

Emerging Stocks Down Under

- Dante Alighieri (1265 - 1321), Author of the Divine Comedy



LEAF RESOURCES

Making moves

ORTHOCELL

Ready for takeoff

INVION

It just gets better and better

LEAF RESOURCES

Making moves

Stocks Down Under rating: ★ ★

ASX: LER 52-week range: A\$0.03 / A\$0.125

Market cap: A\$ 157M Share price: A\$ 0.097

Leaf Resources is a pine chemical manufacturer (yes, pine chemical) based in Maryborough, QLD. Since 1996, the company has been responsible for extracting, manufacturing and supplying various chemicals that are used in everything from car tires and disinfectants to inks and adhesives. The company has a special focus on the environment, making sure to employ environmentally friendly processes in its operations. Historically, the company has had trouble getting to profitability, but that might be about to change with a key acquisition!

READ MORE

ORTHOCELL

Ready for takeoff

Stocks Down Under rating: ★ ★ ★

ASX: OCC 52-week range: A\$0.32 / A\$0.66

Market cap: A\$ 101M Share price: A\$ 0.52

Orthocell is a commercial-stage regenerative medicine company operating out of Perth. The company developed CelGro for soft tissue repair and dental bone regeneration, Ortho-ATI for tendon regeneration and Ortho-ACI for cartilage regeneration. With a well-diversified portfolio of drugs at its disposal, we believe Orthocell is a company ready to make waves in the regenerative medicine space.

READ MORE

INVION

It just gets better and better

Stocks Down Under rating: ★ ★ ★

ASX: IVX 52-week range: A\$0.008 / A\$0.02

Market cap: A\$ 77.6M Share price: A\$ 0.013

Invion is a Melbourne-based life-sciences company currently developing IVX-PDT, a photodynamic therapy with applications in cancer treatment. IVX-PDT is based on the PhotoSoft technology, a photosensitiser that can potentially be used to treat skin, lung, prostate and ovarian cancer. With a significant advancement in the PDT space in recent years, Invion is in a prime position to capitalize on IVX-PDT, having the sole right to license and distribute the technology in Australia and New Zealand.

READ MORE

LEAF RESOURCES

Making moves

Stocks Down Under rating: ★ ★ ★

ASX: LER Market cap: A\$ 157M 52-week range: A\$0.03 / A\$0.125 Share price: A\$ 0.097

Leaf Resources is a pine chemical manufacturer (yes, pine chemical) based in Maryborough, QLD. Since 1996, the company has been responsible for extracting, manufacturing and supplying various chemicals that are used in everything from car tires and disinfectants to inks and adhesives. The company has a special focus on the environment, making sure to employ environmentally friendly processes in its operations. Historically, the company has had trouble getting to profitability, but that might be about to change with a key acquisition!

Share price chart



Source: Tradingview

Environment, environment, environment

Leaf Resources is primarily involved in the extraction of chemicals. It uses the Glycell process to extract sugars and related products (mainly cellulose and cellulosic fuels) from plants. Traditionally, these chemicals are extracted through steam explosions and chemical treatments. This is both bad for the environment and quite expensive.

The Glycell process, on the other hand, can break down plant biomass at a much lower temperatures through glycerol, which uses much less energy while simultaneously generating a higher yield of cellulose. Cellulose is converted into cellulosic sugars through a process known as enzymatic hydrolysis.

In 2020, the company acquired Essential Queensland, a Queensland-based pine chemical company. Leaf acquired the rights to Essential's proprietary natural organic solvent extraction technology (NOSE) through this acquisition.

NOSE is used to extract turpentine and rosin from pine trees. Traditional extraction methods are extremely expensive and require harmful chemicals, such as sulphuric acid or hexane. NOSE replaces this with an organic solvent that does not create any harmful by-products during the process. The company also ensures that only parts of trees that would otherwise be considered waste are used for extraction purposes, thereby further reducing its carbon footprint.

Leaf is extremely serious about its commitment to sustainability. Its practices actively encourage reforestation, as forest owners can be more productive with their wood and invest more in reforestation. The company envisions a fossil-free chemical industry. However, considering its past growth record, we don't expect to see that vision materialise anytime soon.

