

Equity Research

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Evoke Pharma, Inc. (EVOK-\$11.51)

Rating: BUY

Target Price: \$19.00

Simple, Low-Risk Story; Initiating With A BUY Rating And \$19 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2012A	0.0A	0.0A	0.0A	0.0A
2013E	0.0A	0.0A	0.0E	0.0E
2014E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2012A	(0.38)A	(0.38)A	—	—
2013E	(0.09)A	(0.09)A	(0.10)E	(0.10)E
2014E	—	—	—	—
<u>FY</u>	<u>2012A</u>	<u>2013E</u>	<u>2014E</u>	
REV	0.0A	0.0E	0.0E	
EPS	—	(0.38)E	(1.83)E	
P/E	—	(30.3)x	(6.3)x	

- **We are initiating coverage of Evoke Pharma with a BUY rating and \$19 price target:** Evoke is developing an intranasal form of metoclopramide (EVK-001) for the treatment of diabetic gastroparesis in women. We believe that the program is relatively low risk given data in this patient population from a recent Phase II trial, coupled with the well-characterized nature of metoclopramide. We also like the large commercial opportunity since there were over 3.6M metoclopramide prescriptions written in the last 12 months and there are approximately 2 million patients already taking metoclopramide. We think peak sales for EVK-001 should most likely approach \$230M by 2023 (seven years after 2016 launch). We believe the company is adequately capitalized through its Phase III data in mid-2015 and, if results are positive, we believe that Evoke could get acquired.
- **Sound rationale for intranasal metoclopramide:** Gastroparesis is characterized by slow gastrointestinal transit, and chief symptoms are nausea and vomiting. The nature of gastroparesis makes it difficult for patients to digest oral tablets; therefore, the alternative delivery developed by Evoke provides an innovative solution we view as a meaningful improvement to existing dosing alternatives.
- **Other positives in the story:** (1) We believe that EVK-001 may also be able to capture a segment of patients taking antiemetics due to FDA's recent concern about serotonin syndrome in that drug class and estimate approximately \$140M in incremental revenues by capturing just 2% of antiemetic prescriptions; (2) Evoke has a clear and simple regulatory pathway to approval that requires only a single Phase III trial and no advisory panel given that the drug has been on the market for over 30 years and is well understood by FDA; (3) There is intellectual property protection until 2030; (4) We see EVK-001 as attractively positioned as a take-out asset since it straddles both the gastroenterology and primary care markets, where several specialty pharmaceutical players already have synergies.
- **Valuation and risks:** We value Evoke by applying a 3x multiple to risk-adjusted, discounted peak sales of EVK-001 in 2023. We assign 90% probability to peak revenues of \$230M and 10% probability to higher sales of \$415M. Chief risks to the story include high placebo response in the Phase III trial (we estimate a 60% probability of success and utilize that in our valuation); additional cash needs in 2015, and progression of new investigational agents for gastroparesis, which may have data readouts in late 2013/early 2014.

Current Statistics

Market Cap (\$Mil)	\$70.2	Float Shares (Mil):	6.800
Avg. Daily Trading Volume (3 mo.):	NA		
Shares Out (Mil):	6.097		

We are initiating coverage of Evoke Pharma with a BUY rating and \$19 price target

Summary

- **We are initiating coverage of Evoke Pharma with a BUY rating and \$19 price target:** Evoke is developing an intranasal form of metoclopramide (EVK-001) for the treatment of diabetic gastroparesis in women. We believe that the program is relatively low risk given supportive data in this patient population from a recent Phase II trial, coupled with the well-characterized nature of this molecule. While the results for the Phase II trial failed to attain statistical significance, the data in female patients who comprised 79% of patients in the trial were statistically significant for the 10 mg dose of EVK-001 ($p=0.0247$) while male patients demonstrated a strong placebo response (rather than lack of efficacy in the treatment group) that was similar to the response seen in male patients taking study drug. Since the Phase III program will focus on female patients where the drug already demonstrated success, we believe that the trial has a strong likelihood of a positive outcome. We also like the large commercial opportunity since there were over 3.6 million prescriptions written for metoclopramide in the last 12 months and there are approximately 2 million patients already taking metoclopramide. We think that peak sales for EVK-001 should most likely approach \$230 million by 2023 (seven years after launch in 2016) assuming conservative starting pricing of only \$10/day and annual 6% price increases. We think that the company is adequately capitalized through its Phase III data release in mid-2015 and if Phase III EVK-001 data are positive, we believe that Evoke could get acquired.
- **Rationale for intranasal metoclopramide:** Gastroparesis is characterized by slow gastrointestinal transit, and chief symptoms are nausea, vomiting, fullness, and abdominal pain. Women have slower gastrointestinal transit than male patients. The nature of the disease makes it difficult for patients to digest oral tablets, which accumulate in the stomach without releasing their active ingredient and then rapidly dump several doses into the system at once; therefore, the alternative delivery route developed by Evoke provides an innovative solution that we view as a meaningful improvement to existing dosing alternatives. Unlike other reformulated specialty pharmaceutical products that provide only modest incremental benefit over existing generics, we believe that EVK-001 could result in improved dose absorption and tolerability compared with oral metoclopramide, and that these benefits can be easily communicated to physicians.
- **Other positives in the story:** (1) We believe that Evoke's product may also be able to capture a segment of patients taking antiemetics due to FDA's recent concern about serotonin syndrome in that drug class and estimate approximately \$140M in incremental revenues by capturing just 2% of the ~15 million annual antiemetic prescriptions. We note that the *Journal of the American Medical Association (JAMA)* recently highlighted the safety of metoclopramide use in the treatment of morning sickness, which speaks to other off-label uses as well as the perceived safety of the drug in pregnant women. (2) Evoke has a clear and simple regulatory pathway to approval that requires only a single Phase III trial given that the drug has been on the market for over 30 years and is well understood by FDA; (3) There is intellectual property protection until 2030; (4) We see EVK-001 as attractively positioned as a take-out asset since it straddles both the gastroenterology and primary care markets, where several specialty pharmaceutical players such as Forest Laboratories, AstraZeneca, Takeda, and Salix already have synergies.
- **Valuation and risks:** We value Evoke by applying a 3x multiple to risk-adjusted, discounted peak sales of EVK-001 in 2023. We assign 90% probability to peak revenues of \$230 million (assuming 20% penetration of existing oral metoclopramide prescriptions) and 10% probability to higher sales of \$415 million (assuming ~17% penetration of prescriptions used by approximately 2 million patients). Chief risks to the story include high placebo response in the Phase III trial (we estimate a 60% probability of success in 2H:15 and utilize this risk adjustment in our valuation); additional cash needs in 2015, and progression of new investigational agents for gastroparesis that may have data readouts in late 2013/early 2014.

Company History

Evoke Pharma was founded in 2007 by CEO David Gonyer and Chief Business Officer Matthew D'Onforio. The company acquired its sole asset, EVK-001, from Questcor in June 2007. Evoke paid \$0.65 million upfront for global product rights to the compound and is also responsible for the following payments:

- \$0.5 million upon first patient dosing in its Phase III clinical trial of EVK-001 (expected in mid-2014).
- \$1.5 million upon the FDA's acceptance of the EVK-001 NDA (expected in late 2015).
- \$3.0 million upon FDA approval of EVK-001 (estimated in 2H:16).
- \$47 million in commercial milestones and a low-single-digit royalty on net sales.

Evoke held its IPO in October 2013, selling a total of 2,415,000 shares for gross proceeds of \$28.98 million at \$12.00/share (including full exercise of the over-allotment), which it plans to use to complete clinical development of EVK-001. We summarize the company's other financing transactions in Exhibit 1.

Exhibit 1: Historical Financial Transactions

Date	Event	Funds Raised (\$ in millions)	Financing Type
March 2007	Common Stock Offering/Inception	NA	916,000 at \$0.005
June 2007-June 2010	Series A Convertible Preferred Stock	gross \$18.3M	12,195,068 shares at \$1.50
February 2008	Loan and Security Agreement	\$2.5M	Debt
February 2008	Loan and Security Agreement	NA	Warrant for 50,000 shares of preferred stock @ \$1.50 exercise price.
June 2012	Loan and Security Agreement	\$3M	4.5% Debt
June 2012	Loan and Security Agreement	NA	Warrant for 60,000 shares of preferred stock @ \$1.50 exercise price.

Source: Evoke Pharmaceuticals and Cantor Fitzgerald research

There are slightly fewer than 6.1 million shares outstanding, but the company has a number of outstanding options and warrants that can increase the share count to 6.9 million shares, as seen in Exhibit 2.

