

**Speculative**

See key risks on Pages 3-4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

## Analyst

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## Authorisation

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# Immutep (IMM)

## Manufacturing process established for IMP761 (autoimmune disease targeting antibody)

### Recommendation

**Buy** (unchanged)

### Price

**\$0.355**

### Valuation

**\$0.60** (unchanged)

### Risk

**Speculative**

### GICS Sector

**Pharmaceuticals & Biotechnology**

### Expected Return

|                       |              |
|-----------------------|--------------|
| Capital growth        | <b>69.0%</b> |
| Dividend yield        | <b>0.0%</b>  |
| Total expected return | <b>69.0%</b> |

### Company Data & Ratios

|                        |                       |
|------------------------|-----------------------|
| Enterprise value       | <b>\$225.1m</b>       |
| Market cap             | <b>\$312.1m</b>       |
| Issued capital         | <b>879.1m</b>         |
| Free float             | <b>97%</b>            |
| Avg. daily val. (52wk) | <b>\$428,821</b>      |
| 12 month price range   | <b>\$0.235-\$0.52</b> |

### Price Performance

|                | (1m)  | (3m)  | (12m)  |
|----------------|-------|-------|--------|
| Price (A\$)    | 0.30  | 0.29  | 0.48   |
| Absolute (%)   | 20.34 | 24.56 | -25.26 |
| Rel market (%) | 15.84 | 20.25 | -25.65 |

### Absolute Price



SOURCE: IRESS

## IMP761 ready to go for first clinical trials

Immutep (IMM) has just announced that a GMP-compliant manufacturing process has been established for the Company's LAG-3-targeting immunotherapy drug, IMP761, designed to treat autoimmune diseases. IMM has employed Northway Biotech - a contract development and manufacturing organisation (CDMO) – to ensure ongoing supply of IMP761 to facilitate IND-enabling studies and future clinical trials.

IMM's CEO, Marc Voigt, has said of the achievement, "We are pleased to have a GMP manufacturing process for IMP761 in hand with our manufacturing partner Northway Biotech as we move towards initiating IND-enabling studies in the first half of 2023 and subsequent clinical development. As a first-in-class LAG-3 immunosuppressive antibody, IMP761 has been designed to address the root cause of autoimmune diseases by specifically silencing self-reactive exhausted effector T cells that express LAG-3 and accumulate at disease sites."

## Second clinical trial agreement for INSIGHT-005

Immutep has also announced that it has entered into a second clinical trial collaboration agreement with Merck KGaA (ie, Merck Germany) and Pfizer. The investigator-initiated study (part of the INSIGHT platform of studies) will be explorative and open-label (ie, not a randomised controlled trial – and a normal initial study step) to evaluate the safety and efficacy of the combination of eftilagimod- $\alpha$  + avelumab (BAVENCIO®) in up to 30 patients with metastatic urothelial cancer.

## Investment view: Valuation \$0.60, Retain Buy (Spec.)

IMM remains adequately funded through to a Phase 3 trial of their most mature asset, eftilagimod- $\alpha$  in NSCLC, and the first of the safety trials using IMP761, as Phase 1 trials are considerably less expensive than other clinical stage investigations. The announcements described here have no effect on our valuation of the stock, which remains unchanged at \$0.60 p/s and we retain our Buy (Speculative) rating.

### Earnings Forecast

| June Year End        | FY22  | FY23e | FY24e | FY25e |
|----------------------|-------|-------|-------|-------|
| Revenues             | 1.0   | 10.0  | 62.5  | 82.5  |
| EBIT (\$m)           | -35.4 | -28.8 | 33.3  | 50.4  |
| NPAT (\$m)           | -35.3 | -28.7 | 33.4  | 50.5  |
| EPS underlying (cps) | -4.1  | -3.4  | 3.9   | 5.9   |
| EPS growth (%)       | nm    | nm    | -216% | 51%   |
| PER (x)              | nm    | nm    | 8.1   | 5.3   |
| FCF yield (%)        | nm    | nm    | nm    | nm    |
| EV/EBITDA (x)        | (5.4) | (6.6) | 5.7   | 3.8   |
| Dividend (cps)       | -     | -     | -     | -     |
| Franking             | 0%    | 0%    | 0%    | 0%    |
| Yield (%)            | 0%    | 0%    | 0%    | 0%    |
| ROE (%)              | 0%    | -47%  | 35%   | 35%   |

