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Pharnext

Research update

Clinically healthy

Pharma & biotech

The past weeks have been eventful for Pharnext, with the company releasing its H121 results, announcing multiple C-Suite appointments, and conducting its R&D day. On the business front, the financing situation appears manageable following the June 2021 convertible debt financing, and the pivotal Phase III PREMIER trial remains on track to conclude enrolment in Q222. However, the continued stock price softness (triggered by the financing) remains an overhang. We believe there is the possibility for a sentiment reversal and stock price re-rating following positive progression towards the commercialisation of PXT3003.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	3.6	(23.4)	(1.61)	0.00	N/A	N/A
12/20	2.8	(21.4)	(1.17)	0.00	N/A	N/A
12/21e	3.6	(27.7)	(0.68)	0.00	N/A	N/A
12/22e	3.9	(30.8)	(0.64)	0.00	N/A	N/A

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

R&D day update on the PREMIER Phase III trial

The pivotal Phase III PREMIER study (a double-blinded, placebo-controlled study enrolling 350 patients across two arms), which commenced in March 2021, remains on-track with 40 of the 50 clinical sites being activated, patient enrolment expected to complete in Q222 and the 15-month study to conclude in Q323. Dosing for the high-dose arm will be undertaken using twice the low-dose amount in the previous PLEO-CMT trial and will be dispensed using individual 5ml stick packs (to mitigate the high-dose arm related formulation issues with the first Phase III study). As a reminder, PXT3003 remains the most clinically advanced asset for the treatment of Charcot-Marie-Tooth Disease type 1A (CMT1A) (>$1bn market) and holds the orphan drug designation in the United States and Europe.

Sufficient headroom but dilution concerning

The June 2021 convertible-bond funding (OCEANE-BSA), worth €81m across 35 tranches, could provide Pharnext a sufficiently long cash runway to take the clinical study to its conclusion although we expect a need to raise a further c €15m to commercialise the asset. By the end of November 2021, the company drew down the first five tranches totalling €17.5m and we estimate that tranche six (€3m) will be drawn down in December 2021. We note that at current trading levels, the financing remains highly dilutive, and we do not rule out alternative options to secure financing at better terms.

Valuation: €273.6m or €5.7 per basic share

Our total valuation goes down slightly to €273.6m from €287.7m due to a lower pro forma net cash position (net debt of €6.5m at the end of H121 offset by the subsequent conversion of €9.2m of debt to equity up to 30 November). However, the basic per share valuation comes down significantly to €5.7 (from €13.1), following additional equity issued to cover for the conversion of the initial tranches of the June 2021 convertible debt.

3 December 2021

Price	**€0.09**
Market cap	**€4m**
Net debt (€m) at end H121	6.5
Shares in issue	48.3m
Free float	23%
Code	ALPHA
Primary exchange	Euronext Paris
Secondary exchange	OTC Pink

Share price performance

%	1m	3m	12m
Abs	(46.0)	(89.1)	(97.6)
Rel (local)	(44.7)	(89.0)	(98.0)
52-week high/low		€3.98	€0.09

Business description

Pharnext is developing new therapies for both rare and common neurological disorders using its proprietary Pleotherapy platform, which unearths new therapeutic effects from drug combinations. Its lead programme is PXT3003 for Charcot-Marie-Tooth disease type 1A, which has entered pivotal Phase III trials. It also has PXT864 for Alzheimer's disease, which has completed Phase IIa but has been deprioritised.

Next events

Phase III PREMIER trial recruitment	Q222
Additional data from the PLEO-CMT-FU extension study	Q222
Top-line data from the animal factorial study	Q123

Analyst

Jyoti Prakash, CFA +91 981 880 0393

Maxim Jacobs, CFA +1 646 653 7027

healthcare@edisongroup.com

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R&D day highlights: The PREMIER trial

Pharnext held its R&D day on 27 October 2021, and provided an update on the pivotal Phase III PREMIER trial for PXT3003 in CMT1A. The trial is a randomised, two-arm (high-dose PXT3003 arm from the previous PLEO-CMT trial versus control in a 1:1 ratio), double-blinded, placebo-controlled study evaluating 350 patients across a range of functional assessments over a 15-month period. The trial will enrol subjects between 16 and 65 years of age with genetically confirmed mild-to-moderate CMT1A (CMTNS-V2[1] score >2 and ≤18). The first participant was randomised at the end of March 2021.

