

MGC Pharmaceuticals

Initial CannEpiL purchase orders received

MGC Pharmaceuticals continues to put the building blocks in place for its seed-to-pharmacy medicinal cannabis business. It has received its first formal purchase orders for CannEpiL in the UK, and has already received repeat orders from new distributors in Australia. It recently appointed distributors for Brazil, Germany, Austria and Switzerland. Its Phase II study of CogniCann in dementia is recruiting faster than expected. Preliminary approvals are in place for its Malta production hub, but it will need to raise funds for construction. We adjust our valuation to A\$157m (vs A\$135m).

| Year end | Revenue (A\$m) | PBT* (A\$m) | EPS* (c) | DPS* (c) | P/E (x) | Yield (%) |
|----------|----------------|-------------|----------|----------|---------|-----------|
| 06/17 | 0.1 | (8.5) | (0.9) | 0.0 | N/A | N/A |
| 06/18 | 0.3 | (9.0) | (0.8) | 0.0 | N/A | N/A |
| 06/19e | 1.2 | (6.8) | (0.6) | 0.0 | N/A | N/A |
| 06/20e | 2.4 | (7.7) | (0.6) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalised, excluding exceptional items.

First CannEpiL shipment to the UK

MGC received a UK import licence in April and delivered its first shipment of CannEpiL in May. It has entered distribution agreements with Grow Biotech and IPS Specials, which have already received initial CannEpiL prescriptions. MGC is an early mover in the UK medical cannabis market, where regulations came into effect in November 2018 allowing specialists to prescribe medical cannabis products.

Building blocks in place, repeat orders received

MGC is steadily putting the building blocks in place for its medicinal cannabis business. While no cash receipts for sales were reported for Q119, it received its first formal purchase orders for CannEpiL in Australia and the UK in April, totalling over A\$200k; recent repeat orders have taken the total to ~A\$300k.

Preliminary approvals for Malta production facility

MGC has received preliminary approval for its GMP-certified medicinal cannabis production and cultivation facility in Malta. It will be in a position to start construction once final permits are received. Given the proposed facility is significantly larger than originally envisaged, we have increased our estimated cost from ~A\$10m (€6m) to ~A\$15m (€9m). We envisage the new facility being operational by H221.

Additional funds needed for Malta construction

MGC had A\$4.1m net cash on 31 March. Cash burn averages A\$1.7m/quarter. Based on our estimated cost of A\$15m for constructing and commissioning the Malta production facility, the company will likely need to raise substantial additional funds before the end of 2019 (we model A\$14m indicative long-term debt in FY20).

Valuation: A\$157m or A\$0.13 per share

We have increased our valuation to A\$157m or A\$0.13/share (vs A\$135m or A\$0.11 per share) as we have increased our expected post-approval price for CannEpiL to bring it closer to Epidiolex pricing. We have reduced near-term revenue forecasts to reflect the slow start-up of CannEpiL sales, and increased forecast Malta facility capex from A\$10m to A\$15m.

Initial CannEpiL orders

Pharma & biotech

10 July 2019

Price **A\$0.05**
Market cap **A\$61m**

| | |
|----------------------------------|----------|
| Net cash (A\$m) at 31 March 2019 | 4.1 |
| Shares in issue | 1,213.4m |
| Free float | 78.9% |
| Code | MXC |
| Primary exchange | ASX |
| Secondary exchange | N/A |

Share price performance



| | | | |
|------------------|---------|---------|--------|
| % | 1m | 3m | 12m |
| Abs | 0.0 | 50.0 | (19.0) |
| Rel (local) | (3.3) | 40.3 | (23.6) |
| 52-week high/low | A\$0.08 | A\$0.03 | |

Business description

MGC Pharmaceuticals is an Australia-headquartered specialist medical cannabis biopharma company, which has most of its operations based in Europe. Management has many years of technical, clinical and commercial experience in the medical cannabis industry.