SOURCE: BELL POTTER SECURITIES ESTIMATES

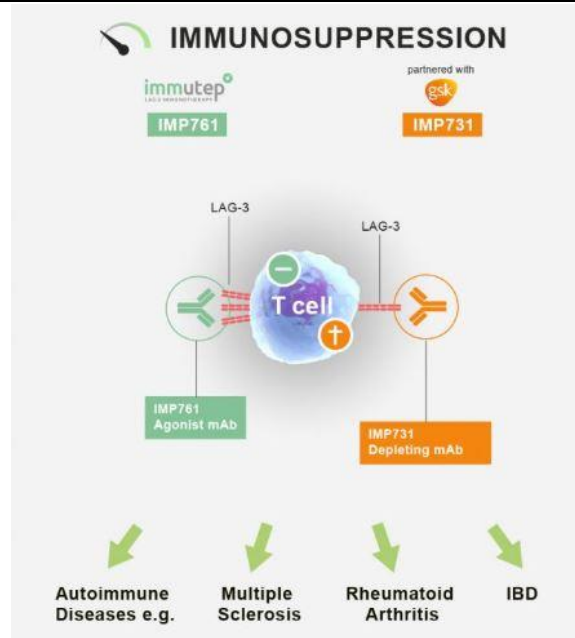
### What is IMP761?

IMP761 is a first-in-class immunosuppressive agonist antibody to LAG-3. IMP761 is being developed and investigated for its ability to silence autoimmune memory T-cells that accumulate at the disease site(s). It is a humanised IgG4 monoclonal antibody and is mechanistically distinct from any of the known LAG-3 antibodies.

A suppression of the LAG-3 pathway has been associated with the development of autoimmune diseases, so using an antibody (such as IMP761) that stimulates the LAG-3 pathway may be useful to treat this family of diseases.

Note this is not the same immunosuppressive antibody that IMM has licensed to GSK (that one is called IMP731 and works slightly differently – see image below).

**Figure 1 - Schematic MOA for IMP761 versus IMP731**



SOURCE: COMPANY

IMM has published positive pre-clinical (non-human primate model) results with IMP761 in a model of T-cell mediated inflammatory responses<sup>1</sup>, and an *ex vivo* model of juvenile arthritis<sup>2</sup>. The company now looks set to ramp up manufacture and move to obtain INDs from the FDA for the first clinical trials in 2023. We keenly await further announcements regarding this asset.

<sup>1</sup> Angin, Brignone, & Triebel;. *J Immunol*, (2020) 204 (4): 810–818.

<sup>2</sup> Sag et al. *Pediatric Research* (2021) 90:744–751

# Immutep (IMM)

## COMPANY DESCRIPTION

Immutep (IMM) is a clinical-stage biopharmaceutical company, focused on the development of novel immunotherapies for the treatment of cancer and autoimmune diseases. Its core technology is based on LAG-3 (lymphocyte activation gene-3) protein, a key mediator of the immune system. IMM is listed on the ASX and has its American Depository Receipts (ADRs) listed on NASDAQ. It is based in Sydney, with operations in US, Germany and France. The company's LAG-3 assets come from the acquisition in 2014 of a private French biotech company founded by Dr. Frederic Triebel (now IMM's CSO and CMO), who first discovered the LAG-3 gene and developed the various LAG-3 assets IMM holds.

IMM have an impressive track record of high quality commercial and clinical trial collaborations with Tier 1 pharmaceutical companies. This is an important history that raises our confidence in the company's future prospects of commercially successful partnerships.

## INVESTMENT STRATEGY

We have a Buy (speculative) recommendation on Immutep (IMM). Our investment thesis is based on: \$0.60 Valuation.

LAG-3 could become the third major immune checkpoint target, after PD-1/PD-L1 and CTLA-4 checkpoint inhibitors, in the treatment of cancer. Clinical results in the industry highlight its potential. Bristol Myers Squibb new drug, Opdualag™, was approved in March this year (2022) by the FDA for the treatment of adult and paediatric patients >12 years of age with unresectable or metastatic melanoma.

