EDISON

Pharnext

Research update

Approaching clinical validation

Pharma & biotech

We revisit our assessment for Pharnext after an eventful few weeks that saw the company announce encouraging new data (five years of trial time) from its PLEO-CMT-FU open-label extension study, complete patient enrolment in its pivotal Phase III PREMIER trial and make progress in raising new, non-dilutive financing. We maintain our outlook for the PREMIER study (likely to conclude in Q423), bolstered by the positive data from the extension study (sustained benefit to patients after five years of treatment). The recently announced €12m fixed-rate financing should ease the funding overhang in the short term, but we estimate the need to raise up to €10m in Q422 and a further €50m in FY23. We raise our overall valuation slightly to €267.4m (from €265.6m) but pare the per share valuation to €0.41 (from €2.0) following recent debt-to-equity conversions.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	2.8	(21.4)	(1.17)	0.00	N/A	N/A
12/21	3.6	(30.6)	(1.01)	0.00	N/A	N/A
12/22e	4.1	(29.2)	(0.07)	0.00	N/A	N/A
12/23e	3.0	(30.2)	(0.05)	0.00	N/A	N/A

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

PREMIER trial on track for readout in Q423

We view the on-time completion of enrolment in the pivotal Phase III PREMIER trial (387 participants versus the target of 350) as a key milestone for Pharnext and believe the company will meet its Q423 deadline for trial completion, based on current visibility. More importantly, we expect the positive data from the long-term, open-label PLEO-CMT-FU study (which continued to show a sustained benefit for patients after five years of treatment) to have a strong read-across for the PREMIER trial. Success would make PXT3003, which holds the orphan drug designation in the United States and Europe, the first drug to be approved for Charcot-Marie-Tooth disease type 1A (CMT1A), a potential $1bn market.

Fixed-rate loan eases short-term funding need

The drawdown of the 11th OCEANE-BSA tranche in May 2022 culminates the dilutive convertible debt financing, and we expect the €12m fixed-rate loan (9.5% interest) raised in June to ease the short-term funding need and allow the company to get rid of the €8m cash covenant related to the 2018 IPF Partners debt. We estimate the gross cash balance of €8m at end-FY21, along with the proceeds from the fixed-rate debt (€12m) and tranches 7–11 of the OCEANE facility (net proceeds of c €11) to be sufficient to fund operations and honour upcoming debt repayments up to Q422. We project the need to raise a further €10m in Q422 and €50m in FY23 (modelled as illustrative debt).

Valuation: €267.4m or €0.41 per basic share

Our total valuation for Pharnext goes up slightly to €267.4m from €265.6m due to lower opex assumptions and rolling forward our NPV, offset by higher net debt. The per share valuation, however, comes down materially to €0.41 (from €2.0), given the additional shares in circulation following the recent debt-to-equity conversions.

28 June 2022

Price	**€0.003**
Market cap	**€2m**
	US$:€0.95
Estimated net debt (€m) at end H122	27.0
Shares in issue	660m
Free float	51%
Code	ALPHA
Primary exchange	Euronext Paris
Secondary exchange	OTC Pink

Share price performance

%	1m	3m	12m
Abs	(68.3)	(95.9)	(99.7)
Rel (local)	(65.8)	(95.5)	(99.7)
52-week high/low		€1.31	€0.00

Business description

Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapies for neurodegenerative diseases lacking curative and/or disease-modifying treatments. Its lead programme is PXT3003 for Charcot-Marie-Tooth disease type 1A, which has recently completed patient enrolment in a pivotal Phase III trial, with readout expected in Q423 (orphan drug designation in the US and Europe). PXT864 for Alzheimer's disease has completed Phase IIa and will be further advanced through partnerships. Both of Pharnext's lead assets originated from the Pleotherapy R&D approach.