Next events

| | |
|---|---------|
| Finalise contracts for Malta production facility | Q2/Q319 |
| Update on China nutraceutical test marketing campaign | Q319 |
| Initiate CannEpiL epilepsy Phase II | TBA |

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CannEpil shipments begin to large UK market

MGC delivered its first shipment of CannEpil to the UK at the beginning of May. This follows the receipt in April of a controlled drug import licence for the importation of CannEpil into the UK via its distribution partner Lenis. MGC has also entered distribution agreements with Grow Biotech and IPS Specials, which will provide direct access to the medical cannabis market via a network of 5,500 pharmacies across the UK. Grow Biotech and IPS Specials have already received initial prescriptions to supply CannEpil to patients in the UK.

UK regulations that came in to effect on 1 November 2018 made the medical use of cannabis legal for patients with exceptional clinical need. NHS guidelines allow specialist doctors to prescribe medical cannabis products where there is clear published evidence of benefit that could not be achieved by a licensed medicine.

The import licence and distribution agreements position MGC as an early mover in the UK medical cannabis market. With a population of 66 million, the UK represents a large potential market; the demand for medical cannabis products is forecast to reach €8.8bn per year by 2028.¹

Additional distributors already placed repeat orders in Australia

In early May, MGC signed new non-exclusive distribution agreements with two Australian medicinal cannabis distribution and logistics specialists, Health House International and Cannvalate. The agreements cover CannEpil and CogniCann, as well as the company's other cannabinoid-based investigational medicinal products (IMPs): MXP100 (100% cannabidiol (CBD)) and MXC1:1 (50% tetrahydrocannabinol (THC) and 50% CBD). MXC1:1 was developed for the relief from symptoms of spasticity and certain types of inflammatory pain.

The cannabinoid-based IMPs can be supplied to patients in Australia under the Therapeutic Goods Administration's Authorised Prescriber Scheme and the Special Access Scheme, or for use in clinical trials.

The company commented that initial distribution of CannEpil in Q119 was slower than anticipated due to Australian regulatory and compliance matters that have since been resolved. The appointment of the new distributors has helped to drive sales growth.

On 16 April the company announced it had received its first formal purchase orders for CannEpil in Australia and the UK, totalling more than A\$200,000 in revenues for MGC. On 13 June it announced that it had already received additional orders from Health House International and Cannvalate, bringing the total orders for MGC in the first month to ~A\$300k. The additional orders reflect strong initial demand from the market, and positive patient feedback encouraging doctors to issue new and repeat prescriptions for the products.

The company has completed the first phase of the development of the International Library of Cannabinoids (ILC) digital platform, in tandem with the Royal Melbourne Institute of Technology (RMIT). The ILC platform aims to facilitate increased understanding for doctors of cannabinoid treatments, which may translate to increased prescription of cannabinoid-based products.

New distributors for Germany, Austria, Switzerland and Brazil

MGC appointed two new distributors in June to expand its product reach in Europe and South America.

1 Prohibition Partners: The European Cannabis Report [4th Edition](#)

On 21 June it signed a distribution agreement with German company Mexacare, for the distribution of its cannabinoid products, including CannEpil and CogniCann, in Germany, Austria and Switzerland. The MGC products will be distributed via Mexacare's established network of pharmacies and medical professionals, alongside its diagnostic devices and complementary medical products.

On 19 June MGC signed an exclusive distribution agreement for its products in Brazil with ONIX Empreendimentos e Participações (ONIX). The ONIX subsidiary OnixCann is an established distributor of cannabinoid-based products to doctors and patients in Brazil. OnixCann has a digital platform, CANTERA, which connects potential patients with the relevant medical professionals, facilitating safe and legal access to cannabinoid products.

The distribution agreements further expand the market access for MGC's cannabinoid products, and should help underpin further sales growth. The German medical cannabis market is estimated to grow to €7.7bn by 2028,¹ while the market in Brazil and Latin America is expected to reach US\$8.5bn over the same time frame.²

Non-pharma business units generating material revenues

While MGC's primary focus is on commercialising cannabinoid-derived medicines, its non-pharmaceutical business units have generated material revenues in the June quarter.