Opdualag™ is a fixed-dose combination of two check-point therapies: nivolumab (PD-1 inhibitor) and relatlimab (a novel LAG-3-blocking antibody), administered as a single intravenous infusion. BMY's relatlimab has thus become the first LAG-3 drug to be approved.

This provides validation for LAG-3 and its interaction with MHC Class II proteins, and we expect IMM to benefit from this approval.

We expect efti to have broad utility across multiple cancer indications in combination with different treatment modalities, including other immuno-oncology agents and chemotherapeutic agents. We view a multi-billion dollar sales potential for the uniquely acting efti. Within that forecast, we model that IMM has the potential to earn peak in-market sales of >\$250m p.a. from royalty revenues for efti alone.

## KEY RISKS

Key risks we consider to be specific to IMM include, but are not limited to:

**Further validation of efficacy of efti required:** Research and understanding around LAG-3 as a target is recent and ongoing. Compare this to other approved checkpoint targeting therapies that have a history of successful clinical application. There is currently one approved LAG-3 therapy on the market: BMY's Opdualag™.

For IMM's lead product 'efti', however, there is still a risk as it is a new approach to targeting LAG-3 as an agonist (activating the pathway), vs. the more common approach of targeting LAG-3 as an antagonist antibody (releasing the brake on the T cell) such as BMY's relatlimab. Therefore the onus of validating this drug class as an APC activator rests solely on IMM's shoulders and Phase 3 trials should be focussed on this risk.

Clinical risk: There is a risk that one or more of IMM's ongoing clinical trials fail to reach their endpoints. Though IMM has presented encouraging clinical data to date, some were not blinded and had a small number of patients. There is no guarantee that early data will translate to positive outcomes in larger trials. Underwhelming results from any of IMM's

ongoing trials is likely to impact the company's ability to monetise those assets and negatively impact the sentiment around the company and its valuation.

**Timing and clinical risk on externally partnered products:** For its partnered products LAG525 and GSK2831781, IMM is reliant on Novartis (NVS) and GlaxoSmithKline (GSK) respectively for development timelines. The ability of IMM's products to reach the market and translate into royalty revenue streams depends on these partners.

**Reliance on partnerships to unlock value:** The success of IMM's business model is underpinned by its ability to ultimately attract valuable partnering deals for its assets, given IMM lacks the commercial infrastructure to support commercialisation. Our valuation is underpinned, in part, by IMM's ability to attract a valuable partnering deal for 'efti' for the US & EU markets. Failure to attract partners or to negotiate attractive deal terms as we have postulated will impact our forecasts.

**Regulatory risk:** Successful commercialisation of IMM's products is ultimately dependent on getting approval from the regulatory authorities to commercially launch the product. IMM is likely to partner its products and not look to commercialise them itself. While IMM's partners (current and future), with superior experience in navigating regulatory channels, will be responsible for obtaining approvals. Failure to satisfy regulatory requirements could result in the product failing to reach the market.

**Funding risk:** IMM had cash reserves of \$73.9 million, giving cash runway into early calendar year 2024 based on the forecast cash burn for FY23. The company may require additional capital if the Board decides to expand the clinical program for any additional studies. Additional partnerships may alleviate the need to raise capital, however if IMM needs to raise money, it will be dilutive to shareholders

