials of the intranasal formulation of metoclopramide (EVK-001), it was observed that this route of administration permitted a superior safety profile and potentially better efficacy vs. the oral formulation. Evoke's management licensed the rights to the intranasal formulation of metoclopramide in 2007, and have conducted the largest proof-of-concept trial ever performed in diabetic gastroparesis. This was a 287-patient trial that enrolled men and women with diabetic gastroparesis. It benchmarked 10mg and 14mg doses of intranasal metoclopramide against placebo over a four-week treatment period. In this trial, intranasal metoclopramide met statistical significance in a pre-specified subgroup analysis that solely assessed female subjects enrolled into the trial. These individuals made up 69% of the overall trial population. Evoke is currently preparing to conduct a single pivotal Phase 3 trial with intranasal metoclopramide in order to obtain a label for the drug in treatment of diabetic gastroparesis. Given the fact that over two-thirds of diabetic gastroparesis sufferers are women, and considering the litany of GI tract drugs that show a gender disparity effect, we believe that Evoke's clinical trial initiative has a high likelihood of generating positive results and that the intranasal metoclopramide formulation has a substantial probability of commercial success. The side effect profile of metoclopramide is extremely well-known and we believe that Evoke could file for approval of its intranasal formulation of the drug with only data from one pivotal Phase 3 trial in addition to the results previously generated in the Phase 2b study. Further, since metoclopramide has been approved for over 30 years to treat diabetic gastroparesis, we believe that Evoke would be able to file for approval via the simplified 505(b)(2) pathway and would not be required to face an advisory panel vote prior to regulatory approval in the U.S. The firm's intranasal formulation of metoclopramide is covered by U.S.-issued patents that expire in 2021 – 2030 without patent term extensions.

We are initiating coverage on EVOK with a Buy rating and an 18-month price target of \$60.00 per share, implying a total firm value of \$600mm, assuming 10mm shares outstanding as of mid-2015. An investment in EVOK may involve above-average risk and volatility, since the firm is still a development-stage entity.

Investment Positives

Risk-Mitigated Drug Profile. Metoclopramide, in our view, is one of the most risk-mitigated drug development opportunities we have seen. The oral version has been approved since June 1985, generates millions of prescriptions annually and is known to be effective for the same indication in which Evoke Pharma aims to deploy its intranasal formulation. In our view, the firm could move EVK-001 through Phase 3 development within the next 18 months and potentially secure approval in the U.S. by late 2016.

Multiple Near-Term Value Drivers. Evoke is slated to initiate a single pivotal trial in early 2014; close enrollment in this trial in the third quarter of 2014; and release top-line data in mid-2015. We expect the firm to file for approval of EVK-001 in late 2015.

Capital-Efficient Business Model. As of September 30th, 2013, Evoke Pharma had recorded an accumulated deficit of roughly \$21 million since inception in 2007. In our view, the fact that the firm has burned so little money since inception is extremely encouraging. We would point investors to the fact that management has guided towards the cost of a pivotal trial program in diabetic gastroparesis as being under \$15 million. In

the recently-completed IPO on the NASDAQ Capital Market, Evoke raised \$25.2 million in gross proceeds (not including the over-allotment). From our perspective, these funds should be sufficient to sustain operations through to the filing of a New Drug Application (NDA) for intranasal metoclopramide (EVK-001) in the U.S.

Significant M&A Precedent. We would also draw investors' attention to the fact that there have been several recent M&A transactions in the GI tract sector that involved agents treating various GI tract motility disorders. In our view, if Evoke Pharma can successfully generate positive pivotal data in the diabetic gastroparesis market, it could potentially become the subject of an acquisition transaction involving one of the more-established specialty pharmaceuticals firms seeking to bolster their flagging pipelines. However, even if such a transaction never materialized, we believe that the Evoke management team would be able to launch intranasal metoclopramide in the U.S. independently using a contract-based specialty sales force.

Investment Risks

Financial Outlook and History of Unprofitable Operations. Evoke Pharma has incurred operating losses since its inception and, in our view, may not achieve sustainable profitability for several years. Although the firm has been able to obtain capital in order to fund its operations, it is not known whether the company will be able to continue this practice, or be able to obtain other types of financing to meet operating needs. While the company recently managed to successfully raise \$25.2 million through an initial public offering (IPO) to support the advancement of its lead pipeline drug candidate in the U.S., which in our view removes any financing overhang for at least 12 – 15 months, we believe that any additional broadening of the clinical-stage pipeline could require additional capital. Furthermore, the company is expected to expend significant resources on the pivotal trial program for its lead candidate, EVK-001. Although the funds raised in the IPO should be sufficient to cover these expenses, we note that Evoke Pharma would likely have to raise significant additional capital in order to support commercialization if it elects to launch the product independently. Given these factors, shares of Evoke Pharma may constitute above-average risk and volatility, in our opinion.

FDA Unpredictability. Drug development is a multi-year process that requires human clinical trials prior to market entry. The agency may require more clinical data from Evoke Pharma prior to granting approval for any of its regulatory applications, necessitating further trials. Review times at the FDA may prove longer than expected. Also, the agency could elect not to accept Evoke Pharma's regulatory filings petitioning for approval of EVK-001. If clinical data and/or other supporting evidence are not accepted or considered insufficient grounds for approval, marketing authorization for Evoke's only drug candidate could be delayed or might not occur at all, preventing the firm from realizing the commercial potential of its lead program.

Partnership Risk. Evoke Pharma has embarked upon a development path that involves focusing on clinical advancement of its lead drug candidate in diabetic gastroparesis, while eschewing an emphasis – at least for the time being – on building commercial infrastructure and becoming a fully-integrated specialty pharmaceuticals company. The firm aims to optimize the commercialization of its lead program by either partnering this agent with an established firm in the healthcare sector or launching the drug independently with a specialty sales force. This introduces several elements of risk from a partnering perspective – the possibility that the company's partnership deals may not involve terms that are lucrative enough to justify the investment that Evoke has made in the development of its lead agent; the possibility that Evoke's partners do not invest sufficiently in the commercialization of Evoke's products; and the risk that the firm's partners may not be the best-positioned competitively to ensure maximal penetration of Evoke's only drug into their target markets. Furthermore, should Evoke fail to attract a

partner at all, the company would have to raise substantial additional capital to fund the establishment of a proprietary sales force or the hiring of a contract sales force. Such infrastructure may not be capable of supporting the successful launch of EVK-001.

Insufficient Diversification Risk. While we view Evoke Pharma as a risk-mitigated investment opportunity because of the fact that metoclopramide in its oral form has been approved and prescribed for treatment of diabetic gastroparesis over many years, we note that the firm does not have a pipeline beyond EVK-001, its proprietary intranasal formulation of metoclopramide. Accordingly, therefore, if EVK-001 fails to demonstrate statistically significant efficacy and acceptable safety and tolerability in the envisaged pivotal trial program, Evoke Pharma may find itself without strategic options.

Competitive Landscape. Evoke Pharma is aiming to compete with other companies within the drug industry, many of which have more capital, more extensive research and development capabilities, and greater human resources. Some of these competitors include AstraZeneca, GlaxoSmithKline, Ironwood Pharmaceuticals and Salix Pharmaceuticals. These companies all have drugs already on the market for various GI tract disorders and many of their franchises are well-entrenched. In addition, these competitors may develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any products or processes that Evoke Pharma may be capable of developing. Finally, there are several generic versions of orally-bioavailable metoclopramide already on the market, with more potentially being launched in the coming years. Purveyors of these generics are likely to engage in aggressive pricing in order to secure market share, which may make it difficult for Evoke Pharma and / or its partners to establish a niche for EVK-001.

Intellectual Property Risk. The company relies on patents and trade secrets to protect its products from competition. A court might not uphold Evoke Pharma's intellectual property rights, or it could find that Evoke infringed upon another party's property rights. In addition, generics firms could potentially find loopholes in Evoke's intellectual property estate, which may enable them to launch generic versions of EVK-001 and/or other pipeline candidates prior to the expiration of patent protection.

Reimbursement Risk. Following the institution of broad-based healthcare reform policy, reimbursement agencies have grown more wary of systematically reimbursing for drugs that are either unnecessary or provide marginal benefit at excessive cost. If Medicare spending growth continues to outpace GDP growth, and the government's ability to fund healthcare becomes impaired, changes could be made to reimbursement policy that would negatively affect Evoke Pharma, despite what we believe to be the compelling value proposition inherent in EVK-001.

Additional Risks. Following its recent IPO in September 2013, Evoke Pharma had about \$23.7 million in cash and equivalents. While the firm is not projected to burn a significant amount of cash near-term, these estimates could change if the firm began developing additional pipeline candidates beyond the current pipeline or if the firm were to be required to perform additional clinical studies beyond the envisaged pivotal trials. Other sources of cash could include: licensing fees from partnerships, warrant and option exercises, or the issuance of more shares. If EVK-001 fails to demonstrate efficacy and safety in pivotal clinical development, Evoke Pharma may not be able to raise cash at all.

Industry Risks. Emerging biotechnology and pharmaceuticals stocks are inherently volatile and increasingly subject to development and regulatory risk. Meeting or missing commercialization milestones may result in a significant change in the perception of the company and the stock price. We do not anticipate volatility subsiding in the near term.

For additional risk considerations, please refer to the company's SEC filings.

Valuation

Comparables Analysis: Given that Evoke Pharma is currently unprofitable and considering our belief that sustainable profitability is a few years away, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, it appears the stock is worth \$60.00 per share, utilizing our estimate of a ~\$480 million risk-adjusted net present value (rNPV) for EVK-001 in diabetic gastroparesis. This assumes that the shares trade in-line with the comps' present average enterprise value of ~\$540 million and that the firm has ~10 million shares outstanding (fully-diluted) and roughly \$60 million in cash as of mid-2015.

Table 1: Comparable Company Analysis
(Millions, Except Per-Share Data)

Development stage	Therapeutic focus	Company	Ticker	Rating	Closing price (11/18/13)	Shares (MM)	Market cap (\$MM)	Cash (\$MM)	Debt (\$MM)	Enterprise value (\$MM)	
Pre-registration	CNS / Neuropsychiatry	ACADIA Pharmaceuticals	ACAD	Not Rated	\$21.03	91	1911	196	0	1715	
Phase 2 / 3	Neuropsychiatry / Pain / Ophthalmology	Ampio Pharmaceuticals	AMPE	Buy	\$8.11	42	339	32	0	307	
Pre-approval	Infectious Diseases	Durata Therapeutics	DRTX	Not Rated	\$10.75	27	286	67	19	238	
Marketed / Phase 3	Metabolic Diseases	Furiex Pharmaceuticals	FURX	Not Rated	\$38.00	10	394	35	57	416	
Phase 1 / 2	Fibrosis / Oncology	Galectin Therapeutics	GALT	Buy	\$5.90	17	100	5	0	94	
Phase 2b	Liver Disorders	Intercept Pharmaceuticals	ICPT	Not Rated	\$49.43	19	948	162	0	786	
Marketed	Pain / Inflammatory Disorders	Ironwood Pharmaceuticals	IRWD	Buy	\$10.05	121	1214	242	179	1151	
Marketed	CNS / Pain / Gastrointestinal Disorders	Progerics Pharmaceuticals	PGNX	Not Rated	\$3.75	51	193	76	0	117	
Marketed	Rare Diseases / Liver Disorders	RapTOR Pharmaceuticals	RPTP	Not Rated	\$12.02	60	717	88	50	679	
Phase 2b	Gastrointestinal Disorders	Sucampo Pharmaceuticals	SCMP	Not Rated	\$6.74	42	282	55	58	285	
Phase 3	Gastrointestinal Disorders	Synergy Pharmaceuticals	SGYP	Buy	\$4.40	90	397	82	0	315	
Phase 3	Gastrointestinal Disorders	Ventrus Biosciences	VTUS	Not Rated	\$2.89	90	261	33	0	227	
Average							588	Discrepancy			540
Current valuation	Gastrointestinal Disorders	Evoke Pharma Inc.	EVOK	Buy	\$8.15	7	56	24	0	32	
Derived 18-month target price											
Target valuation (18-month)	Gastrointestinal Disorders	Evoke Pharma Inc.	EVOK	Buy	\$60.00	10	603	60	0	Projected 540	

Source: First Call and Aegis Capital Corp. estimates

Free Cash Flow: We estimate that Evoke Pharma is likely to be free cash flow negative for the foreseeable future. We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value (rNPV) framework to derive our \$60.00 price target. This approach is described further in the next section of the report.

Our detailed analysis is split into five principal components – our discounted cash flow model including the rNPV assessment of EVK-001 (presented overleaf); our assessment of the market for this agent and the associated sales model for the drug; the residual value of EVK-001's potential applicability in other GI tract motility and nausea-related disorders; and the near-term financial outlook for the company. Our historical income statement and financial projections are presented at the back of this report.

Risk-Adjusted Net Present Value Analysis

We have projected the total firm value for Evoke Pharma Inc., based on a sum-of-the-parts valuation of the firm's lead drug candidate in diabetic gastroparesis, calculated using a risk-adjusted Net Present Value (NPV) approach; the rNPV of this candidate in certain other GI tract motility and nausea-related disorders; and the projected cash position as of mid-2015. Peak annual global sales for the firm's lead drug candidate, intranasally-administered metoclopramide, are projected to be ~\$410 million in aggregate. These yield a total risk-adjusted NPV of \$480 million (see Table 2 below), factoring in a 40% effective tax rate, 30% marketing offset and 15% discount rate.

Table 2: Composite Risk-Adjusted Net Present Value Analysis

EVK-001 - U.S. Only	
Total diabetic gastroparesis patients ¹	16MM
Patients seeking treatment ²	1.4MM
Peak market share ³	35%
Treatment revenue/prescription/course of therapy ⁴	\$920
Peak sales ⁵	\$410MM
Launch ⁶	2016
Peak sales year	2023
Protection expires ⁷	2032
Discount rate	15%
Probability of success ⁸	90%
Risk-adjusted NPV ⁹	\$480MM
NPV per share	\$50.00
Estimated Net Cash Position (\$MM; mid-2015)	\$60MM
Additional Value Drivers (usage of EVK-001 in other GI tract disorders)	\$50MM
Total enterprise value	\$600MM
Shares Outstanding (MM; mid-2015)	10MM
Present value-derived price target	\$60.00
<u>Notes on assumptions:</u>	
¹ Adult diabetic gastroparesis patients - only United States market (Source: National Institute of Health, Centers for Disease Control and Prevention)	
² Patients prescribed only oral metoclopramide currently (not other gastroparesis medications) (Source: Aegis Capital Corp. estimates)	
³ Peak market share - blended; factoring in competition from oral metoclopramide generics	
⁴ Revenue/year/prescription - projected \$6/day (\$9 - \$15 range from Evoke); average of 120 days on therapy; 3% annual price increases	
⁵ Peak sales - treatment revenue/year x treated patients x peak market share	
⁶ Launch in late 2016 / early 2017	
⁷ Patent expiry starting in 2030; Hatch-Waxman extensions may provide up to an additional five years of protection	
⁸ Probability of success - oral metoclopramide approved for diabetic gastroparesis; EVK-001 has positive Phase 2b data; starting Phase 3	
⁹ Cash flow fully taxed at 40% following launch; net operating loss carry-forwards are estimated to offset tax liability until 2020	

Source: Company reports; Aegis Capital Corp. estimates

If successful in pivotal development with EVK-001, we believe that Evoke Pharma could be acquired by a larger firm either prior to EVK-001 approval or shortly thereafter. Several prior precedent transactions in the GI tract disorders space could be possible comps to what Evoke Pharma could command in a takeout if EVK-001 succeeds in Phase 3 trials. These transactions include the \$2.6 billion acquisitions of Santarus in November 2013 and the \$300 million acquisition of Oceana Therapeutics in November 2011, both by Salix Pharmaceuticals.