It has completed the first tranche of a bulk order of cosmetics raw materials under the five-year supply agreement put in place when it sold its MGC Derma unit to CannaGlobal in January. The order totals €438k (~A\$700k), of which a payment of €160k has already been received by the company. The balance is due in Q319 on the completion of product line manufacturing.

In addition, it has received a payment of €108k from Mabsut Life for orders of CBD wide spectrum raw material completed in Q119. MGC is also developing four new formulas to be used in Mabsut's CBD-based vapouriser/e-cigarette marketed as PhenoPen. These formulas will look to provide relief from symptoms of anxiety, inflammation, pain and insomnia. The sales form part of a multi-year supply agreement signed with Mabsut in November 2017, which the company believes is on track to deliver annualised revenues of ~A\$1m in 2019.

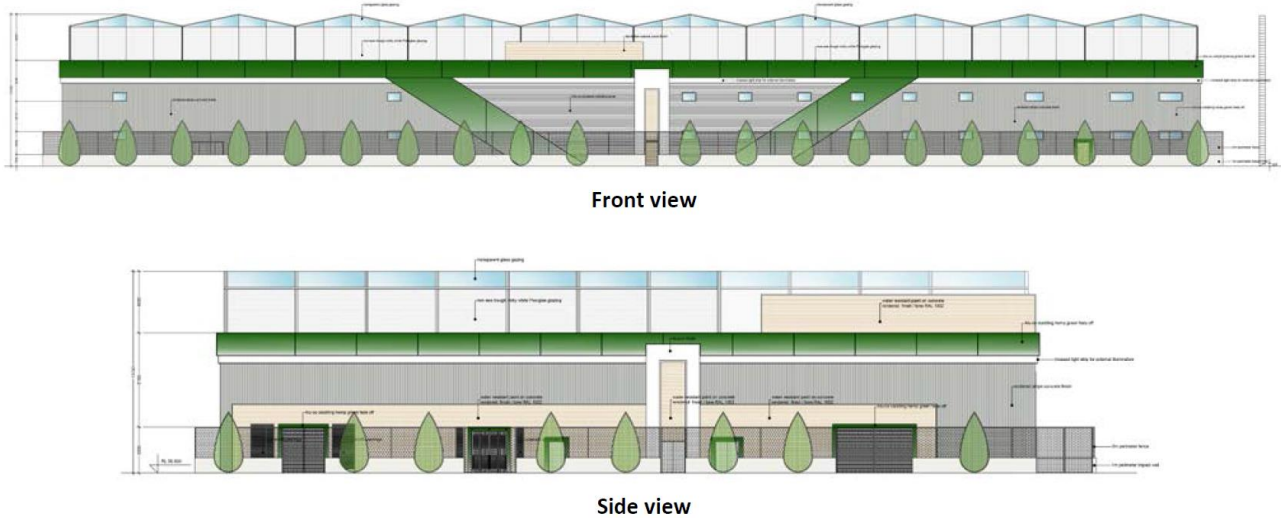
Preliminary approvals for Maltese facility

MGC has received preliminary approval from the relevant government departments for its GMP-certified medicinal cannabis production and cultivation facility in Malta. Once it has received an acquisition of immovable property permit from the Maltese Industrial Parks, it will be able to start the civil work as the first phase of the facility's construction.

Exhibit 1 shows the architectural design of the facility to be built on the 6,000m² site, with the extraction and production facilities on the ground floor and glass house for cannabis cultivation on the second floor. Given the current proposal is 50% larger than the 4,000m² facility envisaged in the letter of intent signed with the Maltese government in April 2018, we have increased our estimate of the cost from ~A\$10m (€6m) to ~A\$15m (€9m). We envisage the new facility being fully operational, including GMP certification, by H221.

The company expects to be able to leverage the key expertise that it developed as it obtained EU GMP certification for its Slovenian medical cannabis manufacturing and production facility to expedite development in Malta. Thanks to the country's warm climate, the Maltese facility is expected to produce high-yielding cannabis crops at a relatively low cost. Once operational, it will become the hub of the company's seed-to-pharmacy operations focused on supplying key markets in Europe, the UK and internationally.