Exhibit 2: Total Basic and Potentially Diluted Shares Outstanding

Existing Common Stock	3,681,752
IPO	2,100,000
Total Basic Shares	5,781,752
Stock Options as of 6/30/13	123,250
Common Stock Reserved Under Equity Incentive Award Plan	510,000
Employee Stock Purchase Plan	30,000
Common Stock Issuable Upon Exercise of Warrants	22,000
Warrants issued to underwriters	84,000
Over-allotment option	315,000
Potential Total Diluted Shares	6,866,002

Source: Evoke Pharmaceuticals and Cantor Fitzgerald research

Industry Overview

There are multiple pharmaceutical companies focused on gastroenterology. Larger players include AstraZeneca, Takeda, and Shire. Mid-cap companies such as Forest Laboratories, Actavis, Salix, NPS, Ironwood, and Santarus also promote a variety of gastrointestinal products. Finally, there are several development-stage gastrointestinal companies such as Synergy, Ventrus, privately held Tioga, and Ocera, which are actively working on pipeline products in the space. Privately-held Rhythm Pharmaceuticals is also working to develop a subcutaneous treatment for diabetic gastroparesis. We summarize the pure-play gastrointestinal companies in Exhibit 3:

Exhibit 3: Gastrointestinal Comparables

General Information				
Ticker	Name	Close Price	Shares Out	Market Cap
Gastrointestinal Comparables		10/31/2013		
IRWD	Ironwood Pharmaceuticals	9.61	97	936
OCRX	Ocera Therapeutics, Inc.	7.74	11	87
SGYP	Synergy Pharmaceuticals, Inc.	4.04	90	364
SLXP	Salix Pharmaceuticals, Ltd.	71.75	62	4,425
VTUS	Ventrus Biosciences, Inc.	2.84	20	56
Mean		19.20	56	1,174

Source: Cantor Fitzgerald research and FactSet

Other players in Metoclopramide include generic companies such as Teva, Actavis, Hospira and Anchen (formerly Par). Salix manufactures Metozolv ODT, a branded orally disintegrating metoclopramide tablet that generates minimal sales for the company. Additionally, Ani Pharms and Baxter manufacture different formulations of Reglan, another branded formulation of metoclopramide. We note that there is also a large parallel therapeutic category amongst the 5-HT₃ receptor antagonists, which are antiemetics used to treat nausea and vomiting. The key product in this space is generic ondansetron, which is marketed by a number of manufacturers.

Company Overview

The key catalysts for Evoke are focused around the initiation of its Phase III program and data readouts. In addition to its pivotal Phase III gastroparesis trial in women, the company will also conduct a thorough QT study as well as a parallel study in males. We summarize critical data points in Exhibit 4.

Exhibit 4: Evoke Milestones

Date	Product	Indication	Milestone/Event
May-14	EVK-001	Female Diabetic Gastroparesis	Presentation of Phase II data at Digestive Disease Week
1H:14	EVK-001	Female Diabetic Gastroparesis	Start of Phase III study
1H:14	EVK-001	No labeled indication associated with data	Start of parallel male study with futility analysis
3Q:14	EVK-001	Female Diabetic Gastroparesis	Start of Thorough QT study (cardiac safety)
4Q:14	EVK-001	Female Diabetic Gastroparesis	Top line data from Thorough QT study (cardiac safety)
Mid 2015	EVK-001	Female Diabetic Gastroparesis	Phase III top line data
Mid 2015	EVK-001	No labeled indication associated with data	Results from male study futility analysis

Source: Company reports and Cantor Fitzgerald research

EVK-001 is a novel formulation of metoclopramide that may allow for improved dosing:

Evoke is currently developing EVK-001, a 10 mg intranasal metoclopramide spray that is dosed four times per day for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. This product is comprised of an amber glass vial directly attached to a pre-assembled spray pump unit with a protection cap. Each multi dose sprayer system comes preassembled and capable of

delivering a 30-day supply (120 doses at 4 doses per day.) The sprayer is a standardized metered sprayer technology utilized in other nasal spray products. Management indicated that it closely followed the 2002 FDA Guidance Document on Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products and has collected three years of stability data on its formulation. According to the FDA guidance, a nasal spray drug product consists of the formulation and the container closure system; and the most critical attributes are the reproducibility of the dose, the spray plume, and the particle/droplet size distribution. Management indicated that its vial and spray pump have been used in other FDA-approved products and that it has conducted all of the necessary Chemistry, Manufacturing, and Controls (CMC) work on the product, including tests for leachables and extractables. Patheon is the contract manufacturer for EVK-001.

EVK-001 is currently protected by three patents summarized in Exhibit 5. Additionally, Evoke has filed a method of use patent application that would focus on the drug's ability to treat gastroparesis in females. We believe that the drug's manufacturing process and container closure system may provide another barrier to entry, and management indicated that generic competitors would need to replicate its dose reproducibility and particle size, which may be a higher hurdle to generics than copying oral solid forms. The original formulation that was acquired from Questcor had discoloration issues, and management noted that it tested over 60 formulations to identify one that did not discolor.

Exhibit 5: Intellectual Property

Patent #	Expiration	Description
5,760,086	2016	Nasal Administration for the Treatment of Delayed Onset Emesis
6,770,262	2021	Nasal Administration of Agents for the Treatment of Gastroparesis
8,334,281	2030	Nasal Formulations of Metoclopramide
PCT/US2012/052096	2032*	Treatment of Symptoms Associated with Female Gastroparesis

Source: Evoke Pharmaceuticals and Cantor Fitzgerald research

*if granted

Gastroparesis:

Gastroparesis is a condition defined by delayed gastric emptying in the absence of a mechanical obstruction, and is characterized by nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain. Approximately 29% of gastroparesis is associated with diabetes. The disease is diagnosed using scintigraphy, wireless motility capsule, and breath testing. Gastroparesis is treated via a combination of fluids and nutritional support, glycemic control, and pharmacologic therapy. Metoclopramide is the first-line recommended drug for gastroparesis. Other agents used for the treatment of gastroparesis include domperidone (not approved in the U.S. but obtainable via compounding pharmacies), intravenous erythromycin, antiemetic agents such as ondansetron, and tricyclic antidepressants.¹ Studies have shown that women with diabetes have delayed gastric emptying² and that women are more susceptible to gastroparesis than men.³

Metoclopramide is the only FDA-approved therapy to treat gastroparesis that can be given orally, intravenously, or subcutaneously. Clinical guidelines issued by the American College of Gastroenterology recommend starting patients at the lowest effective dose, short-term use, and use of "drug holidays". Careful monitoring of tardive dyskinesia is also advised.⁴

¹ Camilleri, M, et. al. Clinical Guideline: Management of Gastroparesis. Am J Gastroenterol 2013; 108-18-37.

² Laway, BA. Prevalence of abnormal gastric emptying in asymptomatic women with newly detected diabetes and its reversibility after glycemic control-a prospective case control study. J. Diabetes Complications. 2013 Jan-Feb; 27(1)78-81.

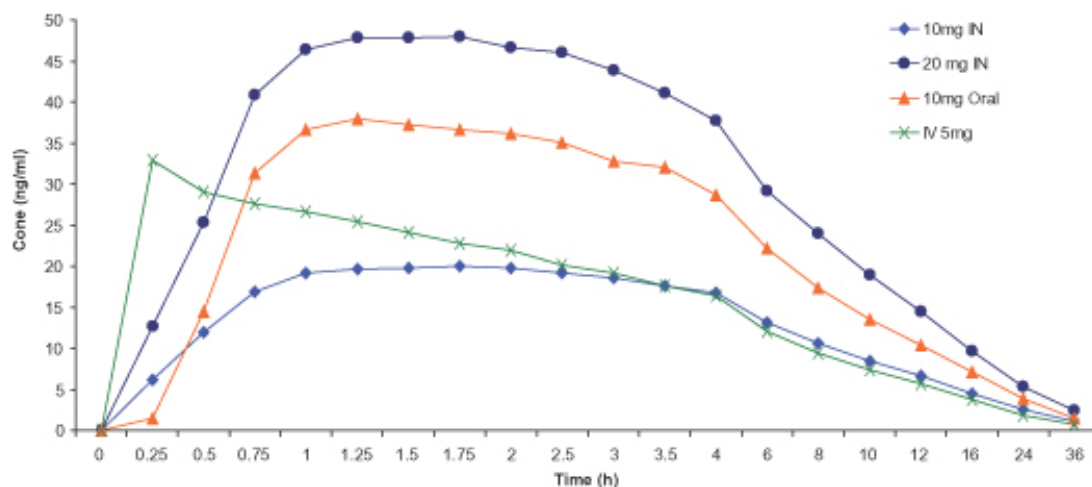
³ Gangula, P.R.R., et. al. Gender Bias in Gastroparesis: Is Nitric Oxide the Answer? Dig Dis Sci. 2011 September; 56(9): 2520-2527.

⁴ Camilleri, M, et. al. Clinical Guideline: Management of Gastroparesis. Am J Gastroenterol 2013; 108-18-37.

Metoclopramide oral dosing may be suboptimal in gastroparesis patients due to poor gastric emptying. Intranasal administration could lead to smoother delivery than the oral route since it bypasses the stomach and delivers drug directly to the bloodstream (thereby avoiding the local side effects associated with IV administration and dose-dumping associated with the oral form). Management believes that physicians should readily understand the benefits associated with this route of administration.

