Esperion Therapeutics (ESPR)

Rating	OUTPERFORM* [V]
Price (09 Aug 13, US$)	16.69
Target price (US$)	23.00[1]
52-week price range	18.44 - 14.00
Market cap. (US$ m)	255.85
Enterprise value (US$ m)	177.53

**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

Q2 Results: Study 007 Data Coming in Sept; New Details of Planned Ph 2b Disclosed

ESPR is developing a novel oral agent ETC-1002 for lowering cholesterol. If successful in Phase II, we expect ESPR will sign a lucrative global partnership or be acquired for this asset. In its Q2 earnings release, ESPR tightened its timing guidance for Phase II data and new trial starts, and provided new details of its planned Phase IIb trial.

- **Key upcoming data.** Data in Sept. from Study 007 will provide the first look at safety and efficacy of ETC-1002 added to statins, which is important because the statin add-on market is several times larger than the statin intolerant market, where ETC-1002 has already shown consistent activity. Investor perception of the drug and the potential to partner (or be acquired) would be greatly enhanced if these results are clean. We currently use a low 25% probability adjustment for this market in our model.
- **Expanded Ph 2b plans.** ESPR announced plans for Study 008, which will now include 322 patients (previously 180-200), compare two doses of ETC-1002 (120mg and 180mg) to ezetimibe, include two smaller combination arms of ETC-1002 plus ezetimibe, and importantly now includes both statin intolerant and statin tolerant patients (previously only statin intolerant). This larger, more robust trial design is still expected to read out in H2:14.
- **Timelines tightened:** ESPR disclosed that it now expects (1) Proof of concept Ph 2a statin add-on data (Study 007) in first half of Sept. (previously September); (2) initiate Ph 2b (Study 008) in October (previously Q4), and (3) Ph 2b data in H2:14 (Study 008) – no change pending enrollment rate.

Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US$)	-36.31	-3.12	-1.71	2.06
Prev. EPS (US$)	—	-2.23	-1.77	2.11
P/E (x)	-0.5	-5.4	-9.7	8.1
P/E rel. (%)	-2.8	-35.0	-70.6	65.0
Revenue (US$ m)	—	—	—	78.0
EBITDA (US$ m)	-10.1	-21.6	-30.2	42.1
OCFPS (US$)	-33.42	-2.12	-1.55	2.20
P/OCF (x)	—	-7.9	-10.8	7.6
EV/EBITDA (current)	-23.8	-11.1	-7.9	5.7
Net debt (US$ m)	16	-78	-127	-173
ROIC (%)	901.89	410.73	573.84	-799.96

Number of shares (m)	15.33	IC (current, US$ m)	-1.13
BV/share (Next Qtr., US$)	5.2	EV/IC (x)	-32.5
Net debt (Next Qtr., US$ m)	-84.9	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-106.6	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

Upcoming Study 007 Data – First Post-IPO Catalyst

ESPR expects to report data from Study 007 in the first half of September, which is a slight tightening of prior guidance for September.

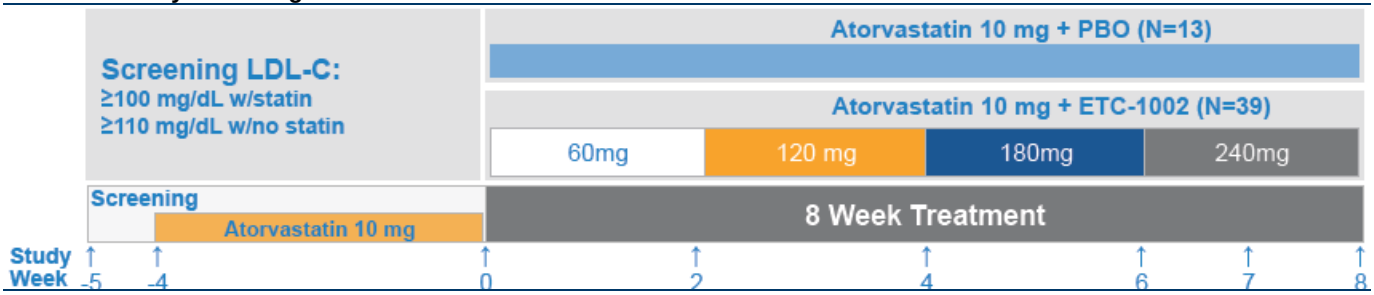
Study 007 tests ETC-1002 in patients who do not achieve their LDL-C goal while on stable statin therapy. The trial has a similar forced dose titration as Study 006 (in statin intolerant patients). In this trial, patients are treated with escalating doses of ETC-1002 on top of a 10mg dose of atorvastatin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

Demonstration of clear efficacy and clean safety in this population is important in defining the market opportunity for ETC-1002 beyond the statin intolerant market.

