

# Investment opportunity in a potential future blockbuster cancer drug

*FivepHusion - optimising cancer therapeutics to improve patient treatment outcomes and quality of life*

## OUR COMPANY

FivepHusion was established in 2018 and is headquartered in New South Wales, Australia. The Company is focused on the commercialisation of a novel advanced clinical-stage drug co-formulation that enhances the effect of chemotherapy in the treatment of a range of adult and childhood cancers. FivepHusion's goal is to deliver a product that will be progressively adopted as the 'gold standard' for the treatment of solid tumours by oncologists around the world - with associated potential revenues peaking at USD >1+ billion per annum.

The outcome of initial patient trials of FivepHusion's first product, Deflexifol®, has confirmed it has the potential to provide oncologists with an enhanced treatment option for the lead indication, metastatic colorectal cancer (mCRC).

## THE PROBLEM WE SOLVE

The increasing worldwide cancer prevalence is a result of population aging and expansion and changes in individuals' exposure to risk factors. For some decades, the backbone treatment for hard-to-treat cancers has been based on the administration of 5-fluorouracil (5-FU) with its biomodulator, leucovorin (LV). Currently, due to the chemical incompatibility of standard formulations, oncologists serially administer these two agents, leading to adverse side effects, sub-optimal tumour co-exposure and limited efficacy.



In the case of mCRC, FivepHusion's initial target indication, the best clinical practice produces a tumour treatment response in only ~55% of patients, with a typical life expectancy of 20-30 months.

## OUR SOLUTION

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Deflexifol® is an 'All-in-One' co-formulation of 5-FU and LV which addresses the significant limitations with current treatment, offering a "best in class" therapy and demonstrating greater safety, tolerability and superior efficacy. Initial trials suggest response rate improvements and the extension of patient life expectancy. Deflexifol® optimises 5-FU/LV administration and offers a 10-fold increase in 5-FU/LV co-exposure, and greater patient tolerability allows for a 40+% increase in 5-FU dosing, which may further improve patient outcomes.

## INVESTMENT HIGHLIGHTS

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Deflexifol® has the potential to become a 'blockbuster' drug and represents a compelling investment opportunity.

- Deflexifol® is positioned to become the new 'go-to' standard of care for the treatment of mCRC patients.
- Developmental and regulatory risks for Deflexifol® as an optimised formulation are low, particularly in comparison to a typical New Molecular Entity.
- FivepHusion has established strategic collaborations with:
  - Syneos Health: A global contract research and commercialisation services company.
  - Pfizer CentreOne: A global contract development and manufacturing company.
  - Allarity Therapeutics: A US/Danish clinical-stage "precision oncology" company actively advancing in-licensed oncology therapeutics.
- These alliances provide FivepHusion with access to the global expertise, resources, capabilities and technology to accelerate development of Deflexifol®, and resources de-risking commercialisation.
- FivepHusion is further mitigating commercial risks by commencing the design of a Phase III registration trial that will facilitate a low hurdle to approval.
- Composition of Matter IP granted.
- Patent pipeline and market protection to >2044.
- Peak sales potential USD 1B (for mCRC indication only).
- Limited competition. Few novel treatments, including those in development, have the potential to displace 5-FU for the first-line treatment of solid tumours.
- KOLs confirm most oncology practices would adopt a novel formulation with the anticipated benefits of Deflexifol® within two years of its planned launch in 2028.
- Safety and efficacy improvements underpin the justification for pricing Deflexifol® at a premium over current 5-FU/LV based treatments.

## WHERE ARE WE AT?

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Deflexifol® has demonstrated promising results across two Phase I/II clinical studies in end stage patients with a range of solid tumours, including metastatic colorectal cancer. Most of these patients had already failed prior 5-FU and other therapies.

The superior tolerability of Deflexifol®, with fewer side effects, allowed it to be administered at a >40% higher dose than standard 5-FU treatment.

