Esperion Therapeutics (ESPR)

Rating	**OUTPERFORM* [V]**
Price (06 Nov 13, US$)	14.77
Target price (US$)	26.00[1]
52-week price range	18.89 - 14.00
Market cap. (US$ m)	226.83
Enterprise value (US$ m)	148.21

**Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.*
[1]Target price is for 12 months.
[V] = Stock considered volatile (see Disclosure Appendix).

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SMALL & MID CAP RESEARCH

Q3 In-line; Major Readouts in 2014

The Q3 release was in line with expectations. Upcoming presentation of Study 006 at AHA could raise the profile of this program, though the data is not expected to be substantially different from results previously released. The next key data release will be from Phase IIb trials in H2:14, which we expect will be a trigger for significant outperformance. Our positive view on ESPR is based on the large market opportunity and significant scarcity value of its novel oral pill for lowering cholesterol.

- **ESPR reported Q3 net loss of ($5.2M) and EPS of ($0.34)** vs. consensus loss of ($6.5M) and EPS of ($0.41). We had estimated net loss of ($6.3M) and an EPS of ($0.41). ESPR ended Q3 with approximately $85.4M in cash and expects to end 2013 with ~$75M in cash, which should support operations to the end of 2015. Our 2013 EPS estimate changes to ($3.00) from ($3.12) due to the lower than expected Q3 expenses.
- **Study 006 data presentation at AHA:** Full details of Study 006 will be in an oral presentation at the AHA meeting on Nov. 18. We do not expect significant new efficacy data, but we could get greater disclosure around observed adverse events such as changes in hemoglobin and uric acid.
- **Catalysts:** (1) Phase IIb statin intolerant data in H2:14; and (2) Phase IIb statin add-on data potentially in H2:14
- **Valuation:** Our $26 target is based on a probability adjusted DCF, assuming a 55% probability of success in statin intolerant and 33% probability in statin add-on patients.

Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US$)	-36.31	-3.00	-1.71	2.06
Prev. EPS (US$)	—	-3.12	—	—
P/E (x)	-0.4	-4.9	-8.6	7.2
P/E rel. (%)	-2.4	-31.3	-60.6	55.6
Revenue (US$ m)	—	—	—	78.0
EBITDA (US$ m)	-10.1	-20.4	-30.2	42.1
OCFPS (US$)	-33.42	-2.21	-1.55	2.20
P/OCF (x)	—	-6.7	-9.5	6.7
EV/EBITDA (current)	-15.4	-7.6	-5.1	3.7
Net debt (US$ m)	16	-79	-127	-174
ROIC (%)	901.89	1,033.10	1,527.67	-2,129.64

Number of shares (m)	15.36	IC (current, US$ m)	-1.13
BV/share (Next Qtr., US$)	5.0	EV/IC (x)	-75.0
Net debt (Next Qtr., US$ m)	-78.6	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-102.6	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

A Review of Study 006

30% LDL-C Reduction in Statin Intolerant Patients

Study 006 was designed to measure the activity of ETC-1002 in a population of patients who were intolerant to two or more statins. ESPR reported results from this trial in June 2013, and the study met its primary endpoint of LDL-C reduction. ESPR is moving forward with a planned Phase IIb trial, testing longer duration.

Key results from study 006 include:

- **Clear Activity:** There was an average 32% reduction in LDL-C at eight weeks in patients who were intolerant to two or more statins (Exhibit 1). There was a dose response up to 120mg (week four). Doses above 120mg had little additional impact on efficacy.
- **Well Tolerated:** The drug was well tolerated and there were no discontinuations due to muscle pain or weakness. The frequency of muscle-related complaints was the same in the treatment and placebo groups. This is important because all patients had failed prior statins due to adverse events.
- **No Overt Toxicities up to 240mg:** There were no adverse events that appeared with increased ETC-1002 doses up to 240mg, and lab measures associated with organ toxicity were not impacted (e.g., ALT/AST, bilirubin, CK, and creatinine).
- **Hemoglobin Decreased Modestly:** As has been previously observed, there was a dose dependent decrease in hemoglobin (0.7 g/dL reduction at the highest dose)(Exhibit 2). Some patients had more significant drops, with roughly 1/3 of patients experiencing a ≥1 g/dL drop in hemoglobin compared to the baseline and 14% having a hemoglobin drop below the lower limit of normal (Exhibit 3).
- **Uric Acid Increase:** Uric acid increased modestly, though details of that data were not reported. One patient did have an adverse event of gout, which could have been related to increased uric acid. This patient had a history of gout, so it could be unrelated to treatment. It will be important to see if patients with a history of gout ultimately are excluded from Phase III trials.
- **Reduced Inflammation:** The study also demonstrated reductions in the levels of high sensitivity C-reactive protein (hsCRP), an important marker of inflammation.