The GI tract disorders market is highly competitive. Several well-established pharmaceutical companies – such as AstraZeneca, Novartis, and Salix – currently possess significant GI tract disorders franchises. In addition, we note that various drug makers such as AWD Pharma, Novel Laboratories, Sanofi S.A., and Valeant Pharmaceuticals International all make versions of oral metoclopramide. The drug is available worldwide under various trade names, including Afipran[®] (Norway), Cerucal[®] (AWD Pharma), Clopamon[®] (Aspen, South Africa), Contromet[®] (Adcock-Ingram, South Africa), Degan[®] (Lek), Maxeran[®] / Plasil[®] / Primperan[®] (Sanofi) Pramin[®] (Rafa, Israel), Pulin[®] (Malaysia), Reglan[®] (Schwarz Pharma in the USA), and Tomit[®] (Indonesia).

Company Overview

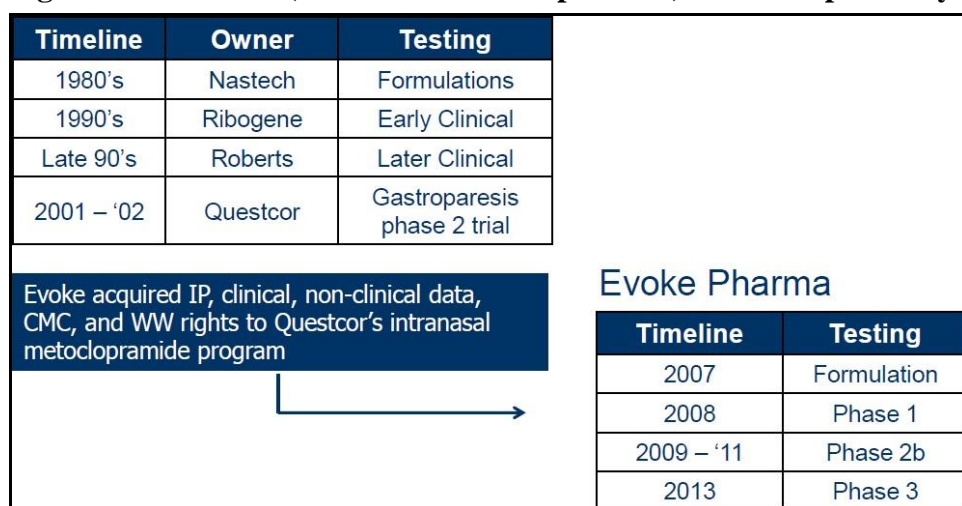
Evoke Pharma is a development-stage specialty pharmaceuticals firm developing a novel, intranasal formulation of metoclopramide to treat diabetic gastroparesis. The company was founded in California and incorporated in the State of Delaware on January 29, 2007.

EVK-001 Development History

The intranasal version of metoclopramide that Evoke obtained had initially been formulated by Nastech Pharmaceutical Co., a firm that specialized in developing nasal spray-based formulations of various small molecule and peptide drugs. In the 1980s, following the approval of oral metoclopramide in June 1985, Nastech developed a proprietary formulation of metoclopramide for intranasal administration and subsequently licensed this candidate to a firm called RiboGene, Inc., which performed early clinical development and then licensed the drug to Roberts Pharmaceutical Corp. in July 1998.

RiboGene contracted with Roberts to develop the intranasal metoclopramide formulation, which was at the time known by the trade name Emitasol[®], and granted Roberts an option to exclusively market the product in the U.S., Canada and Mexico. The intranasal dosing of Emitasol[®] was originally intended for both the prevention and treatment of chemotherapy-induced emesis, particularly the market for delayed-onset emesis (defined as nausea and vomiting occurring 24 to 72 hours after chemotherapy). Under the terms of that initial agreement, RiboGene was to provide up to \$7 million in funding for the development of Emitasol[®] through completion of Phase 3 development and the submission of a New Drug Application (NDA) with the balance of costs, if any, to be provided by Roberts. Upon approval, Roberts would have been eligible to exercise its option to market Emitasol[®] under the RiboGene patents by making a milestone payment of \$10 million plus subsequent undisclosed royalties on product sales.

Figure 1: EVK-001 (Intranasal Metoclopramide) Ownership History



Source: Company reports, Evoke Pharma, Inc.

Shortly after RiboGene licensed Emitasol to Roberts, Shire Pharmaceuticals Group plc entered into a merger with Roberts in a transaction involving a tax-free exchange of Shire shares. The merged firm's key development projects included Reminyl[®] (galantamine) for Alzheimer's disease, Dirame[®] (propiram) for analgesia, Lambda[®] (lanthanum phosphate) for hyperphosphatemia, and RL0903 (GnRH implant) for prostate cancer, along with Emitasol[®], which thus became one of five candidates that the merged company had in Phase 3 development at the time. However, in the aftermath of this

transaction, Shire elected not to pursue the development of the intranasal metoclopramide product candidate in the nausea indication and, in July 2001, the exclusive option to develop and market the drug that Roberts had originally held expired.

The rights to Emitasol[®] were assumed by Questcor Pharmaceuticals, which had merged with RiboGene. In the same time frame that Questcor regained the North American rights to Emitasol[®] from Shire, four licensing agreements for the marketing of the drug had been established in Italy, Austria, Poland, Czech Republic, Russia, Hungary, Slovak Republic, South Korea and Chile. Intranasal metoclopramide was launched in Italy as Pramidin, and was distributed by Crinos to treat a variety of gastrointestinal disorders and emesis. The drug was partnered with CSC Pharmaceuticals Handels GmbH in Austria, Poland, the Czech Republic, Russia, Hungary and the Slovak Republic, and with Laboratorios Silesia S.A. in Chile. In December 2000, Questcor inked a partnership agreement with Ahn-Gook Pharmaceuticals for intranasal metoclopramide to be marketed under the trade name Emitasol[®] in Korea. Ahn-Gook also signed an agreement with Crinos to obtain the intranasal metoclopramide finished product. Subsequently, Ahn-Gook obtained regulatory approval of Emitasol[®] in Korea and also expanded its relationship with Questcor to include 12 additional Asian territories in 2003.

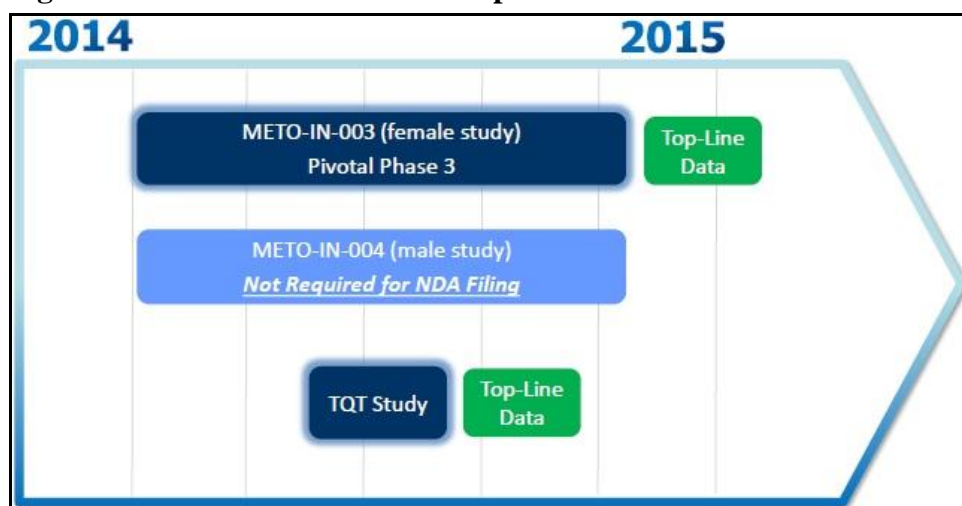
Evoke Pharma Licensing Transaction – Intranasal Metoclopramide

In June 2007, Evoke licensed in the worldwide rights, data, patents and other related assets associated with EVK-001 from Questcor Pharmaceuticals. The firm paid Questcor \$650,000 in the form of an upfront payment, and will be required to make additional development- and sales-related milestone payments totaling up to \$52 million, including up to \$5 million in payments if EVK-001 achieves the following development targets:

- \$0.5 million upon initial dosing in the proposed EVK-001 U.S. pivotal trial;
- \$1.5 million upon the FDA's acceptance for review of an NDA for EVK-001
- \$3 million upon the FDA's approval of EVK-001

The remaining \$47 million in milestone payments depend on EVK-001's commercial success and will only apply if EVK-001 receives regulatory approval. In addition, Evoke is required to pay Questcor a low single-digit royalty on net sales of EVK-001 if it is successfully commercialized. Evoke's obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, slated to occur in 2030.

Figure 2: EVK-001 Clinical Development Timeline

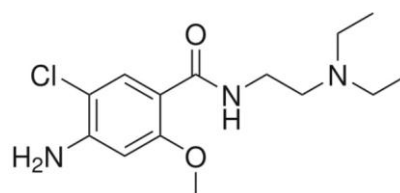


Source: Evoke Pharma, Inc.

EVK-001 Overview

Evoke Pharma's lead drug candidate is a proprietary, intranasal formulation of metoclopramide. This molecule was first described by Dr. Louis Justin-Besançon and Charles Laville in 1964¹. A member of the benzamide family, it comes from a class of organic compounds rich in pharmacological activity, which includes analgesics, anti-emetics, and anti-psychotics². Metoclopramide binds to dopamine D₂ receptors with nanomolar affinity (K_i 28.8nM), where it works as an antagonist³, and is also a mixed serotonergic 5-HT₃ antagonist / 5-HT₄ agonist. This is a well-known drug that was originally approved in the U.S. as an oral tablet and intravenous injection in 1979 and which is still used globally. The chemical structure of metoclopramide is depicted below.

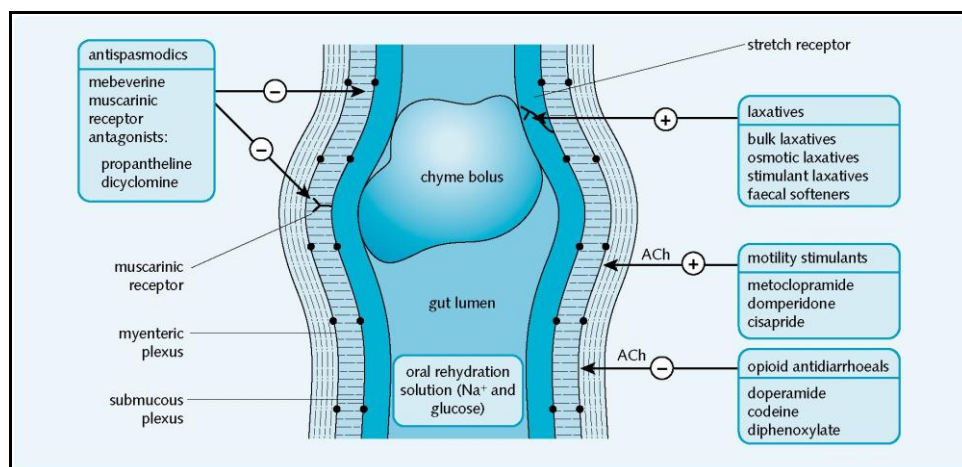
Figure 3: Metoclopramide Chemical Structure



Source: ADIS R&D Insight

The figure below shows metoclopramide's positioning vs. other motility-inducing agents. Like other prokinetic agents, it works via the modulation of the dopaminergic pathway to stimulate the peristalsis of the jejunum and duodenum, increase the tone and amplitude of gastric contractions, and relax the pyloric sphincter and duodenal bulb⁴. These gastroprokinetic effects make metoclopramide useful in the treatment of gastric stasis.

Figure 4: Gastric Motility Medication Pathways



Source: Crash Course – Gastrointestinal Motility (2008)

Due to the fact that its pharmacology profile is promiscuous, metoclopramide is associated with a litany of side effects, including restlessness (akathisia) and focal dystonia. Infrequent side effects include blood pressure changes, hyperprolactinaemia leading to galactorrhea, constipation, depression, headache, and extrapyramidal effects. Rare but serious side effects that have been associated with this agent include

¹ Justin-Besançon and Laville, Biology Society Annals 158: 723-727 (1964)

² Sigma-Aldrich

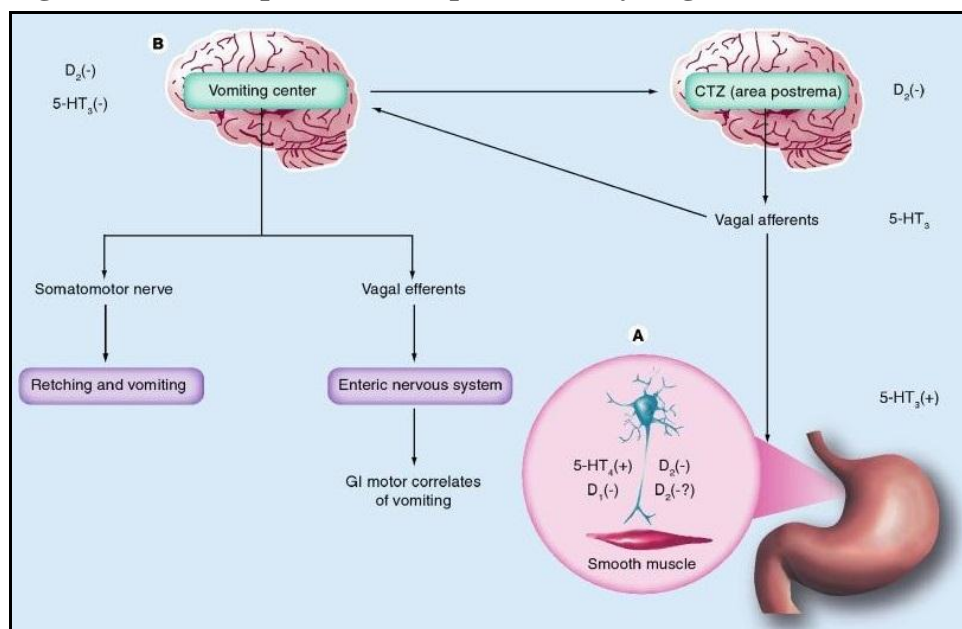
³ Matsui *et al.*, Journal of Pharmacology & Exp. Therapeutics 287: 725-732 (1998)

⁴ Lee and Kuo, Expert Review of Endocrinology & Metabolism 5: 653-662 (2010)

agranulocytosis, supraventricular tachycardia, hyperaldosteronism, neuroleptic malignant syndrome, akathisia and tardive dyskinesia (TD). A potentially irreversible and disfiguring disorder characterized by involuntary movements of the face, tongue, or extremities, TD is one of the most concerning side effect issues with metoclopramide. Although the risk of TD as a result of metoclopramide use has not been extensively studied, one published study reported a TD prevalence of 20% among patients treated for at least three months⁵. Prevalence is highest among the elderly, especially women, yet it is impossible to predict who will develop the condition. Both the risk of syndrome emergence and the likelihood of irreversibility may increase with therapy duration and the total cumulative dose. There is no known effective treatment for established cases of TD, although the syndrome may remit, partially or completely, within several weeks-to-months after metoclopramide is withdrawn. Metoclopramide itself, however, may suppress the signs of tardive dyskinesia, thus masking the underlying disease process.