2 Prohibition Partners: The LATAM Cannabis [Report](#)

Exhibit 1: Malta hub is designed with production facilities on the ground floor and a glass house on top


Source: MGC Pharmaceuticals

Recruitment in CogniCann dementia study progressing rapidly

The company has reported a high level of applications to participate in its Phase II trial of the benefits of CogniCann in dementia and Alzheimer's disease patients, which commenced recruitment earlier this year. The trial leverages IP secured through the company's medical advisory board, led by professor Uri Kramer, which is based on experience gained through the use of medicinal cannabis products in Israel.

The study is being conducted in partnership with the Institute for Health Research at the University of Notre Dame in Western Australia. The randomised, double-blind, crossover, placebo-control trial is evaluating the impact of 16 weeks of CogniCann treatment on behavioural changes, quality of life, level of discomfort and pain in 50 dementia patients aged 65 years and over living in residential aged-care facilities. The company now expects to be able to conclude the study in Q220, 12 months ahead of schedule.

We model a market launch of CogniCann as an approved pharmaceutical product in Australia and Europe in FY25. If the company's expectation of rapid recruitment is met for the current Phase II study and is repeated in a subsequent pivotal study, then it is possible that the market launch could be achieved earlier (if approved).

Genetic research delivers cost-effective, high-yielding strains

MGC's research team, in collaboration with the University of Ljubljana, has successfully developed proprietary genetic strains of cannabis with high levels of cannabinoids. Genetic strain MXC-10 has a very high THC level (35%) and low CBD (<1%). One of its original genetic strains, MXC-81, has been substantially improved, and now contains over 20% CBD and <1% THC, compared to 10% CBD and <1% THC in 2015. MGC has also developed additional high-yielding strains with different ratios of THC and CBD.

The high yields of THC and/or CBD per kilogram of raw material will improve the economics of active pharmaceutical ingredient (API) production for MGC. This will allow MGC to scale up API production in a cost-effective manner.

China healthcare products offer near-term potential

On 17 April, MGC signed a marketing and distribution agreement with the Chinese e-commerce platform YuShop global, to sell its CBD and hemp-enhanced nutraceuticals products in China. The products include CBD Hemp Protein Powder, BCAA CBD capsules, CBD Water Soluble Solution and CBD Herbal V-pen (Exhibit 2). Chinese consumers will be targeted via YuShop's online platform and network of 1,500 retail channel partners.

YuShop is conducting a 28-day beta test of flagship MGC nutraceutical products online and within 20 retail locations in four Chinese cities. The test marketing will provide the data to support a full-scale sales campaign planned to roll out across the rest of China in July.

Although MGC's primary focus is on medical cannabis products, the YuShop agreement, which provides access to the large Chinese health products market, could provide an important near-term revenue stream for the company. Chinese consumers are expected to purchase over US\$20bn of vitamins and supplements in 2020.³

Given the early stage of the project, we do not yet include revenue from China in our financial forecasts or valuation.

Exhibit 2: Selected MGC nutraceutical products



Source: MGC Pharmaceuticals

Cannabis cultivation research licence granted in Australia

On 29 May, MGC announced it had been granted a cannabis research licence in tandem with the RMIT by the Australian Office of Drug Control. A subsequent cannabis research permit that outlines the types of cannabis plants to be cultivated, as well as the quantities and timeframes is required before cultivation can begin; the company expects to receive the permit in the near term. The licence and permit will authorise MGC and RMIT to cultivate cannabis for use in research at its facility in Melbourne, Australia. The botanical and preclinical research will focus on the optimisation of plant breeding and cultivation processes and extracting APIs to assess their efficacy on prostate, melanoma and other cancer cells. All intellectual property resulting from the trials will belong to the company.

