EDISON

# Hepion Pharmaceuticals

Development update

## Phase IIa trial commenced

Pharma & biotech

**On 5 August 2020, Hepion announced that it had dosed the first NASH patient with CRV431 in its Phase IIa 'AMBITION' pilot study. The primary endpoint of AMBITION is to assess the safety and tolerability of CRV431 at a 75mg dose and the company expects data from the trial in Q420. The goal of the study outside the endpoints is to gather a range of different biomarkers in these patients to examine CRV431 for activity, which will be used to support the design of future studies.**

| Year end | Revenue ($m) | PBT* ($m) | EPS* ($) | DPS ($) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/18 | 0.0 | (9.8) | (55.87) | 0.0 | N/A | N/A |
| 12/19 | 0.0 | (7.9) | (4.32) | 0.0 | N/A | N/A |
| 12/20e | 0.0 | (15.0) | (1.79) | 0.0 | N/A | N/A |
| 12/21e | 0.0 | (11.4) | (1.33) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalized, excluding intangible amortization, exceptional items and share-based payments.

## First patient dosed in Phase IIa trial

Hepion initiated its Phase IIa trial AMBITION and announced the first patient was dosed with CRV431. The primary objective of the study is to assess the safety and tolerability of a once daily 75mg dose over 28 days. The secondary objective is to evaluate the percentage decrease of non-invasive anti-fibrotic markers from baseline to the end of the study. The company aims to generate exploratory anti-fibrotic biomarker data and utilize the information in future clinical trials. The study is a multi-centre, single-blind, placebo-controlled design with an expected cohort of 18 subjects. CRV431 will be administered orally to patients presumed to have NASH with stage 2 or 3 fibrosis. Hepion expects data from the Phase IIa trial by year end.

## Phase Ib dosing study data expected soon

On 29 June 2020, the company stated that it had progressed to the final dose level of 375mg in the multiple ascending dose study. Completion of the study is expected in Q320 followed by data shortly thereafter. CRV431 was administered once daily for 28 days to 16 healthy volunteers at increasing dose levels (75mg, 150mg, 225mg and 300mg), all of which were deemed to be safe and well tolerated with no dose-limiting side effects. The results for the final dose are yet to be announced.

## Clinical trial program outlook

Following successful completion of the smaller Phase IIa trial later this year, Hepion expects to initiate a larger Phase IIb trial in Q221. The company will look to enrol approximately 200 NASH patients once daily for 24 weeks at a dose yet to be determined.

## Valuation: No change at $53.5m or $5.93/basic share

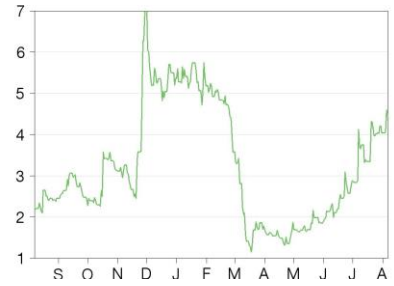
Our valuation remains at $53.5m or $5.93/basic share ($5.91 diluted). We will re-evaluate our model on the announcement of data from the Phase I multiple-ascending dose study.

**7 August 2020**

| | |
|---|---|
| **Price** | **US$4.4** |
| **Market cap** | **US$40m** |

| | |
|---|---|
| Net cash ($m) at 31 March 2020 + ATM | 20.55 |
| Shares in issue | 9.03m |
| Free float | 99.47% |
| Code | HEPA |
| Primary exchange | NASDAQ |
| Secondary exchange | N/A |

### Share price performance




| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | 53.1 | 170.6 | 90.1 |
| Rel (local) | 45.4 | 130.1 | 63.6 |

| 52-week high/low | US$7.0 | US$1.2 |
|---|---|---|

### Business description

Hepion Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing therapeutics for chronic liver disease. The company's lead asset is CRV431, a cyclophilin inhibitor being developed for the treatment of non-alcoholic steatohepatitis.

### Next events

| | |
|---|---|
| Completion of Phase Ib dosing study | Q320 |
| Data from Phase Ib dosing study | Q320 |
| Data from Phase IIa study | Q420 |
| Initiate Phase IIb study | Q221 |

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## Moving on up

The current Phase IIa study announced on 5 August is a pilot study designed to examine a range of biomarkers for clinical activity in NASH patients. The study will use a much lower dose of drug (75mg) than has been tested in the Phase I dosing study, because it is not designed to measure NASH resolution, but rather just those early biochemical signs of efficacy. This will allow the program to be completed quickly as patients will only be followed for 28 days of once-daily dosing and we should have a much better idea at its completion if the drug has clinical activity without having to commit to a major clinical program.

