

Esperion Therapeutics (ESPR)

SMALL & MID CAP RESEARCH

Positive Results in Statin Add-on Study

The results of Study 007 are a significant positive for ESPR: (1) demonstrated efficacy on top of statins, (2) no new safety signals – drugs well tolerated in combination, (3) efficacy compares well to Zetia, and (4) drug profile favorable for future partnering/acquisitions. We are raising our TP to \$26 from \$23.

- **ETC-1002 lowers LDL-C by 22% on top of Lipitor:** In Study 007, ETC-1002 plus low dose Lipitor (10mg) lowered LDL-C by 22% vs. 0% for placebo ($p < 0.0001$). Previously ESPR had guided that 20% would be clinically and commercially meaningful. This compares well to Zetia which showed a 16% LDL-C reduction on top of 10mg atorvastatin (Exhibit 1).
- **Safety was clean:** ESPR reported no increase in muscle toxicity (a statin toxicity), and no decrease in hemoglobin relative to placebo (a signal seen in other ETC-1002 trials). ESPR did report a modest increase in uric acid (seen in prior trials), and reported one discontinuation due to elevated liver enzymes, but this is likely an anomaly as this was at the lowest dose and has not been seen in other trials. There was a reported increase in atorvastatin blood levels (1.7x) at the highest dose of ETC-1002.
- **Larger market opportunity:** The primary target market for ETC-1002 is statin intolerant patients (~2M). The statin add-on market is much larger (~11M). Demonstrated efficacy and safety with statins are key for this drug to gain wider adoption and are important for attracting a partner or acquirer.
- **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 (up from 25%).



Rating **OUTPERFORM***
Price (03 Sep 13, US\$) 16.12
Target price (US\$) (from 23.00) 26.00¹
52-week price range 18.44 - 14.00
Market cap. (US\$ m) 247.56
Enterprise value (US\$ m) 169.25

*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.
¹Target price is for 12 months.

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Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US\$)	-36.31	-3.12	-1.71	2.06
Prev. EPS (US\$)	—	—	—	—
P/E (x)	-0.4	-5.2	-9.4	7.8
P/E rel. (%)	-2.7	-33.7	-67.7	62.0
Revenue (US\$ m)	—	—	—	78.0
EBITDA (US\$ m)	-10.1	-21.6	-30.2	42.1
OCFPS (US\$)	-33.42	-2.12	-1.55	2.20
P/OCF (x)	—	-7.6	-10.4	7.3
EV/EBITDA (current)	-22.9	-10.7	-7.6	5.5
Net debt (US\$ m)	16	-78	-127	-173
ROIC (%)	901.89	410.73	573.84	-799.96
Number of shares (m)	15.36	IC (current, US\$ m)		-1.13
BV/share (Next Qtr., US\$)	5.2	EV/IC (x)		-30.9
Net debt (Next Qtr., US\$ m)	-84.9	Dividend (current, US\$)		—
Net debt/tot cap (Next Qtr., %)	-106.6	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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Study 007 Overview

Study 007 tested ETC-1002 in patients who did not achieve their LDL-C goal while on stable statin therapy. The trial had a similar forced dose titration as Study 006 (in statin intolerant patients). In this trial, patients were treated with escalating doses of ETC-1002 on top of a 10mg dose of atorvastatin calcium (Lipitor), the most commonly prescribed dose.

All patients received low dose statin (10mg atorvastatin) for 4 weeks prior to starting either ETC-1002 or placebo. Patients in the ETC-1002 group started at 60mg for 2 weeks, and then escalated to 120mg, 180mg, and 240mg each for two weeks.

Our expectation ahead of the results was as follows:

“We believe that the minimum meaningful effect would be an approximate 20% reduction in LDL-C on top of statins. Clearly, the bigger the drop, the better, when considering efficacy. A smaller effect would call into question the market opportunity in this indication.”

ESPR provided only top-line data with some additional details provided on the call.

- 22% reduction in LDL-C vs. 0% for placebo ($p < 0.0001$)
- A 15% reduction was achieved at the 120mg dose
- There was a trend in lower CRP, an important measure of inflammation
- There was no decrease in hemoglobin relative to placebo (as has been seen in other studies)
- There was an increase in blood levels of statin in patients treated with both drugs. The increase was 1.7x.

Exhibit 1: Study 007 Design

	Study 007
Stage	Ph 2a
# of pts	58 (3:1)
Patients	Hypcholesterolemia (residual risk)
Design	Forced titration
Duration	8 weeks
Doses	60, 120, 180, 240 mg
Results	22% reduction in LDL-C ($p < 0.0001$)

Source: Company data, Credit Suisse estimates

Favorable Relative to Zetia

In statin intolerant patients, ETC-1002 has demonstrated a 30-40% LDL-C reduction compared to 15-20% for Zetia. In Study 007, ETC-1002 demonstrated a 22% reduction in LDL-C, which again was better than the 16% seen for Zetia in a similar population when combined with 10mg of atorvastatin.