Metoclopramide stimulates gut motility by affecting different receptors in the GI tract. Most importantly, it acts as an antagonist of the dopamine D₂ receptor subtype. Dopamine has a direct relaxant effect on the gut by activating muscular D₂ receptors in the lower esophageal sphincter and stomach (fundus and antrum). It also inhibits acetylcholine release from intrinsic myenteric cholinergic neurons by activating pre-junction D₂ receptors, indirectly inhibiting the smooth musculature. The drug promotes gut motility at a molecular level via three mechanisms: inhibition of pre-synaptic and post-synaptic D₂ receptors; stimulation of presynaptic excitatory 5-HT₄ receptors; and antagonism of pre-synaptic inhibition of muscarinic receptors⁶. This promotes release of acetylcholine, which in turn leads to increased lower esophageal sphincter (LES) and gastric tone, increased intra-gastric pressure, improved antroduodenal coordination and accelerated gastric emptying. Overall, metoclopramide leads to increased gastric emptying by enhancing antral contractions, as well as decreasing post-prandial fundus relaxation. However, its prokinetic properties are limited to the proximal gut. The figure below depicts the receptors on which metoclopramide acts to exert GI tract control.

Figure 5: Metoclopramide Receptor Pathway Regulation



Source: Medscape

⁵ Food and Drug Administration [press release dated February 26, 2009]

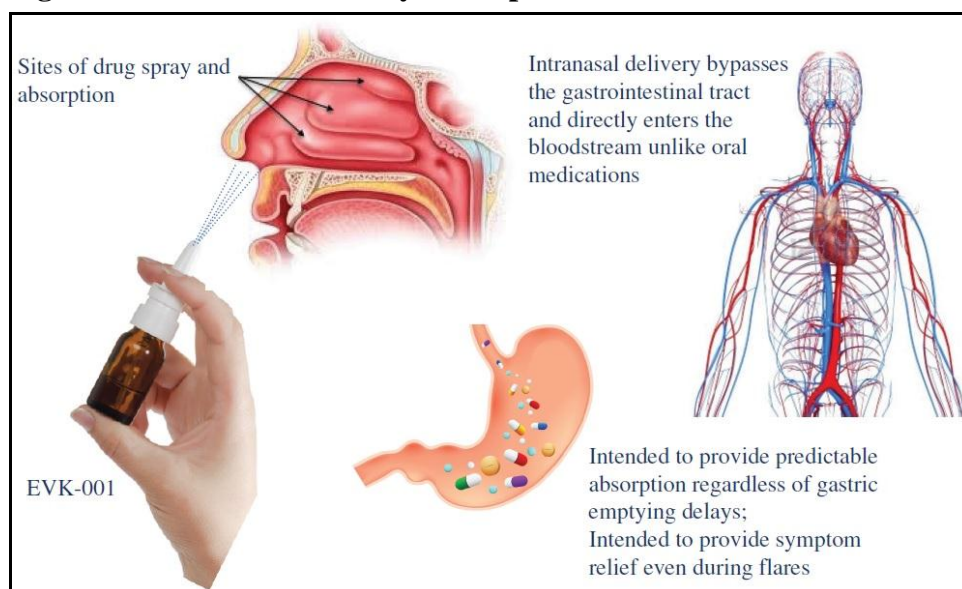
⁶ Tonini *et al.*, *Alimentary Pharmacology & Therapeutics* 19: 379-390 (2004)

The intranasal delivery of metoclopramide was first promulgated as a way to accelerate the onset of the drug's therapeutic activity and also to avoid off-target effects associated with first-pass metabolism, which occurs when the drug is administered in oral form. Metoclopramide undergoes first-pass hepatic metabolism and exhibits significant individual variation in metabolism. The drug is partially metabolized by the cytochrome P450 (CYP) system. It is primarily metabolized via the CYP2D6 isoform and to a lesser extent by CYP3A and CYP1A2⁷. Oral bioavailability ranges from 30% – 100%, while approximately 20% – 30% of the drug is excreted unchanged in the urine⁸. Impaired clearance of the drug is seen in cirrhosis as well as renal insufficiency.

Inter-individual differences in the genotype and phenotype of CYP2D6 may increase the risk for complications from metoclopramide, including the aforementioned TD⁹. Moreover, metoclopramide acts not only as a substrate for CYP2D6, but also as a competitive inhibitor of the enzyme. This is similar to other neuroleptic agents, such as haloperidol, thioridazine, chlorpromazine, perphenazine and risperidone¹⁰. As a result, concomitant use of metoclopramide with a neuroleptic agent may increase the bioavailability of each drug and lead to an increased risk of TD.

Nastech originally developed an intranasal formulation of metoclopramide to permit rapid absorption and reduce the risk of off-target side effects due to unpredictable patient-to-patient variations in the metabolism of the drug. As shown below, the spray-based delivery of metoclopramide into the nasal passages permits the drug to come into contact with the nasal mucosa, where it is absorbed and transported directly into the bloodstream.

Figure 6: Intranasal Delivery Concept



Source: Evoke Pharma, Inc.

The intranasal formulation of metoclopramide is likely to have three key advantages vs. oral formulations: a) faster onset of action; b) predictability of absorption due to avoidance of first-pass metabolism; and c) flexibility and ease of use as a step-down from intravenous injections, because the intranasal formulation retains the rapidity of action onset that the injection-based formulations of metoclopramide possess.

⁷ Desta *et al.*, Drug Metabolism & Disposition 30: 336-343 (2002)

⁸ Bateman. Clinical Pharmacokinetics 8: 523-529 (1983)

⁹ Muller *et al.*, Pharmacogenomics Journal 4: 77-87 (2004)

¹⁰ Shin *et al.*, Drug Metabolism & Disposition 27: 1078-1084 (1999)

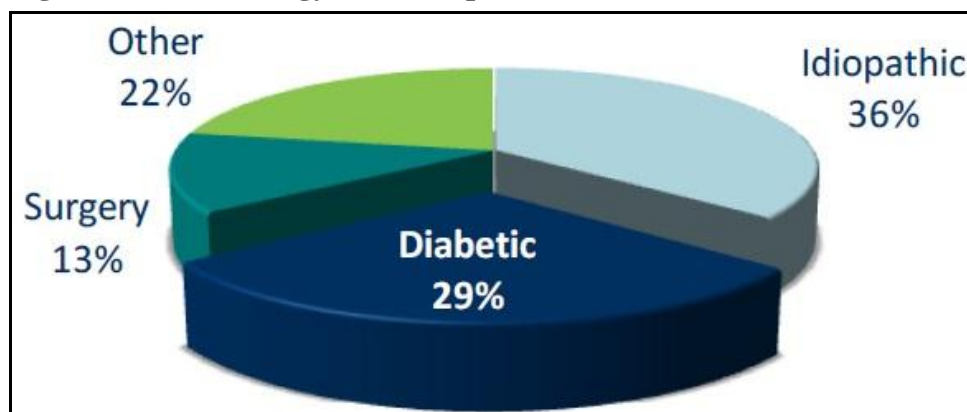
Diabetic Gastroparesis

Gastroparesis – also called delayed gastric emptying – is a condition consisting of paresis (partial paralysis) of the stomach, resulting in the retention of food in the stomach for a longer period of time than normal. Typically, the stomach contracts to move food down into the small intestine for digestion. The vagus nerve controls these contractions. Gastroparesis could ensue under conditions in which the vagus nerve is damaged and the muscles of the stomach and intestines do not work normally. Food then moves slowly or stops moving through the digestive tract. While gastroparesis can be the result of uncontrolled diabetes, gastric surgery with vagus nerve injury, reactions to medicines like narcotics and certain antidepressants, Parkinson's disease, multiple sclerosis (MS), or rare diseases like amyloidosis or scleroderma, it may also occur idiopathically.

Epidemiology

It is projected that over five million diabetic individuals suffer from some form of gastroparesis. Roughly half of all Type 1 diabetes sufferers exhibit symptoms of reduced or arrested gastric motility, while approximately 30% of patients with Type 2 diabetes experience this condition. Furthermore, roughly 12 million individuals are estimated to suffer from gastroparesis of non-diabetic etiology. Standardized rating scales can be used to diagnose the condition and evaluate the severity of gastroparesis symptom severity.

Figure 7: U.S. Etiology of Gastroparesis



Source: Centers for Disease Control and Prevention (CDC)

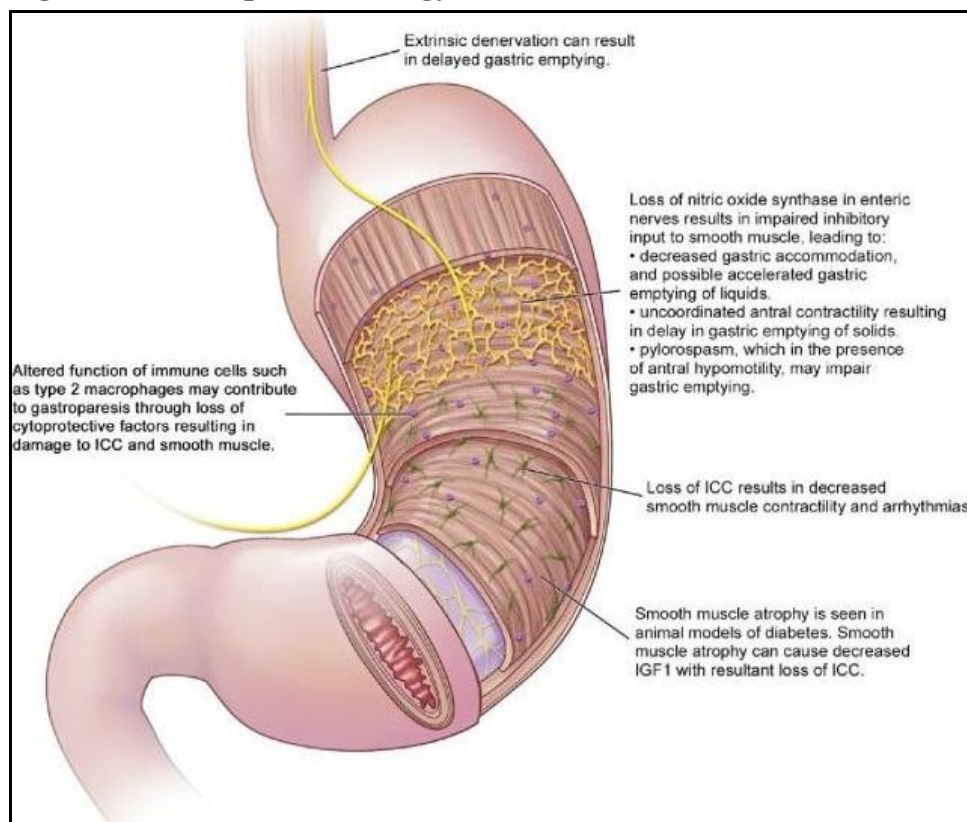
A particularly striking feature of this type of condition is its gender disparity – the disease is considered to afflict four times as many women as men. Those whose symptoms are the most severe are also invariably women. It has been hypothesized that the female GI tract just typically has lower basal motility than the male – however, this has not been proven to place women at higher risk of developing gastroparesis.

Symptomatology

The primary symptoms of gastroparesis are nausea and vomiting. Other symptoms of gastroparesis include: bloating with or without abdominal distension, early satiety (feeling full quickly when eating), and, in severe cases, weight loss due to a reduced intake of food because of the symptoms. Abdominal pain also occurs frequently, although the cause of the pain is unclear. Reduced intake of food and restriction of the types of food that are eaten can lead to nutritional deficiencies. The disease can also exacerbate other conditions, such as poor glucose control in diabetics.

As shown in the figure below, gastroparesis develops as a result of deficient signaling capacity to the smooth muscle that drives peristaltic motion – the rhythmic contractions of the GI tract that act to move food through the esophagus, the stomach, the small intestine, and the large intestine. Deficiencies in the muscle itself can also contribute.

Figure 8: Gastroparesis Biology



Source: National Institutes of Health (NIH)

Diagnosis

Since symptom severity is not the principal driver for diagnosis and the gastric emptying time represents the main diagnostic criterion for gastroparesis, some individuals may be diagnosed with gastroparesis even though they do not have substantial symptoms. The disease can be diagnosed via X-ray, manometry, and gastric emptying scans.

Therapy

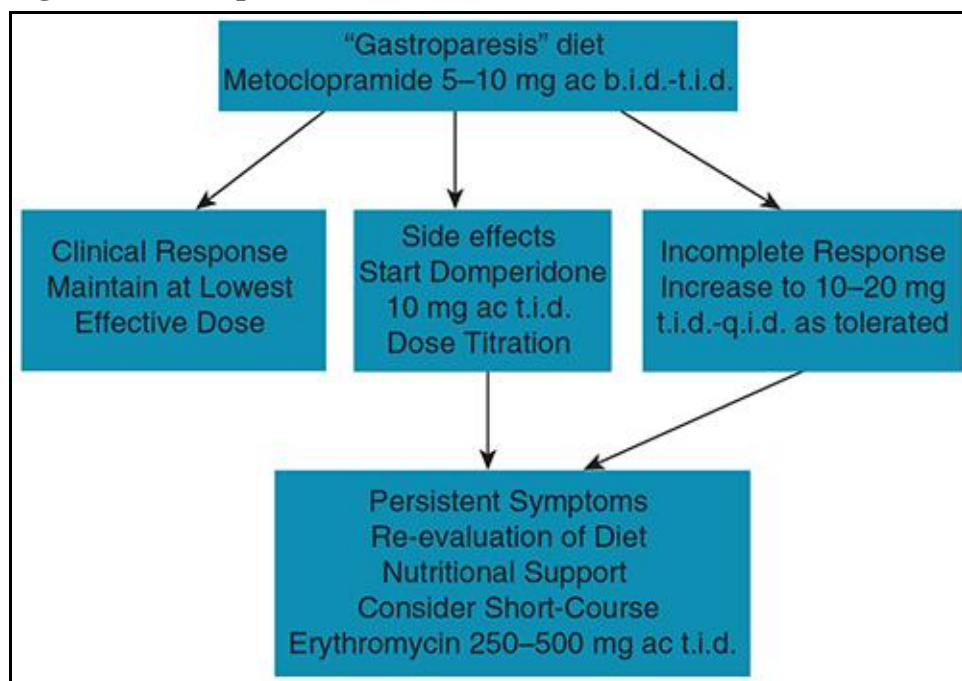
Treatment is geared towards alleviating symptoms, correcting malnutrition, and restoring adequate eating and drinking ability. Patients with severe nausea and vomiting might require hospitalization for intravenous fluid and electrolyte replacement, and prokinetic and/or antiemetic drugs may need to be administered intravenously. Glycemic control must be optimized in diabetics, since acute hyperglycemia can impair gastric motor function and inhibit the action of prokinetic drugs. In Type 1 diabetics, gastroparesis may indicate a need for insulin-pump therapy. Thus far, limited pharmacological options are available to U.S. patients. Metoclopramide remains the sole FDA-approved drug for diabetic gastroparesis, and is maintained in the guidelines of the American Gastroenterological Association (AGA) as front-line therapy. Other drugs that regulate GI tract function – e.g. proton pump inhibitors, anti-emetics, and non-dopaminergic prokinetics – are routinely employed off-label to treat gastroparesis symptoms.