## OTHER DEVELOPMENT OPPORTUNITIES

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In addition to the primary focus on the commercialisation of Deflexifol® for mCRC treatment, FivepHusion is developing a pipeline of related business opportunities.

- Deflexifol® has the potential to be approved for the treatment of all cancers currently treated with standard 5-FU/LV, such as breast, gastric and pancreatic cancers. FivepHusion is also leveraging Deflexifol's unique attributes to investigate new 5-FU/LV uses, including the treatment of paediatric brain cancers.



- An ongoing Phase Ib/IIa brain cancer trial, involving all major Australian paediatric oncology centres, is generating encouraging results.
- Finalisation of the right to commercialise the ResectAssist™ platform technology developed by the University of Wollongong. ResectAssist™ is a biodegradable drug delivery device which can be implanted directly into a tumour with the expectation that drug uptake will be increased by several fold, with an associated increase in response rate and safety outcomes. ResectAssist™ can deliver a variety of cancer drugs and is expected to be useful for a range of tumour indications. A phase 1b clinical trial in pancreatic cancer is planned to commence in late 2025 / early 2026.

# THE MARKET

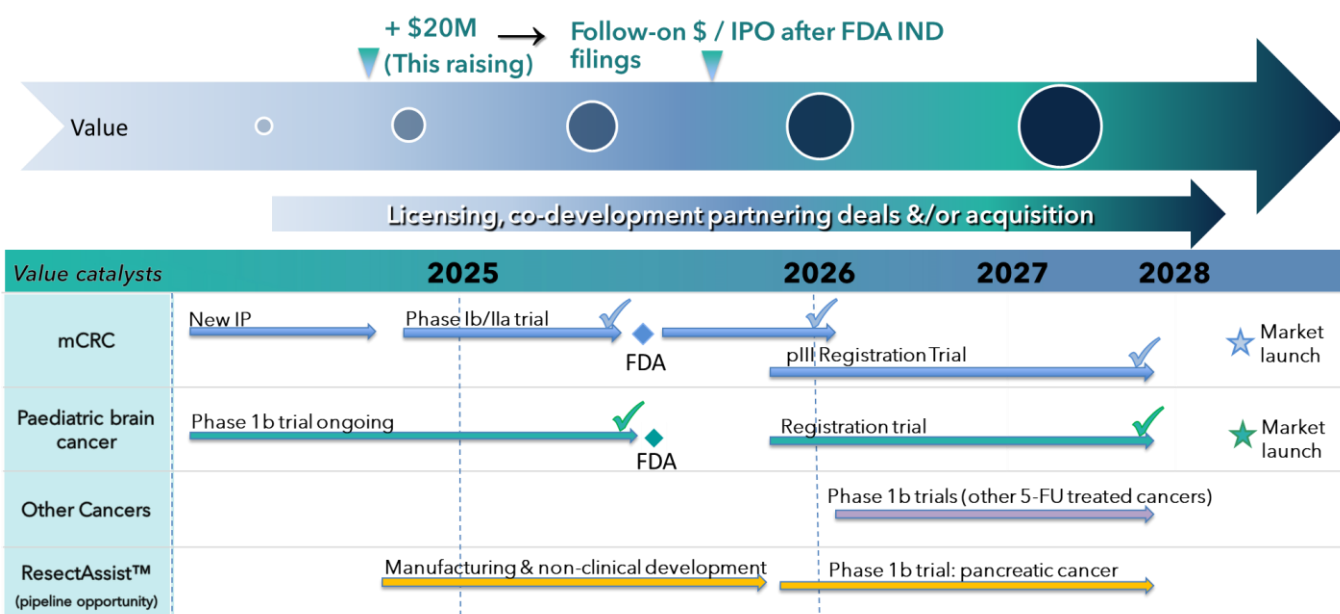
Globally, colorectal cancer is the third most diagnosed cancer in men and the second most in women. An average of ~95% of mCRC patients are treated with 5-FU/LV. The progressive global adoption of Deflexifol® as an improved treatment regime for mCRC, following its planned commercial launch in 2028, is anticipated to deliver sales revenues exceeding USD 500 million by 2030 building over time to a peak approaching USD 1+ billion. These projected revenues will be supplemented as applications of Deflexifol® for the treatment of additional indications are approved.

