



# Equity Raising Presentation

Gary Phillips, CEO

30 July 2024

*Not for release to US wire services or distribution in the United States*

# Disclaimer

## **Disclaimer**

This presentation has been prepared by, and is the sole responsibility of Syntara Limited ABN 75 082 811 630 (the **Company** or **Syntara**) and is dated 30 July 2024. The Company is under no obligation to update or keep the information represented in this presentation current past the date of presenting. All information is subject to change without notice.

This presentation contains summary information about the Company as at the date of this presentation (unless otherwise stated) and has been prepared in relation to a placement of fully paid ordinary shares in the Company (**Shares**) and a conditional second tranche placement of Shares.

## **Risks**

The Company's business is subject to a number of significant known and unknown risk factors both specific to its business and of a general nature, some of which are beyond the control of the Company. In considering the prospects of the Company, the recipient should consider the risks that could affect the financial performance of the Company. You should carefully consider these risks in light of your financial and investment objectives, financial situation and particular needs (including financial and taxation issues) and seek professional advice from your accountant, financial adviser, stockbroker, lawyer, tax adviser or other independent and qualified professional adviser if you have any questions. Some of the risks that you and your professional advisers should consider before deciding whether to invest in the Company are set out in the Risks section of this presentation. There may be additional risks to those set out in the Risks section of this presentation that should be considered in light of your personal circumstances. For specific risks related to the issues arising from the sale of the mannitol business unit, please refer to the Risk section under the heading "Mannitol business unit".

## **Limitation of financial product advice**

At no time should this presentation be considered to be the giving of financial product advice by the Company, its directors, officers, employees, agents or advisors. The information contained in the presentation has been prepared without regard to the recipients' financial circumstances or investment objectives, financial situation or particular needs (including financial or taxation issues). It is incumbent upon the recipient to make its own independent assessment of the Company and take independent advice as necessary.

## **Use of third party information**

Any information or views expressed in this presentation were prepared by the Company. Information contained may have been obtained from publicly available sources that have not been independently verified. No warranty or representation is made to the accuracy of any third-party information contained in this presentation, and no responsibility or liability is accepted by the Company, its directors, officers, employees, agents or advisors for errors, omissions or misstatements made.

## **Past performance**

Recipients should note that any past performance information given in this presentation is provided for illustrative purposes only and should not be relied upon as, and is not, an indication of the future performance of the Company, including future share price performance.

## **Forward-looking statements**

This document contains forward-looking statements, including statements concerning the Company's future financial position, plans, and the potential of its products and product candidates, which are based on information and assumptions available to the Company as of the date of this document. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking 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 all. Other factors that may cause such differences include the risks described in the Risks section of this presentation. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.

# Disclaimer

## **Geographical restrictions**

The distribution of this presentation in jurisdictions outside Australia may be restricted by law. Please refer to the Foreign jurisdiction selling restrictions section of this presentation. This presentation may not be released to US wire services or distributed in the United States, and may not be distributed to any person, and securities may not be offered or sold in any country outside of Australia except to the extent permitted in accordance with the Foreign jurisdiction selling restrictions section of this presentation. Persons residing in any such jurisdiction who come into possession of this presentation should observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of law.

## **No offer of securities**

Information contained in this presentation does not constitute an offer to sell or a solicitation of an offer to buy or sell Company securities in the United States or in any jurisdiction in which such offer would be illegal. This presentation is not a prospectus, product disclosure document, or other offering document or contract under Australian law or any other law. The Shares have not been, and will not be, registered under the US Securities Act of 1933 or the securities laws of any state or other jurisdiction of the United States. The Shares may not be offered or sold, directly or indirectly, in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

## **Effect of Rounding**

A number of figures, amounts, percentages, estimates, calculations of value and fractions in this presentation are subject to the effect of rounding. Accordingly, the actual calculation of these figures may differ from the figures set out in this presentation.

## **Currency**

All financial information in this presentation is in Australian Dollars (\$) or AUD) unless otherwise stated. Certain amounts have been converted into Australian Dollars for the purpose of this presentation.

## **Financial data**

Investors should note that this presentation contains proforma financial information. The proforma financial information provided in this presentation are for illustrative purposes only. Although certain historical financial information has been derived from audited financial statements, the information contained in this presentation is not in statutory format and does not conform with the disclosure requirements of applicable accounting standards and other mandatory reporting requirements in Australia.

## **No reproduction**

You must not copy, reproduce, quote or refer to this document of the information in this document, in whole or in part, without the prior written consent of the Company, which may be withheld in its absolute discretion.

