EDISON

Basilea Pharmaceutica

Interim results

Cresemba growth, pipeline expansion

Pharma & biotech

Basilea reported a strong set of interim 2018 results; H118 total revenues grew to CHF59.9m (+30%, H117 CHF46.2m). Notable is Cresemba's (invasive mould infections) performance; its revenue contribution increased 30% to CHF26.3m (H117 CHF20.3m), which includes royalties on sales of CHF10.8m (H117 CHF5.3m) received from partners. Zevtera (severe bacterial infections) sales remain lacklustre; however, the US opportunity is key and the two required registration ceftobiprole trials (SAB and ABSSSI) are now underway. We value Basilea at CHF1,239m.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (c)	P/E (x)	Yield (%)
12/16	66.0	(50.9)	(5.06)	0.0	N/A	N/A
12/17	101.5	(18.9)	(1.78)	0.0	N/A	N/A
12/18e	124.0	(29.6)	(2.74)	0.0	N/A	N/A
12/19e	137.3	(26.7)	(2.48)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Cresemba steady growth continues

Basilea's reported H118 total revenues include product sales (CHF6.5m vs H117 CHF9.8m), contract revenues (CHF40.1m vs H117 CHF31.4m) and other revenue (CHF13.3m vs CHF5m), which comprises mainly BARDA reimbursements related to the Phase III ceftobiprole trials. In-market sales for Cresemba amounted to $120m in the 12 months ending 31 March 2018 (+94% vs the comparable 2017 period). Cresemba continues to benefit from steady growth in the US and the increasing contribution from early launch countries in Europe.

Revenue guidance updated

Management has updated FY18 total revenue guidance to CHF120-130m from CHF105-115m, reflecting stronger than anticipated sales of Cresemba. In the US, partner Astellas has reported Cresemba sales of $54m (+59%) for H118 ($34m in H117) and the drug looks easily on track to meet Astellas' guidance of $100m for its fiscal year. Basilea expects a widening of FY18 operating loss to CHF25-35m from initial guidance of CHF10-20m, relating mainly to the in-licencing of derazantinib in H118 and its associated programme-related costs. Management expects cash burn per month to reduce to CHF7m (average) in H218.

Pipeline expansion and trial initiations

In H118 Basilea expanded its oncology portfolio by in-licensing the worldwide (ex-Greater China) rights to ArQule's derazantinib (Phase II iCCA), an oral tyrosine kinase inhibitor (pan FGFR). It has initiated the two Phase III cross-supportive ceftobiprole registration trials needed for US marketing approval (acute bacterial skin and skin structure infections (ABSSSI) in February and *Staphylococcus aureus bacteraemia* (SAB) in August).

Valuation: rNPV of CHF1,239m or CHF115/share

Our revised valuation of CHF1,239m or CHF115/share (vs CHF1,285m previously) reflects an increase in our R&D assumptions as per guidance. Additionally, we roll forward our DCF and update for net cash of CHF51.3m at 30 June 2018.

21 August 2018

Price	**CHF59.9**
Market cap	**CHF707m**
	US$1.00/CHF
Net cash (CHFm) at 30 June 2018	51.3
Shares in issue (including 1m treasury shares)	11.8m
Free float	91.46%
Code	BSLN
Primary exchange	SIX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.7)	(17.2)	(23.2)
Rel (local)	(12.5)	(17.3)	(23.7)
52-week high/low	CHF82.9	CHF59.9	

Business description

Basilea Pharmaceutica is focused on anti-infectives and oncology. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). The R&D pipeline includes three clinical-stage assets for cancer resistance.

Next events

BAL101553 glioblastoma phase I/IIa data	End 2018
Derazantinib Phase II interim iCCA data	H119
Ceftobiprole Top-line data (Phase III ABSSSI study)	H219

Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr Daniel Wilkinson +44 (0)20 3077 5734

healthcare@edisongroup.com

Edison profile page

Strong start to 2018

Basilea has updated full-year 2018 total revenue and operating loss guidance. Revised guidance is for total revenues of CHF120-130m (previous guidance CHF105-115m). This reflects management's expectations of higher revenue contributions from Cresemba and Zevtera (updated guidance of CHF75-85m from CHF60-65m). Given that Zevtera still accounts for a minority of the combined revenues (H118 CHF1.6m), the upgrade is a reflection of stronger than anticipated Cresemba revenues (CHF26.3m). Of importance is the contract revenue contribution from the deferred revenue recognition related to the Toctino upfront payment of £145.6m (CHF224.1m) received in 2012, which will reduce from CHF18.8m in H118 to CHF4.9m in H218 and to zero in 2019. We expect contributions from Cresemba revenue growth to more than make up the shortfall here.