Table 2 - Financial summary

| A\$m                            | FY21          | FY22          | FY23e         | FY24e         | FY25e        | Valuation Ratios (A\$m)                       | FY21        | FY22        | FY23e       | FY24e        | FY25e        |
|---------------------------------|---------------|---------------|---------------|---------------|--------------|---|-------------|-------------|-------------|--------------|--------------|
| <b>Year Ending 30 June</b>      |               |               |               |               |              | Reported EPS (cps)                            | -7.2        | -4.1        | -3.4        | 3.9          | 5.9          |
| <b>Total Revenue</b>            | -             | <b>1.0</b>    | <b>10.0</b>   | <b>62.5</b>   | <b>82.5</b>  | Normalised EPS (cps)                          | -7.2        | -4.1        | -3.4        | 3.9          | 5.9          |
| <b>Revenue growth</b>           | <b>nm</b>     | <b>nm</b>     | <b>900%</b>   | <b>524.5%</b> | <b>32.1%</b> | EPS growth (%)                                | nm          | nm          | nm          | -216%        | 51%          |
| COGS                            | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | <b>PE(x)</b>                                  | <b>nm</b>   | <b>nm</b>   | <b>nm</b>   | <b>8.1</b>   | <b>5.3</b>   |
| Gross profit                    | -             | 1.0           | 10.0          | 62.5          | 82.5         | <b>EV/EBIT (x)</b>                            | -6.3        | -5.4        | -6.6        | 5.7          | 3.8          |
| <b>GP Margin</b>                | <b>0%</b>     | <b>0%</b>     | <b>100%</b>   | <b>100%</b>   | <b>100%</b>  | P/NTA (x)                                     | 3.9         | 3.4         | 5.2         | 3.1          | 1.9          |
| Employee costs                  | -15.3         | -29.6         | -30.5         | -15.2         | -15.7        | Book Value Per Share (cps)                    | 9.8         | 10.5        | 7.2         | 11.1         | 17.0         |
| Scientific consumables          | -6.3          | -7.8          | -9.3          | -12.1         | -14.5        | Price/Book (x)                                | 3.2         | 3.0         | 4.4         | 2.8          | 1.9          |
| Amortisation expense            | -1.9          | -1.9          | -1.9          | -1.9          | -1.9         | DPS (cps)                                     | -           | -           | -           | -            | -            |
| Other expenses                  | -10.4         | 0.0           | 0.0           | 0.0           | 0.0          | Payout ratio %                                | 0.0%        | 0.0%        | 0.0%        | 0.0%         | 0.0%         |
| Grant income                    | 4.0           | 2.9           | 2.9           | 0.0           | 0.0          | Dividend Yield %                              | 0.0%        | 0.0%        | 0.0%        | 0.0%         | 0.0%         |
| Total Expenses                  | -29.9         | -36.4         | -38.8         | -29.2         | -32.1        | Franking %                                    | 0.0%        | 0.0%        | 0.0%        | 0.0%         | 0.0%         |
| <b>EBIT</b>                     | <b>-29.9</b>  | <b>-35.4</b>  | <b>-28.8</b>  | <b>33.3</b>   | <b>50.4</b>  | FCF yield %                                   | nm          | nm          | nm          | nm           | nm           |
| Add back D&A                    | 1.9           | 1.9           | 1.9           | 1.9           | 1.9          | Net debt/Equity                               | 79%         | 83%         | 83%         | 79%          | 85%          |
| <b>EBITDA</b>                   | <b>-28.1</b>  | <b>-33.5</b>  | <b>-26.9</b>  | <b>35.1</b>   | <b>52.3</b>  | Net debt/Assets                               | 71%         | 77%         | 74%         | 74%          | 81%          |
| Interest expense                | 0.0           | 0.1           | 0.1           | 0.1           | 0.1          | Gearing                                       | 44%         | 45%         | 45%         | 44%          | 46%          |
| Other items                     | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | Net debt/EBITDA (x)                           | Net Cash    | Net Cash    | Net Cash    | 2.1          | 2.4          |
| Pre tax profit                  | (29.9)        | (35.3)        | (28.7)        | 33.4          | 50.5         | Interest cover (x)                            | na          | na          | na          | na           | na           |
| Tax expense                     | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | <b>Revenues Analysis</b>                      |             |             |             |              |              |
| <b>NPAT - reported</b>          | <b>(29.9)</b> | <b>(35.3)</b> | <b>(28.7)</b> | <b>33.4</b>   | <b>50.5</b>  | <b>Year End 30 June (AUD\$m)</b>              | FY21        | FY22        | FY23e       | FY24e        | FY25e        |