Marketed Diabetic Gastroparesis Drugs

There are two basic categories of diabetic gastroparesis pharmacological interventions. The anti-emetic medications include prochlorperazine (e.g. Compromid), diphenhydramine (e.g. Benadryl, Unisom), lorazepam (e.g. Ativan), and serotonin receptor antagonists such as ondansetron (Zofran). Other agents used to combat nausea include anticholinergic drugs such as a scopolamine patch (commonly used for motion sickness), drugs used for treating nausea in cancer chemotherapy patients such as aprepitant (Emend), and medical marijuana (Marinol). These agents are primarily employed to prevent / control nausea and vomiting, but do not address other symptoms of the disease.

The second, and in our view more important, category of medications for diabetic gastroparesis are the agents that control gastrointestinal motility. These medications include cisapride, metoclopramide, domperidone and erythromycin. However, only metoclopramide and erythromycin are readily available in the U.S. market. As shown in the decision tree below, these agents are typically employed in a sequential manner, with administration being determined by the level of responsiveness to each drug. While metoclopramide is the most favored agent for chronic use, erythromycin is generally only deployed as short course therapy because of the side effect profile (skin rashes, nausea, cramping and abdominal pain) and because tachyphylaxis (buildup of tolerance) develops over time because of down-modulation of motilin receptor expression in the gut.

Figure 9: Gastroparesis Treatment Decision Tree



Source: American College of Gastroenterology

Propulsid™ (cisapride) – Johnson & Johnson

Initially introduced to the U.S. market in 1980, Propulsid™ (cisapride) was a highly successful drug upon market launch and was considered a highly effective prokinetic agent with very potent gastrointestinal tract motility-inducing efficacy. However, cisapride has been withdrawn from many markets owing to its potential to induce cardiac arrhythmias, which is probably related to its class III anti-arrhythmic properties rather than stimulation of the serotonergic (5-hydroxytryptophan / 5-HT) receptor 4 (5-HT₄).

Despite the withdrawal, cisapride's manufacturer – Janssen Pharmaceutica, a division of Johnson & Johnson – makes it available for carefully selected patients. A long Q_T interval (>450 msec), electrolyte disturbances, and concurrent use of drugs that inhibit cytochrome P450 3A4 or prolong the Q_T interval, are all contraindications to the use of cisapride, and the dose should remain as low as possible (ideally <40 mg daily).

Reglan™ (metoclopramide hydrochloride)

The initial formulations of metoclopramide were developed for intravenous administration via injection and for oral use in the form of tablets. Reglan™ was the first official brand name for the product in the U.S. Introduced first as an injection by firms such as Baxter Healthcare, the drug is currently available as a generic through firms as diverse as Actavis, Northstar Healthcare, Teva and Vantage. Hospira makes an injectable generic version of the drug as well.

Metozolv™ (metoclopramide hydrochloride orally-disintegrating tablets)

In September 2007, Salix Pharmaceuticals acquired exclusive, worldwide rights to metoclopramide-Zydis® from Wilmington Pharmaceuticals LLC. Initially, Wilmington submitted an NDA seeking approval to market Metozolv™ ODT and on February 26, 2009, Wilmington received a Complete Response Letter (CRL) from the FDA, indicating that the agency would require a Risk Evaluation and Mitigation Strategy (REMS) for Metozolv prior to approval of the NDA. In a separate action on February 26, 2009, the FDA issued a class-wide requirement for all manufacturers of metoclopramide in the U.S. to provide REMS plans for their products.

On September 8, 2009 the FDA granted marketing approval for Metozolv™ ODT (metoclopramide HCl) 5mg and 10mg orally disintegrating tablets. Metozolv™ ODT is indicated for the relief of symptomatic gastroesophageal reflux or short-term (4 – 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy and diabetic gastroparesis or the relief of symptoms in adults associated with acute and recurrent diabetic gastroparesis. In August 2011 the FDA agreed that a REMS would no longer be required for Metozolv™ ODT.

On November 3, 2010, Salix received a Paragraph IV notification from Novel Laboratories, Inc. stating that Novel had filed an Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of metoclopramide HCl ODT, 5mg and 10mg. The notification letter asserted non-infringement of U.S. Patent No. 6,413,549 (the '549 patent). Upon examination of the relevant sections of the ANDA, Salix concluded that the '549 patent would not be enforced against Novel Laboratories. On March 15, 2010, Salix received a Paragraph IV notification from Zydus Pharmaceuticals, stating that Zydus had also filed an ANDA application to seek approval to market a generic version of the Metozolv™ ODT product. Similar to the Novel ANDA, Salix observed that the Paragraph IV filing asserted non-infringement of the '549 patent and concluded, again in a manner similar to the case involving Novel, that the '549 patent would not be enforced. At this juncture, Salix does not generate substantial sales from Metozolv™ as the product has largely been cannibalized by generic competitors.

Motilium® / Motinorm Costi® / Nomit® (domperidone)

An anti-dopaminergic drug, developed by Janssen Pharmaceutica, domperidone is a specific blocker of dopamine receptors. Like metoclopramide, domperidone has both anti-emetic and prokinetic effects, although CNS reactions are uncommon since it does not effectively cross the blood-brain barrier. The drug can still influence the vomiting center in the area postrema of the medulla, which is outside this barrier. The prokinetic effects seem comparable to those of metoclopramide. Domperidone improves short-term quality-of-life in diabetic gastroparesis patients. This drug is available in Europe, Canada, South America, and Australia; though not approved by the FDA thus far, it is currently available in the U.S. under the Investigative New Drug program.

Diabetic Gastroparesis Investigational Drugs

While there are currently several therapeutic agents in development for the treatment of diabetic gastroparesis, Evoke Pharma appears to be at an advantage because it is focusing on a reformulated version of a known existing drug with proven efficacy. Evoke only requires a single successful Phase 3 trial in order to file for approval of its candidate. All of the other drugs in development are likely, in our view, to be required to conduct much larger and more onerous pivotal development programs because they are not eligible for approval under the 505(b)(2) pathway for the diabetic gastroparesis indication.

Table 3: Diabetic Gastroparesis Completed Clinical Trials

Drug	Dosage	Route	Clinical Stage	Trial Design	Trial Size	Results
Metoclopramide	10mg QID	intravenous	Phase 2	placebo-controlled	13 patients	Significant outcome improvement Cisapride promoted faster gastric emptying than metoclopramide (subsequently cisapride was withdrawn from the market)
	10mg	intravenous	Phase 2	comparator-controlled (cisapride 2.5, 5, 10mg) placebo-controlled	10 patients	
	10mg	oral / intranasal	Phase 2a	open-label, comparator-controlled	89 patients	Statistically significant improvement in total symptom score
	10mg / 14mg	intranasal	Phase 2b	placebo-controlled, randomized, double-blind	287 patients	Statistically significant improvement on mGCSI-DD (p<0.02) in pre-specified female-only subgroup
Erythromycin	200mg IV	intravenous / oral	Phase 2	placebo-controlled, randomized	10 patients	IV erythromycin improved gastric emptying times to a greater extent than oral erythromycin
	250mg TID oral	oral tablets	Phase 2	comparator-controlled (metoclopramide 10mg TID)	13 patients	Significant improvement with both drugs but greater with erythromycin
Domperidone	20mg QID	oral tablets	Phase 2b	comparator-controlled (metoclopramide 10mg QID)	93 patients	Equal effectiveness vs. metoclopramide; domperidone had less severe CNS side effects
TZP-102	10mg / 20mg	oral tablets	Phase 2b	placebo-controlled, randomized, double-blind	201 patients	No statistical significance reached for either dose on GSDD composite score in final 2 weeks of 12-week treatment period

Source: Company reports; ClinicalTrials.gov (<http://www.clinicaltrials.gov/>)

We note that there are unlikely to be other drugs in the foreseeable future that could compete with intranasal metoclopramide to the same extent as oral metoclopramide generics. In addition, the experimental therapies currently undergoing clinical testing do not, in our view, possess similar rationales supporting their mechanisms of action when compared to Evoke's candidate. Indeed, the usage of ghrelin peptide pathway modulators is likely to invite skepticism given the negative clinical data generated with the Tranzyme candidate TZP-102 in diabetic gastroparesis (see table above).

Other experimental approaches include injecting a nerve toxin to allow the stomach to release food. Botulinum toxin type A (sold primarily under the trade names Botox™ and Dysport™) is a bacterially-derived neurotoxin originally obtained from the bacterium *Clostridium botulinum*, which causes food poisoning, and is most commonly known therapeutically for its cosmetic use in treating skin wrinkles. Researchers have found that Botox injections relax the pyloric muscle in some people, thereby allowing the stomach to release more food into the small intestine. The benefits are temporary, however, and more studies are needed to determine the overall usefulness of this treatment.

There have also been investigational studies aimed at assessing the impact of implanting an electrical device in the GI tracts of patients with gastroparesis in order to control the stomach muscles. Electrical gastric stimulation uses application of a direct current to cause stomach contractions. Working much like a heart pacemaker, this “stomach pacemaker”, consisting of a tiny generator and two electrodes, is placed in a pocket that surgeons create on the stomach's outer edge. Stomach pacemakers have been shown to improve stomach emptying and reduce nausea and vomiting in some people with gastroparesis, but more studies are needed. We believe that this approach is also unlikely to obviate the need for usage of drugs like metoclopramide. The table overleaf lists ongoing trials in diabetic gastroparesis with newer investigational drugs. In our view, none of these programs is as mature as the EVK-001 initiative.

Table 4: Experimental Diabetic Gastroparesis Drugs – Competitive Landscape

Drug Name	Generic Name	Sponsor	Mechanism of Action	Target Population	Clinical Stage	Trial Size	Primary Endpoint	Status
IC351 / Cialis*	tadalafil	Eli Lilly & Co. / Duke University	PDE5 inhibitor	Adult Type 1 diabetics	Phase 4	10 patients	Improvement in gastric emptying	Data slated for December 2013
RM-131	NA	Rhythm Pharmaceuticals	Ghrelin peptide agonist	Adult Type 1 & 2 diabetics	Phase 2	185 patients	Impact on gastric emptying Change vs. baseline in gastric emptying time	Data expected in early 2014
TD-5108	velusetrag	Theravance	Serotonin (5-HT ₄) receptor agonist	Adults with diabetic or idiopathic gastroparesis	Phase 2a	32 patients	Change in gastric emptying half time	Data in early - to mid-2014
GSK962040	camicinal	GlaxoSmithKline	Selective motilin receptor agonist	Parkinson's disease patients with delayed gastric emptying	Phase 2a	70 patients	Relationship between co-administration of camicinal on L-dopa PK exposure	Data release in 2Q 2014
EVK-001	metoclopramide (intranasal)	Evoke Pharma	Dopaminergic antagonist	Adult female patients with diabetic gastroparesis	Phase 3	200 patients	Change in Gastroparesis Symptom Assessment (GSA) total score (baseline vs. week 4)	Trial slated to initiate enrollment in early 2014

Source: Company Reports; EvaluatePharma; ADIS R&D Insight; ClinicalTrials.gov (<http://www.clinicaltrials.gov/>)

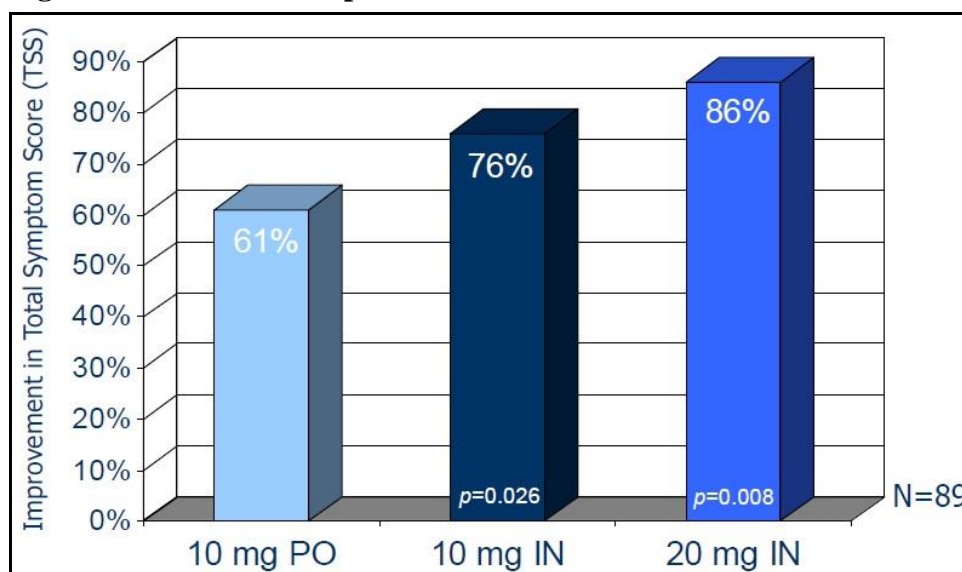
EVK-001 Clinical Data

An overview of the proof-of-concept clinical data generated thus far with EVK-001 should, in our view, indicate that the drug has robust activity in the diabetic gastroparesis indication. Evoke Pharma successfully in-licensed a substantial body of data with the drug – the principal components being a Phase 2 comparator-controlled, open-label study that enrolled 89 patients, along with issued intellectual property around the intranasal formulation, all non-clinical pharmacokinetic (PK) and pharmacodynamic (PD) data, and the relevant chemistry, manufacturing and controls (CMC) information.

Proof-of-Concept Efficacy Data

Questcor, along with its former North American collaborative partner Shire Pharmaceuticals Group plc, concluded a U.S.-based Phase 2 clinical trial with intranasal metoclopramide in diabetic gastroparesis in late 2000 and released the results of that trial in October 2000. The study showed that both the intranasal formulation and oral metoclopramide administered in tablet form were bioavailable when administered to diabetic gastroparesis patients, and also suggested that treatment using the intranasal formulation could potentially enhance the clinical response compared to the oral version.

Figure 10: Phase 2 Comparator-Controlled Clinical Data



Source: Questcor Pharmaceuticals, Inc.