In addition, severe gastroparesis patients may vomit the oral metoclopramide before it is fully absorbed, whereas healthy patients are able to properly absorb oral medication and may therefore have different PK profiles from gastroparesis patients. In a Phase I study 40 healthy volunteers were randomized to receive a single dose of one of four formulations of metoclopramide: 1) 10 mg intranasal EVK-001, 2) 20 mg intranasal EVK-001, 3) 10 mg tablet, and 4) 5 mg intravenous. As seen in Exhibit 6, healthy volunteers who took the 10 mg oral metoclopramide dose were able to achieve higher plasma concentrations over the subsequent 36 hours than volunteers taking the 10 mg intranasal metoclopramide dose. However, we would expect to see a different result in actual gastroparesis patients who may not be able to absorb the oral dose as easily as healthy volunteers and would likely have worse absorption of an oral dose. Management indicated that the lower exposures associated with the intranasal dose may lead to safety advantages over the oral formulation, though there is no evidence thus far to suggest lower rates of tardive dyskinesia.

Exhibit 6: Plasma Metoclopramide Concentration Post-Dose



Source: Evoke Pharmaceuticals and Cantor Fitzgerald research
IN=intranasal; IV=intravenous

The established nature of the compound along with prior clinical work suggests that Phase III results should be positive, in our view:

Evoke most recently evaluated EVK-001 in a Phase IIb clinical trial. The study randomized 287 patients to receive four intranasal doses of placebo, 10 mg EVK-001, or 14 mg EVK-001 daily for 28 days. The primary endpoint was a change from the seven-day baseline to Week 4 of the treatment period in the mGCSI-DD (modified Gastroparesis Cardinal Symptom Index Daily Diary) total score. The mGCSI-DD is an instrument in which patients rate four symptoms (nausea, bloating, early satiety, and upper abdominal pain) using a score of 0 (none) to 5 (very severe) with the mGCSI-DD score reported as the average of the scores for each of the four symptoms. In the study, 79% of patients were female. The study failed to attain statistical significance as summarized in Exhibit 7 due to the high placebo response noted in male patients. However, as seen in both exhibits 7 and 8, both doses of EVK-001 led to significant symptom improvement in female patients using both the per-protocol GCSI-DD scoring system as well as the modified GCSI-DD total score, which was recommended by FDA.

We do see a placebo response even amongst female patients in this trial since we think that symptoms may resolve on their own to some extent over the four-week treatment period. This placebo response represents the chief risk to the success of the Phase III program, in our view.

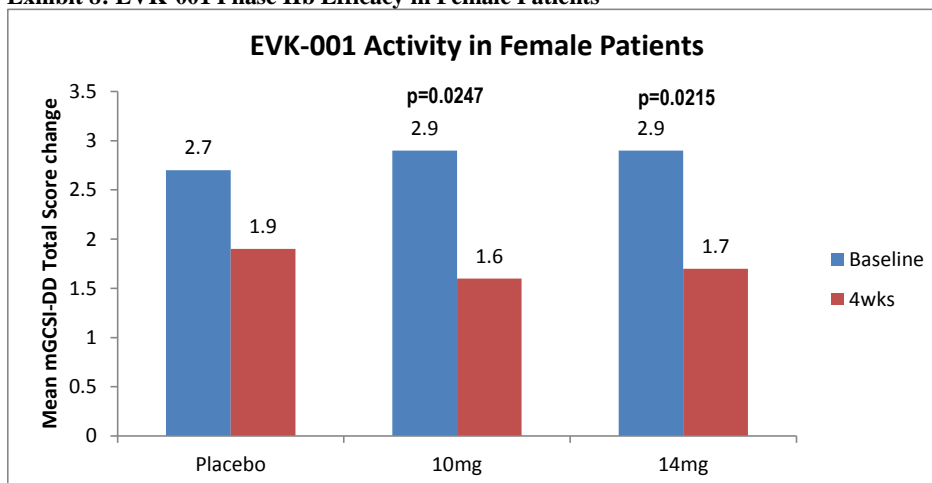
Exhibit 7: EVK-001 Phase IIb Clinical Trial Results

mGCSI-DD Total Score	EVK-001 10 mg	EVK-001 14 mg
	p-values	p-values
All Subjects	0.1504	0.3005
Females	0.0247	0.0215
Males	0.4497	0.2174
GCSI-DD Total Score		
All Subjects	0.2277	0.5266
Females	0.0485	0.0437
Males	0.4054	0.0972

Source: Company reports

The modified GCSI-DD (or mGCSI-DD) score was calculated as per FDA guidance and consisted of four symptoms as described above; The per-protocol endpoint was the GCSI-DD Total Score, which consisted of nine symptoms collected on a severity rating scale of 0 to 5.

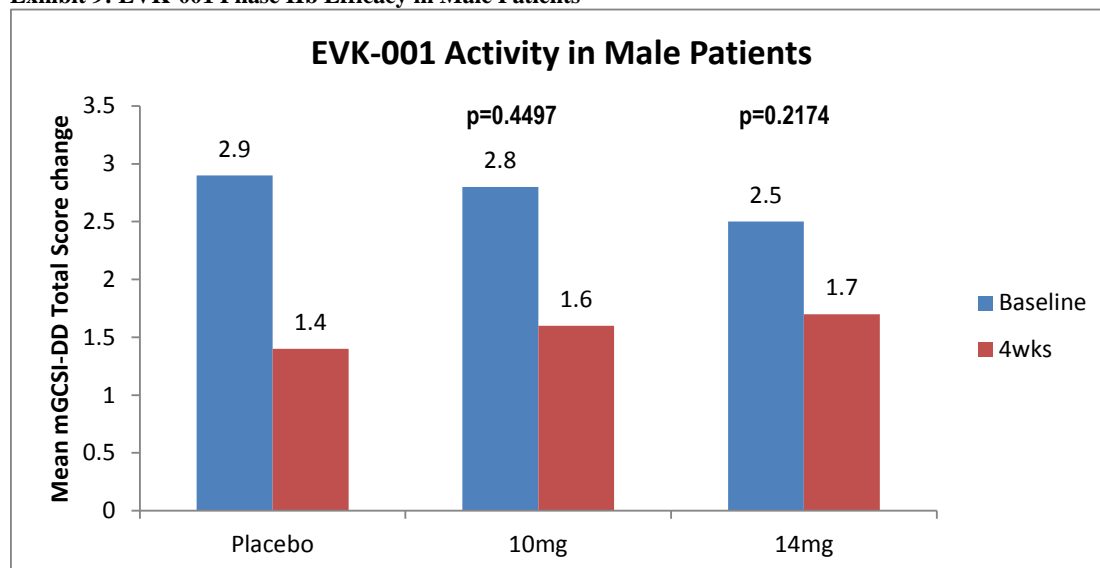
Exhibit 8: EVK-001 Phase IIb Efficacy in Female Patients



Source: Evoke Pharmaceuticals and Cantor Fitzgerald research

Male patients taking EVK-001 also had lower mGCSI-DD scores after treatment, but the improvement was not statistically significant due to the high placebo response as seen in Exhibit 9. Again, this placebo response remains our key worry about EVOK.

Exhibit 9: EVK-001 Phase IIb Efficacy in Male Patients



Source: Evoke Pharmaceuticals and Cantor Fitzgerald research

As seen in Exhibit 10, adverse events were consistent with safety issues identified in the Reglan label (though CNS effects such as somnolence, dizziness, and fatigue appeared to be more moderate than oral metoclopramide where these adverse events occur in approximately 10% of patients). Additionally, the intranasal delivery route was likely associated with some minor local side effects in the drug groups. There was also a higher incidence of dysgeusia in the drug-treated patients (a dysfunction of tasting ability), 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. Management elaborated that the study coordinator at the dysgeusia center asked patients if the drug tasted bad during clinic visits, which likely led to this bias, in our view.

Exhibit 10: Frequency of Adverse Events

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: Cantor Fitzgerald research and Evoke Pharmaceuticals

GERD=gastroesophageal reflux disease; URI=upper respiratory infection

As summarized in Exhibit 11, five patients experienced a serious adverse event (SAE), with three patients taking placebo and the other two taking 14 mg EVK-001. However, none of the SAEs were found to be related to the drug therapy.