Moving toward greener pastures

Leaf is a company that has been around for over two decades. Formerly known as AquaCarotene Limited, the company was involved in the Bioenergy space, making use of proprietary technologies to extract chemicals from various materials.

The company's switch towards its current form began in July 2014, after a scoping study confirmed the commercial viability of the Glycell process. In October, the company formed a partnership with ZeaChem, the US-based chemical provider, to conduct further research into Glycell. The company also raised \$1.7m at \$0.15 per share to commercialise the technology.

In November, pulp produced through Glycell was deemed suitable for cardboard manufacture and the company's focus shifted to improving and commercialising its new technology. Finally, Leaf and ZeaChem signed an agreement in February 2016 to establish a collaborative project utilizing the Glycell process, with Leaf acquiring a 13% stake in its partner.

However, Glycell was still in its infancy and the company had to go through several institutional placements to fund its operations. That might be about to change due to two key reasons. The first is the acquisition of Essential Queensland in July 2020. This acquisition has allowed Leaf to diversify its offerings through NOSE and achieve a major milestone in its goal of becoming a global supplier of renewable chemicals.

The second is the construction of the Apple Tree Creek Plant, which was completed in March 2021. The plant has the capacity to produce 8,000 tonnes of pine chemicals per annum, but management has decided to increase its capacity to 16,000tpa due to strong demand. This expansion will be funded by Leaf's \$8m capital raise in July 2021. We believe this plant will serve as a steppingstone for the company to fossil-free chemical production worldwide.

On the right track

It seems that Leaf finally has all the necessary tools to become profitable. While the Glycell process was a major breakthrough, it was not enough on its own. The company needed multiple proprietary technologies with large commercial opportunities and we believe the acquisition of Essential Queensland has provided just that.

We expect revenues to consistently rise over the next few years with Leaf finally out of the research phase and in the commercialisation phase. The Apple Tree Creek Plant should help provide a sustainable source of revenue as the company continues to expand its portfolio of chemical extraction technologies.

More importantly, the company's Managing Director is Ray Mountford, responsible for NOSE and the founder of Essential Queensland. We believe that with Mountford at the helm, the company has an expert in chemical manufacturing guiding it. So even if Leaf fails to come up with new chemical extraction processes of its own, the company can acquire proprietary technologies to expand its business, just like it did with Essential Queensland.

Leaf Resources hasn't generated much revenues in the last twelve months, i.e. only around \$24,000, so there is a lot of work to be done. But with approximately \$8.7m in cash following the recent capital raise, we believe the company has sufficient runway to get to meaningful revenue levels.

However, at a market capitalisation of \$165m, we believe most if not all of that revenue potential is already factored into the share price. So, for now Leaf Resources a three-star investment in our book. We're neutral on the stock until the valuation comes down or revenues go up substantially, or both.

ORTHOCELL

Ready for takeoff

Stocks Down Under rating: ★ ★ ★

ASX: OCC Market cap: A\$ 101M 52-week range: A\$0.32 / A\$0.66 Share price: A\$ 0.52

Orthocell is a commercial-stage regenerative medicine company operating out of Perth. The company developed CelGro for soft tissue repair and dental bone regeneration, Ortho-ATI for tendon regeneration and Ortho-ACI for cartilage regeneration. With a well-diversified portfolio of drugs at its disposal, we believe Orthocell is a company ready to make waves in the regenerative medicine space.

Share price chart



Source: Tradingview

Generating new therapies

Orthocell listed on the ASX in 2014 and initially had two main products: Ortho-ATI and Ortho-CTI. Ortho-ATI was the company's lead product for tendon regeneration, with Ortho-CTI being developed for cartilage regeneration. Lastly, the company was in late-stage development for its tissue regeneration technology, called CelGro, with initial human trials underway.

Cartilage tissue is the main connective tissue in the human body and is widely found in joints and bones. Ortho-CTI uses healthy cartilage cells (by extracting healthy articular cartilage from the patient through surgery) and uses it to grow healthy tissue over five weeks. These cells are then deployed into the joint through surgery, where they begin to generate new cartilage, hopefully resulting in complete recovery of the joints over 6-9 months.

Ortho-ATI, on the other hand, is used to treat damaged tendons. It makes use of healthy tendons (using a sample extracted through a biopsy) to cultivate tendon cells in a lab. These cells are then injected into the affected tendon around 4-5 weeks after the biopsy using ultrasound guidance. By late 2015, Ortho-ATI was being used commercially and had already been used to treat over 300 patients.