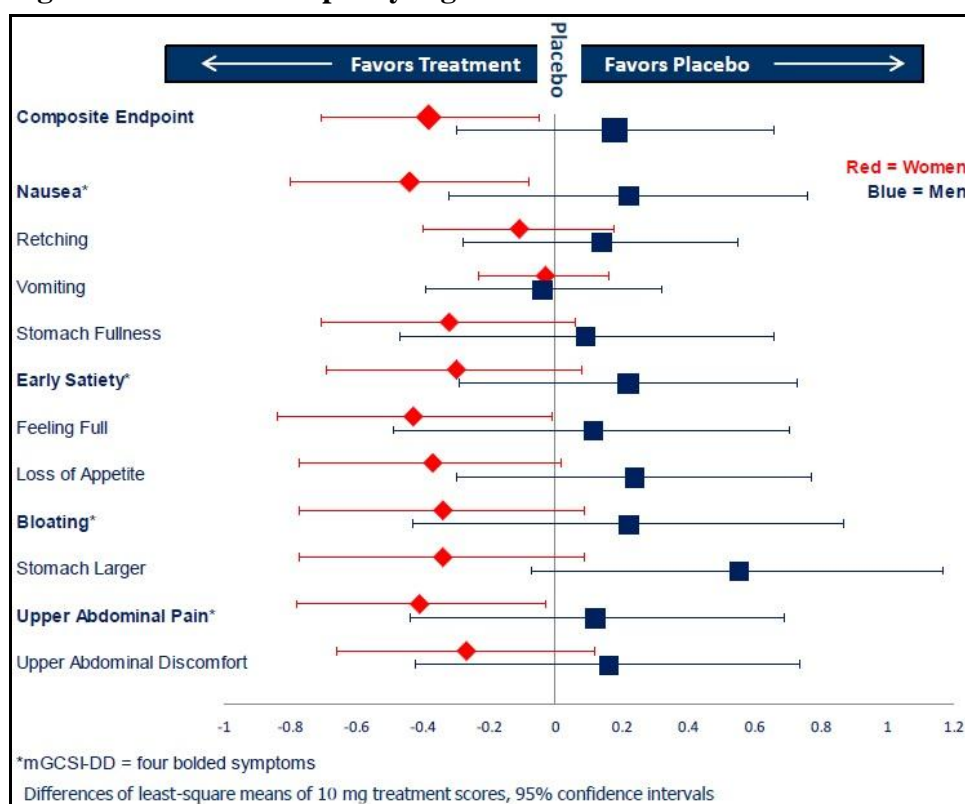
Following the in-licensing of the drug, Evoke designed and executed a large Phase 2b trial in diabetic gastroparesis. The firm wanted this trial to be as robust as possible. Accordingly, the study was a U.S.-based, multi-center, double-blinded, randomized, placebo-controlled study evaluating two doses of intranasal metoclopramide in a four-week paradigm involving single-dose administration and steady-state PK sampling.

Dosing of the drug was conducted on a *quis in die* (QID) regimen, with a single spray being dosed 30 minutes before meals and once at bedtime. The company randomized a total of 289 individuals and completed the study with 225 evaluable patients remaining. This equated to 75 subjects per group. Symptom response in this trial was measured via the modified Gastroparesis Cardinal Symptom Index – Daily Diary (mGCSI-DD). In our view, the design of this trial was crucial because it was large and well-controlled enough to provide data that, in our view, should have been sufficient to guide the appropriate assumptions concerning a pivotal clinical development program for EVK-001.

This trial, known as the METO-IN-002 study, reported a statistically significant improvement in mGCSI-DD for intranasal metoclopramide vs. placebo ($p < 0.025$) solely in women. The methodology that led to the identification of the activity of the drug in women alone represented a pre-specified analysis, and not a *post hoc* assessment. Investors have been somewhat skeptical of this data because the primary endpoint was not significant for the intent-to-treat (ITT) population due to the presence of a high placebo response in male subjects. Since the ITT population was 71% female and 29% male ($n=289$), we believe that the subgroup analysis revealing a gender disparity effect with intranasal metoclopramide can be trusted. The probability of an interaction effect between drug activity and patient gender was statistically significant ($p=0.038$).

Further, it was observed via systematic literature review that the gender difference was previously not observed in earlier controlled studies of intranasal metoclopramide, although this was most likely due to the fact that the earlier trials were underpowered and therefore could not show a gender disparity effect. In contrast, the METO-IN-002 trial was the largest gastroparesis study ever conducted, and through its robustness it appears to have revealed a gender disparity effect with this therapy that could not be detected previously in smaller studies. The benefit in women was also consistent across both the primary and secondary endpoints, and the treatment effect appeared similar across both dose groups (10mg and 14mg) of intranasal metoclopramide.

Figure 11: Gender Disparity Signal – METO-IN-002 Trial Data



Source: Evoke Pharma, Inc.

We note that the company does not have a specific mechanistic explanation to account for the difference in treatment efficacy between male and female gastroparesis sufferers. However, we note that the results of Evoke's Phase 2b trial are consistent with what is known about gender effects in other GI motility disorders. The functional GI tract and GI tract motility disorders, including gastroparesis, are significantly more common in females than in males. Also, healthy females generally have slower gastric emptying

rates than healthy males. In a study conducted at Temple University, it was shown that gastric emptying of solid food in normal young women is slower than in age-matched men, even in the first 10 days of the menstrual cycle when estrogen and progesterone levels are low, and that the delay in gastric emptying of solids in women appears to be primarily due to altered distal gastric motor function¹¹. One explanation as to why women are afflicted with gastroparesis more often than men may be that less vigorous antral contractions may contribute to slower breakdown of food particles and thus delay the rate of emptying. Furthermore, irritable bowel syndrome (IBS) has a similar gender differential for women compared to men. Similar to gastroparesis, no absolute biologic mechanism has been determined for this difference, but several leading theories are accepted by researchers and the FDA alike. For example, gender-based differences in enteric innervation, hormonal action, and brain function, specifically in the areas that generate/control anxiety and emotion, have been hypothesized to be at the core of the gender disparity seen in the efficacy profiles of GI tract drugs, including EVK-001.

In addition to gender difference for incidence, gastrointestinal disorders present and respond differently by gender. There is consensus among thought leaders in GI motility that women exhibit higher symptom prevalence, their neural and sensory pathways differ, and hormones, such as estrogen and progesterone, may play a role. While the EVK-001 Phase 2b trial is the first report of a gender-based difference in response to metoclopramide among diabetic gastroparesis patients, gender effects have been reported in drug studies for other GI disorders, e.g. irritable bowel syndrome (IBS). For example, products like Lotronex[®] (alosetron), Zelnorm[®] (tegaserod) and Amitiza[®] (lubiprostone) were approved by the FDA based on effectiveness in women, but not in men.

Table 5: METO-IN-003 Phase 3 Pivotal Trial Design

Objective	Demonstrate safety and effectiveness of metoclopramide nasal spray versus placebo in reducing the symptoms of gastroparesis
Design	U.S. multicenter (60 sites), randomized, double-blind, placebo-controlled, parallel-group clinical study to evaluate the efficacy, safety and population pharmacokinetics of Metoclopramide Nasal Spray in female subjects with diabetic gastroparesis
Study Drug	Metoclopramide Nasal Spray (200 mg/mL) and placebo (vehicle) 10 mL amber glass vial and metered dose sprayer delivering 50µL (10 mg) per spray
Dose Regimen	One spray 30 minutes before meals and at bedtime (QID) for 28 days
Subjects	18 to 75 year old Type 1 and Type 2 diabetic females with documented delayed gastric emptying by scintigraphy at screening only and a mean GSA total score of ≥ 1.4 and < 3.5 during the 7-day baseline period (washout)
Primary Endpoint	Change in the average GSA total score for baseline versus Week 4 of the treatment period
Statistics	Sample size=200 (100 per dose group) 90% power ($\alpha=0.05$ two-sided, $SD=0.65$) to detect a mean difference of 0.3 between treatment groups

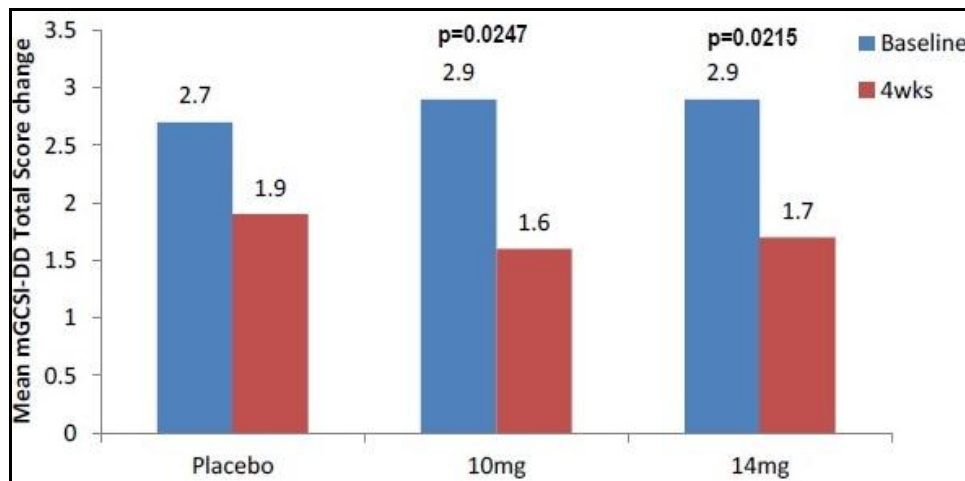
Source: Evoke Pharma, Inc.

One of the most encouraging attributes of the Evoke Pharma clinical development program is the continuity level. Looking at the Phase 3 trial design, it is clear that the company was seeking to preserve as many characteristics of the Phase 2b trial in the pivotal design as possible. The statistical powering assumptions are robust, in our view, considering the fact that the Phase 2b trial effectively included approximately the same number of subjects in its subgroup analysis as are being enrolled in the Phase 3 study. The Phase 2b study utilized the mGCSI-DD outcome measure as its primary endpoint,

¹¹ Parkman *et al.*, Gastroenterology 140: 101-15 (2011)

while the Phase 3 trial is slated to utilize the Gastroparesis Symptom Assessment (GSA) rating scale instead. In our view, the differences between these two rating scales are not meaningful. We note that the firm has already retrospectively evaluated its Phase 2b data in a *post hoc* manner using the GSA system; statistically significant and virtually identical magnitudes of improvement were recorded using the GSA vs. the mGCSI-DD ($p=0.025$ in women subjects evaluated via the GSA vs. $p=0.0247$ using the mGCSI-DD).

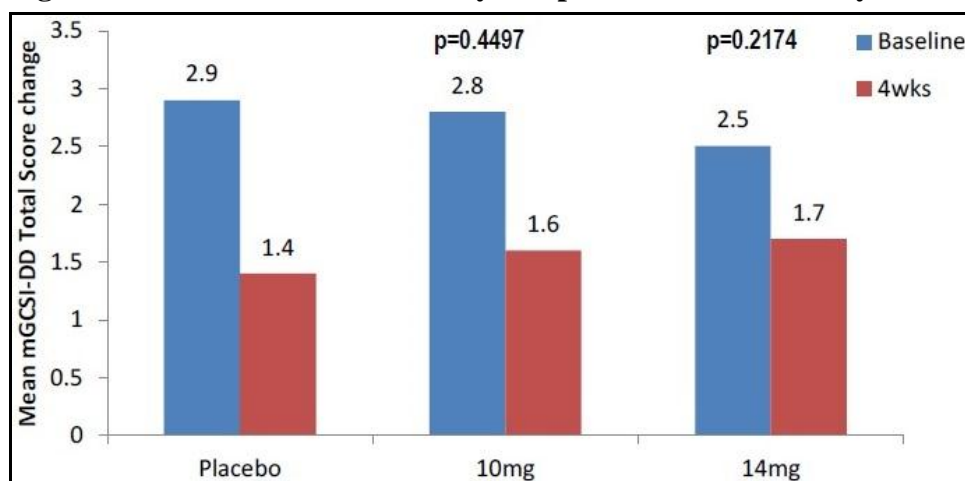
Figure 12: METO-IN-002 Primary Endpoint Data – Women Only



Source: Evoke Pharma, Inc.

In addition, Evoke has agreed to the FDA's request to conduct a similar late-stage study in males, wherein the firm expects to look at the data after completing the pivotal trial in women alone. Evoke could enroll up to 100 male patients in this additional study. It is important to note, however, that even if Evoke were to see a signal in the male component of its clinical development program, the FDA has stipulated that it would only be prepared to give the firm approval for EVK-001 in women alone. The agency has also given Evoke the formal sanctioning to submit its NDA even before obtaining top-line data in male patients, since the firm will not be basing its submission on those results. The chart below shows the data obtained from the Phase 2b trial in the male subjects, and clearly demonstrates why statistical significance was not achieved – the placebo response in these individuals was much larger than was seen in the female individuals.

Figure 13: METO-IN-002 Primary Endpoint Data – Men Only

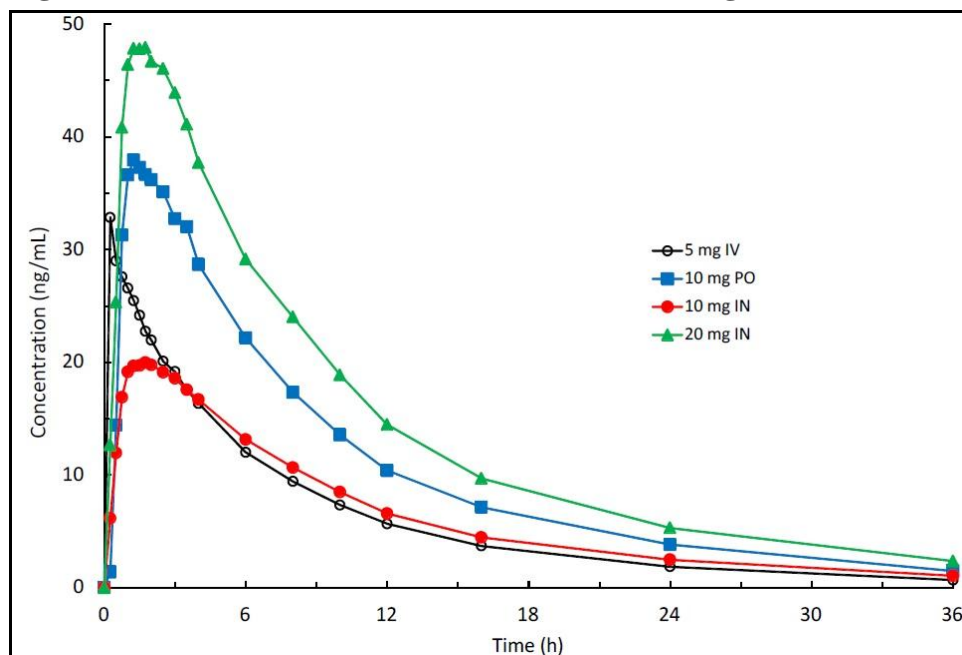


Source: Evoke Pharma, Inc.

Clinical Safety, Tolerability and Bioavailability Data

The intranasal formulation of metoclopramide that is the basis for the EVK-001 candidate was developed with the aim of providing advantages in terms of speed of onset and reduced variability of absorption. In a Phase 1 trial conducted by Evoke, designated as the METO-IN-001 study, 40 healthy volunteers were randomized to receive a single dose of one of four formulations of metoclopramide: 1) 10mg intranasal EVK-001; 2) 20mg intranasal EVK-001; 3) a 10mg oral tablet formulation; and 4) a 5mg intravenous injection formulation. The results are depicted below.

Figure 14: METO-IN-001 Pharmacokinetic Profiling Data



Source: Evoke Pharma, Inc.

The pharmacokinetic profiling data from the METO-IN-001 trial, showing the relative bioavailability of the intranasal formulation vs. the tablet, are depicted in the table below.