## **Disclaimer**

The business, financial condition, operating results and prospects of the Company may change after the date of this presentation. You should be aware that past performance is not indicative of future performance. Neither the Company, Canaccord Genuity (Australia) Limited (**Lead Manager**) or any of their respective related bodies corporate and affiliates, and their respective officers, directors, employees, agents, partners, contractors or advisers (collectively, Associated Persons) represents or warrants in any way, express or implied, that the information, opinions, conclusions or other information contained in this presentation, is fair, accurate, complete, up to date or correct or guarantees the performance of the Company or its securities, the payment of a return on the securities of the Company (including the Shares), or the future value of the securities of the Company (including the Shares). Any new or change in circumstances that arise after the date of this presentation will be disclosed by the Company to the extent required and in accordance with the Corporations Act.

*Not for release to US wire services or distribution in the United States*

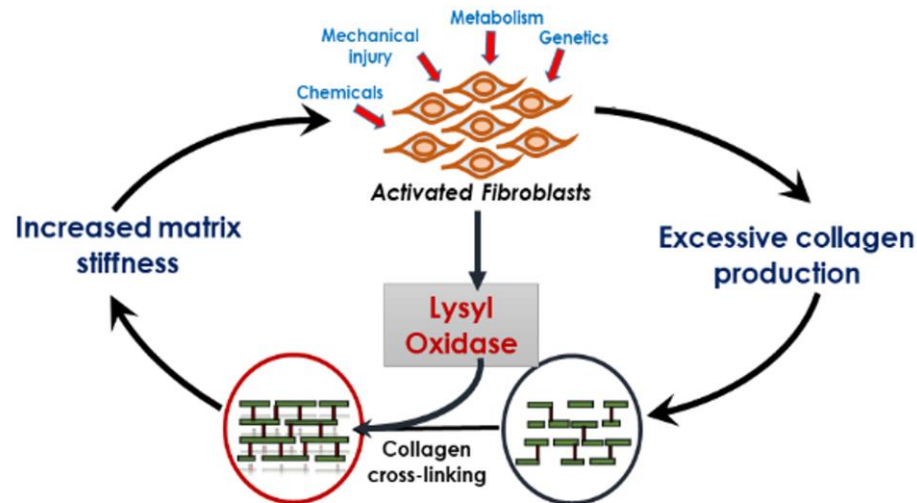
<b>Who We Are</b>	<ul style="list-style-type: none"> <li>Clinical stage drug development company with a pipeline of pre-clinical and clinical stage assets in fibrosis and inflammation</li> <li>Focused on first and best in class disease modifying drugs to improve quality of life and extend life expectancy</li> <li>Prioritising haematological malignancies with high unmet need</li> </ul>
<b>Priority Programs</b>	<ul style="list-style-type: none"> <li><b>Myelofibrosis (MF) - Market opportunities in excess of US\$1b per annum</b></li> <li>Recent history of biotech exits in excess of US\$1.7b</li> <li>SNT-5505 Monotherapy study reported positive data Q3 23</li> <li>Follow on Phase 2 MF combination trial with JAK inhibitor 14/15 recruited</li> <li>Routine Safety Monitoring meeting unanimously approved study continuation</li> <li><b>Interim data of the Phase 2 study expected to be delivered at American Society of Hematology (Dec 2024) triggering FDA discussions on pivotal study design and expected interest from strategics in 1H 2025</b></li> <li><b>Top line results expected mid 2025</b></li> </ul> <hr/> <ul style="list-style-type: none"> <li><b>Myelodysplastic Syndrome (MDS) - \$3.2b market opportunity</b></li> <li>Strong pre-clinical rationale published in Nature Communications 2023</li> <li>Financial support and drug supply to two grant supported studies <ul style="list-style-type: none"> <li>Phase 1c/2 study in <u>low / intermediate risk</u> MDS patients supported by Australian grant expected to commence Q4 2024 and deliver initial results H1 2025</li> <li>Phase 1c/2 study in high risk MDS patients expected to commence in 1H 2025 – German grant pending</li> </ul> </li> </ul>
<b>Other Programs</b>	<ul style="list-style-type: none"> <li><b>iRBD/Parkinson's And Scar Trials</b> - Phase 2 trials in areas of high unmet need expected to deliver clinical proof of concept data in H2 2025. iRBD study primarily funded by Parkinson's UK</li> <li><b>Drug Discovery and Development</b> - Funding of team with global track record in scientific research and commercialisation to protect existing patent positions and progress inflammation / fibrosis pipeline</li> </ul>
<b>Sale of MBU</b>	<ul style="list-style-type: none"> <li>Q4 2023 sale of the mannitol business unit secured \$14m savings per annum, deferred payments and long term royalty streams</li> <li>Under the terms of the sale agreement SNT claims ~\$5.1m currently owing from the acquiror of the mannitol business. If necessary, SNT intends to vigorously pursue legal remedies against the acquiror to recover the amounts claimed</li> </ul>
<b>Equity Raising</b>	<ul style="list-style-type: none"> <li>The Company is currently undertaking a \$5 million two-tranche placement to provide certainty of funding for its priority clinical programs and provide time for the Company to actively pursue the acquiror of the MBU for amounts claimed under the sale agreement</li> </ul>