Research collaboration shows potential in glioblastoma

In addition to the collaboration with RMIT described above, MGC has established a number of other research collaborations as it seeks to better understand the potential applications of medicinal cannabis, and to develop new products and improved production processes.

One of these research collaborations, with the National Institute of Biology and University Medical Centre in Ljubljana, Slovenia, presented the results of a preclinical study on the effectiveness of cannabinoids in glioblastoma brain cancer at a recent scientific conference. The data were presented at the Second International Annual Congress on Controversies on Cannabis-based Medicines in Barcelona, Spain, on 23–24 May.

³ SEO Agency, 25 November 2018: [The Huge Vitamins and Dietary Supplements Market in China](#)

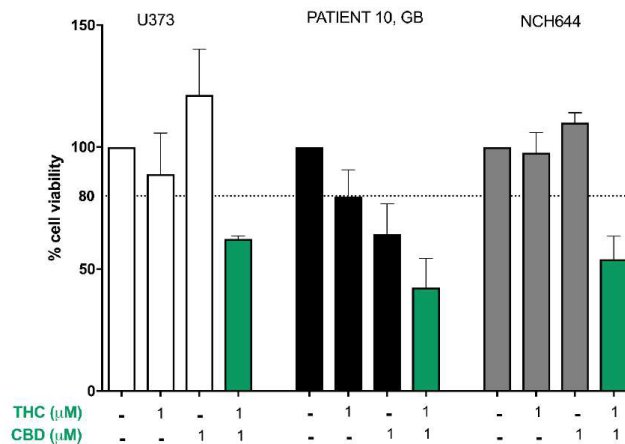
The study showed the CB2 cannabinoid receptor was highly expressed in all glioblastoma tumour tissue samples examined. It also showed that cannabinoids, particularly higher levels of THC, reduced the viability of glioblastoma cells in vitro. There was a synergistic effect of combining THC and CBD resin at a 1:1 ratio in three glioblastoma cell lines, as shown in Exhibit 3. Other investigators have previously shown that a combination of THC and CBD synergistically inhibits glioblastoma cells in tissue culture.⁴

We note that other medical cannabis companies are also investigating THC/CBD combinations in glioblastoma. In February 2017, GW Pharmaceuticals (NASDAQ: GWPH) reported positive [results](#) from a 21-patient Phase II study of a proprietary THC/CBD combination in addition to standard chemotherapy in glioblastoma patients. Patients treated with THC/CBD had an 83% one-year survival rate, versus 53% with placebo.

Tilray (NASDAQ: TLRY) has proposed a Phase Ib study of THC/CBD in glioblastoma patients (clinicaltrials.gov reference: [NCT03529448](#)), but this study is not yet recruiting patients.

While we do not expect MGC to undertake a clinical study in glioblastoma in the foreseeable future, the conference presentation is an example of the company's ongoing efforts to develop new evidence-based medicinal cannabis products.

Exhibit 3: Synergistic inhibition of combining THC/CBD 1:1 in cultured glioblastoma cells



Source: MGC Pharmaceuticals

Valuation

We have increased our valuation to A\$157m or A\$0.13/share (vs A\$135m or A\$0.11 per share) as we have increased our expected post-approval price for CannEpiL to bring it closer to Epidiolex pricing. We currently estimate pricing post regulatory approval of US\$10,000 per patient per year across markets, which is still a steep discount to Epidiolex (cannabidiol) sold by GW Pharmaceuticals, which is priced at around US\$32,500 in the United States. As a result of this pricing change, our peak sales estimate for the juvenile epilepsy market increased from A\$90m to A\$160m and for the adult epilepsy market from A\$300m to A\$490m. This increase was mitigated by near-term revenue forecasts to reflect the slow start-up of CannEpiL sales, and increased forecast Malta facility capex from A\$10m to A\$15m. Our valuation is based on a 15-year, sum-of-the-parts risked DCF valuation model of the company's CannEpiL product for epilepsy and CogniCann for dementia in Europe and Australia, as well as API sales of cannabis flowers and resin. We assume 3% annual market growth, but do not include any terminal value. Exhibit 4 summarises the key

⁴ Marcu et al, Cannabidiol enhances the inhibitory effects of Δ9-tetrahydrocannabinol on human glioblastoma cell proliferation and survival, *Mol cancer Ther*, 2010.

assumptions and constituent parts of our valuation. We use a 12.5% discount rate and apply an average tax rate of 10% from 2022 onwards. The company does not currently have patent protection for its product pipeline.