Next events

Top-line data from animal factorial study	Q123
Conclusion of PREMIER trial	Q423

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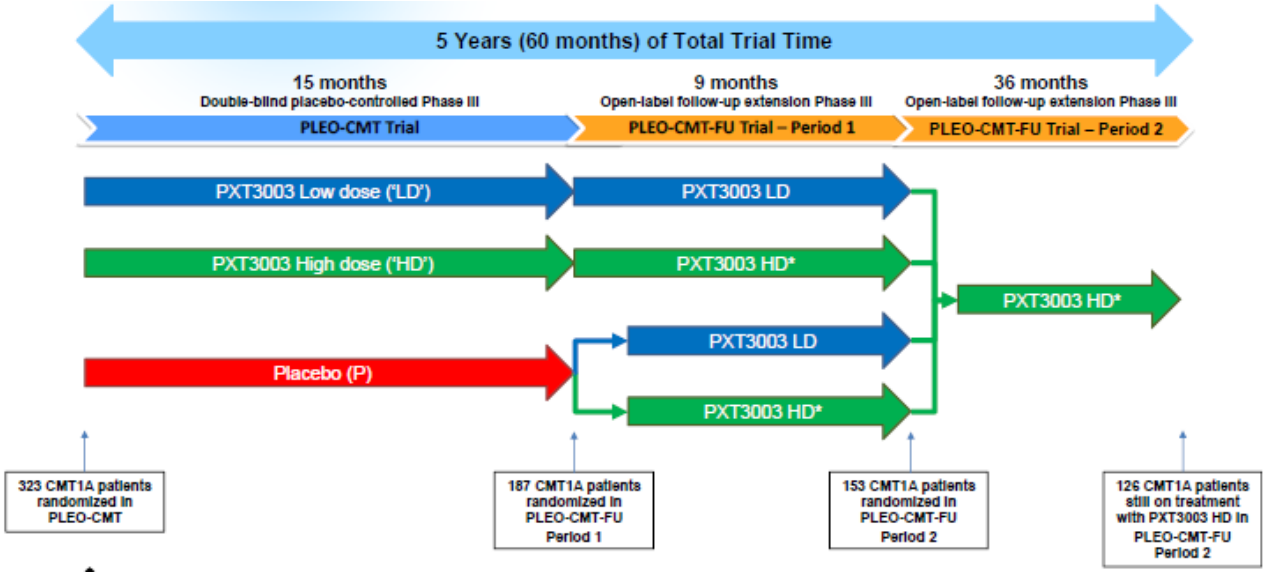
Edison profile page

PLEO-CMT-FU latest data indicate continued benefit

Pharnext has been undertaking an open-label extension study (PLEO-CMT-FU) following the culmination of the earlier PLEO-CMT trial and recently presented five years' worth of trial data (15 months of PLEO-CMT trial and nine months of PLEO-CMT-FU, trial period one; 36 months of PLEO-CMT-FU, trial period two), wherein PXT3003 continued to show a sustained benefit to the 126 CMT1A patients who had chosen to continue on the extension study. In trial period one, the high- and low-dose cohorts continued to receive their respective doses while the placebo arm was randomised between the high and low dose. In trial period two, all cohorts received the high-dose treatment (Exhibit 1).

Exhibit 1: Design of First double-blinded Phase III PLEO-CMT trial and open label extension studies