Ortho-CTI also saw sporadic use in Australia and Southeast Asia. The company was granted patents in numerous jurisdictions, including the US, Australia and Hong Kong, for its various products during this time and continued to expand its clinical presence across Asia. In November 2015, Ortho-CTI was used for the first time on a patient in Singapore.

Trials and tribulations

Despite having access to early commercial opportunities, Orthocell continued to commission clinical trials for Ortho-ATI, mainly to determine its effectiveness against alternatives, such as surgery. One such trial began in July 2016, with results showing that Ortho-ATI was less invasive than traditional treatments (e.g., cortisol injections and physiotherapy) and showed significantly better results.

By the end of 2016, CelGro had also performed extremely well in early-stage clinical trials. It had shown safety and tolerability for being used as a barrier membrane to allow bone growth in dental applications and to treat full-thickness tendon tears.

November 2017 was a pivotal month for the company. Not only did Orthocell treat its 1,000th patient, but it also received CE Mark for CelGro. CE Mark is regulatory approval that allows the specified drug to be sold and marketed in the European Union. CelGro was used for the first time within the EU in May 2018.

Prior to that, in October 2016, the company received approval for a human nerve regeneration study using CelGro. The first results were published in May 2019, showing an 83% improvement in muscle power, which indicated that CelGro could be used to support nerve regeneration.

CelGro further showed an 89% success rate in tendon regeneration and a 96% success rate in nerve repairs in quadriplegic patients in later studies. All these successful studies and the various use-cases for CelGro implied a potential addressable market of over US\$2bn, which leads us to believe that Orthocell is not going to find it difficult to grow its business worldwide once approvals are in place.

In December 2020, Orthocell received market approval for CelGro in Australia for dental bone and tissue regeneration. Shortly after, the company received FDA 510(k) clearance, allowing Orthocell to market and supply CelGro in the US.

CelGrowing to profitability

As of now, CelGro has only obtained approval for a small percentage of its total use cases. We believe that as Orthocell continues to further research and trial its therapies, it will be able to address a much larger portion of the market.

The company is currently busy securing patents for CelGro in multiple jurisdictions. On top of that, Ortho-ATI and CTI continue to show extremely positive results when compared to traditional regenerative treatments.

We believe that Orthocell will continue to go from strength to strength as it further expands its operations and offers its treatments to more patients. This is evident in the company's financial performance as revenue increased 21% in 1HY21 (\$446,201) over the corresponding period and other revenues increased by 500% (\$228,664). With over \$17m in cash at the end of 1HY21, the company has financial runway for the two to three years. By that time, we believe Orthocell should be able to become profitable.

Keeping all these factors in mind, we think Orthocell is a four-star opportunity. While already having numerous products out in the market, we believe the company can leverage its current technology to address many other unmet needs in the regenerative medicine space. We expect Orthocell to continue to seek approval for other use-cases, such as nerve regeneration, vastly expanding its addressable market in the years to come.

INVION

It just gets better and better

Stocks Down Under rating: ★ ★ ★

ASX: IVX Market cap: A\$ 77.6M 52-week range: A\$0.008 / A\$0.02 Share price: A\$ 0.013

Invion is a Melbourne-based life-sciences company currently developing IVX-PDT, a photodynamic therapy with applications in cancer treatment. IVX-PDT is based on the PhotoSoft technology, a photosensitiser that can potentially be used to treat skin, lung, prostate and ovarian cancer. With a significant advancement in the PDT space in recent years, Invion is in a prime position to capitalize on IVX-PDT, having the sole right to license and distribute the technology in Australia and New Zealand.

Share price chart



Source: Tradingview

A change of heart

Invion was founded in 2000, originally focusing on the treatment of respiratory diseases. However, after unencouraging results, in 2017 the company began to transition to cancer treatment through a strategic alliance with the Cho Group, a Chinese investment conglomerate.

Cho initially acquired equity to the tune of 17.69% of existing shares through a placement at \$0.003 per share. The Cho Group would eventually increase its share in the company to 66%. Invion acquired a license for NGPDT technologies to treat all cancers in Australia and New Zealand from the Cho Group. The Cho Group also agreed to provide non-dilutive funding for research and the clinical trials of IVX-PDT.