Exhibit 11: Serious Adverse Events in Phase IIb Study

Dose	Subject Age/Sex	Serious Adverse Event	Study Drug Action	Treatment Relationship	Outcome
Placebo	43F	Diabetic ketoacidosis	Drug Withdrawn	None	Recovered
Placebo	33F	Kidney Infection	Dose Not Changed	None	Recovered
Placebo	60F	COPD	Dose Not Changed	None	Recovered
		Non-cardiac chest pain	Dose Not Changed	None	Recovered
14mg	65F	Worsening of gastroparesis symptoms	Dose Not Changed	None	Recovered
14mg	41F	Cholelithiasis	Drug Withdrawn	None	Recovered

Source: Cantor Fitzgerald research and Evoke Pharmaceuticals

SAE=serious adverse event; COPD=chronic obstructive pulmonary disease

The company has agreed to a straightforward registration program

Evoke held an end-of-Phase II meeting with the FDA in which Evoke and the agency agreed on two mandatory studies: 1) a four-week Phase III gastroparesis study in female patients and 2) a thorough QT study to assess cardiac safety (since this study was not previously conducted for metoclopramide). The female study is similar to the Phase IIb in design but will enroll 200 patients and will only evaluate the 10 mg EVK-001 dose. However, the primary endpoint in this trial differs from the Phase IIb study and will be a change in average Gastroparesis Symptom Assessment (GSA) score from baseline versus Week 4 of the treatment period. Previously the mGCSI-DD was used in the Phase IIb

study, which measured the total score change from baseline to Week 4. The company already retrospectively evaluated its Phase IIb results post-hoc using the GSA scoring system and indicated that it observed statistically significant and nearly identical magnitude of improvement in the GSA compared to the mGCSI-DD (management indicated that the p-value was 0.025 in female patients using the GSA, which compares to 0.0247 in this patient group using the mGCSI-DD). In addition, Evoke agreed to conduct a similar study in males that will employ a futility efficacy analysis (the company plans to look at the data from males after completing the female trial and could enroll up to 100 male patients). Management indicated that it expects enrolling males to be challenging and the final study results from the male trial are not required to be included in the company's new drug application (NDA) for EVK-001, though FDA does want the company to attempt to study males. Management indicated that even if the male data are positive, efficacy data in males would still be excluded from the product label. However, from a safety perspective the company may try to supplement its existing safety database with data from the male patients. Finally, management does not anticipate any Risk Evaluation and Mitigation System (REMS)-related issues and indicated that it can use the existing 2009 REMS for metoclopramide, which is not protected by any patents.

Exhibit 12: Primary Endpoint Comparison

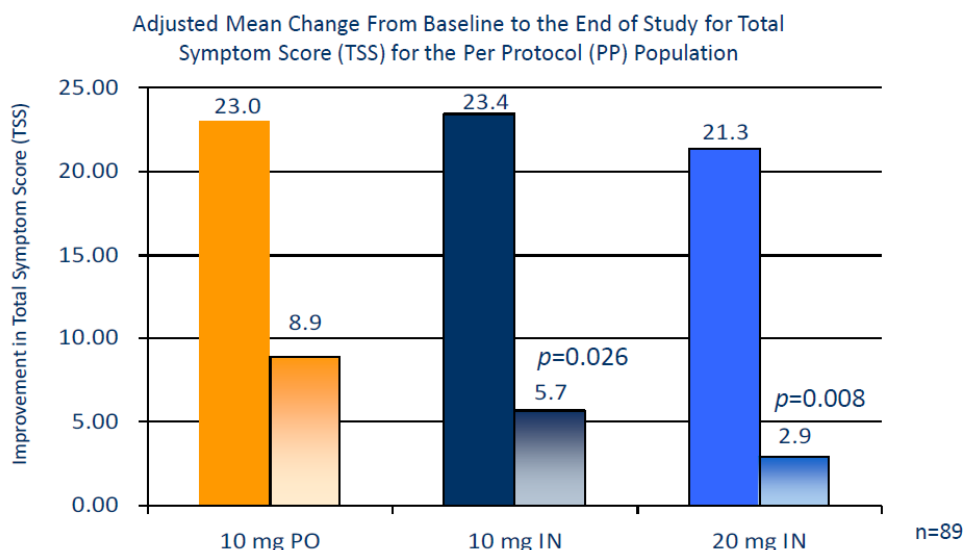
	Composite Primary Endpoint	
	mGCSI-DD (Phase II trial)	GSA (Phase III trial)
Symptoms	Nausea, Early Satiety, Bloating, Upper Abdominal Pain	Nausea, Early Satiety, Bloating, Upper Abdominal Pain, Vomiting
Scoring	0-5	0-4

Source: Cantor Fitzgerald research and Evoke Pharmaceuticals

Early head-to-head data against oral metoclopramide were also encouraging, which gives us even more comfort with Evoke's Phase III program:

Questcor previously conducted a Phase II trial in 89 patients using a different endpoint of Total Symptom Score (which is comprised of the sum of six patient-rated frequency items plus the sum of six investigator-rated severity items). This study compared two doses of intranasal metoclopramide, 10 mg and 20 mg, with 10 mg of oral metoclopramide and found that patients in the "per protocol" population taking either dose of intranasal metoclopramide had statistically significant symptom improvements compared with patients taking oral metoclopramide. However, in the intent to treat population, patients taking the 10 mg intranasal metoclopramide failed to statistically separate from oral metoclopramide. (We display the more positive "per protocol" results below.) We believe that these data are directionally positive since they illustrate that the intranasal form is at least as efficacious as the oral form, and furthermore, suggest additional incremental efficacy associated with intranasal delivery.

Exhibit 13: Results of Phase II IN/PO Metoclopramide Study



Source: Evoke Pharmaceuticals poster presented at Digestive Disease Week 2013 and Cantor Fitzgerald research

Safety concerns about Tardive Dyskinesia have pressured metoclopramide prescribing but physicians' perception can be improved, in our view:

In 2009, the FDA issued a Black Box warning regarding the risk of tardive dyskinesia (TD) after at least four studies demonstrated a connection between TD and metoclopramide use. TD is a difficult-to-treat disorder characterized by repetitive, involuntary, and purposeless movements. One study compared 51 patients from the Portland Veterans Affairs Medical Center taking at least 20 mg of metoclopramide daily for at least three months with 51 controls from the same center and found that 29% of patients taking metoclopramide acquired TD vs. 17.6% of the controls ($p=0.08$).⁵ A similar study enrolling patients from the San Diego VA Medical Center found that 27% of patients taking metoclopramide experienced TD vs. 12% of controls ($p=0.08$).⁶ Lastly, the FDA label for Reglan (metoclopramide) recommends the treatment duration to be less than three months, but many patients take the drug for longer periods, which can increase the risk for TD. Shaffer et al ran a study in 2004 on 87 patients using metoclopramide that acquired TD and found that the average dose was 33 mg per day and the average length of usage was over two years (753 days).⁷ The FDA Office of Surveillance and Epidemiology (OSE) conducted a study using prescription claims and found that almost 20% of patients used metoclopramide for more than 90 cumulative days.⁸ Evoke management believes that patients utilize approximately 5-11 prescriptions per year based on the company's market research.

The Black Box warning has adversely affected metoclopramide usage. According to a 2013 study conducted at the North Shore University Health System, metoclopramide usage decreased from 70% of patients that entered the system before the warning to 24% of patients that entered the system after the warning.⁹ Also, the total number of prescriptions decreased from 6.9 million in 2008 to 3.8 million (44% decline) in 2012, according to Source Healthcare Analytics (summarized in Exhibit 14). Metoclopramide usage in the hospital decreased as well, from 28.9 million pack units in 2008 to 7.7 million pack units (73% decline) in 2012.

⁵ Ganzini et al. Archives of Internal Medicine, Volume 153, 1993

⁶ Sewell et al. Biological Psychiatry Volume 36, 1994

⁷ Shaffer et al. J Am Pharm Assoc Vol 44(6), 2004.

⁸ Kaplan et al. Pharmacoepidemiology and Drug safety. Volume 16, 2007

⁹ Ehrenpreis et al. American Journal of Gastroenterology. Volume 108, 2013

The Tardive Dyskinesia Black Box has led to reduced metoclopramide utilization, but the market is still quite large since there is nothing else available for gastroparesis

There is evidence that contradicts the high incidence of TD in the VA studies. First, a Scandinavian study estimated from total drug sales and prescriptions statistics that the incidence of metoclopramide-associated TD was one in 2,000–2,800 treatment years.¹⁰ Another study using data from the national registry in the U.K. showed that out of 15.9 million metoclopramide prescriptions given between 1967 and 1982, only four adverse events were classified as TD.¹¹ A review article that summarizes these trials along with the VA data concludes that risk of TD from metoclopramide use is likely to be <1%, which is much less than the estimated 1-10% risk previously suggested in national guidelines¹². Finally, we note a recently published article in *JAMA* on the safety of metoclopramide use in the treatment of morning sickness in pregnant women. The study found no safety risk in more than 40,000 women treated with metoclopramide during pregnancy (from a cohort of over 1.2 million pregnancies in Denmark from 1997-2011). We believe that these results further support the tolerability of the compound.

Even under very conservative scenarios it is difficult to ignore the large number of metoclopramide prescriptions written each year:

We summarize the prescription trends for metoclopramide in Exhibit 14.

¹⁰ Wilholm et al. British Medical Journal. Volume 288, 1984

¹¹ Bateman et al. British Medical Journal. Volume 291, 1985

¹² Rao, A.S. and Camilleri, M. Review article: metoclopramide and tardive dyskinesia. *Aliment Pharmacol Ther* 31, 11-19.