The list of biomarkers that the company stated it will examine are presented in Exhibit 1. These include both biomarkers for fibrosis and NASH (such as collagen and Pro-C3 respectively) as well as broader exploratory targets such as genomics and gene-gene interactions. All of the data gathered across these categories will be combined with the measured safety and pharmacokinetic data and integrated into the company's big data analytics platform termed AI-POWR. The goal with AI-POWR is to provide additional insight by examining how these markers form a network of responses to the drug using machine learning and other analytics. A major limitation of studying NASH has historically been the lack of definitive diagnostics outside of biopsy, and we believe this platform (and moreover this study in general) is an attempt to gain some traction in understanding the effects of this drug without having to resort to repeated biopsy. This being said, we have relatively little insight into what is powering AI-POWR and what insight it will be able to reveal outside the basic biomarker data, and any assumptions that machine learning can provide improved insight should be accompanied with caveats that this is entirely dependent on the quality of the machine learning and the data provided to it. We expect the data set from the AMBITION study to be incredibly rich and at the very least, we hope that AI-POWR will aid in its understanding.

**Exhibit 1: Biomarkers examined in the Phase IIa AMBITION study**

| Biomarker | Note |
|---|---|
| Collagen | A major component of fibrotic tissue, a target of cyclophilin |
| Matrix metalloproteinases | Proteins that degrade fibrotic tissue |
| Lipidomics | To examine lipid release from liver fat |
| Genomics | Gene expression profiles |
| Liver transaminases | Released as signs of liver damage |
| Pro-C3 | A proposed biomarker for NASH |
| ELF score | A score of biochemical markers correlated with fibrosis |
| Gene-gene and gene-protein network analysis | To probe deeper interactions |
| Fibroscan | A specialized ultrasound to identify steatosis |

Source: Edison Investment Research

Although the company has started the Phase IIa study, it is still engaged in the ongoing Phase Ib dosing study. The final dosing cohort (375mg) in the Phase Ib was announced on 29 June because the company had not reached a dose-limiting toxicity on the previous dose levels. The multiple-ascending dose portion of the study is examining the safety and pharmacokinetics of volunteers exposed to once-daily CRV431 for 28 days. We expect the study to be completed in Q320 and data to be announced in the same quarter, but the decision to progress the clinical program to the Phase IIa study suggests that no major issues have been raised to date.

## Valuation

Our valuation remains at $53.5m or $5.93/basic share ($5.91 diluted). We will re-evaluate our model on the announcement of data from the Phase I multiple-ascending dose study. Although we are encouraged by the fact that the clinical program is progressing, we want to evaluate the existing data before drawing judgements regarding the viability of the program.

**Exhibit 2: Valuation**

| Program | Market | Probability of success | Launch year | Peak revenue ($m) | Valuation ($m) |
|---|---|---|---|---|---|
| CRV431 | US | 10% | 2026 | 370.8 | 23.71 |
| | Europe | 10% | 2027 | 373.0 | 19.42 |
| | R&D & milestones | 100% | | | (10.18) |
| Total | | | | | 32.95 |
| Net cash and equivalents (Q120 + ATM) | | | | | 20.55 |
| Total firm value ($m) | | | | | 53.50 |
| Total basic shares (m) | | | | | 9.03 |
| Value per basic share ($) | | | | | 5.93 |
| Convertible preferred stock (m) | | | | | 0.02 |
| Dilutive options and warrants (m) | | | | | 0.0 |
| Total diluted shares (m) | | | | | 9.1 |
| Value per diluted share ($) | | | | | 5.91 |