The company indicated that patient enrolment has not been affected so far by COVID-19 and remains on track for completion in Q222. Of the 50 recruited trial sites (Exhibit 1) 40 sites have been activated, which reassures us on the company's ability to meet its study completion target of Q323.

Exhibit 1: Clinical trial sites by location

Country	No. of trial sites
United States	20
Canada	5
France	6
Germany	5
Italy	4
Spain	4
Belgium	1
Netherlands	1
Denmark	1
Israel	3

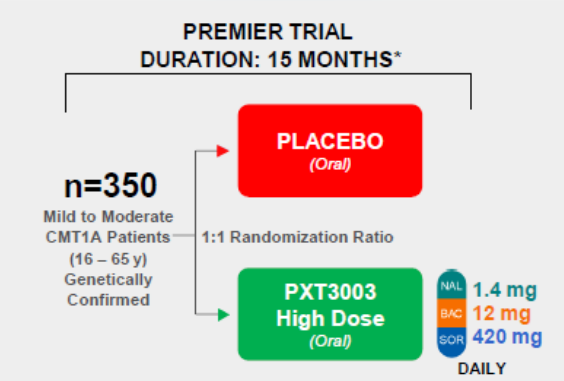
Source: Pharnext R&D day presentation, October 2021

The primary endpoint, as advised by the FDA and EMA, continues to be the improvement on the 12-point Overall Neuropathy Limitations Scale (ONLS) score over the trial duration. The secondary endpoints will comprise the 10-meter walk test (10mWT), quantified muscular testing of the hand and foot, Patient Global Impression of Severity (PGI-S), Patient Global Impression of Change (PGI-C) and CMTNS-V2. The company has stated that the PREMIER trial has been 90% powered to demonstrate efficacy (0.4-point ONLS change) even with a 20% dropout rate. As a reminder, the FDA indicates that powering should be above 80% for pivotal studies.

The company also provided an update on the dosage, formulation and administration of the drug. The formulation (12mg baclofen, 1.4mg naltrexone, 420mg sorbitol) will be administered as a 10ml oral dose twice a day for a period of 15 months (titration dose of 5ml twice a day for the first two weeks) (Exhibits 2 and 3). The key takeaway, however, is the series of measures the company has taken to mitigate the chemistry, manufacturing and control (CMC) issues related to the high-dose batch in the previous Phase III trial (precipitation and crystal formation in some batches due to a reaction between baclofen and paraben), which led to the premature discontinuation of the high-dose arm. Instead of using the high-dose formulation of the PLEO-CMT trial, the PREMIER trial will use twice the amount of the low-dose formulation (from that study) and for which the company faced no manufacturing issues during the first Phase III trial as well as in the previous Phase II trial and subsequent open-label extension study following the first Phase III trial. Moreover, the drug dispensation will be done using individual 5ml stick packs versus the 100ml bottles used previously, for better convenience and compliance. We are encouraged by these improvements and expect them to de-risk the manufacturing issues faced earlier by the company.

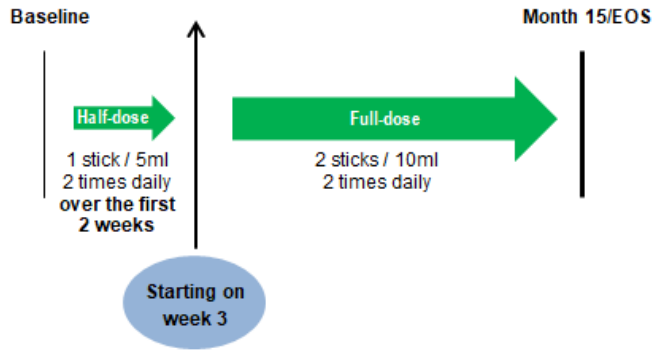
1 Charcot-Marie-Tooth Neuropathy Score version 2