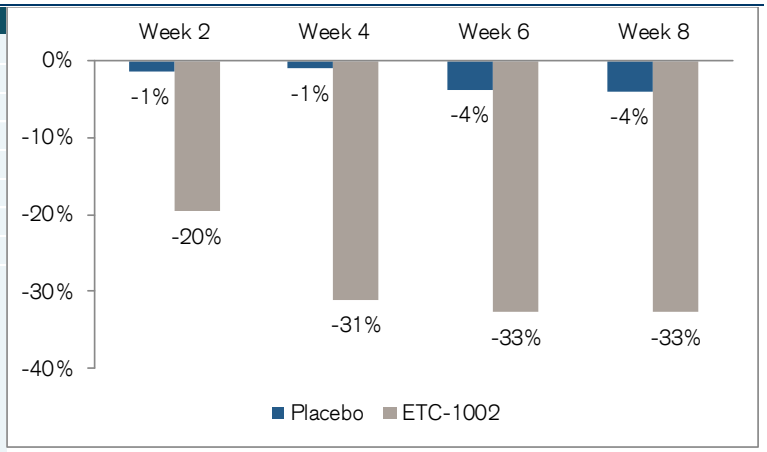
Forced Titration Dose-Response Design

In Study 006, each patient randomized to ETC-1002 was started at the low dose (60mg) and subsequently increased the dose every two weeks (60mg, 120mg, 180mg, and 240mg) for a total of eight weeks of treatment. This design has several strengths and weaknesses.

- **Strengths:** Each patient received each dose of the drug for two weeks, thus serving as his/her own control. Because there were not parallel groups at each dose, inter-group variability was not an issue when comparing across dose groups.
- **Weaknesses:** It is difficult to discern dose response from time dependence. We are confident in the dose response for efficacy. LDL-C levels continue declining up to 120mg and then the benefit tapers off. For safety, it is difficult to interpret if the drop in hemoglobin, seen at the highest dose (240mg) and at the longest time point (eight weeks) is dose or time dependent. We assume from prior experience that the impact is likely dose dependent.

Exhibit 1: Consistent Efficacy in Statin Intolerant Patients

	Study 006
Stage	Ph 2a
# of pts	54 (2:1)
Patients	Hypcholesterolemia (statin intolerant)
Design	Forced titration
Duration	8 weeks
Doses	60, 120, 180, and 240 mg
Best dose	120mg
Pbo subtracted	-29%
Results	Week 2: Placebo (-1.4%); 60mg (-19.5%) p<0.0001 Week 4: Placebo (-1.0%); 120mg (-31.0%), p<0.0001 Week 6: Placebo (-3.8%); 180mg (-32.6%), p<0.0001 Week 8: Placebo (-4.0%); 240mg (-32.6%), p=<0.0001



Source: Company data, Credit Suisse research.

Exhibit 2: Mean Change (SD) in Hemoglobin from Baseline

	ETC-1002 N=37	PBO N=19
Baseline	14.8 (1.0)	14.4 (1.2)
Wk 2 (60mg)	-0.2 (0.4)	0 (0.5)
Wk 4 (120mg)	-0.3 (0.5)	-0.1 (0.4)
Wk 6 (180mg)	-0.5 (0.5)	0 (0.6)
Wk 7 (180mg)	-0.5 (0.5)	-0.1 (0.3)
Wk 8 (240mg)	-0.7 (0.7)	-0.1 (0.6)

Source: Company data, Credit Suisse research.

Exhibit 3: Hemoglobin Abnormalities at Any Visit, Number (%) of Patients

	ETC-1002 N=37	PBO N=19
<LLN	5 (14%)	0
>1 g/dL below LLN	0	0
>2 g/dL below LLN	0	0
<10 g/dL	0	0
≥1 g/dL below baseline	12 (32%)	1 (5%)
≥2 g/dL below baseline	1 (3%)	0

Source: Company data, Credit Suisse research.