| Add back                        | -             | -             | -             | -             | -            | GSK deal - risk adjusted milestone            | -           | -           | -           | -            | -            |
| Non recurring items net of tax  | -             | -             | -             | -             | -            | Novartis deal - P3 recruitment milestone      | -           | -           | 10.0        | -            | -            |
| <b>Reported normalised</b>      | <b>(29.9)</b> | <b>(35.3)</b> | <b>(28.7)</b> | <b>33.4</b>   | <b>50.5</b>  | EOC Pharma P3 recruitment milestone           | -           | 1.0         | -           | -            | -            |
| <b>Cashflow (A\$m)</b>          |               |               |               |               |              | Potential left deal US/EU and sales royalties | -           | -           | -           | 62.5         | 82.5         |
| Gross cashflow                  | -17.6         | -35.7         | -23.6         | 24.0          | 48.6         | <b>Interim Results</b>                        |             |             |             |              |              |
| Net interest                    | 0.0           | 0.1           | 0.1           | 0.1           | 0.1          | <b>Revenues</b>                               | 2H21        | 1H22        | 2H22        | 1H23e        |              |
| Income tax paid                 | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | EBIT  | 0.0         | 0.0         | 1.0         | 0.0          |              |
| <b>Operating cash flow</b>      | <b>-17.6</b>  | <b>-35.6</b>  | <b>-23.5</b>  | <b>24.1</b>   | <b>48.7</b>  | EBIT  | -7.3        | -22.6       | -17.2       | -18.4        |              |
| Maintenance capex               | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | NPAT  | -22.6       | -17.2       | -18.1       | 0.0          |              |
| Capitalised R&D                 | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | <b>Balance Sheet (A\$m)</b>                   |             |             |             |              |              |
| <b>Free cash flow</b>           | <b>-17.6</b>  | <b>-35.6</b>  | <b>-23.5</b>  | <b>24.1</b>   | <b>48.7</b>  | Cash  | FY21        | FY22        | FY23e       | FY24e        | FY25e        |
| Purchase of other intangibles   | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | Receivables                                   | 6.1         | 5.0         | 2.0         | 12.5         | 16.5         |
| Proceeds from issuance          | 52.9          | 51.9          | 0.0           | 0.0           | 0.0          | Other current assets                          | 1.7         | 2.9         | 2.9         | 2.9          | 2.9          |
| Movement in borrowings          | -0.2          | 0.0           | 0.0           | 0.0           | 0.0          | Inventory                                     | -           | -           | -           | -            | -            |
| Redemption of preference shares | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | Property, Plant and Equipment                 | 0.0         | 0.0         | 0.0         | 0.0          | 0.0          |
| Dividends paid (common stock)   | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | Intangibles                                   | 12.8        | 11.0        | 9.1         | 7.2          | 5.4          |
| <b>Change in cash held</b>      | <b>35.1</b>   | <b>16.3</b>   | <b>-23.5</b>  | <b>24.1</b>   | <b>48.7</b>  | Right of use assets                           | 0.3         | 0.5         | 0.5         | 0.5          | 0.5          |
| Cash at beginning of period     | 26.3          | 60.6          | 76.9          | 53.4          | 77.5         | Other non current assets                      | 0.5         | 0.5         | 0.5         | 0.5          | 0.5          |
| FX adjustment                   | -0.8          | 0.0           | 0.0           | 0.0           | 0.0          | <b>Total assets</b>                           | <b>82.1</b> | <b>96.8</b> | <b>68.4</b> | <b>101.1</b> | <b>151.9</b> |
| <b>Cash at year end</b>         | <b>60.6</b>   | <b>76.9</b>   | <b>53.4</b>   | <b>77.5</b>   | <b>126.2</b> | Trade payables                                | (4.8)       | (2.9)       | (3.1)       | (2.3)        | (2.5)        |
| <b>Balance Sheet (A\$m)</b>     |               |               |               |               |              | Other liabilities                             | (0.4)       | (0.4)       | (0.4)       | (0.4)        | (0.4)        |
| Cash                            | 60.6          | 76.9          | 53.4          | 77.5          | 126.2        | Other liabilities                             | (0.9)       | (0.9)       | (1.0)       | (1.0)        | (1.1)        |
| Receivables                     | 6.1           | 5.0           | 2.0           | 12.5          | 16.5         | Debt  | (2.5)       | (2.5)       | (2.5)       | (2.5)        | (2.5)        |
