# B SYNT∧R∧<sup>™</sup>

Bioshares

Gary Phillips, CEO

August 7<sup>th</sup> 2025



# Forward looking statement

This document contains forward-looking statements, including statements concerning Syntara's future financial position, plans, and the potential of its products and product candidates, which are based on information and assumptions available to Syntara as of the date of this document. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forwardlooking statements. All statements, other than statements of historical facts, are forward-looking statements.

These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. For example, despite our efforts there is no certainty that we will be successful in developing or partnering any of the products in our pipeline on commercially acceptable terms, in a timely fashion or at we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.



# Investment Highlights





Australian-founded clinical stage drug developer.



Backed by specialist healthcare investors – 49% institutional.



Focus on first-in-class and best-in-class drugs backed by in house long-life patent portfolio.



Funded to mid-2026 with near term data to drive value over the next 12-18 months.



Multiple shots on goal from additional Phase 2, Phase 1 and preclinical assets.



Experienced team with **proven track record** in licensing deals – \$100m raised.



Three Phase 2 studies in **blood cancer indications** with addressable market value >\$4.5 bn.



**\$8.5m in non-dilutive** grant funding awarded in last 3 years.



Positive Interim data update from ongoing phase 2 blood cancer trial reported in June 2025

Interim data reported June 2025 from Phase 2 clinical trial of amsulostat (SNT-5505) in treatment of blood cancer myelofibrosis, at 2025 European Hematology Association Meeting.

## Shareholders & Cash



Financial Information (ASX: SNT)	
Share price – 21 July 2025	\$0.055
Market cap	A\$89.4m
Cash balance (30 Mar 2025)	A\$18.0m
Enterprise value	A\$71.4m

Institutional Ownership	30 June 25
D&A Income Limited	18%
Platinum Investment Management Limited	11%
Total Institutional Ownership	> <b>48.6</b> %



<sup>\* 21</sup> May 2025 recorded volume was 303,525,200 due to internal crossing of stock by substantial holder (maintains same beneficial owner)

 $<sup>\</sup>ensuremath{^{**}}$  19 June 2025 recorded volume was 127,701,110 due to block trade of shares between institutions

# Myelofibrosis

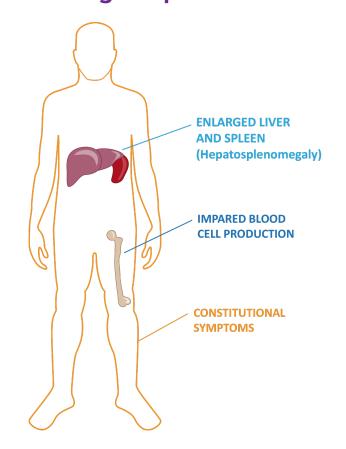


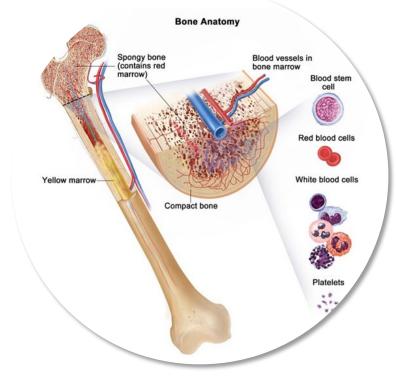
# A rare type of bone marrow cancer that disrupts the body's normal production of blood cells

### **Key Facts**

- Orphan disease affects ~15 in 1m people worldwide (USA ~ 20,000 patients)
- Age of onset typically from age 50;
   5 years median survival
- 11% transformation to leukemia
- Reduced red blood cells can cause extreme tiredness (fatigue) or shortness of breath
- Reduced white blood cells can lead to an increased number of infections
- Reduced platelets can promote bleeding and/or bruising
- Enlarged spleen due to insufficient healthy blood cell production from the bone marrow causing abdominal pain
- Other common symptoms include fever, night sweats, and bone pain

Myelofibrosis characterised by a build up of scar tissue (fibrosis) in bone marrow and abnormal proliferation of blood precursor cells reducing the production of blood cells





# Myelofibrosis

### 8 SYNTARA

## **Limited treatment options currently**

### **Current standard of care (SoC): JAK inhibitors**

• Class of drugs used in the management of splenomegaly (enlarged spleen) and other constitutional symptoms



- Symptom improvement assessed using patient reported questionnaire that provides
   Total Symptom Score (TSS)
- CT or MRI scan used to measure spleen volume reduction (SVR)

### **JAK inhibitors have significant limitations**

- Offer limited survival benefits and are associated with significant dose-limiting tolerability issues including cytopenias and increased risk of infection
- 75% discontinuation at 5 years
- Median overall survival only 14 16 months after discontinuation

### **Amsulostat (SNT-5505)**

In contrast to SoC, amsulostat intervenes at the source, clearing fibrosis from the bone marrow and reducing growth factor activity; thus enabling increased production of healthy blood cells

### Clinical positioning:

- ✓ Distinct mode of action
- ✓ Improved tolerability
- ✓ Profile suitable for combination with SoC
- In addition to symptomatic relief, potential for disease modification.

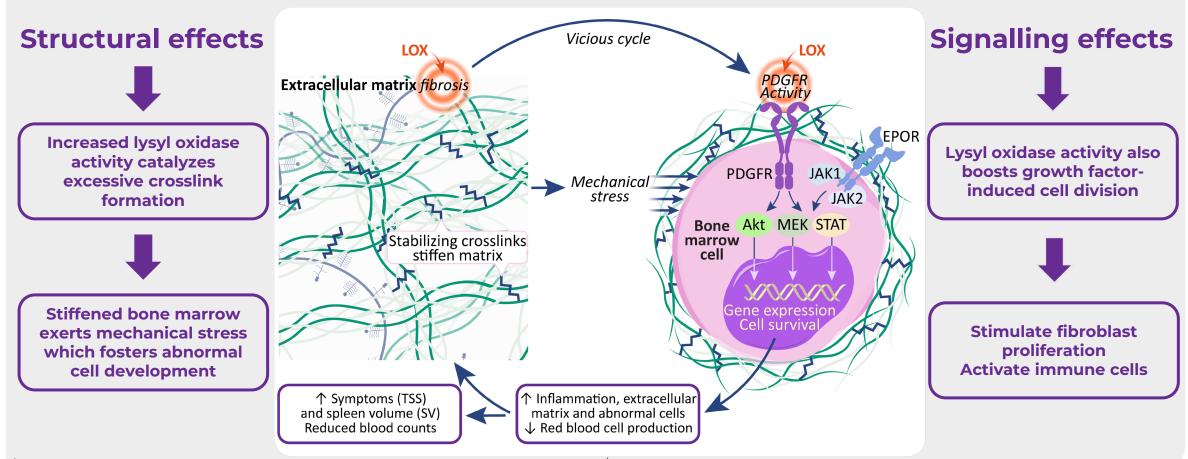
# Commercial Opportunity

- Current SoC; revenue ~US\$1.9b per annum
- Recent biotech exits after Phase 3 in excess of US\$1.7b

# Lysyl Oxidases in Myelofibrosis

## Amsulostat designed to improve the bone marrow microenvironment

Lysyl oxidase gene family upregulated in the bone marrow (BM) of myelofibrosis patients;
 increased lysyl oxidase activity adversely impacts BM health in several ways<sup>1</sup>



### Amsulostat Trial: Add-On



### MF-101 Add-on to RUX (study in progress, NCT4676529)

 This add-on phase aims to further evaluate the safety and efficacy of amsulostat (200 mg BID) in patients with MF on stable background regimens of ruxolitinib (RUX) over a 52-week period

#### STUDY POPULATION **DESIGN ENDPOINTS PRIMARY** DIPSS Int-2/high risk PMF or Phase 2a open label study to evaluate Safety TEAEs Post-ET/PV MF safety, PK/PD, and efficacy BMF grade 2 or higher **SECONDARY** Symptomatic disease (≥ 10 on the Symptom score\* MFSAF v4.0) Spleen Volume Reduction (SVR) TREATMENT COHORT Treated with RUX > 12 weeks Platelet response (stable background dose for ≥ 8 RUX dose modifications Amsulostat 200 mg BID + stable dose of weeks) and not achieved PK/PD RUX, n = 15 (planned)complete response (CR) by IWG Changes in BMF Grade\*\* Treatment for 52 weeks or until disease criteria IWG Response progression, unacceptable toxicity or dose limiting toxicity

Interim data (extract 5 May 2025); data not available for all endpoints

<sup>\*</sup>MFSAF v4.0 (Myelofibrosis Symptom Assessment Form v4.0; 7-day recall), assessed at baseline (BL), weeks 12, 24, 38 and 52

\*\*Bone marrow biopsy within 3 months prior to Day 1 treatment; bone marrow biopsies scheduled at baseline, weeks 12, 24 and 52

BMF: bone marrow fibrosis; DIPSS: Dynamic Dynamic International Prognostic Scoring System; IWG: International Working Group; PK/PD: pharmacokinetic/pharmacodynamic; PMF: primary myelofibrosis; Post-ET: post-essential thrombocythemia; PV: post-polycythemia vera; TEAE: treatment emergent adverse event





## Comparable open label Phase 2 studies for drugs under development

	Latest	Phase 2 Open Label Trial results in Suboptimal Patient Population					
Drug	Program Status	N	Baseline Characteristics (median, range)	Safety Grade 3/4 events ≥ 10%	TSS50	SVR25	SVR35
Pelabresib <sup>1</sup>	P3 naïve MF completed		Not reported	Thrombocytopenia 33% Anemia 19% Increased blast phase progression <sup>4</sup>	37% (30/81) at W24	27% (22/81) at W24	20% (16/81) at W24
	Not pursuing suboptimal indication	86		All grade diarrhea (35%), constipation (25%), nausea (24%), abdominal pain (23%). Managed with standard prophylaxis	Not reported at W48	Not reported at W48	20% (16/80) at W48
Navtemadlin 2	P3 suboptimal recruiting	28	RUX duration: 21.6 mths (7-129) SV: 2039 mL (650-3549) TSS: 15 (2.2-49.1)	Thrombocytopenia 28% Anemia 18% All grade diarrhea (64%) and nausea (68%); require anti-diarrheal and anti- emetic prophylaxis in P3	32% (6/19) at W24	42% (8/19) at W24	32% (6/19) at W24
Navitoclax <sup>3</sup>	P3 suboptimal completed accrual	34	RUX duration: 19 mths (4.4-71) SV: 1695 mL (465-5047) TSS: Not reported	Thrombocytopenia 56% Anemia 32% Pneumonia 12% Dose reduced 76% (Navitoclax), 68% (Rux) mainly due to AEs	26% (9/34) at W24	35% (12/34) at W24	26% (9/34) at W24 24% (8/34) at W48



## **Baseline Characteristics**

### Heterogenous population with a high disease burden

- Patients (pts) in the trial had been on RUX for an average of three years, with symptom scores, spleen sizes and blood counts indicative of high disease burden
- Study is ongoing data extracted 5 May 2025
  - 13 pts reached 12 weeks
  - 11 pts reached 24 weeks
  - 8 pts reached 38 weeks
  - 5 pts reached 52 weeks (completed) and 3 pts scheduled to complete Q3, 2025
- Withdrawal rate consistent with other MF studies of pts with similar disease severity
  - Pts who discontinued had on average longer time on RUX, more likelihood of disease progression

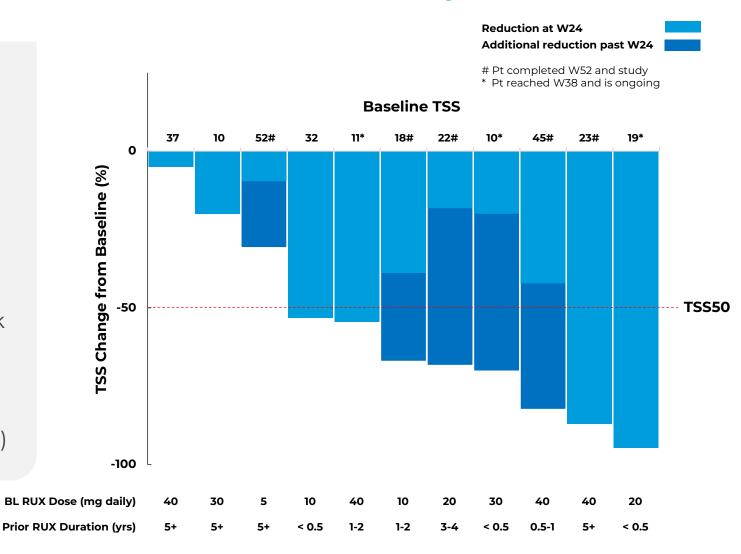
Characteristic	N=16
Age, median (range), years	71 (46-82)
Sex, male, n (%)	7 (44)
Time since MF diagnosis, median (range), months	60 (7–135)
Diagnosis, n (%)	
Primary MF	7 (44)
Post-PV MF	7 (44)
Post-ET MF	2 (13)
Prior RUX therapy (months), median (range)	38 (5–89)
Daily RUX dose (mg), median (range)	20 (5–40)
MF-SAF v4.0 TSS score, median (range)	23 (10–52)
DIPSS, n (%)	
Intermediate-2 High-risk	12 (75) 4 (25)
JAK2 V617F mutation, n(%)	11 (69)
≥1 High Molecular Risk (HMR) mutation, n (%)	7 (44)
Transfusion dependent (TD), n (%)	2 (13)
Hb, median g/L (range)	93 (66-132)
Platelet count, x10 <sup>9</sup> /L, median (range)	116 (18-329)
<del></del>	

# Total Symptom Score



### 73% (8/11) of patients achieved TSS50 at Week 24 or beyond

- At Week 24
  - Median absolute change -6 (range -2 to -20)
  - Median % change -39% (range -5% to -95%)
  - 4/11 pts achieved TSS50
- In the 8 pts continuing past Week 24
  - 3 pts already achieved TSS50 at Week
     24
  - 4 additional pts achieved TSS50
  - 1 pt had further improvements past
     Week 24 (but < 50% reduction overall)</li>

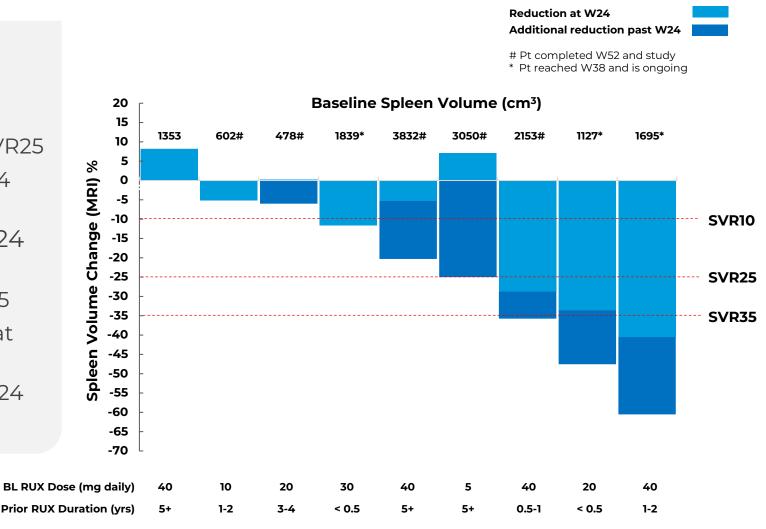


# Spleen Volume Reduction



### 44% (4/9) of patients achieved SVR25 at Week 24 or beyond

- At Week 24
  - 2/11 pts not evaluable for SVR (SV < 450 cm<sup>3</sup>, RUX discontinued)
  - 3/9 evaluable pts (33%) achieved SVR25
  - 1 pt discontinued just after Week 24
- In the 8 pts continuing past Week 24
  - 3 pts with SVR25 at Week 24 had further reductions, achieving SVR35
  - 2/8 pts with no or small reduction at Week 24 had larger reduction
  - 1/8 pts had increase in SV at Week 24 but achieved SVR25 after Week 24



# Strong interest in MF assets from strategics



**Target / Acquiror** 









Date of Announcement	Dec-2024	Feb-2024	June-2023	July-2022	
Drug Name	Elritercept	Pelabresib	Pacritinib	Momelotinib	
Lead Indication / Phase (at transaction)	MDS and MF (ongoing Phase 2 trials)	Myelofibrosis (successful Phase 3 studies)			
Deal Type	License	Acquisition	Acquisition	Acquisition	
Upfront / Milestones (US\$)	US\$200M / US\$1.1B	US\$2.9B	9B US\$1.7B US\$1.9E		
Earnout Payments / Royalty Rate (%)	Not disclosed	Subject to regulatory approvals	None None		

Attractive commercial outcomes for drugs with Phase 2 and 3 data expected to drive interest in amsulostat Phase 2 data

### Conclusions



Interim data<sup>1</sup> suggests that amsulostat combined with ruxolitinib may deliver deep and long-lasting benefit to patients who are sub-optimally controlled on ruxolitinib alone

Consistent with monotherapy data<sup>2</sup>, amsulostat is safe and well tolerated in combination with RUX in a broad population with high disease burden

Despite the relatively small sample size the absolute improvement in symptom score and the number of patients who achieve a TSS50 is very encouraging

Reductions in symptoms and spleen volume that continue to improve over time is a novel finding that indicates amsulostat has the potential to provide a significantly different and well tolerated treatment option for patients on a JAK inhibitor

Remaining 3 patients in study scheduled to complete 12 months treatment in Q3 2025.