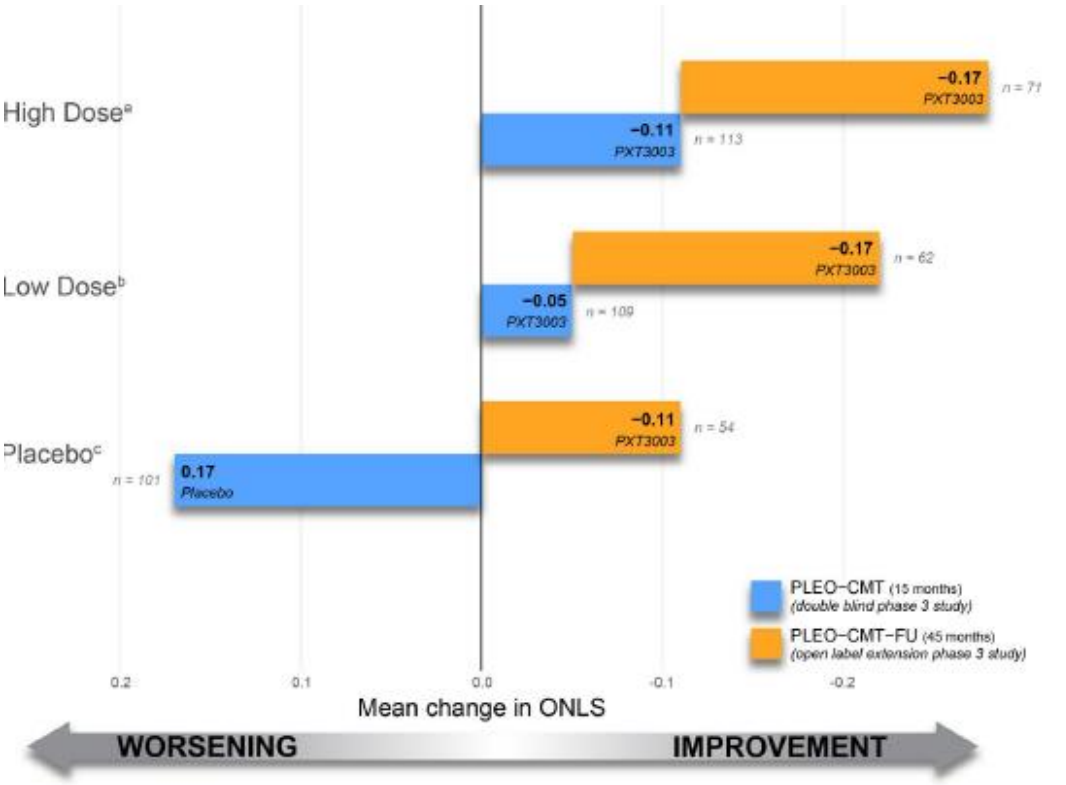


Source: Pharnext corporate presentation, June 2022

We note that while patients across all arms (placebo, low dose and high dose) of the initial study have maintained a meaningful improvement on the Overall Neuropathy Limitations Scale (ONLS),[1] the strongest efficacy signal was observed in the cohort of patients treated with PXT3003 high-dose arm for the entire five-year duration (Exhibit 2). This high-dose formulation is the one being tested in the pivotal PREMIER trial. Another key observation came from patients treated with placebo in the double-blind phase, who showed an initial decline on the ONLS but who then improved when switched to PXT3003 in the ongoing open-label phase.

1 The ONLS is a 12-point scale measuring functional motor disability; the higher the score, the more debilitating the condition.

Exhibit 2: PLEO-CMT-FU study results after five-year total trial time



Source: Pharnext. Note: Data as of 22 April 2022.

We highlight that while the improvement on the ONLS appears modest (for the high-dose arm, improvement has been 0.28 points over five years from the baseline), the delta is likely to be higher given CMT1A is a progressive disease if left untreated. Extrapolating the 15-month decline (0.17 points) in the placebo arm over five years could hypothetically mean a 0.68 point decline in five years without treatment, taking the effective improvement to around 1.0 points (0.68 + 0.28), which can be considered a meaningful outcome given the nature of the disease and no approved curative options (refer to our previous update note for more details). We see the highest benefit in the targeted mild-to-moderate cohort (defined as scoring below 20 on the 36-point Charcot-Marie-Tooth Neuropathy Score scale which, corresponded to between two and four points on the ONLS scale in the first Phase III PLEO-CMT study), which typically includes patients with certain gait abnormalities, although they continue to be functionally unimpaired. According to the company management, there are around 100,000 people afflicted with mild-to-moderate CMT1A in the United States and EU5 combined. For this cohort, timely treatment with PXT3003 can potentially halt progression to a debilitating state and, therefore, may have the highest implied benefit. We expect the most recently reported data from the extension study to have a positive bearing on the ongoing pivotal PREMIER study given that it is evaluating the identical high dose of PXT3003 and using the same primary efficacy ONLS endpoint as the long-term study.

PREMIER trial remains on track for a Q423 readout

On 30 May 2022, Pharnext announced completion of patient enrolment in the pivotal Phase III PREMIER trial, hitting its previously announced goal of Q222. The company confirmed 387 patients have been recruited to the study, against an original target of 350. As a reminder, the PREMIER trial is a randomised, double-blind, placebo-controlled study undertaken across 52 centres globally. The primary endpoint is improvement on the 12-point ONLS, which measures functional motor

disability. The same scale is being used in the extension study. The 15-month study is expected to conclude in Q423 with an anticipated US launch by end-FY24/early FY25, if approved.