Exhibit 2: Efficacy Compares Well to Zetia

TABLE 8: Response to ZETIA and Atorvastatin Initiated Concurrently in Patients with Primary Hyperlipidemia (Mean* % Change from Untreated Baseline[†])

Treatment (Daily Dose)	N	Total-C	LDL-C	Apo B	Non-HDL-C	TG*	HDL-C
Placebo	60	+4	+4	+3	+4	-6	+4
ZETIA	65	-14	-20	-15	-18	-5	+4
Atorvastatin 10 mg	60	-26	-37	-28	-34	-21	+6
ZETIA + Atorvastatin 10 mg	65	-38	-53	-43	-49	-31	+9
Atorvastatin 20 mg	60	-30	-42	-34	-39	-23	+4
ZETIA + Atorvastatin 20 mg	62	-39	-54	-44	-50	-30	+9
Atorvastatin 40 mg	66	-32	-45	-37	-41	-24	+4
ZETIA + Atorvastatin 40 mg	65	-42	-56	-45	-52	-34	+5
Atorvastatin 80 mg	62	-40	-54	-46	-51	-31	+3
ZETIA + Atorvastatin 80 mg	63	-46	-61	-50	-58	-40	+7
Pooled data (All Atorvastatin Doses) [‡]	248	-32	-44	-36	-41	-24	+4
Pooled data (All ZETIA + Atorvastatin Doses) [‡]	255	-41	-56	-45	-52	-33	+7

Zetia provides 16% reduction in LDL-C over 10mg of atorvastatin

* For triglycerides, median % change from baseline.

[†] Baseline - on no lipid-lowering drug.

[‡] ZETIA + all doses of atorvastatin pooled (10-80 mg) significantly reduced total-C, LDL-C, Apo B, non-HDL-C, and TG, and increased HDL-C compared to all doses of atorvastatin pooled (10-80 mg).

Source: Company data, Credit Suisse estimates

Phase IIb Plans: Larger, More Definitive Trials to Read out in H2:14

ESPR has significant Phase II data on which to design a large randomized trial, and the planned Phase IIb studies in statin intolerant patients and residual risk patients (statin add-on) are intended to provide the support needed to go to Phase III in 2015.

ESPR plans to initiate the Phase IIb trial in statin intolerant patients in Q4:13/Q1:14, with top-line results in H2:14. The two studies will be randomized, parallel group Phase IIb trials, testing at least two doses of ETC-1002 versus placebo.

- **Study 008** will treat 322-statin intolerant patients (failed two or more statins) at two or three doses of ETC-1002 for 12 weeks versus Zetia as a control. The exact size and design of the trial have not been disclosed, but the company expects to start the study in Q4:13.

- **Study 009** will evaluate residual risk patients treated with both a statin and ETC-1002 (likely two different doses). The exact size and design of the trial have not been disclosed, but the company expects to start the study in Q1:14.

The details of both trials have not been fully described. Our expectation is that ESPR will test the 120mg dose and potentially one higher dose in both trials.

Exhibit 3: ESPR Pipeline

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

Source: Company data, Credit Suisse estimates

Exhibit 4: ESPR News Flow

Timing	Expected News Flow	Program
Residual risk (statin add-on)		
Q1:14	Start Phase IIb (Study-009 & 010)	ETC-1002
Q4:14	Phase IIb trial readout	ETC-1002
Statin intolerant program		
Oct. 2013	Start Phase IIb (Study-008)	ETC-1002
H2:14	Phase IIb data (Study-008)	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 5: ESPR Earnings Model

	2012A	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	14.9	20.9	24.6	25.8	27.1	28.5	29.9	31.4	33.0	34.6
G&A	2.2	6.7	9.3	11.3	11.9	12.5	13.1	13.7	14.4	15.1	15.9
Total Operating Expenses	10.2	21.6	30.2	35.9	37.7	39.6	41.6	43.6	45.8	48.1	50.5
Operating income (loss)	(10.2)	(21.6)	(30.2)	42.1	(33.7)	16.9	27.7	(14.9)	(2.3)	36.4	68.9
Total Other Income (Expense)	(1.5)	(2.9)	1.3	1.7	1.5	1.5	1.0	1.0	1.0	1.0	1.0
Pre Tax Income	(11.7)	(24.5)	(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)	(24.5)	(28.9)	43.8	(32.2)	18.4	28.7	(13.9)	(1.3)	37.4	45.4
EPS - basic (proforma)	(\$36.31)	(\$3.12)	(\$1.71)	\$2.09	(\$1.52)	\$0.86	\$1.34	(\$0.64)	(\$0.06)	\$1.72	\$2.07
EPS - diluted (proforma)	(\$36.31)	(\$3.12)	(\$1.71)	\$2.06	(\$1.52)	\$0.82	\$1.27	(\$0.64)	(\$0.06)	\$1.63	\$1.97
Shares outstanding - basic (proforma)	0.32	7.86	16.85	20.98	21.19	21.40	21.51	21.61	21.72	21.83	21.94
Shares outstanding - diluted (proforma)	0.32	7.86	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 (unadjusted)	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

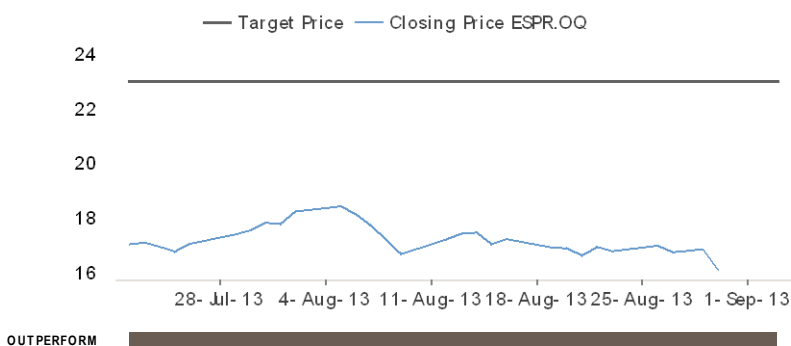
Companies Mentioned (Price as of 03-Sep-2013)**Esperion Therapeutics** (ESPR.OQ, \$16.12, OUTPERFORM[V], TP \$26.0)**Disclosure Appendix****Important Global Disclosures**

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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 *

* Asterisk signifies initiation or assumption of coverage.



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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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