Management now expects a widening of FY18 operating loss to CHF25-35m from initial guidance of CHF10-20m, R&D expenses are anticipated to be higher due to the $10m upfront paid to ArQule for the in-licencing of derazantinib in H118 and its associated programme-related costs. In H118, net cash used for operating activities increased to CHF60.4m (H117 CHF36.6m), reflecting one-time effects in the period (the $10m upfront payment to Arqule plus cost of in-licensing some preclinical assets). Importantly management expect cash burn in H218 to reduce to CHF7m average per month.

Basilea reported H118 total revenue of CHF59.9m (+30%), which includes product sales of CHF6.5m (vs H117 CHF9.8m), contract revenues of CHF40.1m (vs H117 CHF31.4m) and other revenue of CHF13.3m (vs H117 CHF5.0m), which comprises mainly BARDA reimbursements related to the Phase III ceftobiprole trials required for a US registration. With the commercialisation of Cresemba and Zevtera (ex US) largely in the hands of multiple licensing and/or distribution partners, a higher amount of the associated revenues (be that milestones, royalties, transfer price sales or deferred revenues) will fall into the contract revenue line as opposed to product sales. Exhibit 1 provides details of the H118 revenue breakdown.

Exhibit 1: Basilea H118 total revenue breakdown

Revenues (CHFm)	H118	H117	Notes for H118
Total revenues	**59.9**	**46.2**	
Product sales	6.5	9.8	CHF4.9m product revenue relate to upfront payment and product sales to Pfizer. CHF1.6m relate to distribution agreements.
Contract revenues	40.1	31.4	See breakdown below
Royalties on sales	10.8	5.3	CHF2.3m (PFE royalty on Cresemba sales and Astella's royalties on Cresemba US sales)
Milestone payments	2.0	0	CHF2m from Grupo Biotoscana for Cresemba approval in Peru
Other Cresemba and Zevtera contract revenues	8.5	7.2	
Other contract revenues	18.8	18.8	Relating to the 2012 145.6m (CHF 224.1m upfront payment from Steifel (in licensing of Toctino, the US development program terminated in 2016).
Other revenues	13.3	5.0	CHF13.2m BARDA reimbursements related to expenses for the US phase III ceftobiprole trials

Source: Edison Investment Research, Basilea reports and presentations

Basilea reported H118 operating expenses of CHF80.3m (H117 CHF65.3m), as higher R&D expenses offset lower SG&A expenses. R&D expenses increased to CHF57.8m in H118, reflecting the $10m upfront payment for the in-licensing of derazantinib and its associated development costs, the initiation of the US ceftobiprole Phase III studies as well as the ongoing paediatric studies for both ceftobiprole (Zevtera) and isavuconazole (Cresemba). SG&A expenses decreased to

CHF15.9m (H117 CHF34.6m), reflecting the change in the commercialisation model for marketed assets, Cresemba and Zevtera post the Pfizer deal. Basilea reported an H118 operating loss of CHF20.4m (H117 operating loss of CHF19.1m).

Basilea reported gross cash (including financial investments) of CHF247.3m at end June 2018 compared to CHF311m at end December 2017. We believe this should be sufficient to fund operations beyond 2019, even excluding future potential deals for Zevtera in the US or the oncology pipeline. Profitability will be driven by increasing revenues (royalties and milestones on sales of Cresemba worldwide and Zevtera in Europe and the rest of the world); the higher revenues plus fairly stable combined R&D, selling, general and administrative expenses during the next 12 to 18 months will result in a reduction in operating losses in 2019, even in the absence of any deferred revenue recognition related to the Toctino upfront payment.