Table 6: METO-IN-001 Pharmacokinetic Profiling Data

Parameter* /Dose Group	N†	C _{max} (ng/mL)	T _{max} (hours)	AUC _(infinity) (hours x ng/mL)	t _{1/2} (hours)	F _{ABS} ‡ (%)	F _{REL} § (%)
5 mg IV	39	35 (46)	0.25 (0 – 1.25)	232 (40)	6.80 (26.0)	-	-
10 mg PO	39	44 (36)	1.25 (0.50 – 3.50)	397 (62)	7.12 (28.1)	78.9	-
10 mg IN	38	23(56)	1.50 (0.50 – 3.50)	263 (62)	8.03 (27.1)	47.4	60.1
20 mg IN	39	54 (46)	1.50 (0.75 – 3.50)	540 (57)	8.11 (30.1)	52.5	66.5

*Arithmetic mean (% coefficient of variation) except T_{max} for which the median (range) is reported.
†For AUC_(inf) and t_{1/2}, N = 35 for 10 mg IN, 36 for 20 mg IN, 39 for 10 mg PO, and 38 for 5 mg IV.
‡Absolute bioavailability; based on least squares geometric mean ratios.
§Reglan Tablet label reports absolute oral bioavailability of 80% ±15.5%
Bioavailability relative to the tablet; based on least squares geometric mean ratios.

Source: Evoke Pharma, Inc.

We believe that the PK data showing the bioavailability of EVK-001 is important because it indicates that the drug should have a smoother, more reproducible absorption profile in gastroparesis patients, many of whom have difficulty keeping oral tablets down because of their nausea and vomiting symptoms and for whom – in numerous cases – tablets can become lodged inside so-called solid “bezoars” in the stomach and thus do not get absorbed effectively. Such variability should not occur in the case of EVK-001.

In our view, the safety profile of EVK-001 has proven thus far to be encouraging. In the open-label Phase 2 trial conducted by Questcor, no serious adverse events (SAEs) were recorded with the intranasal formulation of metoclopramide vs. the oral tablet formulation. We note that adverse events seen in Evoke’s completed Phase 2b trial were consistent with safety issues identified in the Reglan label although, as previously hypothesized, the rate of occurrence of central effects such as somnolence, dizziness, and fatigue appeared to be more moderate than that seen with oral metoclopramide, for which these types of adverse events generally occur in 10% of patients.

Table 7: METO-IN-002 Trial Overall Safety Data

AE	Placebo (N=95)	EVK-001	
		10mg N=95	14mg N=95
Dysgeusia	4.2%	12.6%	13.7%
Headache	4.2%	7.4%	8.4%
Dizziness	2.1%	3.2%	3.2%
Somnolence	0.0%	2.1%	2.1%
Fatigue	1.1%	5.3%	6.3%
Depression	3.2%	0.0%	0.0%
Diarrhea	9.5%	3.2%	2.1%
Nausea	4.2%	1.1%	4.2%
GERD	1.1%	4.2%	0.0%
Epistaxis	0.0%	2.1%	3.2%
Cough	2.1%	0.0%	3.2%
Nasal discomfort	0.0%	3.2%	2.1%
Rhinorrhea	1.1%	1.1%	3.2%
Throat irritation	1.1%	0.0%	3.2%
URI	4.2%	0.0%	2.1%
Nasopharyngitis	1.1%	3.2%	1.1%
Hyperglycemia	1.1%	1.1%	3.2%
Hypoglycemia	1.1%	1.1%	3.2%

Source: Evoke Pharma, Inc.

The intranasal delivery route was associated with some minor local side effects in the drug groups. There was also a higher incidence of dysgeusia – dysfunction in taste perception – in the drug-treated patients, but management indicated that, of the subjects reporting dysgeusia, 34% originated from the same clinical site, which suggests that there could have been some site-related bias with regard to eliciting information about this complaint. The study coordinator at the center with the highest incidence of dysgeusia apparently systematically asked patients if the drug tasted unpleasant when these patients visited the clinic, which in our view could have contributed to this bias.

Clinical Development Perspectives

In Phase 2b clinical development, EVK-001 has proven effective in females with diabetic gastroparesis. Similar to other functional GI disorders, this gender effect is likely caused by a collection of known and unknown physiologic differences related to hormonal, neuronal and other dissimilarities between men and women. Key opinion leaders, industry and the FDA have successfully developed, reviewed, approved and marketed other gender disparity-displaying GI disorder products. The regulatory pathway forward for EVK-001 is well characterized and understood within the functional gastrointestinal disease community and regulators.

Although a gender difference in treatment of gastroparesis had never been reported prior to Evoke's clinical trial, the FDA understands and has agreed to accept the Phase 2b clinical trial as supportive evidence for the NDA filing. Furthermore, the FDA has acknowledged that positive data from a single Phase 3 trial conducted only in women should be sufficient for approval. Since women constitute over 80% of the target market for EVK-001, we believe that getting a label for use in women only should not compromise the substantial market opportunity for Evoke Pharma going forward. Evoke will be running a pivotal Phase 3 trial solely in women. The Phase 3 trials for IBS enrolled both genders and the FDA approved these products for use in women only, since the products did not show effectiveness in men. In the case of Zelnorm, one study in women only was recommended by the FDA, which was then reviewed for approval.

In our view, it is crucial for investors to grasp the fact that Evoke is not being asked to prove a negative; in other words, that EVK-001 is not effective in the male population. The FDA's stipulation that Evoke run an exploratory parallel study assessing intranasal metoclopramide's effect in men while it is conducting its pivotal Phase 3 trial simply represents an inquiry into the nature of the gender disparity. Even if EVK-001 were to demonstrate efficacy in male gastroparesis sufferers as well as female subjects, we expect that the FDA would only approve the drug for use in women because of the lack of statistical powering in the male-only trial. However, at this stage we believe that the Phase 3 trial is likely to yield similar data to the Phase 2b trial. Metoclopramide has been used to treat women with gastroparesis for over 30 years with proven efficacy. For Evoke's upcoming single Phase 3 trial, it is expected that EVK-001 will continue to show efficacy in women, along with demonstrating the added advantages associated with a non-oral route of administration.

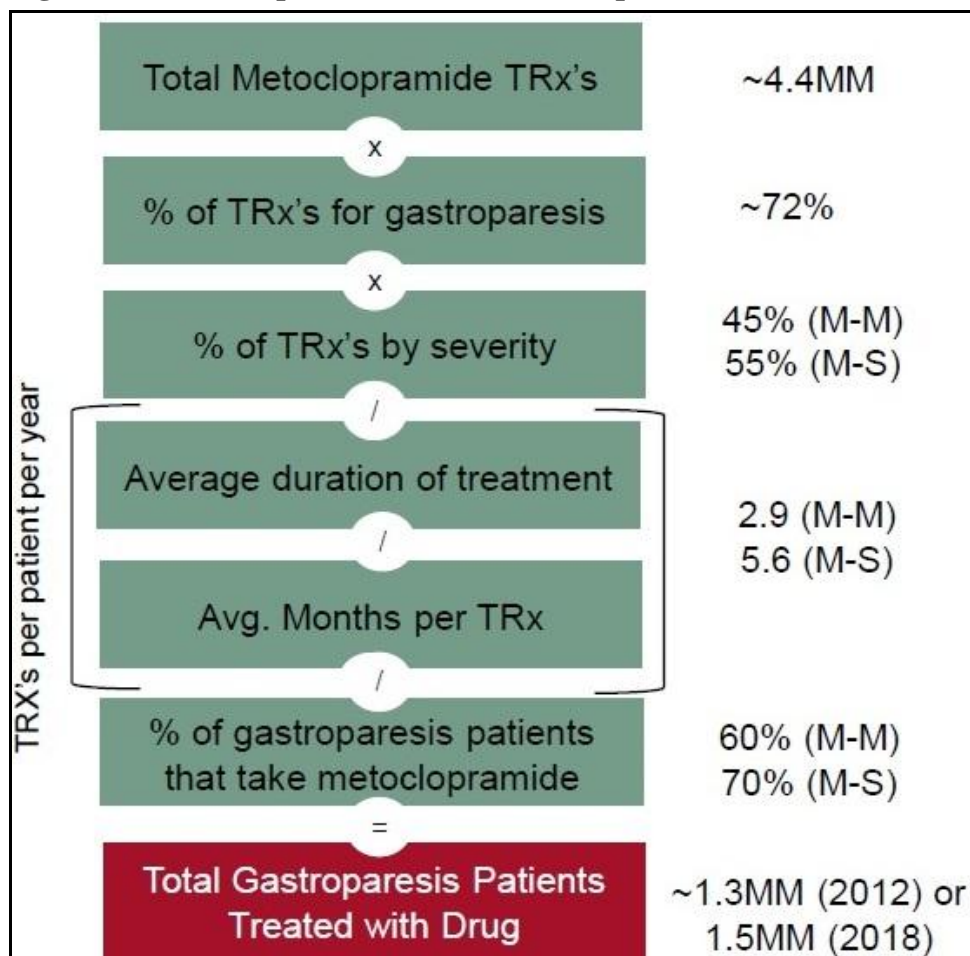
Chemistry, Manufacturing & Control (CMC)

We herein comment briefly on the nature of the CMC package that the firm currently possesses. The medication unit is composed of an amber glass vial directly attached to a pre-assembled spray pump unit with a protection cap. Each multi-dose sprayer system is packaged pre-assembled and capable of delivering a 30-day supply (120 doses at four doses per day.) The delivery apparatus is a standardized metered sprayer technology utilized in other nasal spray products. The company's contract manufacturer for the production of the units is Patheon, a firm with a lengthy track record of commercial-scale manufacturing across the drug industry. Evoke has conducted the three-year stability testing stipulated in the FDA's guidance document dealing with Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products, and its sprayer system has been verified to ensure that the dose reproducibility, physical characteristics of the plume, and droplet / particle size distribution in the spray are all within acceptable limits.

Diabetic Gastroparesis Market Overview

We have assessed the opportunity for EVK-001 (intranasal metoclopramide) in only a single GI tract disorder, diabetic gastroparesis. While the agent could have further potential in related diseases, most notably functional dyspepsia and chemotherapy-induced nausea and vomiting (wherein it was indeed initially being positioned before Evoke took over the commercial rights), we do not model significant product penetration into such markets. The flow chart below illustrates how market research supports the existence of a significant commercial opportunity for EVK-001, even if only factoring in penetration of the existing U.S. oral metoclopramide prescription base alone.

Figure 15: Metoclopramide Diabetic Gastroparesis Market

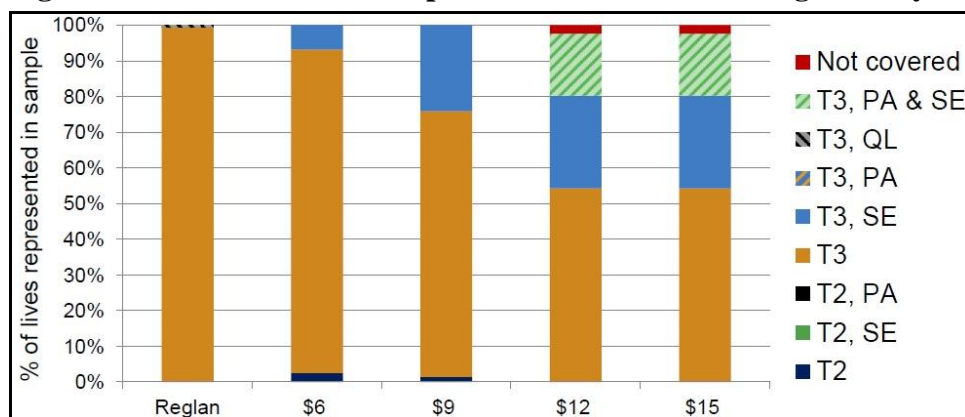


Source: Evoke Pharma, Inc.; Decision Resources

We are assuming that EVK-001 would still carry a black box warning – however, it appears to be somewhat safer than the oral tablet version and therefore we believe that there is potential over time for prescribers to begin switching from oral versions of the drug to EVK-001. In addition, because the oral tablets are all available generically from a wide array of sources, there is currently no active promotional message for Evoke – or its eventual licensees – to contend against. Although alternative dosage forms represent very low percentages of other prescription drug categories such as the antidepressant and atypical antipsychotic markets, in which generically-available oral formulations constitute the bulk of script volumes, we believe that these markets still retain significant brand promotion presences, whereas the metoclopramide market does not.

In terms of pricing, we believe that there could be a substantial hurdle for Evoke to overcome if the market takes the view that the advantages of the intranasal formulation are too incremental to warrant a significant price premium. Currently, oral tablet formulations of metoclopramide are available for less than a dollar per day. We are encouraged to a certain extent by the existence of precedent situations with various other GI tract medications that were introduced into markets containing multiple low-cost alternatives and that were, on average, priced at roughly \$7 – \$10 per day without prohibitive lack of insurance coverage or insurmountable barriers to commercial uptake. Examples would include products such as Amitiza (lubiprostone), Linzess (linaclotide), Nexium (esomeprazole) and Zelnorm (tegaserod). Evoke has obtained survey data from reimbursement agencies indicating that there could be sufficient support for the competitive profile of EVK-001 to permit pricing in the \$9 – \$15 range, which is substantially above our current projection of \$6/day. As shown below, 50% – 75% of the addressable patient population is projected to be covered for use of EVK-001 – at least at the Tier 3 level – assuming the \$9 – \$15 per day range. Prior authorization (PA) and electronic step edit (SE) requirements are likely to be imposed, however.

Figure 16: Intranasal Metoclopramide Insurance Coverage Survey



Source: Evoke Pharma, Inc.; PriceSpective

It is of interest to note that, since the black box warning was applied to oral metoclopramide agents in early 2009, prescriptions of the serotonin receptor antagonist class of anti-emetics – e.g. ondansetron (Zofran), granisetron (Kytril), and palonosetron (Aloxi) – have been growing rapidly in volume. This class of drugs generated nearly 13 million scripts in 2012, up from only about 4 million in 2008. However, the fact that the FDA is currently evaluating the possible fallout from the emergence of a new and dangerous side effect with these drugs – so-called “serotonin syndrome”, which can be fatal if left undetected and untreated – may create a long-term opportunity for intranasal metoclopramide in the nausea and vomiting prevention market.

Serotonin syndrome involves increased heart rate, shivering, sweating, dilated pupils, myoclonus (intermittent tremor or twitching), as well as over-responsive reflexes. Moderate intoxication includes additional abnormalities such as hyperactive bowel sounds, high blood pressure and hyperthermia; a temperature as high as 40°C (104°F) is common in moderate intoxication. The overactive reflexes and clonus in moderate cases may be greater in the lower limbs than in the upper limbs. Mental status changes include hyper-vigilance and agitation. Severe symptoms include severe increases in heart rate and blood pressure that may lead to shock. Temperature may rise to above 41.1°C (106°F) in life-threatening cases. Other abnormalities include metabolic acidosis, rhabdomyolysis, seizures, renal failure, and disseminated intravascular coagulation.

EVK-001 Market Model

We have modeled sales for EVK-001 (intranasal metoclopramide) in the U.S. diabetic gastroparesis population that is considered eligible for treatment with oral metoclopramide. In our view, this is probably the most conservative approach that can be taken, since it assumes that EVK-001 is not likely to expand the market but only take a share of the existing prescription volumes being generated with the oral versions of metoclopramide – all of which carry a black box warning. Although we do not anticipate that EVK-001 could escape a black box itself, we note that if physicians and patients eventually form the view that the drug is positively differentiated from its oral competitors, perhaps there could be potential for market expansion. We base our viewpoint on the fact that prior to the introduction of the black box warning on oral metoclopramide, these products accounted for nearly 7 million prescriptions per year; today, these agents are averaging about 4 million scripts per year. Thus, if EVK-001 is perceived as safer and potentially more effective than the oral metoclopramide formulations, it could contribute to regrowth in the metoclopramide market.