Expectations and risks include:

- **Efficacy:** 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.
- **Safety:** We believe that the risk of increased toxicity is low. There is no evidence to date of overlapping toxicity, and both drugs are metabolized and transported by different mechanisms. It is possible that some new safety signal could arise by the more complete inhibition of the cholesterol synthesis pathway.
- **Limitations:** As with Study 006, the dose titration design does not allow for discrimination between effects that are dose related or time related, since the dose is escalated for each patient every two weeks.

Exhibit 1: Study 007 Design



Source: Company data, Credit Suisse estimates

New Details of Study 008 – Bigger, Better Trial

Study 008 is designed to provide definitive head-to-head efficacy data for ETC-1002 monotherapy vs. Zetia (ezetimibe) monotherapy, and will now also explore the combination of the two drugs. Zetia is the current standard of care in both the statin intolerant and statin add-on markets.

Several new disclosures including a detailed trial design point to a more robust clinical trial.

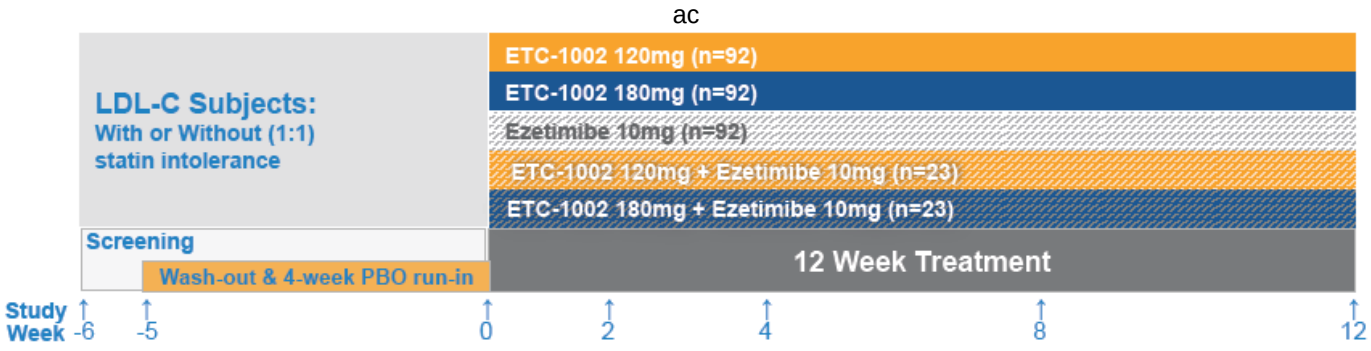
- **Updated timing** – ESPR previously announced plans to initiate Study 008 in Q4. ESPR now expects to start in October, which is on the earlier side.
- **Determination of dose** – ESPR previously stated that it would look at two or three doses of ETC-1002 vs. Zetia. The trial will now include both the 120mg and 180mg doses.

- **Larger trial** – ESPR plans to enroll approximately 322 versus the prior expectation for 180-200 patients.
- **Five arm study** – In addition to comparing two dose of ETC-1002 to Zetia, Study 008 will also investigate the combination of ETC-1002 and Zetia in two additional arms (one for each dose of ETC-1002). These arms will be smaller and are more "exploratory". However, the results from this trial will be important as the combination of ETC-1002 and Zetia could be a viable treatment option for many patients.
- **Broader patient population** – In addition to statin intolerant patients, Study 008 will also enroll statin tolerant patients. The trial is designed to stratify patients based on statin tolerance/intolerance and will enroll an equal number of each type of patient. The inclusion of statin tolerant patients is important because this is a much large patient pool.

Study 008 will enroll patients with high cholesterol (baseline LDL-C of >100). Patients will have a 4 week placebo run in period followed by randomization to one of five arms (Exhibit 2). Patients will remain on treatment for 12 weeks, and the primary endpoint is reduction in LDL-C from baseline. The trial is 90% powered to show a 10% absolute difference between Zetia and ETC-1002 monotherapy (assuming 18% for Zetia and 28% for ETC-1002). While the combination arms are not powered to show a statistically significant difference, they are large enough to determine whether there is added efficacy.

Patients will be stratified for statin tolerance/intolerance. Patients with baseline hemoglobin below 12 and patients with gout will be excluded.

Exhibit 2: Study 008 Design



Source: Company data, Credit Suisse estimates

Q2:13 In Line – Revised Share Count Leads to EPS Changes

ESPR provided new guidance for year-end cash (~$75M) and operating cash usage (~$25M). We have not changed our forward estimates as we had previously had expenses in line with the guidance.

Our full year EPS is significantly impacted based on lower average common shares, as we previously used a pro forma share count for H1:13. We now use the reported shares as we expect this is the way the company will report it for 2013. The Q2 results and revised share count causes our 2013 EPS estimates to change to ($3.12) from ($2.23).

Valuation: Our $23 target price for ESPR is based on a probability adjusted DCF, assuming a 55% probability of success in statin intolerant and 25% probability in statin add-on patients. Additional data in 2013 and 2014 could increase our probabilities for both indications.