Multiple partnerships in place for the anti-infective portfolio

Basilea has multiple licensing deals in place for its commercially available anti-infective products, Cresemba and Zevtera; over 100 countries are covered by strong regional and global partnerships. So far Basilea has received $230m in total upfront and milestone payments. Under the terms of existing agreements, Basilea could receive a total of $1.1bn in potential regulatory and sales milestones if the assets reach predetermined targets. Exhibit 2 highlights the existing partnerships for both Cresemba and Zevtera and outlines the associated deal economics. We note that in many instances, partners have chosen to in-license both products given the significant overlap in the physician-prescribing base.

Exhibit 2: Cresemba and Zevtera partner/distribution agreements

Product	Partner/Distributor *	Territory	Comments
Cresemba	Astellas	US	CHF122m upfront and regulatory milestones received with up to CHF285m of sales milestones outstanding. Tiered royalty starting in the mid-teens and ramping up to mid-20s on sales.
Cresemba	Pfizer	Over 40 countries in Europe (excluding Nordics), Russia, Turkey and Israel. Extended to include China (incl Hong Kong and Macau) and 16 countries in Asia Pacific	CHF73m upfront and up to US$650m sales and regulatory milestones plus mid-teen on sales royalties.
Zevtera	Correvio	Europe (excluding Nordics) and Israel	Upfront CHF5m and regulatory and commercial milestone payments. Participate in sales through a transfer price.
Zevtera	CR Gosun	China, Hong Kong and Macau	CHF3m execution payment and up to CHF145m additional payments on achievement of pre-specified regulatory and commercial milestones.
Cresemba & Zevtera	Unimedic Pharma*	Nordic countries including Sweden, Denmark, Norway and Finland	Upfront and sales milestone payments. Participate in sales through a transfer price.
Cresemba & Zevtera	Grupo Biotoscana (GBT)*	19 countries in Latin America including Brazil, Mexico, Argentina and Colombia	CHF11m upfront plus milestone payments. Participate in sales through a transfer price.
Cresemba	Asahi Kasei Pharma (AKP)	Japan	CHF7m upfront and up to CHF60m regulatory and commercial milestone payments plus double-digit tiered royalties.
Cresemba & Zevtera	Avir Pharma*	Canada	Upfront and sales milestone payments. Participate in sales through a transfer price.
Cresemba & Zevtera	Hikma*	MENA region	Financial terms not disclosed. Participate in sales through a transfer price.

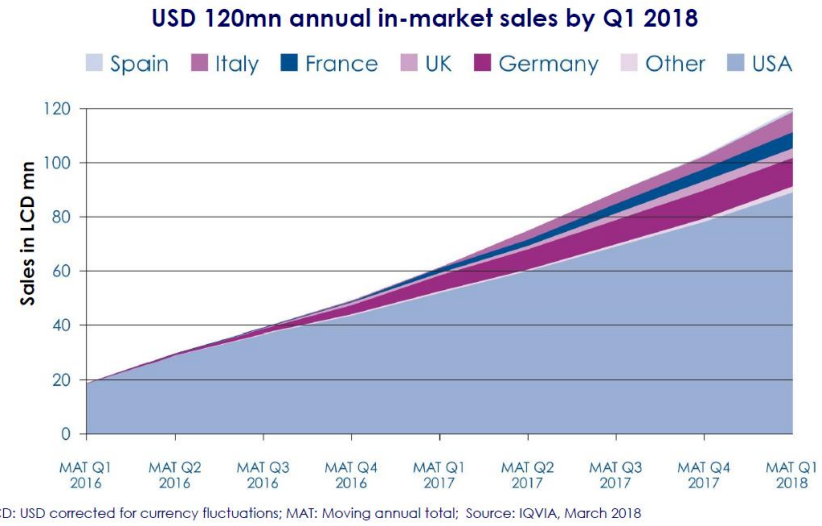
Source: Edison Investment Research, Basilea Pharmaceutica. Note: *Distribution agreements where Basilea supplies product at a transfer price. Cresemba steadily growing in launched markets.

Cresemba (isavuconazole) is a broad-spectrum antifungal for the treatment of severe, life-threatening fungal infections. It is available in the US and major European countries through regional partners. In-market sales for Cresemba amounted to $120m in the 12 months ending 31 March 2018 (+94% vs comparable period; we note in-market sales at 31 December 2017 were just over $100m). Exhibit 3 highlights the steady growth in sales in the US and the increasing contribution from key European markets of Germany, UK and France and new markets such as Italy and Spain. In the US, partner Astellas reported sales of $54m (+59%) for H118 ($34m in H117).