Exhibit 14: Metoclopramide Prescription Model

	2008	2009	2010	2011	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
5mg Branded Oral Tablet	5,769	3,995	2,183	1,599	1,209	967	835	753	696	654	618	587	560
Growth		-30.8%	-45.4%	-26.8%	-24.4%	-20.0%	-13.6%	-9.8%	-7.5%	-6.1%	-5.6%	-5.1%	-4.6%
10mg Branded Oral Tablet	13,734	9,575	5,286	2,230	1,753	1,500	1,368	1,301	1,268	1,255	1,249	1,249	1,255
Growth		-30.3%	-44.8%	-57.8%	-21.4%	-14.4%	-8.8%	-4.9%	-2.5%	-1.0%	-0.5%	0.0%	0.5%
Oral Dissolvable Tablet	0	1,236	24,517	19,674	7,376	3,297	2,532	2,233	2,021	1,857	1,717	1,595	1,490
Growth		-	1883.6%	-19.8%	-62.5%	-55.3%	-23.2%	-11.8%	-9.5%	-8.1%	-7.6%	-7.1%	-6.6%
Oral Solution/Suspension	457,782	376,724	249,407	201,059	174,323	159,986	152,818	149,762	148,264	148,249	148,235	148,220	148,205
Growth		-17.7%	-33.8%	-19.4%	-13.3%	-8.2%	-4.5%	-2.0%	-1.0%	0.0%	0.0%	0.0%	0.0%
Injectable	4,424	4,448	3,652	3,162	1,797	2,104	2,423	2,612	2,847	3,106	3,357	3,594	3,811
Growth		0.5%	-17.9%	-13.4%	-43.2%	17.1%	15.2%	7.8%	9.0%	9.1%	8.1%	7.1%	6.0%
5mg Generic Oral Tablet	1,630,490	1,543,740	1,200,535	1,068,231	1,021,430	981,517	965,813	960,694	960,694	950,895	936,394	917,385	894,129
Growth		-5.3%	-22.2%	-11.0%	-4.4%	-3.9%	-1.6%	-0.5%	0.0%	-1.0%	-1.5%	-2.0%	-2.5%
10mg Generic Oral Tablet	4,818,681	4,393,796	3,346,083	2,862,977	2,632,880	2,402,630	2,284,130	2,224,367	2,167,450	2,103,740	1,962,798	1,891,777	1,868,096
Growth		-8.8%	-23.8%	-14.4%	-8.0%	-8.7%	-4.9%	-2.6%	-2.6%	-2.9%	-6.7%	-3.6%	-1.3%
EVK-001	0	0	0	0	0	0	0	0	58,480	165,382	354,525	478,574	559,863
Growth		-	-	-	-	-	-	-	-	182.8%	114.4%	35.0%	17.0%
Total Metoclopramide Market	6,930,880	6,333,514	4,831,663	4,158,932	3,840,768	3,552,000	3,409,920	3,341,721	3,341,721	3,375,139	3,408,890	3,442,979	3,477,409
Growth		-8.6%	-23.7%	-13.9%	-7.7%	-7.5%	-4.0%	-2.0%	0.0%	1.0%	1.0%	1.0%	1.0%
					-12%								
Market Share	2008	2009	2010	2011	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
5mg Branded Oral Tablet	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Growth		-24.2%	-28.4%	-14.9%	-18.1%	-13.6%	-10.0%	-8.0%	-7.5%	-7.0%	-6.5%	-6.0%	-5.5%
10mg Branded Oral Tablet	0.2%	0.2%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Growth		-23.7%	-27.6%	-51.0%	-14.9%	-7.5%	-5.0%	-3.0%	-2.5%	-2.0%	-1.5%	-1.0%	-0.5%
Branded Oral Dissolvable Tablet	0.0%	0.0%	0.5%	0.5%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%
Growth		-	2500.1%	-6.8%	-59.4%	-51.7%	-20.0%	-10.0%	-9.5%	-9.0%	-8.5%	-8.0%	-7.5%
Oral Solution/Suspension	6.6%	5.9%	5.2%	4.8%	4.5%	4.5%	4.5%	4.5%	4.4%	4.4%	4.3%	4.3%	4.3%
Growth		-9.9%	-13.2%	-6.3%	-6.1%	-0.8%	-0.5%	0.0%	-1.0%	-1.0%	-1.0%	-1.0%	-1.0%
Injectable	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Growth		10.0%	7.6%	0.6%	-38.5%	26.6%	20.0%	10.0%	9.0%	8.0%	7.0%	6.0%	5.0%
5mg Generic Oral Tablet	23.5%	24.4%	24.8%	25.7%	26.6%	27.6%	28.3%	28.7%	28.7%	28.2%	27.5%	26.6%	25.7%
Growth		3.6%	1.9%	3.4%	3.5%	3.9%	2.5%	1.5%	0.0%	-2.0%	-2.5%	-3.0%	-3.5%
10mg Generic Oral Tablet	69.5%	69.4%	69.3%	68.8%	68.6%	67.6%	67.0%	66.6%	64.9%	62.3%	57.6%	54.9%	53.7%
Growth		-0.2%	-0.2%	-0.6%	-0.4%	-1.3%	-1.0%	-0.6%	-2.6%	-3.9%	-7.6%	-4.6%	-2.2%
EVK-001	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.8%	4.9%	10.4%	13.9%	16.1%
Growth		-	-	-	-	-	-	-	-	50.0%	20.0%	20.0%	20.0%
Total Metoclopramide Market	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Source Health Analytics and Cantor Fitzgerald research

Using just metoclopramide retail prescriptions, we estimate that there were approximately 3.6 million prescriptions written over the last 12 months ended September 2013. Of these, 68% were written for the 10 mg dose and 96% were for the oral tablet form, so we therefore believe that the most conservative market opportunity for EVK-001 consists of 2.4 million prescriptions. If we assume daily pricing in the \$10-range, which is comparable to other gastrointestinal compounds and estimate that a branded intra-nasal product could capture 20% of this market, then we arrive at a minimum initial “back of the envelope” EVK-001 opportunity of \$142 million. This is just in the retail metoclopramide market and does not assume price increases over time. If we look out seven years and model annual 6% price increases, then we can derive a \$230 million opportunity for the product. We are not assuming a larger penetration for now since we expect continued cost-sensitivity amongst some patients as well as some potential disliking of the intranasal formulation due to taste disturbances as noted in the Phase II program. If we delve further into hospital use of metoclopramide tablets we learn that approximately 1.5% of hospital units consist of the tablet form. We estimate that Evoke could derive another \$13 million from this segment using the same assumptions of \$300/prescription and 20% penetration. Management has conducted its own payor market research and believes that it can price its product as high as \$15/day with minimal market share loss from reimbursement restrictions. The company believes that the drug would be covered at the Tier 3 level but may also be exposed to prior authorizations and step edits (i.e., the patient must fail one month of oral metoclopramide first). Management also believes that patients receiving IV metoclopramide in the hospital may be able to step down to the intranasal form.

We look to other therapeutic areas such as migraine and antipsychotics to assess the switch rates to alternative formulations that provide tolerability or compliance benefits. We note that alternative dosage forms represent approximately 3% of antipsychotic and migraine prescriptions; but there is still significant branded promotion in these categories whereas none is present in metoclopramide. For this reason we estimate that a higher percent of generic metoclopramide patients may switch to novel forms of the drug.

Using a prescription-based model we conservatively estimate that EVK-001 can generate peak sales in the \$230 million range seven years post-launch (by 2023), with another \$140 million possible assuming a 2% penetration of the antiemetic category

We can also derive upside to our estimates by assuming some off-label use in conditions such as functional dyspepsia or chemotherapy-induced nausea, where antiemetics such as ondansetron are currently utilized. We note that there were approximately 15.5 million prescriptions for 5-HT₃ antinauseant tablets written over the last 12 months ended September 2013. This market grew significantly from 3.9 million prescriptions in 2008 to 12.9 million prescriptions in 2012 after metoclopramide was issued a Black Box Warning. If EVK-001 captures just 2% of this market, we think that Evoke can generate an additional \$140 million in 2023 under our conservative \$10/day pricing scenario. Interestingly, the antiemetic class of drugs was posted to FDA’s safety risks list in early 2013 because of a safety signal identified for serotonin syndrome (a potentially life-threatening drug reaction). The FDA is currently studying this issue and recommending label updates for these products. We think if this occurs, then we would expect physicians to search for another solution to help patients who are taking selective serotonin reuptake inhibitors (SSRIs) (estimated as approximately one in ten patients in the U.S.), which may create a more favorable market opportunity for intranasal metoclopramide. Realistically, in our view, the opportunity may be even more meaningful for a commercially savvy company.

Another way to assess the EVK-001 market opportunity is by looking at a patient-driven model of gastroparesis. According to the American College of Gastroenterology, there have been studies conducted in academic centers reporting up to 40% prevalence in type 1 diabetes and 10-20% in type 2 diabetes.¹³ The American College of Gastroenterology also noted a community-based study that reported a lower prevalence of 5% in type 1 diabetes and 1% in type 2 diabetes.¹⁴ Assuming a diabetes prevalence of 24.5 million in the U.S., the estimated prevalence of diabetic gastroparesis ranges from 330K to 4.2M patients. The actual prevalence is likely somewhere in the middle, which would correspond to 2.3M patients in the U.S. We note that FDA has previously estimated that there were 2 million patients taking metoclopramide.