CMT1A is a genetic peripheral nerve disorder that causes progressive muscle weakness. It is the most common type of CMT and Pharnext estimates the disease afflicts over 150,000 people in the United States and Europe combined (1.5 million people worldwide), with the most severe cases (c 5% of patients) requiring wheelchairs. Pharnext estimates its target patient population to be more than 100,000 (mild-to-moderate CMT1A across the United States and EU5), translating into a market potential of $1bn. There are no approved therapies, with treatment restricted to supportive care such as orthotics, leg braces and physical and occupational therapy, followed by surgery with disease progression. If clinical development is successful, PXT3003 will be the first therapy approved for the indication and will have seven years and 10 years of market exclusivity courtesy of its orphan drug designation in the United States and Europe, respectively. The closest competitors to PXT3003 are in early clinical trials (Engensis/Helixmith, Phase I/IIa and IFB-088/InFlectis, Phase I). We estimate peak sales potential of $626m (€594m) for PXT3003.

Seeking non-dilutive sources of financing

While the underlying business fundamentals and pipeline potential for Pharnext have remained unchanged this past year, the dilutive convertible funding announced in June 2021 has continued to weigh in on the share price. Heeding shareholder concerns, in December 2021 Pharnext decided to prematurely terminate its convertible debt financing agreement with Global Tech Opportunities 13 (GTO13, subscribers of the June 2021 convertible bond issue), truncating the number of tranches to 12 from the earlier 35. While the first six tranches had been used before this announcement (for gross proceeds of €20.5m), the company has subsequently drawn down a further five tranches (7–11) for total gross proceeds of €15.5m (€3.5m in January, €6m in March across two tranches, €3m in April and €3m in May). We note for tranches 7–10 the company received net proceeds of €7.94m (against the €12.5m gross proceeds recorded), which we estimate would result in net proceeds of c €10.5m from the tranches drawn down in H122. According to the latest available information, Pharnext has fully converted the first seven tranches and partially converted the eighth tranche into equity. A total of €24.1m of the overall €36m gross debt issued has been converted to equity, resulting in the issued share count standing at 660m. This figure is likely to grow as there is still €11.9m in outstanding convertible debt (tranches 9–11 and partially tranche 8) that could be converted to equity, resulting in further dilution.

In June 2022, the company announced it has secured €12m in fixed-rate (9.5%) short-term financing from GTO13, a member of the Alpha Blue Ocean group and the company's convertible debt (OCEANE-BSA) holder. As a result, the drawdown of the 12th OCEANE-BSA tranche (worth €3m) has been put on hold. The newly raised funds will be used by the company to pay off the outstanding €8m in venture debt obligations to IPF Partners (raised in 2018 at EURIBOR+11%), releasing Pharnext from the restrictive covenants that required it to maintain a €8m cash balance. The €12m loan is anticipated to be disbursed in five instalments (the first of €3m, followed by two instalments of €2.5m and two of €2m) from June 2022, and each instalment to be drawn down with at least a month's gap in between. We estimate the end-FY21 cash balance of €8m along with the €12m proceeds from the fixed-rate loan and €10.5m from OCEANE-BSA (€30.5 in total) to support operations and debt repayments into Q422, but project the need to raise a further €10m in Q422, €50m in FY23 and €25m in FY24 before reaching profitability in FY25, provided PXT3003 is successfully commercialised. We are modelling all future raises as illustrative debt. While Pharnext has communicated it can potentially use the unused €45m from the original June 2021 OCEANE-BSA agreement (provided certain conditions are met or waived by GTO13), we expect the company to pursue alternate, non-dilutive options for future capital raising.

New board structure in sync with business strategy

After its 17 June 2022 AGM, Pharnext announced several board changes, most notably the appointment of Dr James Kuo as an independent, non-executive director. Dr Kuo has significant experience in the life sciences sector and is chairman of ImmunoPrecise Antibodies, chairman of Monarch Labs, which he co-founded, as well as a board director of Tryp Therapeutics, which he co-founded and took public as CEO. More importantly, Dr Kuo has raised multiple financing rounds as CEO and served as managing director of HealthCare Ventures, a $378m venture capital fund. We expect Pharnext management to seek to use Dr Kuo's knowledge and experience in raising funds from the market to support its own ongoing capital-raising efforts.

