Esperion Therapeutics (ESPR)

SMALL & MID CAP RESEARCH

Rating	**OUTPERFORM* [V]**
Price (22 Nov 13, US$)	11.74
Target price (US$)	26.00[1]
52-week price range	18.89 - 11.74
Market cap. (US$ m)	180.30
Enterprise value (US$ m)	101.67

**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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IPO Class of '13: Defending on Pullback

After an initial strong IPO performance, ESPR has pulled back significantly, and the much reduced enterprise value of $95M warrants investors taking a second look. Since the IPO, ESPR has released positive Phase IIa data (Study 007) in patients not adequately responding to statins and presented its previously released stain-intolerant Phase IIa data (Study 006) at AHA. ESPR has also initiated the larger Phase IIb program and remains on track for data in H2:14.

- **Cash sufficient to achieve key clinical milestones**: ESPR ended Q3 with approximately $85.4M in cash and expects to end 2013 with ~$75M, which should support operations to the end of 2015.
- **Catalysts include:** (1) Phase IIb statin intolerant data in H2:14; and (2) Phase IIb statin add-on data potentially in H2:14.
- **New lipid guidance raises questions but does not change the thesis.** New guidelines potentially expand the number of patients eligible for LDL-C lowering drugs (statins) but remove specific LDL-C treatment goals and highlight the importance of outcomes data. While a significant change from previous guidance, it does not change the necessary path of conducting Phase IIb studies, nor does it reduce the need for new oral drugs for statin intolerant patients (the primary market for ETC-1002).
- **Reiterate positive thesis and $26 target:** Our positive view on ESPR is based on the large market opportunity and significant scarcity value of its novel oral pill for lowering cholesterol. 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$)	-36.31	-3.00	-1.71	2.06
Prev. EPS (US$)	—	—	—	—
P/E (x)	-0.3	-3.9	-6.8	5.7
P/E rel. (%)	-1.9	-24.0	-46.2	42.6
Revenue (US$ m)	—	—	—	78.0
EBITDA (US$ m)	-10.1	-20.4	-30.2	42.1
OCFPS (US$)	-33.42	-2.21	-1.55	2.20
P/OCF (x)	—	-5.3	-7.6	5.3
EV/EBITDA (current)	-10.8	-5.3	-3.6	2.6
Net debt (US$ 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$)	5.0	EV/IC (x)	-51.4
Net debt (Next Qtr., US$ m)	-78.6	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-102.6	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

A Bumpy Start

After an initially successful $14/share IPO (up 44%, IPO to peak), ESPR has significantly lagged and is now trading substantially lower (down 42% from peak and down 16% from IPO price). The result is a current market cap of $180.3M, with cash of $85.4M and an enterprise value of ~$95M. While we acknowledge that the key drivers are likely in the back half of 2014 (no change from IPO), the valuation is now more compelling, and we believe investors who either participated in the IPO or were on the sidelines should consider revisiting the story at the current discounted price.

Exhibit 1: Esperion Price Chart

Source: Yahoo finance

Key Excerpts from Our Recent Initiation:

Portfolio Manager Summary

Esperion's primary asset is a wholly owned, internally discovered oral pill for lowering cholesterol. ETC-1002 is currently in Phase II, and has already demonstrated convincing clinical efficacy in its lead indication for statin intolerant patients. Positive Phase IIa efficacy data in statin intolerant patients (Study 006) showed an approximate 30% average reduction in LDL-C, consistent with earlier studies. The efficacy of ETC-1002 appears roughly double that of Zetia (ezetimibe), the current standard of care in this setting. Also, recent Phase IIa efficacy data in patients treated with ETC-1002 as an add-on to statin therapy (Study 007) showed an additional 22% average reduction in LDL-C. ESPR believes that a 20% reduction in LDL-C on top of statins is clinically meaningful.

We expect the following key value inflection catalysts in the next one to two years:

- **Phase IIb Studies in Statin Intolerant Patients and Residual Risk Patients:** These studies are expected to start in Q4:13 and Q1:14 with read outs in H2:14, and are the key trials that we expect will drive a large pharma partnership or potential takeout.
- **More Regulatory Clarity after Its End of Phase II Meeting in Late 2014 / Early 2015:** This meeting will define the scope of the Phase III program and potentially lift the partial clinical hold. It is critical to the value of a potential takeout or partnership.