Our valuation assumptions were explained in detail in our [initiation report](#).

| Exhibit 4: MGC Pharmaceuticals rNPV valuation | | | | | | | |
|---|-------------|----------------------|------------|-------------|-----------------|----------------------|--|
| Product | Launch* | Peak sales (A\$m)*** | NPV (A\$m) | Probability | rNPV (A\$m)**** | rNPV/share (c/share) | |
| Juvenile epilepsy Europe & Australia | 2019/2024** | 160 | 94 | 20–100% | 18.1 | 1.5 | |
| Adult epilepsy Europe & Australia | 2025 | 490 | 252 | 20% | 49.4 | 4.1 | |
| Dementia Europe and Australia | 2025 | 830 | 424 | 5% | 19.0 | 1.6 | |
| Flower and resin API & food-grade resin sales | 2018 | 60 | | 20–100% | 79.0 | 6.5 | |
| MGC Derma/Cannaglobal | | | | | 7.5 | 0.6 | |
| Admin and unallocated R&D costs | | | | 20–100% | (18.6) | (1.5) | |
| Net Cash end FY19e | | | | 100% | 2.3 | 0.2 | |
| Valuation | | | | | 156.8 | 12.9 | |

Source: Edison Investment Research. Notes: *Financial year of product launch; **sales of investigational CannEpi begin in FY19 at 100% probability, registered pharmaceutical in FY24 at 20% probability; ***peak sales estimates rounded to nearest A\$10m; ****risk-adjusted R&D costs are offset against income for each drug development project.

Financials

MGC has been loss making since listing in February 2016, reporting losses of A\$6.2m in FY16, A\$8.5m in FY17 and A\$9.0m in FY18. We forecast losses before tax of A\$6.8m and A\$7.7m in FY19 and FY20 respectively, as it starts commercial sales of API in Europe and of CannEpi as an investigational medicinal product in Australia. We forecast R&D expenses of A\$1.3m in FY19 and A\$2.8m in FY20.

We assume that constructing and commissioning the cannabis-growing and API extraction facility in Malta will require capital expenditure of A\$15m. The company raised net proceeds of A\$10.5m from stock issues in FY16, A\$9.8m in FY17 and A\$4.7m in FY18. The current net cash balance of A\$4.1m should be sufficient to support operations into FY20. We estimate that additional funds of A\$14m will be required in FY20 to support construction of the new facilities in Malta, which we model as indicative long-term debt.