Exhibit 2: PREMIER trial study design



Source: Pharnext R&D day presentation, October 2021

Exhibit 3: Study drug administration



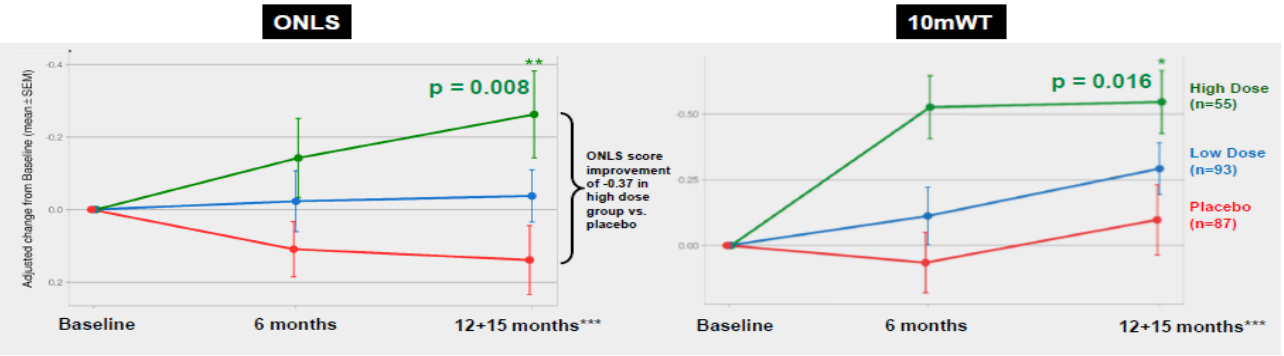
Source: adapted from Pharnext R&D day presentation, October 2021

In addition to the PREMIER trial, the company will also be conducting a 12-week multi-factorial study in an animal model (a critical requirement for a marketing application filing in case of combination therapeutics to showcase that the combination is more effective than the individual constituents in the tested disease area). Pharnext will be conducting the animal factor study under good laboratory practice (GLP) conditions and will use the same animal model of CMT1A disease as the preclinical factor study previously conducted at the Max Planck Institute in Germany. The study is expected to commence in H122 with top-line data to be announced in Q123.

PLEO-CMT data: Promising despite disruption

Pharnext also published study data from its first Phase III trial (PLEO-CMT) in the *Orphanet Journal of Rare Diseases*. Key highlights from the study were discussed by key opinion leader (KOL) and the US lead investigator of the PLEO-CMT study Dr Florian Thomas (Hackensack Meridian School of Medicine) during the R&D day. As a reminder, the PLEO-CMT trial was a randomised, double-blinded study evaluating 323 patients with mild-to-moderate CMT1A across three arms: low-dose PXT3003, high-dose PXT3003 and placebo. While the study managed to achieve statistical significance of improvement in its primary endpoint (ONLS) in that 'high dose' arm versus placebo among the target population defined as the modified full analysis set (mFAS) of 235 patients (mean difference: 0.37 points improvement; p value = 0.008) (Exhibit 4), certain manufacturing issues in some high-dose batches (crystal precipitation; c 2% by volume) led to the premature discontinuation of the high-dose arm and reduced the statistical power of the study (75%) below the threshold 80% as well as the originally planned 90%, resulting in the FDA mandating another follow-up pivotal trial.

Exhibit 4: PLEO-CMT Phase III trial results

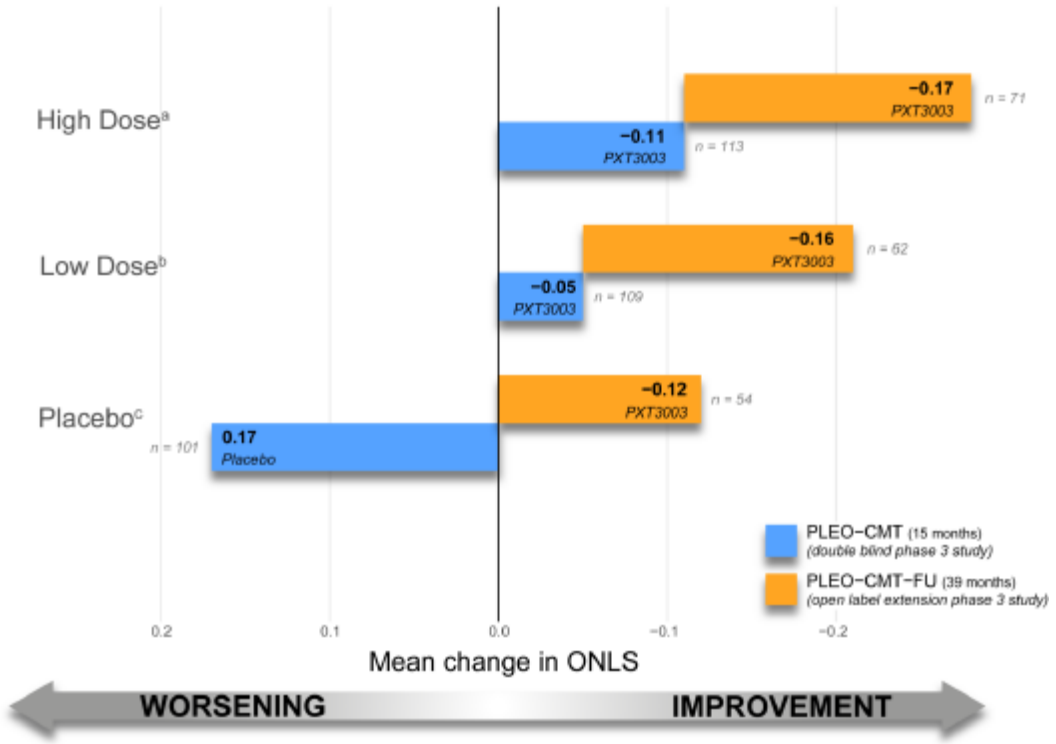


Source: Pharnext R&D day presentation, October 2021. Note: *Dose 4 vs placebo. **ANCOVA with multiple imputation (missing data implemented by multiple imputations following the placebo trend). ***Average of 12 and 15 months, or 12 months if 15 months is missing. ONLS is a 12-point scale assessing functional ability in the legs and hands. 10mWT = assessing locomotor ability and gait over a 10-meter walking distance.

One of the key aspects highlighted by Dr Thomas was the rationale behind ascertaining a small 0.3-point improvement versus placebo on the ONLS scale as clinically meaningful (given the lack of a benchmark as no therapies have been approved thus far for CMT1A). He explained that over 90% of the CMT1A population fell in the mild-to-moderate range (score of 2–4 on the 12-point ONLS scale; the higher the score the more debilitating the condition) and a 0.3-point improvement translated into a material 10% improvement in the ONLS score for the target patients. Dr Thomas also indicated that given the progressive nature of the disease, even stabilising or halting the disease progression may present a meaningful result, an observation we concur with given the high unmet need in the CMT1A space.

Extrapolating the results from the 15-month study over the lifespan of the effected individuals could translate into substantial gains in our opinion, if clinically validated. Pharnext has been undertaking an open-label extension study (PLEO-CMT-FU) and recently presented 4.5 years' worth of trial data, wherein PXT3003 has continued to show a sustained benefit to CMT1A patients (Exhibit5). Interestingly, patients across all arms (placebo, low-dose and high-dose) of the initial PLEO-CMT trial have maintained a meaningful improvement in the ONLS scale, after transitioning to the open-label, high-dose extension trial (PLEO-CMT-FU).

Exhibit 5: PLEO-CMT-FU study results over 4.5 years



Source: Pharnext R&D Day presentation, October 2021

Sizeable commercial opportunity on clinical validation

CMT is the most common inherited peripheral neuropathy and one of the most common inherited neurological disorders, affecting approximately 126,000 individuals in the United States. CMT1A is well established as the most common genetic subtype of the disease, comprising 40–50% of all CMT patients. Pharnext estimates its target patient population to be 100,000 (mild-to-moderate CMT1A across the US and EU5), translating into a market potential of $1bn. Given that there are currently no approved drugs for the treatment of CMT1A (indicating high unmet need) and PXT3003 is the most clinically advanced asset currently undergoing trials in the space, the opportunity remains sizeable for Pharnext. The closest competitors to PXT3003 are all in early clinical trials (Engensis/Helixmith (Phase 1/2a) and IFB-088/Inflectis (Phase I). PXT3003 also holds orphan drug designation in the United States and EU, which should provide seven years of market exclusivity and an unchallenged run following approval, in our opinion. We estimate peak sales potential of c $600m for the drug following approval.

The company recently announced multiple senior-level appointments – appointing Raj Thota as chief manufacturing officer and head of CMC, Abhijit Pangu as the head of regulatory affairs and promoting Xavier Paoli to chief operating officer – to support ongoing development of PXT3003. We see this as a positive development, highlighting the company's efforts towards managing any compliance/regulatory issues (as was seen in the PLEO-CMT trial) assuming the asset transitions from the clinic towards commercialisation. The recent departure of the chief medical officer and head of R&D, Adrian Hepner, to join Coya Therapeutics will likely require the company to manage a quick transition to the newly appointed CMO Dr Burkhard Blank to ensure that the trial progression stays unaffected.

Financials: H121 results in line with expectations

Pharnext's H121 results were in broadly in line with our expectations. Revenue for the period stood at c €2.0m, almost entirely attributable to R&D tax credits, mirroring the trend over the last few years. The operating loss stood at €11.2m, up from €7.8m in H120, driven by higher R&D expenses related to the commencement of the pivotal PREMIER Phase III trial in March 2021. The R&D expenses stood at €9.9m in H121 (€5.5m in H120) and accounted for c 75% of the company's operating expenses for the period. Administrative expenses remained largely stable (€1.0m versus €0.9m) while marketing expenses declined slightly (€2.3m from €2.7m). We have increased our projection for FY21 R&D expenses to €20.8m (from €16.6m), which has resulted on our estimated net loss for the year to increase to €27.8m from the earlier €25.2m. Our estimates for FY22–23 have also been tweaked accordingly.

The company ended the period to June 2021 with net debt of €6.5m (€7.7m cash and €14.1m in debt, excluding repayable advances). The post-reporting cash position has been supplemented by the drawdown of four additional tranches (tranches 2–5) of the OCEANE convertible loan raised in June 2021 (discussed in more detail below) worth €3m each in July, August, September and November 2021 for total proceeds of €12m as per last available information. We expect another drawdown in December 2021 to help fund the pivotal trial (tranche six worth €3m). The OCEANE convertible loan agreement provides financing up to €81m for a period of up to 36 months (we project the company will draw down c €34.5m in FY22 and the remaining €26m in FY23), which should be sufficient to complete the PREMIER study, but we expect the need to raise a further c €15m in 2023 to fund launch-related activities as well as honour c €9m worth of repayable advances due between 2023 and 2025. We are currently modelling all future raises as debt, but reiterate that subsequent conversion to equity would result in further dilution.

OCEANE convertible debt analysis

In June 2021, Pharnext entered into an agreement to raise up to €81m in gross proceeds by issuing convertible bonds to Alpha Blue Ocean. The agreement comprises 35 tranches totalling 8,100 OCEANE-BSAs with a par value €10,000 each (for a total gross value of €81m), which can be drawn down over a period of 36 months. Each OCEANE has a maturity of 12 months. If not converted to equity within the stipulated period, the OCEANE will be automatically converted into shares at a conversion price equal to 94% of the lowest daily volume-weighted average price during the 15 days preceding the date of receipt of the conversion notice. As per latest available information, Pharnext had drawn down the first five tranches (first tranche worth €5.5m and subsequent tranches worth €3m each) of the loan totalling €17.5m by the end of November 2021. While the first two tranches have been fully converted into equity, the third tranche is partially converted as of 30 November 2021 (€10.5m of the debt was converted to equity in total, including €9.2m in H221 to date). We expect another €3m tranche to be drawn down in December 2021 (tranche 6). While the convertible debt financing provides Pharnext with adequate funds to progress the clinical progression of PXT3003, the variable pricing means that the financing has been highly dilutive for the company on conversion to equity, a situation that has been exacerbated by the steep decline in the company's share price since the funds were raised. While we see this sustained softness as an overhang, we continue to believe in PXT3003's potential and scope for re-rating on positive clinical development.

Valuation

We have updated our valuation to reflect the H121 financials as well as the OCEANE convertible debt raised in June 2021. We maintain a 70% probability of success for PXT3003, and our risk-

adjusted net present value (NPV) for the asset remains largely unchanged at €270.8m. The pro forma net cash figure stands at €2.75m (net debt of €6.45m at the end of H121, offset by a subsequent €9.2m decrease in debt to reflect a conversion of this amount of debt to equity after 30 June). Our overall valuation for the company goes down slightly to €273.6m from €287.7m. The per share valuation, however, sees a significant change following conversion of the first few tranches of the OCEANE convertible debt (€5.7 vs €13.1 previously). The shares outstanding currently stand at 48.3m versus 22.4m prior to the convertible financing (tranches 1 and 2 are fully converted, whereas tranche 3 is partially converted as of 30 November 2021).

Exhibit 6: Pharnext valuation

Development programme	Indication	Clinical stage	Probability of success	Launch year	Patent/exclusivity protection	Launch pricing ($/year)	Peak sales (US$m)	rNPV (€m)
PXT3003	CMT1A	Phase III	70%	2024	2031–34	55,000	626	270.8
Total								270.8
Net cash/(debt) (end of H121) (€m)								2.8
Total firm value (€m)								273.6
Total basic shares (m)								48.3
Value per basic share (€)								5.7
Dilutive options and warrants (m)								7.9
Total diluted shares (m)								56.1
Value per diluted share (€)								5.1

Source: Pharnext reports, Edison Investment Research

Exhibit 7: Financial summary

€'000	2019	2020	2021e	2022e
31-December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	3,597.4	2,810.5	3,591.3	3,945.3
Cost of Sales	0.0	0.0	0.0	0.0
Gross Profit	3,597.4	2,810.5	3,591.3	3,945.3
R&D	(15,178.1)	(13,548.4)	(20,837.3)	(25,155.4)
Admin & Marketing	(8,444.6)	(8,175.6)	(8,059.8)	(8,140.4)
EBITDA	(19,501.6)	(18,159.2)	(25,190.6)	(29,312.0)
Normalised operating profit	(20,093.0)	(18,716.5)	(25,108.7)	(29,153.5)
Amortisation of acquired intangibles	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0
Share-based payments	67.7	(197.0)	(197.0)	(197.0)
Reported operating profit	(20,025.3)	(18,913.5)	(25,305.7)	(29,350.5)
Net Interest	(3,283.9)	(2,650.5)	(2,546.6)	(1,692.1)
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0
Profit Before Tax (norm)	(23,376.9)	(21,367.0)	(27,655.3)	(30,845.5)
Profit Before Tax (reported)	(23,309.2)	(21,564.1)	(27,852.3)	(31,042.6)
Reported tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(23,376.9)	(21,367.0)	(27,655.3)	(30,845.5)
Profit After Tax (reported)	(23,309.2)	(21,564.1)	(27,852.3)	(31,042.6)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalised)	(23,376.9)	(21,367.0)	(27,655.3)	(30,845.5)
Net income (reported)	(23,309.2)	(21,564.1)	(27,852.3)	(31,042.6)
Basic average number of shares outstanding (m)	14.5	18.2	40.7	48.3
EPS - normalised (c)	(161.08)	(117.33)	(67.87)	(63.92)
EPS - normalised fully diluted (c)	(161.08)	(117.33)	(67.87)	(63.92)
EPS - basic reported (€)	(1.61)	(1.18)	(0.68)	(0.64)
Dividend (€)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	1,526.5	855.4	740.3	701.8
Intangible Assets	12.1	7.4	0.0	0.0
Tangible Assets	293.2	146.3	38.5	0.0
Investments & other	1,221.2	701.8	701.8	701.8
Current Assets	21,645.1	20,398.4	10,757.9	10,129.4
Stocks	0.0	0.0	0.0	0.0
Debtors	0.0	9,320.2	590.4	648.5
Cash & cash equivalents	16,246.6	11,078.2	10,167.6	9,480.8
Other	5,398.5	0.0	0.0	0.0
Current Liabilities	(9,959.6)	(15,516.6)	(12,761.3)	(11,172.2)
Creditors	(5,792.7)	(11,302.7)	(7,048.3)	(8,151.8)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	(3,806.3)	(3,926.0)	(5,425.0)	(2,732.4)
Other	(360.5)	(287.9)	(287.9)	(287.9)
Long Term Liabilities	(20,457.9)	(18,256.2)	(22,831.2)	(54,598.8)
Long term borrowings	(11,181.4)	(8,157.4)	(12,732.4)	(44,500.0)
Other long term liabilities	(9,276.6)	(10,098.8)	(10,098.8)	(10,098.8)
Net Assets	(7,245.9)	(12,519.0)	(24,094.3)	(54,939.8)
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	(7,245.9)	(12,519.0)	(24,094.3)	(54,939.8)
CASH FLOW	**0**			
Op Cash Flow before WC and tax	(19,569.3)	(17,962.2)	(24,993.6)	(29,115.0)
Working capital	(1,523.1)	1,797.7	4,475.5	1,045.3
Exceptional & other	(476.0)	82.5	0.0	0.0
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(21,568.4)	(16,081.9)	(20,518.0)	(28,069.6)
Capex	0.0	22.0	0.0	0.0
Acquisitions/disposals	193.5	(83.4)	0.0	0.0
Net interest	(1,412.9)	(1,622.2)	(2,546.6)	(1,692.1)
Equity financing	16,494.9	16,271.7	16,080.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	(199.5)	0.0	0.0
Net Cash Flow	(6,292.9)	(1,693.4)	(6,984.6)	(29,761.7)
Opening net debt/(cash)	16,011.4	(1,258.7)	1,005.7	7,990.3
FX	0.0	0.0	0.0	0.0
Other non-cash movements	23,563.0	(571.0)	0.0	0.0
Closing net debt/(cash)	(1,258.7)	1,005.7	7,990.3	37,752.1

Source: Pharnext reports, Edison Investment Research

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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
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

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