Financials

Pharnext's FY21 revenue was in line with our expectations, while the operating and net loss were slightly lower than our estimates. Revenue for the period stood at c €3.6m, almost entirely attributable to research and development (R&D) tax credits. The normalised operating loss stood at €22.9m, up from €18.7m recorded in FY20 but lower than our estimate of €25.1m. This difference is attributed to lower R&D and marketing expenses (€19.6m and €2.1m) versus our expectation of €20.8m and €3.5m, respectively. The R&D expense accounted for 74% of the company's operating expenses for the period (versus 62% in FY20), which we attribute to the start of the pivotal PREMIER Phase III trial in March 2021. We expect this trend to continue in FY22 and decline thereafter after the conclusion of the PREMIER study in Q423. Administrative expenses (€4.7m) for the period were in line with our estimate of €4.5m. We have made minor revisions to our FY22–23 estimates based on the FY21 performance. The company ended the period to December 2021 with net debt of €13.9m (€8.0m cash and €21.9m in debt, including repayable advances).

Valuation

We have updated our valuation to reflect the FY21 financials as well as the latest drawdown of the OCEANE convertible debt tranches. Our expectations for the clinical progression and commercialisation of PXT3003 remain unchanged and we continue to attribute a 70% probability of success to the asset. Our risk-adjusted net present value (NPV) goes up slightly to €267.4m from €265.6m as we lower our operating expenses estimates slightly for the forecast years (based on the FY21 trend) and roll forward our NPV. This has been partially offset by a higher net debt position (H122e net debt of €27.0m versus net cash of €5.9m in our last update). An additional €10.5m of debt was converted to equity since we last wrote about the company, resulting in an increase in issued shares to 660m from 131.5m. This has resulted in our per share valuation coming down to €0.41 versus €2.0 previously. We also note that subsequent conversion of the remaining tranches (8–11) would lead to further dilution.

Exhibit 3: 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	294.4
Total								294.4
Net cash/(debt) (end FY21, pro forma adjusted for subsequent conversions of debt to equity) (€m)								(27.0)
Total firm value (€m)								267.4
Total basic shares (m)								660.0
Value per basic share (€)								0.41
Dilutive options and warrants (m)								22.4
Total diluted shares (m)								682.3
Value per diluted share (€)								0.39