Basilea anticipates growth in existing markets and further launches worldwide to drive top-line growth. Pfizer will roll out the drug in stages across Europe (timing is dependent on individual country pricing and reimbursement discussions as Cresemba received approval through a centralised process in Europe). Launches to date in 2018 include Switzerland, Greece, Ireland and the Netherlands. Further EU launches (not disclosed) are anticipated in H218. Outside Europe and the US, partners are filing or have filed for marketing authorisation, so further approvals should come through in additional territories within the next couple of years. In July 2018, Latin American distribution partner Grupo Biotoscana received the first Cresemba approval in Peru under an expedited review triggering a CHF2m milestone payment to Basilea.

In April 2018 Japanese partner, Asahi Kasei Pharma, started enrolment of the Phase III registration study (n=100) for potential approval in Japan for the treatment of invasive fungal infections (deep-seated mycosis, comprising invasive aspergillosis, chronic pulmonary aspergillosis, mucormycosis and cryptococcosis).

Exhibit 3: Cresemba sales growth in key launched markets



Source: Basilea presentations. Note: In-market sales for 12 months to 31 March 2018.

Zevtera: Success dependent on US Phase III programme

Zevtera/Mabelio (ceftobiprole) is a broad-spectrum antibiotic for the treatment of Gram-positive infections, including methicillin-resistant *Staphylococcus aureus* (MRSA), which are resistant to a number of existing antibiotics, and Gram-negative bacterial infections, including *Pseudomonas*. The product is available in major European countries (through Correvio), Canada (through Avir Pharma) and Argentina (through Grupo Biotoscana). Additionally, partner Hikma has launched Zevtera in Saudi Arabia and has received approval for Cresemba in Jordan; further roll-out into the Middle East, North Africa and Latin America is expected later in 2018 to 2020. Uptake remains slow as sales of antibiotics take time to build after launch due to the requirement for regional reimbursement across Europe, the need to be added to individual hospital formularies and microbial stewardship programmes, and a tendency to keep new antibiotics in reserve use.

The major commercial opportunity for Zevtera resides in the US market; it is not currently approved in the US (further clinical studies are needed to secure approval). In terms of value, in 2017 the US accounted for 50% of anti-MRSA antibiotics and 70-80% of the branded hospital antibiotic market. Importantly, during H118 Basilea initiated the two Phase III cross-supportive ceftobiprole registration trials needed for US marketing approval in accordance with the Special Protocol Agreements that have been agreed with FDA. The TARGET study in ABSSSI started enrolment in February 2018 and the ERADICATE study in SAB (bloodstream infections) was initiated in August

2018. Both trials will be needed to support a US NDA submission. The TARGET trial aims to recruit 674 patients with ABSSSI who require treatment with intravenous antibiotics. This double-blind, multi-centre trial will compare ceftobiprole monotherapy versus vancomycin plus aztreonam. Unlike ceftobiprole (which has both Gram-negative and Gram-positive activity), vancomycin has no activity against Gram-negative bacteria, hence the necessary addition of aztreonam. We expect the ABSSSI study to have a duration of 18-24 months, so top-line data could be available in late 2019.

SAB is an indication where few antibiotics are currently approved and which the FDA considers an area of unmet need; therefore, the SAB study could further differentiate Zevtera from available cephalosporins. The 390-patient, multi-centre ERADICATE study will include patients with endocarditis and other forms of complicated SAB. Basilea anticipates a three-year duration for the study, thus data should be available in H221. A US launch date of 2022/2023 for ceftobiprole could be feasible, with an initial focus of bacteraemia and ABSSSI. Furthermore, data from the TARGET study could be used to support the post-marketing label outside the US.

Critically, the funding for these trials plus the potential trial in community-acquired pneumonia is in place, with up to $118m from BARDA and Basilea funding approximately 30% of the anticipated costs for the Phase III programme. BARDA is a division of the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response.