# INTELLECTUAL PROPERTY

FivepHusion owns granted composition of matter patents for Deflexifol® in the major markets of Australia, United States, Canada, United Kingdom, France, Germany, Italy, Spain, China and India. A new composition of matter patent is in preparation for filing this year and will provide enduring exclusivity and barriers to competition until >2044.

Deflexifol® is additionally protected by a national phase patent family claiming methods of use in brain cancer in these and other major markets.

# TIMELINE TO MARKET - VALUE CREATION



All development steps and timelines are indicative.



## OUR PEOPLE

FivepHusion is led by an exceptional board and management team supported by experienced clinical, regulatory, manufacturing and commercialisation advisory teams. The FivepHusion Board consists of the following experienced biotechnology executives:

- Chairman: **David Ranson**, BEng (Hons), is a serial entrepreneur and has been a director of several research and development focused companies over the past 33 years.
- CEO & Managing Director: **Dr Christian Touli**, BTech (Hons) PhD GAICD, is a motivated and resourceful biotechnology executive, dedicated to the development and commercialisation of breakthrough medicines for patients and to creating value for shareholders. He has over 23 years' experience in cancer research, drug development and biotechnology business development, with broad transactional experience.
- Executive Director: **Dr Bill Ketelbey**, MBBCh FFPM MBA GAICD, is a highly experienced and successful executive in the healthcare and pharmaceutical sector, with more than 30 years' experience leading the development of numerous drugs across a broad range of therapeutic areas.
- Non-Executive Director: **Iain Ross**, BSc Hons, CDir (IoD), has over 40 years' experience in the international life sciences and technology sectors. He is currently Chairman of Silence Therapeutics Plc (NASDAQ:SLN)), and has held significant roles in multi-national companies including Sandoz, Hoffman La Roche and Celltech Group plc.

Additionally, FivepHusion's Founder Advisory Board and collaborators represent an experienced multidisciplinary team in cancer research, chemistry, oncology treatment and clinical trials, and are well placed to support the ongoing development and commercialisation of Deflexifol®.



**David Ranson**  
Executive Chairman

BEng(ElecEng)



**Dr. Christian Touli**  
CEO & Managing Director

Btech Hons; PhD; GAICD



**Dr. Bill Ketelbey**  
Executive Director

MBBCh; FFPM; MBA; GAICD



**Iain Ross**  
Non-Executive Director

BSc Hons; CDir (IoD)



## THE INVESTMENT

FivepHusion is seeking investment of up to A\$20 million in new equity funding to support the on-going development and commercialisation of Deflexifol®.

A follow-on/IPO capital raise is planned for late 2025 / early 2026 following the receipt of FDA (and other regulatory agency) Investigational New Drug (IND) designations for the treatment of 1st-line mCRC and paediatric ependymoma. The INDs will enable commencement of registrational trials leading to a commercial launch of Deflexifol® anticipated in 2028.

## HOW WE WILL SPEND THE FUNDS

The proceeds from the current funding round will be applied to:

- Preparation for mCRC and paediatric brain cancer registration trials
- Undertaking Phase Ib/IIa mCRC & paediatric brain cancer trials.
- Scale up GMP manufacturing.
- Gaining global regulatory agency IND approvals – both indications.
- Development of pipeline opportunities including new indications treatable by Deflexifol® and the ResectAssist™ platform technology.
- Pre/post registration planning including health economics, pricing, reimbursement and refinement of sales strategies.
- Preparation of FivepHusion for a planned IPO in late 2025 / early 2026.



Detsamma Investments Pty Ltd trading as FivepHusion.

Website: <https://fivephusion.com/>