Exhibit 3: Q2:13 Variance Table

Income Statement	2Q:13 Act.	CS 2Q:13 Est	Delta
Revenues	$ -	$ -	$ -
Milestones and partnering revenue	$ -	$ -	$ -
Royalty revenue	$ -	$ -	$ -
Total Net Revenues	$ -	$ -	$ -
Expenses	$ -	$ -	$ -
R&D	$ 3.1	$ 3.2	$ (0.1)
G&A	$ 1.2	$ 2.5	$ (1.3)
Total Operating Expenses	$ 4.3	$ 5.7	$ (1.4)
Operating income (loss)	$ (4.3)	$ (5.7)	$ 1.4
Total Other Income (Expense)	$ (2.6)	$ (0.1)	$ (2.5)
Pre Tax Income	$ (6.9)	$ (5.8)	$ (1.1)
Income tax expense (benefit)	$ -	$ -	$ -
Net Income	$ (6.9)	$ (5.8)	$ (1.1)

Source: Company data, Credit Suisse estimates

Exhibit 4: ESPR News Flow

Timing	Expected News Flow	Program
Residual risk (statin add-on)		
Sept. 2013	Phase IIa data (Study-007)	ETC-1002
Q4:13	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	

Source: Company data, Credit Suisse estimates

Exhibit 5: 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 6: ESPR Earnings Model

	2012A	Q1:13A	Q2:13A	Q3:13E	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	77.7	107.8
Total Net Revenues								78.0	4.0	56.5	69.3	28.7	43.5	77.7	107.8
Expenses															
R&D	8.0	2.1	3.1	4.5	5.2	14.9	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	2.1	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	3.3	4.3	6.6	7.4	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)	(3.3)	(4.3)	(6.6)	(7.4)	(21.6)	(30.2)	42.1	(33.7)	16.9	27.7	(14.9)	(2.3)	29.6	57.3
Total Other Income (Expense)	(1.5)	(0.9)	(2.6)	0.3	0.3	(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)	(4.2)	(6.9)	(6.3)	(7.1)	(24.5)	(28.9)	43.8	(32.2)	18.4	28.7	(13.9)	(1.3)	30.6	58.3
Income tax expense (benefit)															20.4
Net Income	(11.7)	(4.2)	(6.9)	(6.3)	(7.1)	(24.5)	(28.9)	43.8	(32.2)	18.4	28.7	(13.9)	(1.3)	30.6	37.9
EPS - basic (proforma)	($36.31)	($12.24)	($19.82)	($0.41)	($0.46)	($3.12)	($1.71)	$2.09	($1.52)	$0.86	$1.34	($0.64)	($0.06)	$1.40	$1.73
EPS - diluted (proforma)	($36.31)	($12.24)	($19.82)	($0.41)	($0.46)	($3.12)	($1.71)	$2.06	($1.52)	$0.82	$1.27	($0.64)	($0.06)	$1.33	$1.64
Shares outstanding - basic (proforma)	0.32	0.35	0.35	15.33	15.41	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	0.35	0.35	15.33	15.41	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	266.5	369.6
Ex-US (prob adjusted)	12.4	40.4	78.5	177.7	246.4
Total (prob adjusted)	58.8	141.4	225.6	444.2	616.0
Royalty	10.3	24.7	39.5	77.7	107.8
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 09-Aug-2013)*

Esperion Therapeutics (ESPR.OQ, $16.69, OUTPERFORM[V], TP $23.0)

Disclosure Appendix

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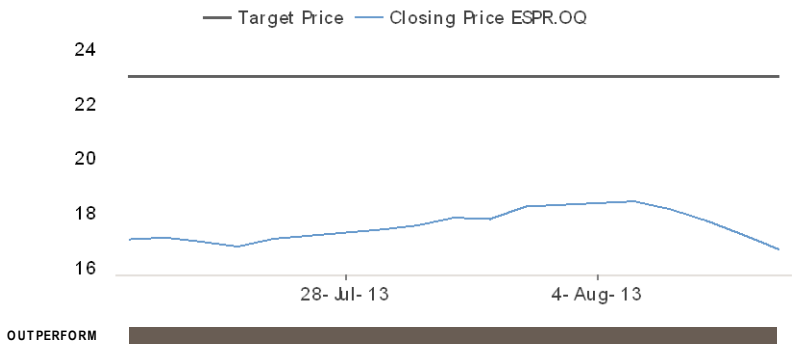
3-Year Price and Rating History for Esperion Therapeutics (ESPR.OQ)

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

** Asterisk signifies initiation or assumption of coverage.*



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Underperform/Sell*	15%	(39% banking clients)
Restricted	3%	

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

Method: Our $23 price target for ESPR is based on a probability adjusted DCF, assuming a very conservative 55% probability of success in statin intolerant and 25% probability in statin add-on patients. Additional data in 2013 and 2014 could increase our probabilities for both indications.

Risk: Risks to our $23 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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