¹³ Camilleri, et al. American Journal of Gastroenterology Volume 108, 2013

¹⁴ Choung et al. American Journal of Gastroenterology Volume 107, 2012

Using a patient-based bottoms-up model generates higher peak estimates in the \$415 million range

In contrast, Evoke management believes that the prevalence of gastroparesis in the U.S. is closer to 12-16 million, of which 80% are women. Management estimates that 29% of gastroparesis is associated with diabetes, which yields a range of 2.8-3.7 million patients. To conservatively evaluate the market opportunity using a bottoms-up analysis we have created a patient-driven model in Exhibit 15 below. We assume that the market is comprised of 2 million patients (based on prior FDA estimates of metoclopramide users) and that each patient receives 2.5 prescriptions per year on average, with each prescription initially valued at \$300. We assume annual price increases of 6%. This analysis generates a peak market opportunity of \$415 million. While we think that these revenue levels are optimistic, we give the company a 10% probability of hitting this target in our valuation. We note that management estimates a range of \$479-861 million for this product, so our estimates are meaningfully lower.

Exhibit 15: Patient-Based Metoclopramide Model

	2016	2017	2018	2019	2020	2021	2022	2023
Patients	2,000,000	2,030,000	2,060,450	2,091,357	2,122,727	2,154,568	2,186,887	2,219,690
Prescriptions/Year	1.0	2.0	2.5	2.5	2.5	2.5	2.5	2.5
Cost/Rx	\$300.00	\$318.00	\$337.08	\$357.30	\$378.74	\$401.47	\$425.56	\$451.09
Penetration	0.5%	5.0%	8.0%	12.0%	15.0%	16.0%	16.5%	16.6%
Value	\$3,000,000	\$64,554,000	\$138,907,297	\$224,175,542	\$301,488,081	\$345,995,762	\$383,889,867	\$415,530,302
Growth		2052%	115%	61%	34%	15%	11%	8%

Source: Cantor Fitzgerald research

Existing competition is not concerning to us and other investigational compounds are further behind in development:

Erythromycin is an antibiotic that is also a motilin agonist that improves emptying rates. It may cause cramping and abdominal pain in some patients. Also, low doses are given to prevent tachyphylaxis (sudden decrease in treatment response). Additionally, domperidone, which is not approved in the U.S., has been associated with prolonged QT interval, which may be a contraindication for diabetic patients with concomitant cardiac conditions. Exhibit 16 summarizes relevant studies of metoclopramide, erythromycin, and domperidone in which they decreased gastric emptying times and improved symptoms associated with gastroparesis such as nausea, vomiting, and bloating.

Exhibit 16: Selected Gastroparesis Studies

Drug	Dose	ROA	Comparator	N	Outcome
Metoclopramide ¹	10 mg QID	Intravenous	Placebo	13	Metoclopramide significantly improved mean symptom scores
Metoclopramide ²	10 mg	Intravenous	Cisapride 2.5, 5.0, 10 mg; Placebo	10	Both Cisapride and Metoclopramide normalized gastric emptying but the highest Cisapride dose resulted in significantly faster emptying than Metoclopramide. Fewer side effects in the Cisapride group.
Erythromycin ³	200 mg IV; 250 mg TID oral	Intravenous/Oral	Placebo	10	IV Erythromycin improved gastric emptying times; gastric emptying improved to a lesser degree with oral Erythromycin
Erythromycin ⁴	250 mg TID	Oral tablets	Metoclopramide 10 mg TID	13	Both drugs significantly improved gastrointestinal symptom scores but the improvement was more pronounced with erythromycin.
Domperidone ⁵	20 mg QID	Oral tablets	Metoclopramide 10 mg QID	93	Drugs were equally effective in alleviating gastroparesis symptoms but Metoclopramide was associated with more severe CNS side effects.

Sources: ¹Ricci, et al. *Journal of Clinical Gastroenterology*, February 1985; ²McHugh et al. *Digestive Diseases and Sciences*, Vol. 37, No. 7, 1992; ³Erbas et al. *Diabetes Care*, Volume 16, Number 11, November 1993; ⁴Janssens et al *New England Journal of Medicine*, April 12, 1990; ⁵Patterson, D. et. al. *American Journal of Gastroenterology*, May 1999; Cantor Fitzgerald research
ROA=route of administration, TID = three times a day QID=4 times a day

As seen in Exhibit 17, there are four other compounds in development for gastroparesis with mechanisms of actions that are distinct from metoclopramide.

Exhibit 17: Gastroparesis Compounds in Development

Company	Product	ROA	Phase	Indication	MOA	Data Expected
Rhythm Pharmaceuticals	RM-131	Subcutaneous	II	Diabetic Gastroparesis	Ghrelin Agonist	4Q:13
Lilly	Cialis	Oral	IV	Diabetic Gastroparesis	PDE5 Inhibitor	1Q:14
Theravance	Velusetrag (TD-5108)	Oral	II	Diabetic or Idiopathic Gastroparesis	5HT4 Agonist	1H:14
GSK	Camicinal (GSK962040)	Oral	II	Delayed Gastric Emptying Associated With Parkinson's Disease	Motilin Agonist	1H:14

Source: Clinicaltrials.gov and Cantor Fitzgerald research
 ROA=Route of Administration; MOA=Mechanism of Action

Management

We summarize the biographies of the two founders of Evoke Pharma in Exhibit 18 below. The company is also in the process of hiring staff to help oversee its clinical program and to comply with the financial reporting requirements associated with being a public company. We feel it important to note that the functions of CEO and Chairman of the Board have been separated in this company to ensure the independent oversight of management.

Exhibit 18: Evoke Management

Executive	Title	Biography
David A. Gonyer, R. Ph.	President and Chief Executive Officer	David Gonyer is one of the co-founders and has served as the President and CEO and as a member of the board of directors since March 2007. From January 2004 to June 2007, he served as VP, Strategic and Product Development of Medgenex, Inc., a subsidiary of Victory Pharma. From April 2000 to December 2004, he was a founder and VP of Sales and Marketing at Xcel Pharmaceuticals, Inc. From December 1996 to April 2000, he served as Director of Marketing at Elan/Dura Pharmaceuticals, Inc. From 1987 to 1996, he held a broad range of management positions in commercial operations, alliance/partnership management, and regional sales at Eli Lilly & Company. He also serves as a member of the board of directors of Neurelis, Inc.. Mr. Gonyer is a Registered Pharmacist and holds a B.Sc. in Pharmacy from Ferris State University School of Pharmacy.
Matthew J. D'Onofrio	Executive Vice President and Chief Business Officer	Matthew D'Onofrio is one of Evoke's co-founders and has served as the EVP, Chief Business Officer since 2010 and as the EVP Corporate Development, Treasurer and Secretary since March 2007. Prior to founding Evoke, Mr. D'Onofrio was VP, Business Development for Victory Pharma, a growing specialty pharma company based in San Diego. From 2002 to 2005, Mr. D'Onofrio led efforts to acquire marketed brands for the growing sales force. Earlier, Mr. D'Onofrio was Director and Head of West Coast Business Development at Vertex Pharmaceuticals, directing partnership efforts associated with the La Jolla research facility as well as other corporate assets. He also held various commercial roles of increasing responsibility over a decade at Eli Lilly & Company, including significant experience in worldwide corporate business development. Mr. D'Onofrio earned a B.S. in Chemistry from San Diego State University and an M.B.A. (Finance) from the Marshall School of Business, University of Southern California.

Source: Company reports and Cantor Fitzgerald research

Financial Performance and Outlook

Revenues: We assume that Evoke will have Phase III data for EVK-001 in 2H:15 and therefore will not have the drug on the market until late 2016 (assuming a 12-month NDA review clock). We forecast 2016 sales of \$15 million, growing to \$230 million at peak in 2023.

COGS: Management estimates that it will cost less than \$10 to manufacture a month's supply of EVK-001. If we assume initial pricing of \$10/day and \$300/month we back into COGS of approximately 4%. We would assume even better margins with increasing product volumes over time.

SG&A: We expect Evoke to increase headcount to include staff to manage its clinical trials, submit its regulatory filing, and initiate pre-marketing activities. We model 2013 SG&A of \$0.7 million growing to \$2.4 million in 2014. Though we do not expect the company to market EVK-001 alone, we have nonetheless modeled in launch costs in 2016 to approximate what we believe is a reasonable launch scenario for a company launching a drug into the primary care space (e.g., Ironwood is spending approximately \$70 million to promote Linzess). Management indicated that it could cover the top 50% of metoclopramide prescribers (or 20,000 doctors) with 200 sales reps.

R&D: Management expects to spend \$15 million to conduct its clinical program for EVK-001. We model \$0.9 million of spending in 2013, \$10 million in 2014, and \$5 million in 2015. We maintain a low degree of spending beyond that point since we do not expect the company to invest in additional research programs. Management indicated that it does not expect to pay an NDA submission fee since Evoke is a small business with just one NDA, but we do anticipate some additional expense associated with the regulatory filing. Management also does not expect an FDA Advisory Panel on this well-known molecule, which also minimizes R&D costs, in our view.

Tax: The company has approximately \$18.6 million in federal and \$18.2 million in state net operating loss carryforwards as of December 31, 2012. We do not expect Evoke to pay taxes until 2019, which is when we model profitability.

EPS: We model a loss of \$0.38 in 2013 and a loss of \$1.83 in 2014. Since we only expect the company to begin generating revenues in late 2016, we do not expect Evoke to turn profitable before 2019.

Valuation

We value Evoke using a weighted blend of the following two scenarios:

- (1) **90% probability:** We apply a 3x multiple to discounted risk-adjusted peak sales of \$230 million (our most conservative peak sales estimate, which assumes only 20% penetration of today's generic, oral, 10 mg metoclopramide market; with 6% annual price increases), which yields a hypothetical price target of \$17.50. We employ a seven-year peak sales duration (assuming that peak sales are reached in 2023 after launch in 2H:16). We utilize a 13% discount rate, which is at the higher end of the risk rates we utilize in our space. We also risk-adjust the sales estimate by 60% to incorporate clinical risk associated with a Phase III asset.
- (2) **10% probability:** We apply a 3x multiple to discounted risk-adjusted peak sales of \$415 million (a more generous scenario, which assumes 16.6% penetration of prescriptions utilized by 2.2 million patients in 2023; with 6% annual price increases), which yields a hypothetical price target of \$31.60. We utilize a 13% discount rate, which is at the higher end of the risk rates we utilize in our space. We also risk-adjust the sales estimate by 60% to incorporate clinical risk associated with a Phase III asset. We include this scenario also since there could be potential upside to Evoke from capturing a small percentage of antiemetic prescriptions given the new concerns about serotonin syndrome in that drug class.

We therefore arrive at a blended price target of \$19.00 using these two calculations.

We summarize our two valuation calculations in Exhibit 19.

Exhibit 19: Evoke Valuation

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Scenario 1 (Prescription Based)											
Revenues (\$ in millions)	\$0.0	\$0.0	\$0.0	\$15.0	\$45.0	\$102.0	\$145.0	\$180.0	\$205.0	\$221.0	\$230.0
Growth					200%	127%	42%	24%	14%	8%	4%
Discount Period	0.2	1.2	2.2	3.2	4.2	5.2	6.2	7.2	8.2	9.2	10.2
Discount Factor	0.98	0.86	0.76	0.68	0.60	0.53	0.47	0.41	0.37	0.32	0.29
Discounted Revenues (\$ in millions)	\$0.0	\$0.0	\$0.0	\$10.1	\$26.9	\$54.0	\$68.0	\$74.7	\$75.3	\$71.8	\$66.1
Risk Adjustment	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Risk Adjusted, Discounted Revenues (\$ in millions)	\$0.0	\$0.0	\$0.0	\$6.1	\$16.2	\$32.4	\$40.8	\$44.8	\$45.2	\$43.1	\$39.7
Scenario 2 (Patient Based)											
Revenues (\$ in millions)	\$0.0	\$0.0	\$0.0	\$3.0	\$64.6	\$138.9	\$224.2	\$301.5	\$346.0	\$383.9	\$415.5
Growth					2052%	115%	61%	34%	15%	11%	8%
Discount Period	0.2	1.2	2.2	3.2	4.2	5.2	6.2	7.2	8.2	9.2	10.2
Discount Factor	0.98	0.86	0.76	0.68	0.60	0.53	0.47	0.41	0.37	0.32	0.29
Discounted Revenues (\$ in millions)	\$0.0	\$0.0	\$0.0	\$2.0	\$38.6	\$73.6	\$105.1	\$125.1	\$127.0	\$124.7	\$119.5
Risk Adjustment	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Risk Adjusted, Discounted Revenues (\$ in millions)	\$0.0	\$0.0	\$0.0	\$1.2	\$23.2	\$44.1	\$63.0	\$75.0	\$76.2	\$74.8	\$71.7
Discount Rate	13.0%										
Share count (in millions)	6.8										
Scenario 1 (Prescription Based)											
Sales Multiple		2.5x	3.0x	3.5x	4.0x	4.5x					
Risk Adjusted, Discounted, 2023 Peak Revenues		\$39.7	\$39.7	\$39.7	\$39.7	\$39.7					
Multiplied Revenues		\$99.2	\$119.0	\$138.9	\$158.7	\$178.5					
Share Count		6.8	6.8	6.8	6.8	6.8					
Value Per Share		\$14.6	\$17.5	\$20.4	\$23.3	\$26.3					
Scenario 2 (Patient Based)											
Sales Multiple		2.5x	3.0x	3.5x	4.0x	4.5x					
Risk Adjusted, Discounted, 2023 Peak Revenues		\$71.7	\$71.7	\$71.7	\$71.7	\$71.7					
Multiplied Revenues		\$179.2	\$215.0	\$250.9	\$286.7	\$322.5					
Share Count		6.8	6.8	6.8	6.8	6.8					
Value Per Share		\$26.4	\$31.6	\$36.9	\$42.2	\$47.4					
Probability of Scenario 1	90%										
Probability of Scenario 2	10%										
Probability Weighted Valuation	\$18.9										

Source: Cantor Fitzgerald research

Risks

- (1) Clinical risk associated with intranasal metoclopramide. More specifically, we are concerned about the possibility of a strong placebo response in the pending Phase III trial of female patients.
- (2) Financing needs may pressure the stock if the company needs to raise cash ahead of the Phase III data release.
- (3) Potential volatility in the stock associated with a high percentage of insider shareholders (59% of the stock is held by insiders).
- (4) Progression of competitive products in gastroparesis.
- (5) Manufacturing risk.

Exhibit 20: Evoke Income Statement (dollars in millions)

	2011	2012	1Q:13A	2Q:13A	3Q:13E	4Q:13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenues:																	
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	15.0	45.0	102.0	145.0	180.0	205.0	221.0	230.0
Total revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	15.0	45.0	102.0	145.0	180.0	205.0	221.0	230.0
Operating expenses:																	
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	1.8	4.0	5.6	6.8	7.7	8.2	8.4
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.4	43.2	98.0	139.4	173.2	197.3	212.8	221.6
R&D	1.8	1.2	0.1	0.1	0.2	0.5	0.9	10.0	5.0	4.0	4.2	4.4	4.6	4.9	5.1	5.4	5.6
SG&A	0.6	0.8	0.1	0.1	0.2	0.2	0.7	2.4	8.0	30.0	100.0	105.0	110.3	111.4	112.5	113.6	114.7
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total operating expenses	2.4	2.0	0.3	0.3	0.4	0.7	1.6	12.4	13.0	34.0	104.2	109.4	114.9	116.2	117.6	119.0	120.4
Operating income (Loss)	(2.4)	(2.0)	(0.3)	(0.3)	(0.4)	(0.7)	(1.6)	(12.4)	(13.0)	(19.6)	(61.0)	(11.4)	24.5	56.9	79.7	93.9	101.3
Interest income	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2
Interest expense	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in fair value of warrant liability	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other income, net	0.01	(0.0)	(0.0)	(0.0)	(0.0)	0.1	(0.1)	(0.1)	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2
Pretax Income	(2.4)	(2.0)	(0.3)	(0.3)	(0.4)	(0.7)	(1.7)	(12.5)	(12.9)	(19.5)	(60.9)	(11.3)	24.7	57.1	79.9	94.1	101.5
Tax Rate	NA	NA	NA	NA	0.0%	0.0%	0.0	0%	0%	0%	0%	0%	15%	38%	38%	38%	38%
Tax expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.7	21.7	30.4	35.7	38.6
Net income	(2.4)	(2.0)	(0.31)	(0.31)	(0.4)	(0.7)	(1.7)	(12.5)	(12.9)	(19.5)	(60.9)	(11.3)	21.0	35.4	49.6	58.3	62.9
Weighted average common shares (diluted)	1.1	3.6	3.6	3.6	3.9	6.8	4.5	6.8	10.0	12.0	12.6	13.2	13.9	14.6	15.3	16.1	16.9
Diluted EPS	(\$2.18)	(\$0.57)	(\$0.09)	(\$0.09)	(\$0.10)	(\$0.10)	(\$0.38)	(\$1.83)	(\$1.29)	(\$1.63)	(\$4.83)	(\$0.85)	\$1.51	\$2.43	\$3.24	\$3.63	\$3.73
Margin Analysis	2011	2012	1Q:13A	2Q:13A	3Q:13E	4Q:13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Gross Margin	-	-	-	-	-	-	-	-	-	96.0%	96.1%	96.1%	96.2%	96.2%	96.3%	96.3%	96.4%
COGS	-	-	-	-	-	-	-	-	-	4.0%	4.0%	3.9%	3.9%	3.8%	3.8%	3.7%	3.7%
SG&A	-	-	-	-	-	-	-	-	-	200.0%	222.2%	102.9%	76.0%	61.9%	54.9%	51.4%	49.9%
R&D	-	-	-	-	-	-	-	-	-	26.7%	9.3%	4.3%	3.2%	2.7%	2.5%	2.4%	2.4%
Operating Margin	-	-	-	-	-	-	-	-	-	-130.7%	-135.5%	-11.2%	16.9%	31.6%	38.9%	42.5%	44.0%
Net Income Margin	-	-	-	-	-	-	-	-	-	-130.1%	-135.3%	-11.0%	14.5%	19.7%	24.2%	26.4%	27.4%
Growth (Y/Y)	2011	2012	1Q:13A	2Q:13A	3Q:13E	4Q:13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Net Sales	-	-	-	-	-	-	-	-	-	-	200%	127%	42%	24%	14%	8%	4%
SG&A	-	47%	-17%	-17%	-	-	-19%	252%	233%	275%	233%	5%	5%	1%	1%	1%	1%
R&D	-	-37%	-53%	-53%	-	-	-19%	962%	-50%	-20%	5%	5%	5%	5%	5%	5%	5%
EBIT	-	-	-	-	-	-	-	-	-	-	-	-	-	132%	40%	18%	8%
Interest income (expense)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	486%	40%	18%	8%
Net Income	-	-	-	-	-	-	-	-	-	-	-	-	-	69%	40%	18%	8%
Diluted EPS	-	-	-	-	-	-	-	-	-	-	-	-	-	61%	33%	12%	3%