Exhibit 4: ESPR Pipeline

Drug	Indication	Stage	Partner
ETC-1002	Hypercholesterolemia (statin intolerant)	Phase IIb	Proprietary
	Hypercholesterolemia (statin add-on)	Phase IIa (completed)	
	Hypercholesterolemia (Type II diabetics)	Phase IIa (completed)	
ESP41091	Type II diabetes and obesity	Preclinical	Proprietary
4WF	Low HDL	Preclinical	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 5: ESPR News Flow

Timing	Expected News Flow	Program
Residual risk (statin add-on)		
Q1:14	Start Phase IIb (Study-009)	ETC-1002
Q4:14	Phase IIb trial readout	ETC-1002
Statin intolerant program		
H2:14	Phase IIb data (Study-008)	ETC-1002
Special population studies		
2014	Phase IIb in diabetics or other risk groups	ETC-1002
Pivotal program		
Mid-2015	Start Phase III study	ETC-1002
H2:16	Completion of Phase III efficacy study	ETC-1002
H1:17	Completion of Phase III safety study	ETC-1002
Regulatory		
Q1:15	End of Phase II meeting	ETC-1002
H2:14	2-year carc. study in animals	ETC-1002
H2:17	NDA filing	ETC-1002
H2:18	Approval and launch	ETC-1002

Source: Company data, Credit Suisse estimates

Exhibit 6: Q3 Variance Table

		CS		Consensus	
	3Q:13	3Q:13		3Q:13	
Income Statement	Act.	Est	Delta	Est	Delta
Revenues	$ -	$ -	$ -		$ -
Milestones and partnering revenue	$ -	$ -	$ -		$ -
Royalty revenue	$ -	$ -	$ -		$ -
Total Net Revenues	$ -	$ -	$ -	$ -	$ -
					$ -
Expenses	$ -	$ -	$ -		$ -
R&D	$ 3.5	$ 4.5	$ (1.0)		$ 3.5
G&A	$ 1.9	$ 2.1	$ (0.2)		$ 1.9
Total Operating Expenses	$ 5.4	$ 6.6	$ (1.2)	$ 6.5	$ (1.1)
					$ -
Operating income (loss)	$ (5.4)	$ (6.6)	$ 1.2	$ (6.5)	$ 1.1
Total Other Income (Expense)	$ 0.2	$ 0.3	$ (0.2)		$ 0.2
Pre Tax Income	$ (5.2)	$ (6.3)	$ 1.0		$ (5.2)
Income tax expense (benefit)	$ -	$ -	$ -		$ -
Net Income	$ (5.2)	$ (6.3)	$ 1.0	$ (6.3)	$ 1.0
					$ -
EPS - basic (proforma)	($0.34)	($0.41)	$0.06	($0.41)	$0.07
EPS - diluted (proforma)	($0.34)	($0.41)	$0.06	($0.41)	$0.07
					$ -
Shares outstanding - basic (proforma)	15.25	15.33	-0.08		
Shares outstanding - diluted (proforma)	15.25	15.33	-0.08		