PDT makes use of light-sensitive drugs. These drugs can be used to kill cancer cells without the side effects that are common for existing cancer treatment therapies.

While a plethora of companies are currently developing PDT for cancer treatment, a major breakthrough came relatively recently. TOOKAD, a PDT drug developed by Steba Biotech, gained approval to be marketed in 31 countries for the treatment of localized prostate cancer in November 2017.

Initially, Invion planned to focus on prostate cancer too. However, the company's lead candidate at the time (IVX-PO2) was being developed primarily for non-melanoma skin cancer. The drug being developed by Invion

was extremely similar to TOOKAD and TOOKAD's approval provides a lot of credibility to the use of PhotoSoft in cancer treatment.

In 2018 Invion finally began to show results, with IVX-PO2 showing considerable success in destroying ovarian cancer cells in an in vitro study. The study took place in collaboration with the Hudson Institute of Medical Research, a collaboration that continues to this day.

Potential, Potential, Potential

In May of 2019, Invion announced that IVX-PO2 had shown significant potential in treating metastatic cancer in animal studies. Metastatic cancer originates in one part of the body and then spreads to another and has proved troublesome for the life-sciences field.

By late 2019, IVX-PO2 had shown considerable potential in treating multiple types of cancer and the company signed a preclinical research agreement with the Peter MacCallum Cancer Centre to further develop its pipeline.

While Invion initially planned to commence clinical trials in 1HY21, further research in collaboration with the Hudson Institute revealed a much better Active Pharmaceutical Ingredient (API) that the company could use instead of IVX-PO2.

Titled INV-043, the new API has shown much better anticancer activity and cancer-targeting characteristics compared to Invion's previously developed APIs. Proof-of-concept studies showed that INV-043 had 50 times greater phototoxicity than earlier APIs. The company now plans to conduct extensive research to see how the immune system responds to INV-043 and whether it can work well with other therapies.

Following this discovery, Invion thought it better to study INV-043 more extensively before commencing with clinical trials. As such, we expect the company to commence Phase-I trials towards the end of 2021 or the beginning of 2022. Despite the delay, it will only strengthen Invion's position in our view. The company was already developing therapies that had shown to be quite effective in cancer treatment and INV-043 only makes the company's position stronger in that regard.

Great results, strong backing, and capable management

While the time to market for any of Invion's drugs cannot be determined right now, we believe the preclinical results point to a lot of positives for the company. We are especially pleased by the strong confidence that the Cho Group has shown. With a majority stake in Invion and the promise to fund any clinical trials, the company should have no trouble surviving the challenges ahead.

PDT is already a proven cancer treatment thanks to TOOKAD and Invion's pipeline seems to build on that extensively. For now, we wait for news about when the company plans to commence clinical trials and which API will be used in those trials.

With just over \$500,000 in cash and equivalents at the end of 1HY21, the company barely had enough to cover a few months of expenditures. However, Invion raised \$4.5m at \$0.014 per share in June this year to help the company get closer to its first clinical trial.

As such, we believe Invion is a four-star investment that carries significant risks, but is founded on innovative technologies that could lead to strong profits in the long run. If further data on INV-043 is positive and the company manages to get to the clinical stage, Invion could become the sole distributor of an innovative cancer treatment in Australia and New Zealand.

Pitt Street Research Pty Ltd

95 Pitt Street, Sydney, NSW 2000, Australia

Pitt Street Research Pty Ltd provides issuer-sponsored research for Small & Mid Cap companies and is founded on more than 40 years of combined experience researching companies in a range of different sectors.

You are receiving this email because you subscribed to our Stocks Down Under newsletter.

All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior written permission from Pitt Street Research Ltd Pty. All intellectual property relating to the Content vests with Pitt Street Research unless otherwise noted.

Stocks Down Under (Pitt Street Research AFSL 1265112) provides actionable investment ideas on ASX-listed stocks. The Content has been prepared for general information purposes only and is not (and cannot be construed or relied upon as) personal advice nor as an offer to buy/sell/subscribe to any of the financial products mentioned herein. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content. Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of market and economic factors, and you should always obtain professional advice to ensure trading or investing in such products is suitable for your circumstances, and ensure you obtain, read and understand any applicable offer document.