Oncology pipeline update

In addition to its commercially launched anti-infectives, Basilea also has an early- to mid-stage clinical pipeline focused on oncology products that target resistance to current therapies. These include BAL101553 (solid tumours including glioblastoma and ovarian cancer) and BAL3833 (solid tumours). Data from the (BAL101553 Phase I/IIa in recurrent glioblastoma multiforme is expected to read out initial data by year-end. Basilea successfully expanded its oncology portfolio during H118 with the in-licensing of ArQules's derazantinib. This adds a complementary oncology asset that targets subtypes of cancers, which arise from FGFR genetic aberrations. Cancer is a complex disease, both in how it arises and how it evades treatment options through multiple mutations. Basilea's R&D efforts are targeting a different part of cancer development and a prolongation cycle for a range of cancers (Exhibit 4). On that note, Basilea recently entered into a licencing and preclinical research collaboration evaluating a biomarker-driven development of a selective kinase inhibitor that controls chromosome segregation during cell division.

Derazantinib (ARQ 087) beefs up oncology pipeline

In April 2018 Basilea in-licensed the worldwide ex-China, Hong Kong, Macau and Taiwan (Greater China) rights to research and develop, manufacture and commercialise ArQule's derazantinib. It paid $10m upfront with up to $326m in milestones, in addition to tiered royalties starting in the single digits then going into double digits. ArQule had already licensed derazantinib's Greater China rights to Sinovant Sciences. This small molecule, oral drug therapy is in registrational Phase II trials for intrahepatic cholangiocarcinoma (iCCA), a form of bile duct cancer. We expect Basilea to start Phase II trials in other FGFR-driven solid cancers mid-2019 as derazantinib could have utility against a wide range of cancers including breast cancer, urothelial cancer and gastric cancer.

Both the FDA and EMA have granted ArQule orphan drug designation for iCCA, which translates into longer exclusivity periods. We assume a US/EU5 launch in 2023 for the iCCA indication following a traditional development path including a Phase III trial. However, we note that depending on the strength of the Phase II data, an accelerated approval in iCCA before this date could be a possibility. Interim analysis of data on 40 patients from the Phase II registrational trial is expected in H119. Given its current stage of development, we model derazantinib for the second-line iCCA indication only. We model peak sales of $59.4m in the US and top EU5.

Our note Oncology product portfolio to drive future growth published July 2018 provides an in-depth dive into derazantinib, BAL101553 and BAL3833.

Exhibit 4: Overview of Basilea's R&D pipeline for oncology indications

Product	Indication	Status	Comments
Derazantinib	iCCA	Phase II	Registrational trial (orphan drug designation by FDA and EMA). Interim results expected H119.
	Solid tumours	Phase II	Start mid-2019.
	Glioblastoma	Phase I/II (oral)	Separate arm of the solid tumour Phase I/IIa trial enrolling, results expected end 2018.
	Glioblastoma and ovarian cancer	Phase IIa (IV)	Expansion part of the ongoing Phase I/IIa study (48-hour infusion) in platinum-resistant ovarian cancer and resistant glioblastoma.
	Newly diagnosed glioblastoma	Phase I	Oral in combination with radiotherapy. This trial has been initiated by The Adult Brain Tumor Consortium.
BAL3833	Treatment-refractory solid tumours including metastatic melanoma and RAS-driven cancers	Phase I	Data at end 2018 are a possibility.

Source: Edison Investment Research, corporate presentations

Valuation: rNPV of CHF1,239m or CHF115/share

Our updated Basilea valuation is CHF1,239m (from CHF1,285m) and primarily reflects an increase in our R&D forecasts for the oncology pipeline. We have increased R&D spend forecasts in 2018 reflecting the derazantinib iCCA trial in addition to the cost of the ongoing paediatric ceftobiprole and isavuconazole trials. We have additionally rolled forward our DCF and updated it for a lower net cash position at the interim results (CHF51.3m at 30 June 2018 vs CHF115.8m at end December 2017). The breakdown of our valuation is shown in Exhibit 5.

