



Investor Presentation
BioShares 2026 - Update

NEXT-GENERATION CANCER THERAPEUTICS

ADDRESSING CLINICIAN NEEDS, FOR THEIR PATIENTS

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NEXT-GENERATION STANDARD OF CARE (SOC)

Optimising 5-Fluorouracil (5-FU) clinical activity to generate superior treatment outcomes

5-FU
(in various
combinations)

- **A standard of care (SOC) for cancers with >8m patient incidence**
- Colorectal (CRC), pancreatic, head & neck, gastric, breast etc....

SOC
but Sub-Optimal

- **Limited efficacy due to chemical incompatibility of its biomodulator leucovorin (LV)**
- New drugs are typically added onto this sub-optimal backbone therapy

Clinical
Opportunity

- **Optimise 5-FU to increase safety & efficacy for existing indications**
- **Exploit advantages to repurpose for strategic opportunities**

**GLOBAL
BLOCKBUSTER
MARKET**

- **Next generation backbone therapy for existing and new cancers**



STRATEGY: (1) Exploit fast-to-market repurposing for paediatric ependymoma

(2) Leverage into larger metastatic colorectal cancer backbone therapy opportunity

A novel & optimised therapy

- Superior co-formulation of **5-fluorouracil (5-FU)** & its biomodulator **leucovorin (LV)**
- **Maximised synergy** achieving greater safety & potency

Broad therapeutic utility & market opportunities

- Priorities:
 - **paediatric ependymoma (brain) cancer (FIRST-IN-CLASS)**
 - **1st line metastatic colorectal cancer (BEST-IN-CLASS)**
- **Significant upside** potential in 5-FU treated tumours
 - pancreatic, gastric, head & neck & breast (BEST-IN-CLASS)

Clinically advanced, technically & commercially low risk

- **3 phase I clinical studies successfully completed (Total N = 68)**
 - **Greater safety, tolerability & efficacy**
- **5x independent surrogate phase II trials**
 - **Greater response rate and survival in mCRC**
- Fast-tracked, low-risk 505(b)(2) regulatory pathway
- Low-cost, scalable manufacture with Pfizer
- **Peak sales estimate \$1.8B (conservative priority + upside)**
- **Composition of matter IP + patent pipeline exclusivity to 2046**

Update



pll ependymoma trial launch (Aug 2026)

REPURPOSING FOR PAEDIATRIC EPENDYMOMA

A leading drug candidate for a significant unmet medical need

PAEDIATRIC EPENDYMOMA

- **The third most common brain cancer in children**
- 4 per million incidence; peak <4 years of age

CURRENT TREATMENT

- **No approved drug therapies**
- Surgical resection and adjuvant radiotherapy

5-FU RATIONALE

- **Off-label compassionate use**
- **Sensitisation via frequent chromosome 1q+**

(PRECEDENT) ST JUDE 5-FU PHASE I TRIAL¹

- **A 48% disease control rate** (5/23 PR and 6/23 SD)
 - Maximum tolerated dose: **400 mg/m² bolus dose**
 - Minimum effective dose: **500 mg/m² bolus dose**



¹Wright et al. 2015, *Neuro Oncol.*, 17(12):1620-27

5-FU ACTIVITY BUT NO SAFE THERAPEUTIC DOSE

Promising mechanism, growing pre-clinical & clinical data set, but limited utility in current formulations

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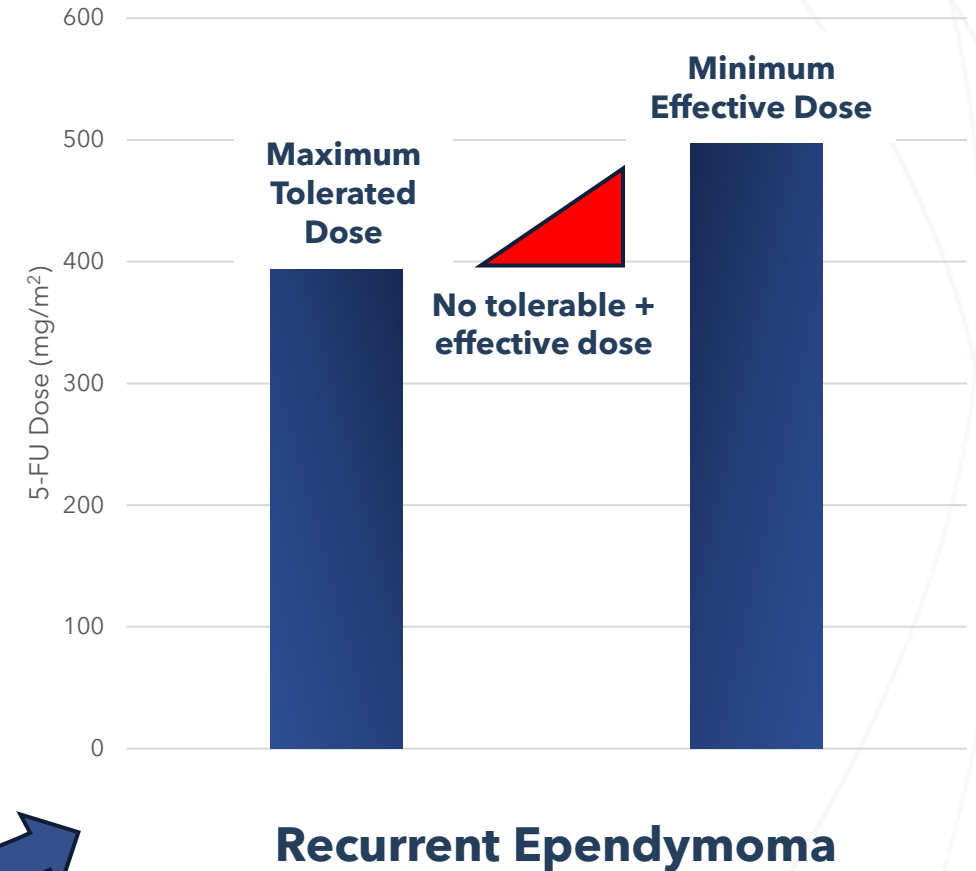
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5-FU has no therapeutic window



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DEFLEXIFOL®: FIRST FOR PAEDIATRIC EPENDYMOMA

Exploiting greater potency & improved safety & tolerability

Phase I/II Deflexifol® at Relapse Trial (DART)

Phase I: Various brain cancers - SUCCESSFULLY COMPLETED

- N = 9: ependymoma (n=6), DMG (n=2) and ETMR (n=1)
- MTD - 525mg/m² bolus + 3000mg/m² infusion
 - **Deflexifol® : ~9x St Jude phase 1 MTD**

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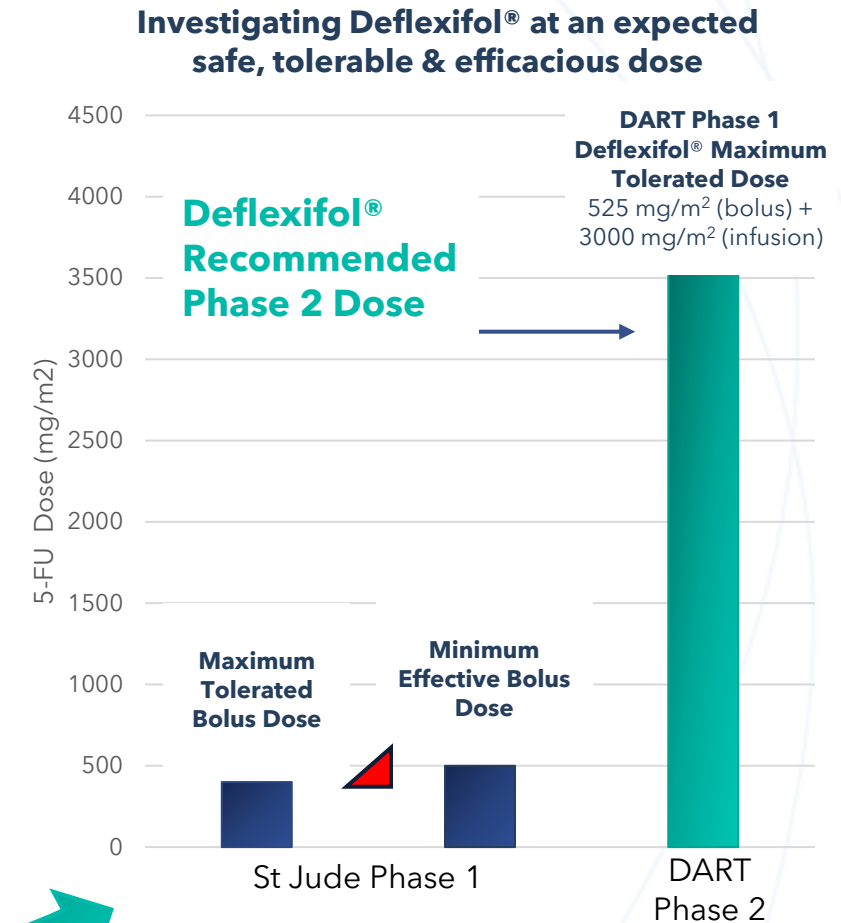
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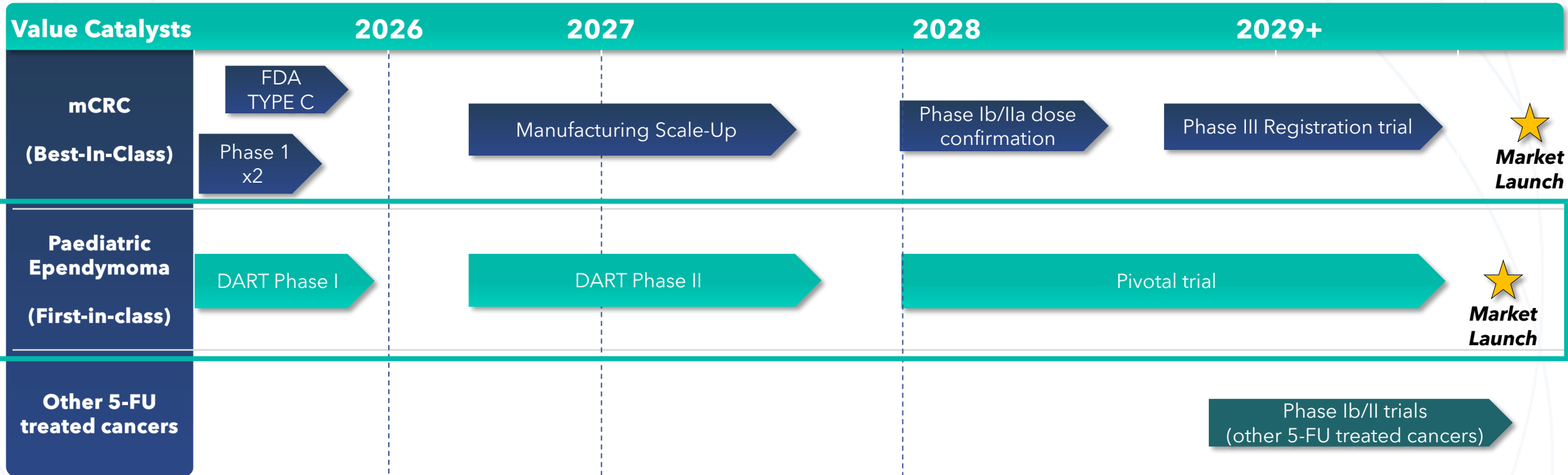
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Phase II: Recurrent or refractory ependymoma

- N = 10, 7 evaluable patients to be recruited (3 evaluable from Phase I)
- Response, survival and safety endpoints
- Eight clinical sites around Australia
- **Estimated top-line data H2 2027**



VALUE CREATION STRATEGY – ACCELERATE TO PIVOTAL TRIAL



Recent Paediatric Brain Cancer Deal Precedents

Licensing, partnering deals &/or acquisition

Date	Type of Deal	Acquirer/Licensee	Target/Licensee	Stage	Upfront (US\$)	Milestones (US\$)	Total Deal Value (US\$)
Mar-25	Acquisition	 Jazz Pharmaceuticals	 CHIMERIX	Phase 3	\$935m	-	\$935m
Jul-24	Licensing Agreement	 IPSEN	 Day One BIOPHARMACEUTICALS	Phase 3	\$111m	\$350m	\$461m
Mar-26	Acquisition	 SERVIER	 Day One BIOPHARMACEUTICALS	Commercial	\$2,500m		\$2,500m

EXPERIENCED LEADERSHIP & STRATEGIC PARTNERS

Established highly experienced Board, Management and Advisory Teams

Board



David Ranson

Executive Chairman
BEng(ElecEng)



Dr. Christian Tooли

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)

Strategic Collaborations



Independent Clinical Advisory Board

Advising on the clinical strategy and trial design for Deflexifol® registration for use in adult cancers



Prof. Stephen Clarke
OAM

Chairman



Prof. John Simes
AO



Prof. Andrew McLachlan
AM



Prof. John Zalcborg
AO



Founder Advisory Board

Inventors of Deflexifol® contributing expertise to ongoing development



Prof. Philip Clingan
OAM



Senior Prof. Marie Ranson



Emeritus Prof. John Bremner
AM

FivepHusion's strategy presents a unique and compelling risk-reward profile

Multiple Blockbuster Markets

- **Paediatric ependymoma - Part of the US\$1.32B paediatric brain cancer market** - rapid path to additional indications
- **Metastatic colorectal cancer (mCRC)** ≤570k patient incidence = **US\$13B mCRC market**
- **8.0m+ solid tumour diagnosed p.a.** (where 5-FU + LV are utilised)

Deflexifol® First-In-Class & Best-In-Class

- **Aiming to be the first approved therapy for paediatric ependymoma**
- 5-FU + LV: Established standard of care' backbone therapy for mCRC (95% of patients).
- **Aims to replace current 'standard of care' (SOC) backbone therapy**

Strong economics

- **Premium pricing** potential vs. generics, **driven by superior safety and efficacy**
- **Rapid uptake** - KOLs believe **Deflexifol®** would be **widely adopted within 2 years** of clinical validation and launch
- Conservative Modelling suggests **peak sales ~\$1.8B+** (multiplies on higher pricing)

Clinically Validated

- 3x company clinical trials demonstrated **higher safety & tolerability** and **potent efficacy**
- Current clinician 5-FU off-label use to treat ependymoma
- 5x independent surrogate Phase II trials confirm rationale and therapeutic mechanism

Fast-tracked & Capital-Efficient

- Paediatric ependymoma - fast-tracked orphan indication; exploiting poor therapeutic window for 5-FU
- **Active Phase II paediatric ependymoma** trial moving towards a pivotal trial
- Fast-tracked development via 505(b)(2) pathway for 5-FU-treated cancers **enabling faster, lower cost approval**
- Rare in oncology: **Deflexifol® is a 'next generation' superior co-formulation** (with composition of matter patents),

Significant Pipeline

- **Broader applications where 5-FU + LV are utilised:** pancreatic, gastric, breast, head & neck cancers

IP Protection

- **Granted Composition of Matter patents and pipeline**, expected **exclusivity to 2046**

Licensing Transactions

- Clear, short-term pathway to **regional and global licensing transaction opportunities with lucrative deal precedents**

Millions of cancer patients are
treated with chemotherapy
unchanged since last century

FivepHusion **is optimising**
treatment safety and efficacy,
& **unlocking multi-billion-**
dollar commercial
opportunities

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