Initial proof-of-concept efficacy data with EVK-001 has been encouraging, with results from a robustly-powered, 287-patient Phase 2b trial having been generated. This trial was designated the METO-IN-002 trial. Using the validated rating scale known as the modified Gastroparesis Cardinal Symptom Index – Daily Diary (mGCSI-DD), EVK-001 showed a statistically significant improvement at the 10mg and 14mg doses vs. placebo following four weeks of treatment ($p < 0.025$) in the female-only subgroup of patients enrolled into the trial. The primary endpoint was not significant for the intent-to-treat (ITT) population – as discussed in a prior section of this report – due to a high placebo response in males. The ITT population was 71% female and 29% male ($n = 289$). The interaction effect was $p = 0.038$. As described earlier, we believe that the gender disparity in drug effectiveness represents a real observation and not an artifact for the following key reasons: a) such a difference was not observed in underpowered studies, while the METO-IN-002 is the largest gastroparesis study ever conducted; b) the observation of a statistically significant treatment effect in women was made following a pre-specified subgroup analysis – not *post hoc* – involving a large proportion ($> 70\%$) of the patients in the trial; and c) the drug is known to be active in this disorder and it is not unusual for GI tract disorders drugs to exhibit gender disparity with a tendency to show better activity in women. Examples of marketed drugs that have shown this effect include both Prilosec (omeprazole) and Zelnorm (tegaserod). The drug was well-tolerated, with no dose-limiting toxicities, $< 10\%$ dropouts (with 5% exiting due to adverse events), and all six serious adverse events (SAEs) reported being classified as unrelated to study drug. There were no deaths and no reports of tardive dyskinesia in this trial.

It is estimated that the total U.S. diabetic gastroparesis patient population could amount to 12 million – 16 million individuals. Within this group, we project that roughly 1.4 million individuals are typically prescribed oral metoclopramide. Our market model focuses solely on the U.S. market. Accordingly, our estimates may be conservative. We utilize pricing at roughly \$6 per day, with an average of 120 days on therapy, and assume annual pricing increases averaging 3%, in-line with inflation.

The risk-adjusted Net Present Value (rNPV) calculation we derive involves the assumption of a 15% discount rate, 40% effective tax rate, 60% probability of success and 35% sales and marketing offset. In our market model, peak U.S. sales exceed \$400 million in 2023, roughly seven years post-launch. We utilize a relatively low peak market penetration rate of ~35% solely in female diabetic gastroparesis patients, which we project as only 70% of the total addressable market (reflecting the proportion enrolled in the Phase 2b trial), even though various publications indicate that the true percentage of women in the diabetic gastroparesis population is probably in the 80% – 85% range.

Table 8: Intranasal Metoclopramide (EVK-001) Estimated Global Sales – Diabetic Gastroparesis Market Size Model

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
U.S. Population	16,000,000	16,200,000	16,402,500	16,607,531	16,815,125	17,025,314	17,238,131	17,453,608	17,671,778	17,892,675	18,116,333	18,342,787	18,572,072	18,804,223	19,039,276	19,277,267	19,518,233	19,762,211	20,009,238	20,259,354
Eligible diabetic gastroparesis patients	1,440,000	1,620,000	1,640,250	1,660,753	1,681,513	1,702,531	1,723,813	1,745,361	1,767,178	1,789,267	1,811,633	1,834,279	1,857,207	1,880,422	1,903,928	1,927,727	1,951,823	1,976,221	2,000,924	2,025,935
Female patients	1,008,000	1,134,000	1,148,175	1,162,527	1,177,059	1,191,772	1,206,669	1,221,753	1,237,024	1,252,487	1,268,143	1,283,995	1,300,045	1,316,296	1,332,749	1,349,409	1,366,276	1,383,355	1,400,647	1,418,155
EVK-001 Market Penetration Rate				1%	7%	18%	23%	26%	31%	33%	35%	32%	29%	27%	24%	22%	20%	18%	14%	11%
Patients on EVK-001				11,625	82,394	214,519	277,534	318,877	383,478	413,321	445,118	410,878	377,013	355,400	319,860	296,870	273,255	249,004	196,091	155,997
Average cost per day (\$)				6.00	6.18	6.49	6.68	6.88	7.09	7.45	7.67	7.90	8.14	8.38	8.63	8.89	9.16	9.43	9.71	10.01
Number of days on therapy				30	120	120	120	120	120	120	120	120	120	120	120	120	120	120	120	120
Average annual cost (\$)				180	742	779	802	826	851	893	920	948	976	1,006	1,036	1,067	1,099	1,132	1,166	1,201
U.S. EVK-001 sales (\$ MM)				2	61	167	223	263	326	369	410	389	368	357	331	317	300	282	229	187

Source: Company Reports and Aegis Capital Corp. estimates

Intellectual Property

The Evoke Pharma intellectual property (IP) portfolio is shown below. We note that, while metoclopramide as a chemical entity is neither eligible for composition-of-matter protection nor New Chemical Entity (NCE) status in the U.S., the company does possess fundamental IP around the intranasal formulation, which should provide protection until the 2021 / 2030 time frame without patent term extensions. Some of the firm's most valuable IP is still pending, including in particular a patent application that Evoke filed on the basis of the observation that intranasal metoclopramide appears to selectively have activity in female diabetic gastroparesis sufferers. Should this patent issue, we believe it would provide adequate blocking protection for EVK-001 until the 2032 time frame.

Table 9: Evoke Pharma Patent Portfolio

Patent Number	Title	Issue Date	Expiry Date	Country	Description
U.S. 6,770,262	Nasal Administration of Agents for the Treatment of Gastroparesis	August 3, 2004	March 29, 2021	United States	A method for the treatment of gastroparesis by the use of metoclopramide nasal formulation
U.S. 8,334,281	Nasal Formulations of Metoclopramide	December 18, 2012	May 13, 2030	United States	The invention is directed toward nasally-administrable solutions comprising metoclopramide, which are stable upon storage, especially long-term storage. This provides 145 days extended patent life.
U.S. 5,760,086	Nasal administration of agents for treatment of delayed onset emesis	June 2, 1998	March 14, 2016	United States	The present invention is directed to a method for prophylactic management of delayed emesis by the use of metoclopramide nasal spray
Non-Provisional Patent Application PCT/US2012/052096	Treatment of symptoms associated with female gastroparesis	N/A	N/A	United States	Nasal formulations of metoclopramide are administered for the treatment of symptoms associated with female gastroparesis. Also provided are methods of treating symptoms of female gastroparesis with nasal metoclopramide.

Source: Company reports

Financial Review and Outlook

Revenue: We do not forecast any revenue from either product sales or research activities in either 2013 or 2014. Management does not provide guidance.

Gross Margins: As a development-stage company, there are historically no costs of goods sold. We project that the gross margins on EVK-001 are likely to exceed 90% upon launch, which should enable healthy cash flow generation.

Operating Expenses: For 2013, we estimate approximately \$1.8 million in operating expenses. We estimate R&D of only \$0.6 million in 2013, as the company advances its lead drug candidate into pivotal clinical development for diabetic gastroparesis in the U.S. However, the R&D expense should rise substantially in 2014 to roughly \$12 million as the single pivotal trial of EVK-001 ramps up enrollment and matures.

Taxes: We assume a roughly 40% corporate tax rate after all net operating loss carry-forwards are exhausted. However, in our view the firm should not have significant tax liabilities prior to 2020. At the end of 2012, Evoke Pharma had ~\$18.6 million in federal and \$18.2 million in state net operating loss carry-forwards. We would expect that the firm could have as much as \$60 million – \$70 million in net operating losses by the time EVK-001 receives approval in the U.S. for the treatment of diabetic gastroparesis. Accordingly, the effective tax rate in the initial years is likely to be negligible.

Share Count: The outstanding fully-diluted share count stands at roughly 6.9 million. The fully-diluted shares account for the conversion of 0.8 million shares in the form of options and warrants. Given the company's cash position, strategic goals, and capital structure, a share repurchase program is unlikely, in our view.

EPS: We forecast EPS of (\$0.55) and (\$2.20) for 2013 and 2014, respectively. Currently, we cannot estimate when the company is likely to achieve cash flow break-even or attain sustainable profitability. However, if the firm's lead drug candidate, EVK-001, demonstrates statistically significant efficacy and positive safety data in the projected single pivotal Phase 3 trial, we anticipate that Evoke should be able to secure approval of the drug in the second half of 2016 and potentially launch it before the end of the year. In our view, the drug's sales ramp should be rapid enough to potentially drive cash flow positive status at Evoke Pharma in either late 2017 or early 2018.

Balance Sheet: The firm held roughly \$23.7 million in cash at the end of the third quarter of 2013, following the completion of an IPO in September 2013. We anticipate that the funds raised in the IPO should cover the cost of the proposed Phase 3 trial for EVK-001, which is slated to cost roughly \$15 million, and thereafter facilitate the filing of a New Drug Application (NDA). Following the receipt of data from its Phase 3 program, we believe that Evoke Pharma may elect to raise additional capital in order to have as many strategic options available as possible (including being able to launch the drug in the U.S. independently using either a contract or in-house specialty sales force).

Cash Flow: We estimate that the firm will consume roughly \$2 million in operating cash flows during 2013 and a further \$15.3 million during 2014. We think additional funding may be required within the next 15 – 18 months to support envisaged operational activities, including the completion of the filing of a New Drug Application (NDA) with the FDA for EVK-001 and potential pre-launch preparations.

Guidance: The firm does not provide financial guidance.

Financing History / Capital Structure

Over the course of its history as a privately-held firm, Evoke Pharma has raised roughly \$18.5 million to support its research activities (see below). In our view, the firm has demonstrated an extremely capital-efficient operating history. Many other companies in the pharmaceuticals arena expend hundreds of millions of dollars in drug development in order to advance a single drug candidate into pivotal clinical trials.

Table 10: Financing History

	Net Proceeds	Shares	Price	Notes
Private Company				
Common Stock	\$ 12	1,242,750	\$ 0.00	
Options	\$ 49,300	123,250	\$ 0.40	
Convertible Preferred	\$ 18,292,515	2,439,002	\$ 7.50	From June 2007 through June 2010, Evoke Pharma issued and sold to investors an aggregate of 12,195,068 shares of its Series A convertible preferred stock at a purchase price of \$1.50 per share, for aggregate consideration of approximately \$18.3 million. The numbers reflect a 5-for-1 reverse split.
Warrants	\$ 165,000	22,000	\$ 7.50	
Public Company				
IPO	\$ 28,980,000	2,415,000	\$ 12.00	Includes 315,000 shares for over-allotment
Option Pool		510,000		
ESPP	\$ -	30,000		
Warrants		84,000	\$ 20.00	
Total Amount	\$ 47,486,827	6,866,002		

Source: Evoke Pharma Inc.

On September 25, 2013, Evoke Pharma priced an IPO, in which the firm sold 2.1 million shares of common stock at a price of \$12.00 per share. Gross proceeds totaled roughly \$25 million, with net proceeds estimated at \$23 million after deducting underwriting fees and cash offering expenses. Evoke also gave the underwriter, Aegis Capital Corp., a 45-day option to sell an additional 315,000 shares to cover over-allotments. The over-allotment was exercised in full on October 3, 2013. The most recent capital structure (see table below) indicates that Evoke has ~6.9 million shares outstanding and issued (fully-diluted) following the IPO. We project that the firm's current cash position should be sufficient to fund operations through the conclusion of the Phase 3 pivotal trial with EVK-001 in diabetic gastroparesis and the filing of an NDA via the 505(b)(2) pathway.

Table 11: Capital Structure

	Number of Shares	Exercise Price	Expiration Date	Total Cash
Cash, cash equivalents and marketable securities				\$ 26,699,400
Common Stock	6,096,752			
Options	663,250	\$0.40		\$265,300
Warrants	106,000	\$7.50	9/24/2018	\$795,000
Fully Diluted Shares	6,866,002			\$27,759,700

Source: Evoke Pharma, Inc.

Evoke Pharma put a \$3 million loan and security agreement in place with Silicon Valley Bank in June 2012. This involves an interest-only period through the end of 2013; a 24-month payback period commences in January 2014. The loan carries a fixed interest rate of 4.50%. By January 2013, the firm had drawn down the entire facility for working capital purposes. We project complete repayment of this loan by the end of 2015, in accordance with the agreement terms.

Management Team

The firm's management team comprises individuals with substantial track records in the biotech and healthcare industries. The firm's CEO, Dave Gonyer, has had an extensive career in the specialty pharmaceuticals and large-cap pharmaceuticals arenas.

David A. Gonyer, R.Ph.

President & Chief Executive Officer

Dave Gonyer has served as Evoke Pharma's President and CEO and as a member of the firm's board of directors since March 2007. From January 2004 to June 2007, Mr. Gonyer served as Vice President of Strategic and Product Development at Medgenex, Inc., a subsidiary of Victory Pharma, Inc. a firm focused on acquiring, developing and marketing products to treat pain and related conditions. From April 2000 to December 2004, he was a founder and Vice President of Sales and Marketing at Xcel Pharmaceuticals, Inc., a specialty pharmaceuticals firm focused on neurological disorders. From December 1996 to April 2000, Mr. Gonyer served as Director of Marketing at Elan/Dura Pharmaceuticals, Inc. Elan was acquired by Perrigo Co. in July 2013 for \$8.6 billion. From 1987 to 1996, Mr. Gonyer held a broad range of management positions in commercial operations, alliance/partnership management, and regional sales at Eli Lilly & Co., one of the world's largest pharmaceutical companies. He currently sits on the board of Neurelis, Inc., a privately held neurologically-focused specialty pharmaceuticals firm. Mr. Gonyer is a Registered Pharmacist and holds a B.Sc. in Pharmacy from Ferris State University School of Pharmacy in Big Rapids, MI.

Matthew J. D'Onofrio, M.B.A.

Executive Vice President, Chief Business Officer / Treasurer / Corporate Secretary

Mr. D'Onofrio has served in his current role at Evoke Pharma since March 2007, after co-founding the company with Dave Gonyer. He has over 20 years of experience in both large and small pharmaceutical firms. Prior to founding Evoke, Mr. D'Onofrio was engaged in a business development role at Victory Pharma, a growing specialty pharmaceuticals firm that was based in San Diego, CA. From 2002 to 2005, Mr. D'Onofrio led efforts to acquire marketed brands for the growing sales force. Earlier, Mr. D'Onofrio was a director and head of the West Coast business development team at Vertex Pharmaceuticals, a biotechnology firm, directing partnership efforts associated with the La Jolla research facility as well as other corporate assets. Mr. D'Onofrio also held various commercial roles of increasing responsibility over a decade at Eli Lilly & Co., including significant experience in worldwide corporate business development. Over the course of his licensing career, Mr. D'Onofrio has developed and executed licensing deals and investments across a wide array of disease states and technologies. He earned a B.S. in chemistry from San Diego State University and holds an M.B.A. (Finance) from the Marshall School of Business at the University of Southern California.

Board of Directors

The firm's Board of Directors includes several senior-level individuals with substantial expertise in the biopharmaceutical industry. In particular, several of the firm's directors have founded or co-founded multiple companies that have gone on to successfully develop and commercialize various products in the specialty pharmaceuticals arena.

Cam L. Garner, M.B.A.