Exhibit 5: Basilea rNPV valuation***

Product	Indication	Launch	Peak sales ($m)	Value (CHFm)	Probability	rNPV (CHFm)	NPV/share (CHF/share)
Cresemba (isavuconazole)	Severe fungal infections	2015 (US); 2016 (EU); 2018 (ROW) 2022 Japan	873	1,015.8	75 -100%*	966.3	89.5
Zevtera/Mabelio (ceftobiprole)	Severe bacterial infections	2015 (EU); 2018 (RoW); 2023 (US); 2023 (China)	550	223.2	75- 100%**	180.6	16.7
BAL101553	Tumour resistance	2023	500	143.4	20%	20.9	1.9
BAL3833	Tumour resistance	2024	500	105.6	15%	6.6	0.6
Derazantinib	iCCA	2023	59	44.3	30%	13.3	1.2
Net Cash at 30 June 2018				51.3	100%	51.3	4.8
Valuation				**1,583.6**		**1,238.9**	**114.7**

Source: Edison Investment Research. Note: *100% probability for the US and EU, 75% for ROW and Japan. **100% probability for the EU, 75% probability for China, ROW and the US. *** Per share calculation excludes one million treasury shares and is based on 10.8m shares outstanding.

Exhibit 6: Financial summary

CHF'000s	2016	2017	2018e	2019e
December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	65,984	101,521	124,010	137,255
Cost of Sales	(5,347)	(9,025)	(11,994)	(12,429)
Gross Profit	60,637	92,496	112,015	124,826
Research and development (gross)	(48,449)	(53,493)	(102,500)	(113,000)
SG&A	(56,077)	(53,139)	(33,861)	(33,415)
EBITDA	(41,570)	(12,236)	(21,877)	(18,819)
Operating Profit (before amort. and except.)	(43,789)	(14,036)	(24,223)	(21,361)
Intangible Amortisation	(100)	(100)	(123)	(228)
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(43,889)	(14,136)	(24,346)	(21,589)
Net Interest	(7,065)	(4,890)	(5,375)	(5,375)
Profit Before Tax (norm)	(50,854)	(18,926)	(29,598)	(26,736)
Profit Before Tax (reported)	(50,954)	(19,026)	(29,721)	(26,964)
Tax	(333)	(334)	(26)	(26)
Profit After Tax (norm)	(51,187)	(19,260)	(29,624)	(26,763)
Profit After Tax (reported)	(51,287)	(19,360)	(29,747)	(26,991)
Average Number of Shares Outstanding (m)	10.1	10.8	10.8	10.8
EPS - normalised fully diluted (CHFc)	(505.74)	(178.36)	(274.34)	(247.83)
EPS - (reported) (CHFc)	(506.73)	(179.28)	(275.47)	(249.95)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	91.9	91.1	90.3	90.9
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	59,264	58,189	59,640	61,188
Intangible Assets	232	326	526	726
Tangible Assets	8,878	7,768	9,019	10,367
Investments	50,154	50,095	50,095	50,095
Current Assets	268,494	292,976	220,988	173,249
Stocks	14,931	15,320	16,431	13,621
Debtors	2,492	4,955	5,776	6,393
Cash	239,030	260,724	186,805	141,259
Other	12,041	11,977	11,977	11,977
Current Liabilities	(72,914)	(79,491)	(54,144)	(66,713)
Creditors	(72,914)	(79,491)	(54,144)	(66,713)
Short term borrowings	0	0	0	0
Long Term Liabilities	(289,844)	(313,114)	(284,293)	(247,903)
Long term borrowings	(195,466)	(196,224)	(195,466)	(195,466)
Other long term liabilities	(94,378)	(116,890)	(88,827)	(52,437)
Net Assets	(35,000)	(41,440)	(57,808)	(80,178)
CASH FLOW				
Operating Cash Flow	(75,003)	19,014	(64,597)	(35,827)
Net Interest	0	0	(5,375)	(5,375)
Tax	0	0	(26)	(26)
Capex	(394)	(711)	(3,720)	(4,118)
Acquisitions/disposals	0	0	0	0
Financing	0	0	0	0
Other	(51,021)	2,633	558	(200)
Dividends	0	0	0	0
Net Cash Flow	(126,418)	20,936	(73,161)	(45,546)
Opening net debt/(cash)	(169,982)	(43,564)	(64,500)	8,661
HP finance leases initiated	0	0	0	0
Other	0	(0)	0	0
Closing net debt/(cash)	(43,564)	(64,500)	8,661	54,207

Source: Edison Investment Research/Company reports

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia