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INVEX THERAPEUTICS LIMITED (ASX:IXC)

In an enviable position, with ample working capital

Invex is in an enviable position, with ample working capital to see the company through the completion of phase 3 clinical trials, having achieved statistically significant results in both primary and secondary endpoints in phase 2 clinical trials. Subsequently, Invex raised A$26m in May 2020 on the back of these results and will proceed as a sole entity until the completion of phase 3 clinical trials, thus strengthening their value proposition pending favorable results. The company currently has a A$49m market cap (A$17m Enterprise value), with A$33m cash in the bank, whilst expensing A$400,000 per quarter. This is something not seen often, hence our interest.

What does Invex do?

Invex is a biopharmaceutical company focused on the repurposing of approved drug, Exenatide, for efficacious treatment of neurological conditions derived from, or involving raised intracranial pressure, such as Idiopathic Intracranial Hypertension (IIH), acute stroke, and traumatic brain injury. In essence, uncontrolled production of fluid in the brain (cerebral spinal fluid), leads to excess pressure that manifests into compounding migraines, putting pressure and compressing the optic nerve around the eye causing deterioration in vision, and in some cases, permanent loss of vision. Invex has trademarked repurposed Exenatide as Presendin™.

Interestingly, 90% (10% men) women are sufferers, and predominantly of child bearing age with no known cause. IIH is confirmed as having Orphan Drug status, a disease or disorder that affects fewer than 5 in 100,000 people (IHH 4.7 per 100,000). The symptoms of IHH are chronic and debilitating migraines, with 25% of sufferers experiencing a permanent loss of vision. Orphan drug legislation provides strong barriers disallowing any competitor the right to market an alternative treatment for seven and ten years, in the United States, and Europe respectively.

Currently there are no approved treatments for IIH, and no new drugs currently being tested in clinical trials, placing Invex in an attractive position to address a market with an unmet clinical need estimated to be worth US$1.6 billion, growing at 3.4% annually (Europe & U.S ex rest of the world).

Invex recently employed Megan Baldwin, CEO of Opthea Limited as a Non Executive Director, to assist with Invex's aspirations. Megan's achievements, growing Opthea into a A$500m market capitalisation company, illustrates a clear strategic benefit given her experience in ophthalmology.

Having achieved strong phase 2 clinical data, Invex has a defined regulatory pathway from the European Medicines Agency (EMA), providing guidance that a single successful phase 3 study will be satisfactory for commercial distribution. Currently Europe contributes 60% of the total addressable market, shared between the U.S and Europe. Invex has patents pending in both Japan and Europe, having been approved in the U.S.

As at April 2021 Invex filed, and received notification from the Food and Drug Administration (FDA), confirmation of a Type C meeting request where Invex will receive written responses to questions submitted by the company surrounding the proposed phase 3 trial design, and statistical analysis plan. Feedback is expected mid-June allowing Invex to ensure the FDA are satisfied with the phase 3 study approach before an Investigational New Drug application is submitted. It is unknown if the FDA will require multiple phase 3 trials, despite orphan status. Given IHH is a not a terminal condition, the FDA could request additional/ extended trials.

It is important to remember that Presendin™ is a repurposed molecule, currently sold as Exenatide in two formulations, Byetta and Bydureon for the treatment of type 2 diabetes by AstraZeneca, generating US$300-400m per annum. Whilst

patents are important, orphan drug status protects against AstraZeneca, (or anyone) competing over a 7-10 period (depending on jurisdiction).

Invex is yet to secure a long term product manufacturer to make the reformulation of Exenatide. This process is critical as the provider needs to be able to supply product for both clinical trials, and commercial production. Further, unit pricing and unit costs needs to be carefully balanced with the ability for customers to pay, coupled with a reimbursement scheme. The company states they are in advanced discussions with a handful of manufacturers.

In summary

As with all biopharmaceutical companies progressing through clinical trials, safety is paramount. As opposed to de novo drugs, Presendin™ (Exenatide) is a repurposed molecule which is administered subcutaneously (injection). Whilst Invex is required to perform minor tolerability and toxicology studies prior to IND application, neither is considered to be at risk of jeopardising the course of business, or the drug's safety profile, however not impossible. Progression of the above studies has been put on standby whilst the company works to lock in a long term supplier. Once confirmed, things begin to look interesting, as the company can ramp up all aspects of the business. The second half of calendar year 2021 could see a strong pipeline of news flow based on the above coming to fruition. Given the current market capitalisation, and the company's relatively low daily turnover, it wouldn't take much for the share price to break its sideways run, and move aggressively to the upside. We acknowledge timing is crucial, where expectations can often be misplaced, or in Invex's case mispriced. That being said, we believe Invex is fundamentally undervalued. For the patient investor who understands the highly speculative and binary nature of biotechnology, we believe value exists around current levels.

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