Chairman of the Board

Cam Garner is one of the co-founders of Evoke and has chaired the Board of Directors since June 2007. He also co-founded a substantial array of specialty pharmaceutical companies, including Zogenix Pharmaceuticals, Cadence Pharmaceuticals, Inc., Somaxon Pharmaceuticals, Inc., Elevation Pharmaceuticals, Inc., DJ Pharma, Verus Pharmaceuticals, Inc., Xcel Pharmaceuticals, Inc. and Meritage Pharma, Inc. He also

served as chairman of Zogenix, Cadence, Verus, Elevation and Meritage. Xcel was acquired in March 2005 by Valeant Pharmaceuticals International, DJ Pharma was sold to Biovail in 2000 and Elevation was acquired by Sunovion Pharmaceuticals Inc. in September 2012. Mr. Garner was CEO of Dura Pharmaceuticals, Inc. from 1989 to 1995 and served as both Chairman and CEO from 1995 to 2000 until Dura was sold to Elan in November 2000 in an all-stock deal that valued Dura at \$1.8 billion. He also serves on the board of directors of Aegis Therapeutics, Inc., Cadence Pharmaceuticals, Inc., Meritage Pharma, Inc., Neurelis, Inc., and Zogenix, Inc. He earned his B.A. in Biology from Virginia Wesleyan College and holds an M.B.A. from Baldwin-Wallace College.

Todd C. Brady, M.D., Ph.D.

Director

A director on the Evoke board since June 2007, Dr. Brady has been an Entrepreneur-in-Residence at Domain Associates, a leading healthcare venture capital firm, since 2013. From 2004 to 2013, he was a Principal at Domain Associates. He is President and CEO of Aldexa Therapeutics and is also a member of the Board of Directors of Novadigm Therapeutics, ParinGenix, Sebacia, Aldexa Therapeutics and Asmacure. Prior to joining Domain, Dr. Brady was co-founder and CEO of Phenome Sciences, a biotechnology firm he merged with Xanthus Pharmaceuticals (acquired by Antisoma), where he was later Executive Vice President of Strategic Development and Planning. He also worked as head of business development and medical director at Aderis Pharmaceuticals (acquired by Schwarz Pharma, now part of UCB). While at Xanthus and Aderis, Dr. Brady was a medical consultant on numerous pre-clinical programs and clinical programs in Phases 1 through 4 of clinical development. Earlier in his career, he was a senior associate at CB Health Ventures (now Excel Medical Ventures), a healthcare-focused venture capital fund. Dr. Brady holds an M.D. from Duke University Medical School, a Ph.D. from Duke University Graduate School, and an A.B. from Dartmouth College.

Scott L. Glenn, M.B.A.

Director

A member of the Evoke board since June 2007, Mr. Glenn is the founder of and has been the Managing Partner of Windamere Venture Partners since its inception in 1999. He is the past Chairman or founder of Prometheus Laboratories, Inc., Santarus Inc., DexCom, Cadence Pharmaceuticals, NovaCardia Inc., Somaxon Pharmaceuticals, Zogenix Pharmaceuticals, SpineWave, and Verus Pharmaceuticals Conception Technologies, and currently serves on the board of directors of Planet Biopharmaceuticals. Prior to his involvement in venture capital, Mr. Glenn was the President and CEO of Quidel Corp. and simultaneously was a founder of La Jolla Pharmaceuticals. Before joining Quidel, Mr. Glenn held various management positions, including Division General Manager, with Allergan. He holds a Bachelor of Science degree in Finance and Accounting from California State University at Fullerton.

Malcolm R. Hill, Pharm.D.

Director

Dr. Hill has over 20 years of academic and pharmaceutical industry experience in new product assessment and clinical trial design and execution, with a special emphasis in pediatrics and drug delivery systems. He has been a Senior Vice President of Research and Development at Meritage Pharma since 2008 and was formerly a member of the senior management team at Dura Pharmaceuticals, where he served as a vice president and corporate officer. At Dura, Dr. Hill was responsible for all clinical development activities related to the Spiros® dry powder inhaler, including numerous asthma programs. Dr. Hill joined the Evoke Board of Directors in June 2007. His academic career spans his role at the National Jewish Medical and Research Center; he has also served as an assistant professor in the Schools of Medicine and Pharmacy at the University of Colorado. Dr. Hill has published over 80 articles on the topics of clinical pharmacology and pharmacokinetics, and the treatment of pediatric asthma and related

conditions. He earned his Doctor of Pharmacy degree from the University of Southern California. Dr. Hill also completed a post-doctoral program at the Veterans Administration Medical Center, San Diego, and a fellowship in the Schools of Medicine and Pharmacy at the Health Sciences Center of the University of Florida.

Kenneth J. Widder, M.D.

Director

Dr. Widder has 32 years of experience working with biomedical companies, and was appointed to the Board of Directors of Evoke Pharma in June 2007. He has been a General Partner with Latterell Venture Partners since 2007 and serves on the boards of Meritage Pharma Inc., Naurex Inc., Vision of Children and the San Diego Museum of Art. Dr. Widder has founded seven companies and was Chairman/CEO of five of these companies. His last company, Sytera Inc., merged with Sirion Therapeutics, an ophthalmology specialty pharmaceutical company. Prior to Sytera, Dr. Widder co-founded and was the initial CEO of NovaCardia, a company acquired by Merck. Prior to NovaCardia, Dr. Widder founded and was Chairman/CEO of Santarus Inc., which developed and currently markets Zegerid, a rapid onset proton pump inhibitor for esophageal reflux disease. Santarus was acquired by Salix Pharmaceuticals in November 2013 for \$2.6 billion. Additionally, Dr. Widder was Chairman and CEO of Converge Medical, a medical device company developing a suture less anastomosis system for vein grafts in coronary bypass surgery. He started his career as a founder, Chairman and CEO of Molecular Biosystems, where he was responsible for the development and approval of Alburnex and Optison, the first two ultrasound contrast agents to be approved in the U.S. Dr. Widder is an inventor on over 30 patents and patent applications and has authored or co-authored over 25 publications. He holds an M.D. degree from Northwestern University and trained in pathology at Duke University.

Ann D. Rhoads, M.B.A.

Director / Chairperson, Audit Committee

Mrs. Rhoads is the newest director of Evoke Pharma, having joined the board in June 2013. Currently, she serves as Executive Vice President and CFO of Zogenix, Inc., a publicly-traded pharmaceutical company, and has worked in that capacity since March 2010. From 2000 through the end of 2009, Ms. Rhoads served as the CFO of Premier, Inc., a healthcare supply management company. From 1998 to 2000, she was Vice President of Strategic Initiatives at Premier, Inc., and from 1993 to 1998 she was a vice president at The Sprout Group, an institutional venture capital firm. Ms. Rhoads holds a B.S. in Finance from the University of Arkansas and a M.B.A. from the Harvard Graduate School of Business Administration. She currently serves on the board of directors of Globus Medical Inc. and previously served on the board of directors of Novellus Systems, Inc. from 2003 until 2012.

Public Companies Mentioned in this Report:

ACADIA Pharmaceuticals (ACAD/NASDAQ)

Ampio Pharmaceuticals (AMPE/NASDAQ – Buy)

AstraZeneca (AZN/NYSE)

Durata Therapeutics (DRTX/NASDAQ)

Eli Lilly & Co. (LLY/NYSE)

Furiex Pharmaceuticals (FURX/NASDAQ)

Galectin Therapeutics (GALT/NASDAQ – Buy)

Intercept Pharmaceuticals (ICPT/NASDAQ)

Ironwood Pharmaceuticals (IRWD/NASDAQ – Buy)

GlaxoSmithKline (GSK/NYSE)

Novartis AG (NVS/NYSE)

Perrigo Co. (PRGO/NYSE)

Progenics Pharmaceuticals (PGNX/NASDAQ)

RapTor Pharmaceuticals (RPTP/NASDAQ)

Salix Pharmaceuticals (SLXP/NASDAQ)

Sanofi S.A. (SNY/NYSE)

Shire Pharmaceuticals (SHPG/NASDAQ)

Sucampo Pharmaceuticals (SCMP/NASDAQ)

Synergy Pharmaceuticals (SGYP/NASDAQ – Buy)

Ventrus Biosciences (VTUS/NASDAQ)

Table 12: Evoke Pharma, Inc. (EVOK) – Historical Income Statements, Financial Projections

FY end December 31

\$ in thousands, except per share data

	2011A	2012A	2013E			2014E					
			1HA	3QA	4QE	2013E	1QE	2QE	3QE	4QE	2014E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-
Expenses											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	1,844	1,166	-	242	79	571	1,500	2,500	3,500	4,500	12,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	571	837	-	294	407	1,250	650	700	750	800	2,900
Total expenses	2,415	2,002	-	535	486	1,821	2,150	3,200	4,250	5,300	14,900
Gain (loss) from operations	(2,415)	(2,002)	-	(535)	(486)	(1,821)	(2,150)	(3,200)	(4,250)	(5,300)	(14,900)
Other income/expense											
Interest income/expense	-	-	-	-	(39)	(15)	(110)	(115)	(120)	(90)	(435)
Change in fair value of preferred stock purchase right	-	-	-	-	39	-	-	-	-	-	-
Change in fair value of warrant liability	13	(15)	-	-	-	-	-	-	-	-	-
Other income/expense	-	-	-	(198)	-	(198)	-	-	-	-	-
Total investment income and other	13	(15)	-	(198)	(0)	(175)	(110)	(115)	(120)	(90)	(435)
Income (Loss) before provision for income taxes	(2,401)	(2,018)	-	(734)	(486)	(1,996)	(2,260)	(3,315)	(4,370)	(5,390)	(15,335)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-
Net loss/income	(2,401)	(2,018)	-	(734)	(486)	(1,996)	(2,260)	(3,315)	(4,370)	(5,390)	(15,335)
Net loss per share (basic)	(2.18)	(1.79)	-	(0.65)	(0.41)	(0.55)	(0.37)	(0.53)	(0.69)	(0.70)	(2.20)
Net loss per share (diluted)	(2.18)	(1.79)	-	(0.65)	(0.41)	(0.55)	(0.37)	(0.53)	(0.69)	(0.70)	(2.20)
Weighted average number of shares outstanding (basic)	1,103	1,124	-	1,135	1,190	3,627	6,187	6,267	6,347	7,677	6,972
Weighted average number of shares outstanding (diluted)	1,103	1,124	-	1,135	1,190	3,627	6,187	6,267	6,347	7,677	6,972

Source: Company Reports and Aegis Capital Corp. estimates

Table 13: Evoke Pharma, Inc. (EVOK) – Historical Income Statements, Long-Term Financial Projections

FY end December 31

\$ in thousands, except per share data

	2011A	2012A	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue										
Product revenue	-	-	-	-	-	2,100	61,000	167,000	223,000	263,000
Service revenue	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	2,100	61,000	167,000	223,000	263,000
Expenses										
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-
Research & development	1,844	1,166	571	12,000	10,600	3,800	2,800	2,400	2,000	1,600
Selling and marketing	-	-	-	-	-	18,000	54,000	70,000	80,000	84,000
General and administrative	571	837	1,250	2,900	9,000	29,000	46,000	56,000	60,000	64,000
Total expenses	2,415	2,002	1,821	14,900	19,600	50,800	102,800	128,400	142,000	149,600
Gain (loss) from operations	(2,415)	(2,002)	(1,821)	(14,900)	(19,600)	(48,700)	(41,800)	38,600	81,000	113,400
Other income/expense										
Interest income/expense	-	-	(15)	(435)	(59)	960	960	960	960	960
Change in fair value of preferred stock purchase right	-	-	-	-	-	-	-	-	-	-
Change in fair value of warrant liability	13	(15)	-	-	-	-	-	-	-	-
Other income/expense	-	-	(198)	-	-	-	-	-	-	-
Total investment income and other	13	(15)	(175)	(435)	(59)	960	960	960	960	960
Income (Loss) before provision for income taxes	(2,401)	(2,018)	(1,996)	(15,335)	(19,659)	(47,740)	(40,840)	39,560	81,960	114,360
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	16,720
Net loss/income	(2,401)	(2,018)	(1,996)	(15,335)	(19,659)	(47,740)	(40,840)	39,560	81,960	97,640
Net loss per share (basic)	(2.18)	(1.79)	(0.55)	(2.20)	(1.88)	(3.92)	(3.21)	2.94	5.74	6.48
Net loss per share (diluted)	(2.18)	(1.79)	(0.55)	(2.20)	(1.88)	(3.92)	(3.21)	2.94	5.74	6.48
Weighted average number of shares outstanding (basic)	1,103	1,124	3,627	6,972	10,467	12,179	12,742	13,467	14,267	15,067
Weighted average number of shares outstanding (diluted)	1,103	1,124	3,627	6,972	10,467	12,179	12,742	13,467	14,267	15,067

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 18-month price target is \$60.00 per share.

Valuation Methodology

Given the fact that Evoke Pharma is currently unprofitable, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, we believe that the stock is worth \$60.00 per share, given our estimate of a \$540 million risk-adjusted net present value (rNPV) for the firm's pipeline. This assumes that the shares trade in line with the comp group average enterprise value of \$540 million and that the firm has roughly 10 million shares outstanding and \$60 million in cash in mid-2015.

Risk Factors

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to complete the clinical development of its candidates and establish commercial infrastructure, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.

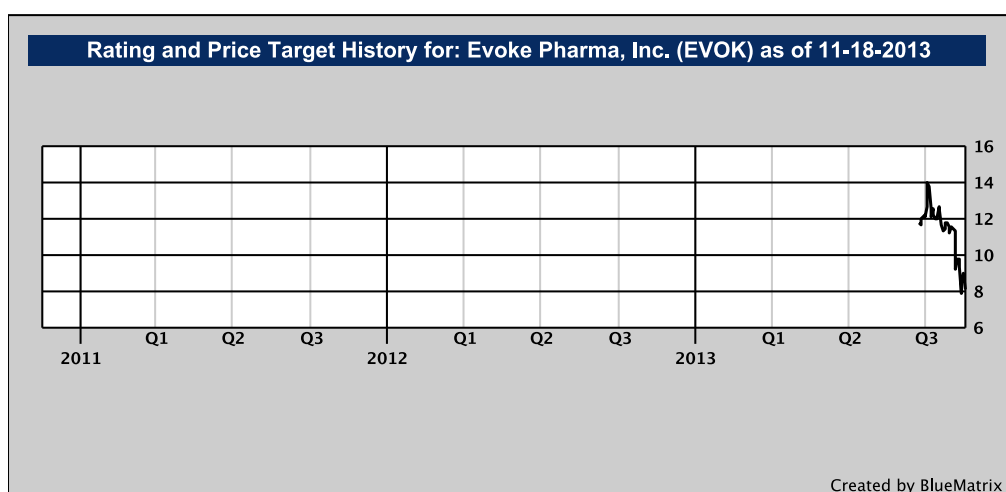
For important disclosures go to www.aegiscap.com.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Evoke Pharma, Inc. within the past 12 months.

Aegis Capital Corp. makes a market in Evoke Pharma, Inc..



Rating	Investment Banking Services/Past 12 Mos.	
	Percent	Percent
BUY [BUY]	81.58	25.81
HOLD [HOLD]	18.42	14.29
SELL [SELL]	0.00	0.00

Meaning of Ratings

- A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
- B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
- C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Aegis Capital Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

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