Exhibit 2: 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 3: 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

Investment Positives

- **Wholly Owned Cardiovascular Franchise with Focus on the Cholesterol Market:** ESPR owns 100% of the commercial rights to ETC-1002, which it acquired from Pfizer (Pfizer had previously acquired the program when it bought the original Esperion for $1.3B in 2004). ESPR does not owe any royalties to Pfizer for the drug, making this asset more attractive from a partnering or takeout perspective.
- **Potential for Blockbuster Sales:** If successful, ETC-1002 targets a mass market of 2-3M patients who are intolerant to statins and up to 12M patients with residual risk (statin add-on). Despite modest efficacy, Zetia has approximately $4B in annual sales (75% add-on therapy and 25% statin intolerant patients). We believe there is a substantial market for a new and more potent oral drug even in a market with projected generic Zetia and generic statins.

- **Solid Efficacy Data in a Blockbuster Indication:** Once-daily, oral ETC-1002 reduces cholesterol (LDL-C) by approximately 30% as a monotherapy. This is approximately twice the activity of Zetia, which is the current standard of care, second line treatment for high LDL-C (~18% reduction). Sales of Zetia are approximately $4B with $1B derived from the statin intolerant market.
- **Tolerability and Toxicity Appear Good:** ETC-1002 therapy is not associated with any major tolerability side effects that would limit its use, such as rash, nausea, etc. It is also not associated with any overt organ toxicity, such as muscle damage (the major limitation of statins) or liver enzyme elevations. There have been no discontinuations of ETC-1002 treatment due to muscle pain or weakness, a common side effect of statins.
- **Scarcity Value of Cardiovascular Biotechs:** ESPR is one of a small number of pure-play cardiovascular biotech companies. It is significant that the company has retained rights to its drug, ETC-1002, because this increases the chance of a takeout or favorable partnership deal. This management team was also responsible for selling the original Esperion to Pfizer in 2004 for $1.3B.

Investment Risks

- **Potential Safety Signals with an Unknown Mechanism:** ETC-1002 treatment is associated with a modest decrease in hemoglobin and a modest increase in uric acid. While neither were cause for treatment disruption or led to any recorded adverse events, it is possible that these side effects could cause regulatory risks, longer-term safety concerns, or limitations on Phase III enrollment. A better understanding of the mechanism for these physiologic changes is important.
- **Partial Clinical Hold:** ETC-1002 is on partial clinical hold with the FDA, limiting the maximum duration of treatment in ongoing trials to six months. The partial clinical hold results from the FDA having classified ETC-1002 as a PPAR activator (based on its chemical structure). This class of drugs has higher regulatory scrutiny because of potential cancer signals. ESPR is conducting the necessary two-year carcinogenicity studies and expects the hold to be lifted at the time of the end of Phase II meeting. ESPR is also collecting significant data from its clinical program and has substantial clinical evidence that ETC-1002 is not acting as a PPAR activator (no edema, no HDL effect, etc.).
- **Outcomes Studies May Be Required:** Our model assumes that ETC-1002 is approved for statin intolerant patients without the need for an outcomes study (on LDL-C lowering alone). To be conservative, we have forecast the need for an outcome study in our model for the statin add-on market. We expect ESPR will have better visibility on the regulatory requirements in its end of Phase II meeting in late 2014. If an outcome study is required, it would delay the launch by up to three years, substantially increase Phase III expenses, and increase clinical/regulatory risk for a partner or acquirer.
- **Binary Risk:** ESPR is highly levered to a single asset (ETC-1002). If there is a major setback in this program, it could put the value of the company at risk. Potential key risks include: (1) any new safety signals, (2) the inability to remove the partial clinical hold, and (3) failure to demonstrate efficacy in larger trials.

Valuation

Our target price of $26 is supported by a DCF methodology, using probability-weighted sales estimates for ETC-1002 modeled through 2030. We assume a 55% probability of success in statin intolerant patients and a 33% probability of success in the statin add-on market. The market opportunity in both indications is further modified by a 55% probability that ETC-1002 faces competition from CETP inhibitors (e.g., Merck's anacetrapib and Eli Lilly's evacetrapib). We model a commercial launch for statin intolerant in 2018 and for statin add-on in 2021.

We use a 38% tax rate and a 12% discount rate, and arrive at a target price of $26.

The most important levers in our valuations are as follows:

(1) **Probability of Success:** We use 55% probability of success for ETC-1002 in statin intolerant patients and 33% for ETC-1002 as a statin add-on.

(2) **Pricing of ETC-1002:** We assume that ETC-1002 is priced at a 30% premium to Crestor, an on-patent statin that is considered best-in-class in terms of efficacy.

(3) **Timing of U.S. and EU Approvals:** We assume U.S. and ex-US launches in 2018 for ETC-1002 in statin intolerant patients. The timing for ETC-1002 is forecast assuming an end of Phase II meeting in late 2014 or Q1:15, and completion of Phase III safety and efficacy studies by H1:17. We assume patent protection until 2030. For the statin add-on market, we assume a launch in 2021, following longer-term outcome studies.

(4) **Competitive Entrants in the Cholesterol Market:** We assume CETP inhibitors, if approved, would compete directly with ETC-1002. If CETP inhibitors are not approved, we forecast a three times greater penetration rate in the statin add-on market and a 50% increase in the statin intolerant market. We assign a 55% probability of success for an approved CETP inhibitor. ETC-1002 would also share the market with generic statins, generic ezetimibe (Zetia), and generic combination products of statins plus ezetimibe.

(5) **We Assume that ESPR Enters into a Partnership for the Global Rights to ETC-1002 and that ESPR Receives a Royalty on Future Sales:** We have modeled probability-adjusted clinical and regulatory milestones for ETC-1002 and a 17.5% royalty on future global sales. In this scenario, the Phase III and launch costs are paid by the partner. If ESPR is not able to partner ahead of Phase III on favorable terms, then there is significant dilution risk from future equity raises to fund expensive late-stage development.

Key Modeling Assumptions

Our model starts with a projection of the total treated population based on current and projected prescription data and we include the following assumptions:

- **Pricing:** We assume that ETC-1002 is at a ~30% premium to Crestor ($153/mo WAC) and Zetia ($155/mo WAC). Crestor is the best-in-class statin, and Zetia is the standard therapy for statin intolerant and statin add-on patients. Although patent protection for Zetia is set to expire in 2017 before ETC-1002 reaches the market, we believe that this price point is a relevant precedent due to the high unmet medical need and the presumed higher efficacy of ETC-1002.

- **Competition:** Our base case assumes a 55% probability of competition from CETP inhibitors. Our model probability adjusts for with or without CETP inhibitors. In the scenario with CETP inhibitors, we use a lower penetration rate for ETC-1002, and this is most pronounced in the statin add-on model (see below).

- **Statin Intolerant Market (55% Probability of Success)**

- Market size is 1.2M treated patients in 2013, growing to 2.6M patients in 2030 (8.9M to 18.9M prescriptions per year).
- We assume ETC-1002 is approved for this indication in 2018. We assume competition from PCSK9 inhibitors, which could reach the market in 2016, and potentially CETP inhibitors, which could reach the market in 2017, pending ongoing outcome studies.
- We assume a peak market share of 30% in this market, assuming CETP inhibitors do not make it to market. If CETP inhibitors make it to market (55% probability), we assume a 20% peak market share.

- **Statin Add-On/Residual Risk Market (33% Probability of Success)**
  - Market size is ~8.8M treated statin add-on patients in 2013, growing to 9.2M in 2030 (63M to 66M Rx per year).
  - We assume ETC-1002 obtains a label for this indication in 2021, after the completion of an outcomes study (This is our conservative assumption)
  - We assume a peak market share of 16%, assuming CETP inhibitors do not make it to market. If CETP inhibitors make it to market (55% probability), we assume a 5.6% peak market share.

Exhibit 4: 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 22-Nov-2013)*

Esperion Therapeutics (ESPR.OQ, $11.74, OUTPERFORM[V], TP $26.0)

Disclosure Appendix

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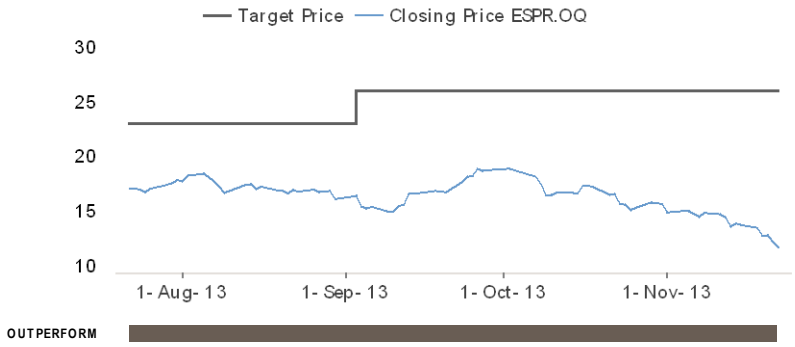
3-Year Price and Rating History for Esperion Therapeutics (ESPR.OQ)

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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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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See the Companies Mentioned section for full company names

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