Source: Company reports, Cantor Fitzgerald estimates, and FactSet consensus

Exhibit 21: Evoke Sales Estimates (dollars in millions)

	2011	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
EVK-001 (Diabetic gastroparesis)													
Sales	0.0	0.0	0.0	0.0	0.0	15.0	45.0	102.0	145.0	180.0	205.0	221.0	230.0
Growth							200%	127%	42%	24%	14%	8%	4%
TOTAL EVOKE REVENUES	0.0	0.0	0.0	0.0	0.0	15.0	45.0	102.0	145.0	180.0	205.0	221.0	230.0

Source: Company report and Cantor Fitzgerald estimates

Exhibit 22: Evoke Balance Sheet (dollars in millions)

	2011	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Assets													
Current Assets:													
Cash and cash equivalents	0.9	0.1	25.9	14.5	102.6	101.4	36.4	16.9	31.7	62.2	107.0	162.6	224.1
Accounts receivable	0.0	0.0	0.0	0.0	0.0	3.0	9.0	20.4	29.0	36.0	41.0	44.2	46.0
Prepaid expenses and other assets	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Inventories	0.0	0.0	0.0	0.0	0.0	0.2	0.6	1.3	1.9	2.3	2.6	2.7	2.8
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total current assets	0.9	0.1	25.9	14.5	102.6	104.6	46.0	38.6	62.6	100.4	150.6	209.5	272.9
Other assets	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	0.9	0.1	25.9	14.5	102.6	104.6	46.0	38.6	62.6	100.4	150.6	209.5	272.9
Liabilities and stockholders' equity													
Current Liabilities:													
Accounts payable and accrued expenses	0.1	0.1	0.0	0.0	0.0	0.3	0.9	2.0	2.8	3.4	2.6	2.0	1.7
Accrued Compensation	0.2	0.4	0.0	0.0	0.0	0.6	1.8	4.0	5.6	6.8	7.7	8.2	8.4
Current portion of long-term debt	0.0	0.0	0.5	1.0	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Warrant Liabilities	0.0	0.1	0.6	1.1	1.6	2.1	2.6	3.1	3.6	4.1	4.6	5.1	5.6
Other Current Liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total current liabilities	0.3	0.57	1.1	2.1	3.1	4.5	6.7	10.5	13.4	15.8	16.3	16.8	17.1
Long-term debt	0.0	1.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	0.3	1.6	4.0	5.0	6.0	7.4	9.7	13.5	16.4	18.8	19.3	19.8	20.1
Preferred Stock	18.2	18.2	18.2	18.2	18.2	18.2	18.2	18.2	18.2	18.2	18.2	18.2	18.2
Common stock	0.0	0.0	27.0	27.0	127.0	147.0	147.0	147.0	147.0	147.0	147.0	147.0	147.0
Additional paid-in capital	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5
Retained Earnings (Accumulated deficit)	(17.8)	(19.9)	(23.5)	(36.0)	(48.9)	(68.3)	(129.2)	(140.4)	(119.4)	(83.9)	(34.3)	24.1	87.1
Total stockholders' equity	0.6	(1.4)	21.9	9.4	96.6	97.1	36.3	25.1	46.2	81.6	131.3	189.7	252.8
Total liabilities and stockholders' equity	0.9	0.1	25.9	14.5	102.6	104.6	46.0	38.6	62.6	100.4	150.6	209.5	272.9

Source: Company report and Cantor Fitzgerald estimates

Exhibit 23: Evoke Statement of Cash Flows (dollars in millions)

	2011	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Operating Cash													
Net Income	(2.4)	(2.0)	(1.7)	(12.5)	(12.9)	(19.5)	(60.9)	(11.3)	21.0	35.4	49.6	58.3	62.9
Share-based compensation expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1
Non-cash interest	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in fair value of purchase right liability	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in fair value of warrant liability	(0.0)	(0.0)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Changes in Working Capital	(0.5)	0.3	(0.5)	0.0	0.0	(2.3)	(4.6)	(8.8)	(6.7)	(5.5)	(5.3)	(3.4)	(2.0)
Operating Cash Flow	(2.9)	(1.7)	(1.7)	(11.9)	(12.4)	(21.3)	(64.9)	(19.5)	14.8	30.5	44.9	55.5	61.5
Investing Cash													
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Investing Cash Flow	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financing activities													
Proceeds from bank credit line and loan advances	0.0	1.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payment on bank credit line	(0.3)	0.0	0.5	0.5	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of common stock	0.0	0.0	27.0	0.0	100.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from exercise of stock options	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Costs in connection with IPO	0.0	0.0	(2.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash provided by financing activities	(0.3)	1.0	27.5	0.5	100.5	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Increase (decrease) in cash and cash equivalents	(3.2)	(0.7)	25.8	(11.4)	88.1	(1.3)	(64.9)	(19.5)	14.8	30.5	44.9	55.5	61.5
Cash and cash equivalents, at beginning of period	4.0	0.9	0.1	25.9	14.5	102.6	101.4	36.4	16.9	31.7	62.2	107.0	162.6
Cash and cash equivalents, at end of period	0.9	0.1	25.9	14.5	102.6	101.4	36.4	16.9	31.7	62.2	107.0	162.6	224.1

Source: Company report and Cantor Fitzgerald estimates

Exhibit 24: Companies Cited

Company Name	Exchange	Ticker	Rating
Actavis Plc	NYSE	ACT	NC
Anchen	NA	NA	NC
ANI Pharmaceuticals, Inc.	NASDAQ	ANIP	NC
AstraZeneca PLC Sponsored ADR	NYSE	AZN	NC
Baxter International Inc.	NYSE	BAX	NC
Forest Laboratories, Inc.	NYSE	FRX	BUY
GlaxoSmithKline plc Sponsored ADR	NYSE	GSK	NC
Hospira, Inc.	NYSE	HSP	NC
Ironwood Pharmaceuticals, Inc. Class A	NASDAQ	IRWD	HOLD
Eli Lilly and Company	NYSE	LLY	NC
NPS Pharmaceuticals, Inc.	NASDAQ	NPSP	NC
Ocera Therapeutics, Inc.	NASDAQ	OCRX	NC
Questcor Pharmaceuticals, Inc.	NASDAQ	QCOR	NC
Rhythm Pharmaceuticals	NA	NA	NC
Salix Pharmaceuticals, Ltd.	NASDAQ	SLXP	HOLD
Santarus, Inc.	NASDAQ	SNTS	NC
Shire PLC Sponsored ADR	NASDAQ	SHPGY	NC
Synergy Pharmaceuticals, Inc.	NASDAQ	SGYP	BUY
Takeda Pharmaceutical Co. Ltd.	Tokyo	4502-JP	NC
Teva Pharmaceutical Industries Limited Sponsored ADR	NYSE	TEVA	NC
Theravance, Inc.	NASDAQ	THRX	NC
Tioga	NA	NA	NC
Ventrus Biosciences, Inc.	NASDAQ	VTUS	BUY

Source: FactSet and Cantor Fitzgerald estimates

Company Description

Evoke Pharma is a small, development-stage specialty pharmaceutical company. Its key pipeline product is an intranasal formulation of metoclopramide, a well-known and widely used drug for the treatment of gastroparesis. The novel drug delivery approach developed by Evoke is expected to both enhance efficacy and tolerability, and therefore represents a meaningful improvement to current metoclopramide formulations, in our view.

Companies Mentioned:

Evoke Pharma, Inc. (EVOK - NASDAQ): BUY
Forest Laboratories, Inc. (FRX - NYSE): BUY
Ironwood Pharmaceuticals, Inc. (IRWD - NASDAQ): HOLD
Salix Pharmaceuticals, Ltd. (SLXP - NASDAQ): HOLD
Synergy Pharmaceuticals, Inc. (SGYP - NASDAQ): BUY
Ventrus Biosciences, Inc. (VTUS - NASDAQ): BUY

Disclosures Appendix

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BUY: We have a positive outlook on the stock based on our expected 12 month return relative to its risk. The expected return is based on our view of the company and industry fundamentals, catalysts, and valuation. We recommend investors add to their position.

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SELL: We have a negative outlook on the stock based on our expected 12 month return relative to its risk. The expected return is based on our view of the company and industry fundamentals, catalysts, and valuation. We recommend investors reduce their position.

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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	85	56.67	20	23.53
HOLD [H]	52	34.67	4	7.69
SELL [S]	13	8.67	2	15.38