FDA guidance on progression to pivotal study sought by Q3 2025.

Encouraging interim Phase 2a data sets amsulostat on a clear clinical and regulatory pathway to commercial value

# Targeting Multiple Near Term Opportunities In High Value Markets

Drug Candidate	Indication	Phase	Anticipated Upcoming Milestones	Addressable market (US\$)
Amsulostat	Myelofibrosis	Phase 2	Interim 12 month data June 2025	~\$1 billion¹
Amsulostat	Myelodysplastic Syndrome Low & intermediate Risk + High risk trials	Phase 1c/2	Interim Data H1 2026	~\$3.2 billion²
SNT-9465	Hypertrophic Scars	Phase 1a/b	Data H1 2026	~\$3.5 billion³
SNT-6302	Keloid Scars	Phase 1c	Pilot study in keloid scars planned	~\$3.5 billion³
SNT-4728	IRBD and Parkinson's Disease	Phase 2	Data H1 2026	~\$3.5 billion <sup>4</sup>

<sup>&</sup>lt;sup>1</sup>MF: Addressable market, The Myelofibrosis market size across the 8MM was valued at \$2.39 billion in 2021: https://www.globaldata.com/store/report/myelofibrosis-market-analysis/

<sup>&</sup>lt;sup>2</sup>MDS: Addressable market, MYELODYSPLASTIC SYNDROME TREATMENT MARKET ANALYSIS, https://www.coherentmarketinsights.com/market-insight/myelodysplastic-syndrome-treatment-market-775

<sup>&</sup>lt;sup>3</sup> Scar modification: Addressable market, Global Scar Market 2020 page 40 and 71. Total scar treatment market in 2019 exceeded US\$19b. Keloid and hypertrophic scar segment ~US\$3.5b

<sup>&</sup>lt;sup>4</sup>IRBD / Parkinson's Addressable market, Parkinson's Disease market size across the 7MM was valued at \$3.4 billion in 2019 and is expected to achieve a CAGR of more than 6% during 2019-2029. https://www.globaldata.com/store/report/parkinsons-disease-major-market-analysis/

# Recent & Anticipated News Flow



### Strong and growing pipeline with advancement in studies expected to provide value inflection points

### COMPLETED Q4 2024

SNT-5505 Phase 2a myelofibrosis combination study (add on to JAK inhibitor) interim 6/9 month data reported at ASH

### O1 2025

Syntara skin scarring clinical development plan for SNT-9465 announced

mvelofibrosis combination study (add on to JAK inhibitor) interim 9/12 month data to be reported at EHA.

#### June 2025

 FDA grants Fast Track Designation to SNT-5505

 SNT-5505 Phase 2a Milan

#### Q2 2025

FDA commence review of SNT-5505 Phase 2a myelofibrosis combination study interim data and review of Phase 2/3 clinical trial

proposal

#### Mid 2025

SNT-5505 Phase 1c/2a low/int and high risk myelodysplastic syndrome studies expected to commence recruitment

#### H<sub>1</sub> 2026

SNT-9465 Phase 1a/b hypertrophic skin scarring trial to report on safety PK/PD and 3 months efficacy

#### H1 2026

SNT-5505 Phase 1c/2a myelodysplastic syndrome studies to report interim safety and efficacy outcomes

#### H1 2026

SNT-4728 iRBD / neuro inflammation study to report safety and efficacy outcomes

#### Q3 2025

Final data and outcome of FDA review of amsulostat Phase 2/3 clinical trial proposal

#### Mid 2025

SNT-9465 Phase 1a/b hypertrophic skin scarring trial commences

### **Key Events Q3 25**

- Outcome of FDA review of amsulostat Phase 2/3 clinical trial proposal
- Final 12 month data from amsulostat MF combination study

# BYNT/R/

Syntara Limited ABN 75 082 811 630



### **Gary Phillips**

Chief Executive Officer gary.phillips@syntaraTX.com.au