Exhibit 5: Financial summary

| | A\$'000s | 2016 | 2017 | 2018 | 2019e | 2020e |
|--|----------|---------|----------|----------|---------|----------|
| Year end 30 June | | AASB | AASB | AASB | AASB | AASB |
| PROFIT & LOSS | | | | | | |
| Sales | | 2 | 120 | 297 | 1,171 | 2,412 |
| Other | | 0 | 0 | 0 | 0 | 0 |
| Revenue | | 2 | 120 | 297 | 1,171 | 2,412 |
| Cost of Sales | | (15) | (158) | (119) | (1,023) | (1,482) |
| Gross Profit | | (13) | (38) | 177 | 148 | 930 |
| R&D expenses | | 0 | 0 | (951) | (1,269) | (2,769) |
| SG&A expenses | | (6,247) | (8,508) | (8,080) | (5,707) | (5,736) |
| Other | | 0 | 0 | 0 | 0 | 0 |
| EBITDA | | (6,260) | (8,546) | (8,854) | (6,829) | (7,575) |
| Operating Profit (before GW and except.) | | (6,276) | (8,629) | (9,182) | (6,935) | (7,769) |
| Intangible Amortisation | | 0 | 0 | 0 | 0 | 0 |
| Exceptionals | | 0 | 0 | 0 | 0 | 0 |
| Operating Profit | | (6,276) | (8,629) | (9,182) | (6,935) | (7,769) |
| Net Interest | | 46 | 127 | 192 | 99 | 24 |
| Profit Before Tax (norm) | | (6,230) | (8,502) | (8,990) | (6,837) | (7,746) |
| Profit Before Tax (reported) | | (6,230) | (8,502) | (8,990) | (6,837) | (7,746) |
| Tax benefit | | 0 | 0 | 0 | 0 | 0 |
| Profit After Tax (norm) | | (6,230) | (8,502) | (8,990) | (6,837) | (7,746) |
| Profit After Tax (reported) | | (6,230) | (8,502) | (8,990) | (6,837) | (7,746) |
| Average Number of Shares Outstanding (m) | | 603.6 | 966.3 | 1,125.5 | 1,208.1 | 1,213.4 |
| EPS - normalised (c) | | (1.03) | (0.88) | (0.80) | (0.57) | (0.64) |
| EPS - diluted | | (1.03) | (0.88) | (0.80) | (0.57) | (0.64) |
| Dividend per share (A\$) | | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| BALANCE SHEET | | | | | | |
| Fixed Assets | | 7,331 | 8,335 | 8,490 | 9,583 | 16,889 |
| Intangible Assets | | 7,084 | 7,076 | 7,083 | 7,083 | 7,083 |
| Tangible Assets | | 211 | 1,258 | 1,334 | 2,428 | 9,734 |
| Investments | | 36 | 0 | 73 | 73 | 73 |
| Current Assets | | 9,030 | 12,485 | 11,504 | 3,893 | 4,745 |
| Stocks | | 157 | 508 | 712 | 602 | 648 |
| Debtors | | 477 | 613 | 932 | 932 | 241 |
| Cash | | 7,896 | 11,364 | 9,859 | 2,358 | 3,855 |
| Other | | 500 | 0 | 0 | 0 | 0 |
| Current Liabilities | | (4,612) | (4,966) | (7,231) | (6,387) | (6,511) |
| Creditors | | (456) | (596) | (961) | (117) | (241) |
| Short term borrowings | | (1,075) | 0 | 0 | 0 | 0 |
| Other | | (3,080) | (4,370) | (6,270) | (6,270) | (6,270) |
| Long Term Liabilities | | (20) | (65) | (73) | (73) | (14,073) |
| Long term borrowings | | (20) | (20) | (22) | (22) | (14,022) |
| Other long term liabilities | | 0 | (45) | (51) | (51) | (51) |
| Net Assets | | 11,729 | 15,789 | 12,691 | 7,017 | 1,050 |
| CASH FLOW | | | | | | |
| Operating Cash Flow | | (3,255) | (4,751) | (6,007) | (6,399) | (5,027) |
| Net Interest | | 34 | 95 | 120 | 99 | 24 |
| Tax | | 0 | 0 | 0 | 0 | 0 |
| Capex | | (248) | (1,131) | (459) | (1,200) | (7,500) |
| Acquisitions/disposals | | 0 | 500 | 119 | 0 | 0 |
| Equity Financing | | 10,528 | 9,810 | 4,701 | 0 | 0 |
| Dividends | | 0 | 0 | 0 | 0 | 0 |
| Other | | (403) | 0 | 0 | 0 | 0 |
| Net Cash Flow | | 6,657 | 4,523 | (1,527) | (7,501) | (12,503) |
| Opening net debt/(cash) | | (146) | (6,800) | (11,344) | (9,837) | (2,337) |
| HP finance leases initiated | | 0 | 0 | 0 | 0 | 0 |
| Other | | (3) | 21 | 21 | 0 | 0 |
| Closing net debt/(cash) | | (6,800) | (11,344) | (9,837) | (2,337) | 10,166 |

Source: MGC Pharmaceutical accounts, Edison Investment Research

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