Source: Company data, FactSet, Credit Suisse estimates

Exhibit 7: ESPR Model

	2012A	Q1:13A	Q2:13A	Q3:13A	Q4:13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues															
Milestones and partnering revenue								78.0	4.0	56.5	59.0	4.0	4.0		
Royalty revenue											10.3	24.7	39.5	84.6	119.4
Total Net Revenues								78.0	4.0	56.5	69.3	28.7	43.5	84.6	119.4
Expenses															
R&D	8.0	2.1	3.1	3.5	5.2	13.9	20.9	24.6	25.8	27.1	28.5	29.9	31.4	33.0	34.6
G&A	2.2	1.3	1.2	1.9	2.2	6.5	9.3	11.3	11.9	12.5	13.1	13.7	14.4	15.1	15.9
Total Operating Expenses	10.2	3.3	4.3	5.4	7.4	20.4	30.2	35.9	37.7	39.6	41.6	43.6	45.8	48.1	50.5
Operating income (loss)	(10.2)	(3.3)	(4.3)	(5.4)	(7.4)	(20.4)	(30.2)	42.1	(33.7)	16.9	27.7	(14.9)	(2.3)	36.4	68.9
Total Other Income (Expense)	(1.5)	(0.9)	(2.6)	0.2	0.3	(3.1)	1.3	1.7	1.5	1.5	1.0	1.0	1.0	1.0	1.0
Pre Tax Income	(11.7)	(4.2)	(6.9)	(5.2)	(7.1)	(23.5)	(28.9)	43.8	(32.2)	18.4	28.7	(13.9)	(1.3)	37.4	69.9
Income tax expense (benefit)															24.5
Net Income	(11.7)	(4.2)	(6.9)	(5.2)	(7.1)	(23.5)	(28.9)	43.8	(32.2)	18.4	28.7	(13.9)	(1.3)	37.4	45.4
EPS - basic (proforma)	($36.31)	($12.24)	($19.82)	($0.34)	($0.46)	($3.00)	($1.71)	$2.09	($1.52)	$0.86	$1.34	($0.64)	($0.06)	$1.72	$2.07
EPS - diluted (proforma)	($36.31)	($12.24)	($19.82)	($0.34)	($0.46)	($3.00)	($1.71)	$2.06	($1.52)	$0.82	$1.27	($0.64)	($0.06)	$1.63	$1.97
Shares outstanding - basic (proforma)	0.32	0.35	0.35	15.25	15.41	7.84	16.85	20.98	21.19	21.40	21.51	21.61	21.72	21.83	21.94
Shares outstanding - diluted (proforma)	0.32	0.35	0.35	15.25	15.41	7.84	16.85	21.26	21.19	22.55	22.66	21.61	21.72	23.00	23.11

Product sales summary	2018E	2019E	2020E	2021E	2022E
US (prob adjusted)	46.4	101.0	147.1	289.9	409.5
Ex-US (prob adjusted)	12.4	40.4	78.5	193.3	273.0
Total (prob adjusted)	58.8	141.4	225.6	483.2	682.5
Royalty	10.3	24.7	39.5	84.6	119.4
US (unadjuted)	84.4	183.6	267.5	644.0	943.9
Ex-US (unadjusted)	22.5	73.4	142.7	429.3	629.3
Total (unadjusted)	106.9	257.1	410.2	1,073.4	1,573.2
Royalty	18.7	45.0	71.8	187.8	275.3

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 06-Nov-2013)*

Esperion Therapeutics (ESPR.OQ, $14.77, OUTPERFORM[V], TP $26.0)

Disclosure Appendix

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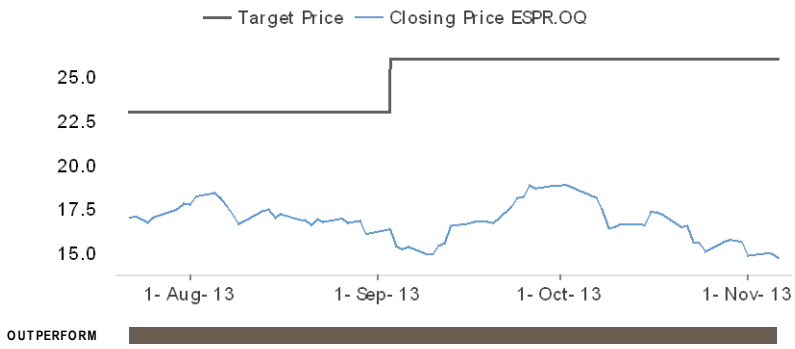
3-Year Price and Rating History for Esperion Therapeutics (ESPR.OQ)

ESPR.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
22-Jul-13	17.05	23.00	O *
03-Sep-13	16.40	26.00	

** Asterisk signifies initiation or assumption of coverage.*



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Underperform/Sell*	15%	(40% banking clients)
Restricted	3%	

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Price Target: (12 months) for Esperion Therapeutics (ESPR.OQ)

Method: Our $26 price target for ESPR is based on a probability adjusted DCF, assuming a very conservative 55% probability of success in statin intolerant and 33% probability in statin add-on patients. Additional data in 2013 and 2014 could increase our probabilities for both indications.

Risk: Risks to our $26 TP include factors that could decrease our probabilities of success for ETC-1002 in statin intolerant and statin add-on markets: 1) inability to remove the partial clinical hold, 2) lack of efficacy or any new toxicities in ongoing trials, 3) increased concern over known safety signals (decreases in hemoglobin and increases in uric acid), and 4) more stringent regulatory requirements (ie FDA requiring an outcome study for approval).

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