Source: Pharnext reports, Edison Investment Research

Exhibit 4: Financial summary

€000s	2019	2020	2021	2022e	2023e
31 December	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue	3,597.4	2,810.5	3,564.8	4,127.1	3,024.0
Cost of Sales	0.0	0.0	0.0	0.0	0.0
Gross Profit	3,597.4	2,810.5	3,564.8	4,127.1	3,024.0
R&D	(15,178.1)	(13,548.4)	(19,614.0)	(23,261.2)	(17,044.2)
Admin & Marketing	(8,444.6)	(8,175.6)	(6,807.6)	(6,875.7)	(16,244.4)
EBITDA	(19,501.6)	(18,159.2)	(22,194.5)	(25,979.4)	(30,264.6)
Operating profit (before amort. and excepts.)	(20,093.0)	(18,716.5)	(22,858.9)	(26,011.8)	(30,266.6)
Amortisation of acquired intangibles	0.0	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0	0.0
Share-based payments	67.7	(197.0)	2.0	2.0	2.0
Reported operating profit	(20,025.3)	(18,913.5)	(22,856.9)	(26,009.8)	(30,264.6)
Net Interest	(3,283.9)	(2,650.5)	(7,760.8)	(3,172.7)	50.2
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0	0.0
Profit Before Tax (norm)	(23,376.9)	(21,367.0)	(30,619.7)	(29,184.5)	(30,216.4)
Profit Before Tax (reported)	(23,309.2)	(21,564.1)	(30,617.6)	(29,182.5)	(30,214.4)
Reported tax	0.0	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(23,376.9)	(21,367.0)	(30,619.7)	(29,184.5)	(30,216.4)
Profit After Tax (reported)	(23,309.2)	(21,564.1)	(30,617.6)	(29,182.5)	(30,214.4)
Minority interests	0.0	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0	0.0
Net income (normalised)	(23,376.9)	(21,367.0)	(30,619.7)	(29,184.5)	(30,216.4)
Net income (reported)	(23,309.2)	(21,564.1)	(30,617.6)	(29,182.5)	(30,214.4)
Average Number of Shares Outstanding (m)	14.5	18.2	30.4	395.7	660.0
EPS - normalised (c)	(161.08)	(117.33)	(100.67)	(7.37)	(4.58)
EPS - normalised fully diluted (c)	(161.08)	(117.33)	(100.67)	(7.37)	(4.58)
EPS - basic reported (€)	(1.61)	(1.18)	(1.01)	(0.07)	(0.05)
Dividend (€)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets	1,526.5	855.4	906.4	876.1	876.1
Intangible Assets	12.1	7.4	0.2	0.0	0.0
Tangible Assets	293.2	146.3	30.1	0.0	0.0
Investments & other	1,221.2	701.8	876.1	876.1	876.1
Current Assets	21,645.1	20,398.4	15,545.2	5,658.3	6,665.0
Stocks	0.0	0.0	0.0	0.0	0.0
Debtors	0.0	9,320.2	7,577.2	678.4	497.1
Cash & cash equivalents	16,246.6	11,078.2	7,968.0	4,979.8	6,167.9
Other	5,398.5	0.0	0.0	0.0	0.0
Current Liabilities	(9,959.6)	(15,516.6)	(19,305.3)	(29,153.5)	(11,476.6)
Creditors	(5,792.7)	(11,302.7)	(8,424.1)	(7,424.0)	(8,208.7)
Tax and social security	0.0	0.0	0.0	0.0	0.0
Short term borrowings	(3,806.3)	(3,926.0)	(8,713.2)	(19,561.5)	(1,100.0)
Other	(360.5)	(287.9)	(2,168.0)	(2,168.0)	(2,168.0)
Long Term Liabilities	(20,457.9)	(18,256.2)	(15,003.0)	(20,822.0)	(69,722.0)
Long term borrowings	(19,596.3)	(17,021.3)	(13,199.9)	(19,018.9)	(67,918.9)
Other long term liabilities	(861.7)	(1,234.8)	(1,803.1)	(1,803.1)	(1,803.1)
Net Assets	(7,245.9)	(12,519.0)	(17,856.7)	(43,441.2)	(73,657.6)
Minority interests	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	(7,245.9)	(12,519.0)	(17,856.7)	(43,441.2)	(73,657.6)
CASH FLOW					
Operating Cash Flow	(19,569.3)	(17,962.2)	(22,196.5)	(25,981.4)	(30,266.6)
Working capital	(1,523.1)	1,797.7	(905.2)	5,898.7	966.0
Exceptional & other	(476.0)	82.5	(632.9)	0.0	0.0
Tax	0.0	0.0	0.0	0.0	0.0
Net operating cash flow	(21,568.4)	(16,081.9)	(23,734.7)	(20,082.7)	(29,300.7)
Capex	0.0	22.0	(46.5)	0.0	0.0
Acquisitions/disposals	193.5	(83.4)	72.3	0.0	0.0
Net interest	(1,412.9)	(1,622.2)	(1,089.0)	(3,172.7)	50.2
Equity financing	16,494.9	16,271.7	32,819.3	3,600.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0
Other	(47.5)	(199.5)	(4,294.3)	0.0	0.0
Net Cash Flow	(6,340.4)	(1,693.4)	3,727.2	(19,655.4)	(29,250.4)
Opening net debt/(cash)	24,673.2	7,156.0	9,869.2	13,945.2	33,600.6
FX	0.0	0.0	0.0	0.0	0.0
Other non-cash movements	23,857.6	(1,019.7)	(7,803.2)	0.0	0.0
Closing net debt/(cash)	7,156.0	9,869.2	13,945.2	33,600.6	62,851.1

Source: Pharnext reports, Edison Investment Research

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