Source: Edison Investment Research

## Exhibit 3: Financial summary

| $'000 | 2018 | 2019 | 2020e | 2021e |
|---|---|---|---|---|
| Year end 31 December | IFRS | IFRS | IFRS | IFRS |
| **INCOME STATEMENT** | | | | |
| Revenue | 0.0 | 0.0 | 0.0 | 0.0 |
| Cost of Sales | 0.0 | 0.0 | 0.0 | 0.0 |
| Gross Profit | 0.0 | 0.0 | 0.0 | 0.0 |
| R&D | (7,593.7) | (3,184.1) | (8,995.6) | (5,147.3) |
| SG&A | (7,000.4) | (4,586.0) | (6,105.9) | (6,289.1) |
| EBITDA | (14,340.9) | (7,677.2) | (15,009.2) | (11,370.2) |
| Normalised operating profit | (14,359.6) | (7,703.9) | (15,035.3) | (11,370.2) |
| Amortisation of acquired intangibles | 0.0 | 0.0 | 0.0 | 0.0 |
| Exceptionals | 0.0 | 0.0 | 0.0 | 0.0 |
| Share-based payments | (234.5) | (66.2) | (66.2) | (66.2) |
| Reported operating profit | (14,594.2) | (7,770.1) | (15,101.5) | (11,436.3) |
| Net Interest and financial income | 4,608.9 | (175.9) | 0.2 | 0.0 |
| Joint ventures & associates (post tax) | 0.0 | 0.0 | 0.0 | 0.0 |
| Exceptionals | 0.0 | 0.0 | 0.0 | 0.0 |
| Profit Before Tax (norm) | (9,750.8) | (7,879.8) | (15,035.1) | (11,370.2) |
| Profit Before Tax (reported) | (9,985.3) | (7,946.0) | (15,101.3) | (11,436.3) |
| Reported tax | 536.0 | 1,227.3 | 2,332.5 | 1,766.4 |
| Profit After Tax (norm) | (10,274.2) | (8,832.6) | (16,940.6) | (13,275.6) |
| Profit After Tax (reported) | (9,449.3) | (6,718.7) | (12,768.8) | (9,669.9) |
| Minority interests | 0.0 | 0.0 | 0.0 | 0.0 |
| Deemed Dividend | (8,451.9) | (5,442.9) | 0.0 | 0.0 |
| Discontinued operations | 0.0 | 0.0 | 0.0 | 0.0 |
| Net income (normalised) | (10,274.2) | (8,832.6) | (16,940.6) | (13,275.6) |
| Net income (reported) | (17,901.1) | (12,161.6) | (12,768.8) | (9,669.9) |
| Basic average number of shares outstanding (m) | 184 | 2,043 | 9,476 | 9,950 |
| EPS - basic normalised ($) | (55.87) | (4.32) | (1.79) | (1.33) |
| EPS - diluted normalised ($) | (55.87) | (4.32) | (1.79) | (1.33) |
| EPS - basic reported ($) | (97.35) | (5.95) | (1.35) | (0.97) |
| Dividend ($) | 0.00 | 0.00 | 0.00 | 0.00 |
| **BALANCE SHEET** | | | | |
| Fixed Assets | 5,221.2 | 6,043.9 | 5,943.0 | 5,779.0 |
| Intangible Assets | 1,870.9 | 1,870.9 | 1,870.9 | 1,870.9 |
| Tangible Assets | 32.4 | 57.2 | 28.9 | 28.9 |
| Investments & other | 3,317.8 | 4,115.9 | 4,043.2 | 3,879.2 |
| Current Assets | 2,968.0 | 14,388.7 | 29,771.3 | 19,386.1 |
| Stocks | 0.0 | 0.0 | 0.0 | 0.0 |
| Debtors | 0.0 | 0.0 | 0.0 | 0.0 |
| Cash & cash equivalents | 2,832.4 | 13,923.0 | 28,511.4 | 18,126.2 |
| Other | 135.6 | 465.7 | 1,259.9 | 1,259.9 |
| Current Liabilities | (2,849.9) | (1,251.9) | (3,041.4) | (2,095.9) |
| Creditors | (748.4) | (491.6) | (1,861.8) | (1,410.0) |
| Tax and social security | 0.0 | 0.0 | 0.0 | 0.0 |
| Short term borrowings | (1,440.0) | 0.0 | 0.0 | 0.0 |
| Other | (661.4) | (760.3) | (1,179.6) | (685.9) |
| Long Term Liabilities | (3,364.3) | (2,995.1) | (17,966.6) | (17,966.6) |
| Long term borrowings | 0.0 | 0.0 | (15,000.2) | (15,000.2) |
| Other long-term liabilities | (3,364.3) | (2,995.1) | (2,966.4) | (2,966.4) |
| Net Assets | 1,975.1 | 16,185.6 | 14,706.3 | 5,102.6 |
| Minority interests | 0.0 | 0.0 | 0.0 | 0.0 |
| Shareholders' equity | 1,975.1 | 16,185.6 | 14,706.3 | 5,102.6 |
| **CASH FLOW** | | | | |
| Op Cash Flow before WC and tax | (14,340.9) | (7,677.2) | (15,009.2) | (11,370.2) |
| Working capital | (970.5) | (754.6) | 853.8 | (945.5) |
| Exceptional & other | (870.7) | (360.6) | 73.2 | 164.0 |
| Tax | 536.0 | 1,227.3 | 2,332.5 | 1,766.4 |
| Net operating cash flow | (15,646.0) | (7,565.1) | (11,749.7) | (10,385.2) |
| Capex | 0.0 | (51.5) | 0.0 | 0.0 |
| Acquisitions/disposals | 900.0 | 0.0 | 0.0 | 0.0 |
| Net interest | 0.0 | 0.0 | 0.0 | 0.0 |
| Equity financing | 12,192.5 | 19,826.5 | 11,290.0 | 0.0 |
| Dividends | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | (1,000.0) | (1,119.4) | 48.0 | 0.0 |
| Net Cash Flow | (3,553.5) | 11,090.5 | (411.7) | (10,385.2) |
| Opening net debt/(cash) | (5,954.0) | (1,392.5) | (13,923.0) | (13,511.3) |
| FX | 0.0 | 0.0 | 0.0 | 0.0 |
| Other non-cash movements | (1,008.0) | 1,440.0 | 0.0 | 0.0 |
| Closing net debt/(cash) | (1,392.5) | (13,923.0) | (13,511.3) | (3,126.1) |

Source: Source: Hepion reports, Edison Investment Research

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