| Other current assets            | 1.7           | 2.9           | 2.9           | 2.9           | 2.9          | Lease liabilities                             | (0.2)       | (0.2)       | (0.2)       | (0.3)        | (0.3)        |
| Inventory                       | -             | -             | -             | -             | -            | <b>Total Liabilities</b>                      | <b>-8.8</b> | <b>-6.9</b> | <b>-7.2</b> | <b>-6.5</b>  | <b>-6.8</b>  |
| Property, Plant and Equipment   | 0.0           | 0.0           | 0.0           | 0.0           | 0.0          | <b>Net Assets</b>                             | <b>73.3</b> | <b>89.9</b> | <b>61.2</b> | <b>94.6</b>  | <b>145.1</b> |
| Intangibles                     | 12.8          | 11.0          | 9.1           | 7.2           | 5.4          | Share capital                                 | 313.4       | 365.3       | 365.3       | 365.3        | 365.3        |
| Right of use assets             | 0.3           | 0.5           | 0.5           | 0.5           | 0.5          | Other equity                                  | -           | -           | -           | -            | -            |
| Other non current assets        | 0.5           | 0.5           | 0.5           | 0.5           | 0.5          | Retained earnings                             | (274.7)     | (310.0)     | (338.7)     | (305.3)      | (254.8)      |
| <b>Total assets</b>             | <b>82.1</b>   | <b>96.8</b>   | <b>68.4</b>   | <b>101.1</b>  | <b>151.9</b> | Reserves                                      | 34.6        | 34.6        | 34.6        | 34.6         | 34.6         |
| Trade payables                  | (4.8)         | (2.9)         | (3.1)         | (2.3)         | (2.5)        | <b>Shareholders Equity</b>                    | <b>73.3</b> | <b>89.9</b> | <b>61.2</b> | <b>94.6</b>  | <b>145.1</b> |
| Other liabilities               | (0.4)         | (0.4)         | (0.4)         | (0.4)         | (0.4)        | SOURCE: BELL POTTER SECURITIES ESTIMATES      |             |             |             |              |              |
| Other liabilities               | (0.9)         | (0.9)         | (1.0)         | (1.0)         | (1.1)        |   |             |             |             |              |              |
| Debt                            | (2.5)         | (2.5)         | (2.5)         | (2.5)         | (2.5)        |   |             |             |             |              |              |
| Lease liabilities               | (0.2)         | (0.2)         | (0.2)         | (0.3)         | (0.3)        |   |             |             |             |              |              |
| <b>Total Liabilities</b>        | <b>-8.8</b>   | <b>-6.9</b>   | <b>-7.2</b>   | <b>-6.5</b>   | <b>-6.8</b>  |   |             |             |             |              |              |
| <b>Net Assets</b>               | <b>73.3</b>   | <b>89.9</b>   | <b>61.2</b>   | <b>94.6</b>   | <b>145.1</b> |   |             |             |             |              |              |
| Share capital                   | 313.4         | 365.3         | 365.3         | 365.3         | 365.3        |   |             |             |             |              |              |
| Other equity                    | -             | -             | -             | -             | -            |   |             |             |             |              |              |
| Retained earnings               | (274.7)       | (310.0)       | (338.7)       | (305.3)       | (254.8)      |   |             |             |             |              |              |
| Reserves                        | 34.6          | 34.6          | 34.6          | 34.6          | 34.6         |   |             |             |             |              |              |
| <b>Shareholders Equity</b>      | <b>73.3</b>   | <b>89.9</b>   | <b>61.2</b>   | <b>94.6</b>   | <b>145.1</b> |   |             |             |             |              |              |

SOURCE: BELL POTTER SECURITIES ESTIMATES

**Recommendation structure**

**Buy:** Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

**Hold:** Expect total return between -5% and 15% on a 12 month view

**Sell:** Expect <-5% total return on a 12 month view

*Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.*

*Such investments may carry an exceptionally high level of capital risk and volatility of returns.*

**Research Team**

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| Anubhav Saxena    | Healthcare                   | 612 8224 2846 | asaxena            |
| Tara Speranza     | Healthcare                   | 612 8224 2815 | tsperanza          |
| Michael Ardrey    | Industrials                  | 613 9256 8782 | mardney            |
| Marcus Barnard    | Industrials                  | 618 9326 7673 | mbarnard           |
| Sam Brandwood     | Industrials                  | 612 8224 2850 | sbrandwood         |
| Daniel Laing      | Industrials                  | 613 8224 2886 | dlaing             |
| Olivia Hagglund   | Industrials                  | 612 8224 2813 | ohagglund          |
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