# Executive Summary

# Syntara is the global leader in lysyl oxidase chemistry and biology

Multi year research program leveraged with extensive scientific collaborations worldwide has delivered three drugs now in phase 1c/2 studies

## Lysyl oxidases mediate the final stage in fibrosis



Lysyl oxidase inhibition provides a true anti-fibrotic therapy, directly addressing the tissue stiffening that occurs due to increases in collagen and number of cross-links.

## SNT-5505 in Oncology

- Clinical PoC: reduction of bone marrow collagen fibrosis grade in 45% of evaluable myelofibrosis patients in 6-month Phase 2 study
- Excellent clinical safety and tolerability with a complementary mode of action to current standard of care
- INDs approved for myelofibrosis and hepatocellular carcinoma
- Potential in haematological indications such as MDS as well as solid tumours; two Nature publications
- Patent priority date of 2018 provides extended IP coverage

## Topical pan-LOX inhibitors in Skin Scarring

- Clinical PoC: significant reduction of collagen and good safety in 3-month placebo-controlled Phase 1c study in patients with established scars
- Lead and back up compounds to support studies in multiple scar types (prevention of scar formation and modification of existing scars) in topical and oral dosage form
- Strong preclinical evidence in models of skin fibrosis and scarring; Nature publication
- Patent priority date of 2019 provides extended IP coverage

# Preclinical science and collaborations validated in high impact publications.

## Myelofibrosis

- Treatment with lysyl oxidase inhibitor significantly reduced reticulin fibrosis and megakaryocyte cell number in GATA-1<sup>low</sup> mice and JAK2V617F female mice

## Pancreatic Cancer

- SNT-5505 anti-fibrotic effects normalise the stroma, providing increased gemcitabine penetration and increased overall survival in pancreatic cancer

## Myelodysplastic Syndrome

- In xenograft mouse model that closely resembles human disease, SNT-5505 on top of 5-azacytidine increased erythroid differentiation and reduced spleen size

## Skin Scarring

- Topical application of SNT-6302 improves scar appearance with no reduction in tissue strength in porcine models of excision and burn injury

International Journal of Hematology  
<https://doi.org/10.1007/s12185-019-02751-6>

ORIGINAL ARTICLE

Novel lysyl oxidase inhibitors attenuate hallmarks of primary myelofibrosis in mice

nature communications



Article <https://doi.org/10.1038/s41467-023-37175-8>

**Inhibition of lysyl oxidases synergizes with 5-azacytidine to restore erythropoiesis in myelodysplastic and myeloid malignancies**

nature cancer



Article <https://doi.org/10.1038/s43018-023-00614-y>

**A first-in-class pan-lysyl oxidase inhibitor impairs stromal remodeling and enhances gemcitabine response and survival in pancreatic cancer**

nature communications



Article <https://doi.org/10.1038/s41467-022-33148-5>

**Topical application of an irreversible small molecule inhibitor of lysyl oxidases ameliorates skin scarring and fibrosis**

# Potential to deliver near term value

Pipeline creates multiple opportunities in high value markets

Drug Candidate	Indication	Phase	Anticipated Upcoming Milestones	Addressable market (US\$)
<b>SNT-5505</b>	Myelofibrosis	Phase 2	Interim 6 month data December 2024	<b>~\$1 billion<sup>1</sup></b>
	Myelodysplastic Syndrome Low & intermediate Risk + High risk trials	Phase 1c/2	Low/Int Risk Data Mid 25 High Risk – Grant Pending	<b>~\$3.2 billion<sup>2</sup></b>
<b>Oral and Topical Pan-LOX inhibitors</b>	Scar prevention	Phase 2	Data H2 2025	<b>~\$3.5 billion<sup>3</sup></b>
	Modification of scarring process	Phase 1c	Pilot study in keloid scars planned	<b>~\$3.5 billion<sup>4</sup></b>
<b>SNT-4728</b>	IRBD and Parkinson's Disease	Phase 2	Data H2 2025	<b>~\$3.5 billion<sup>5</sup></b>

1) 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/>

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

3) Scar Prevention: 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

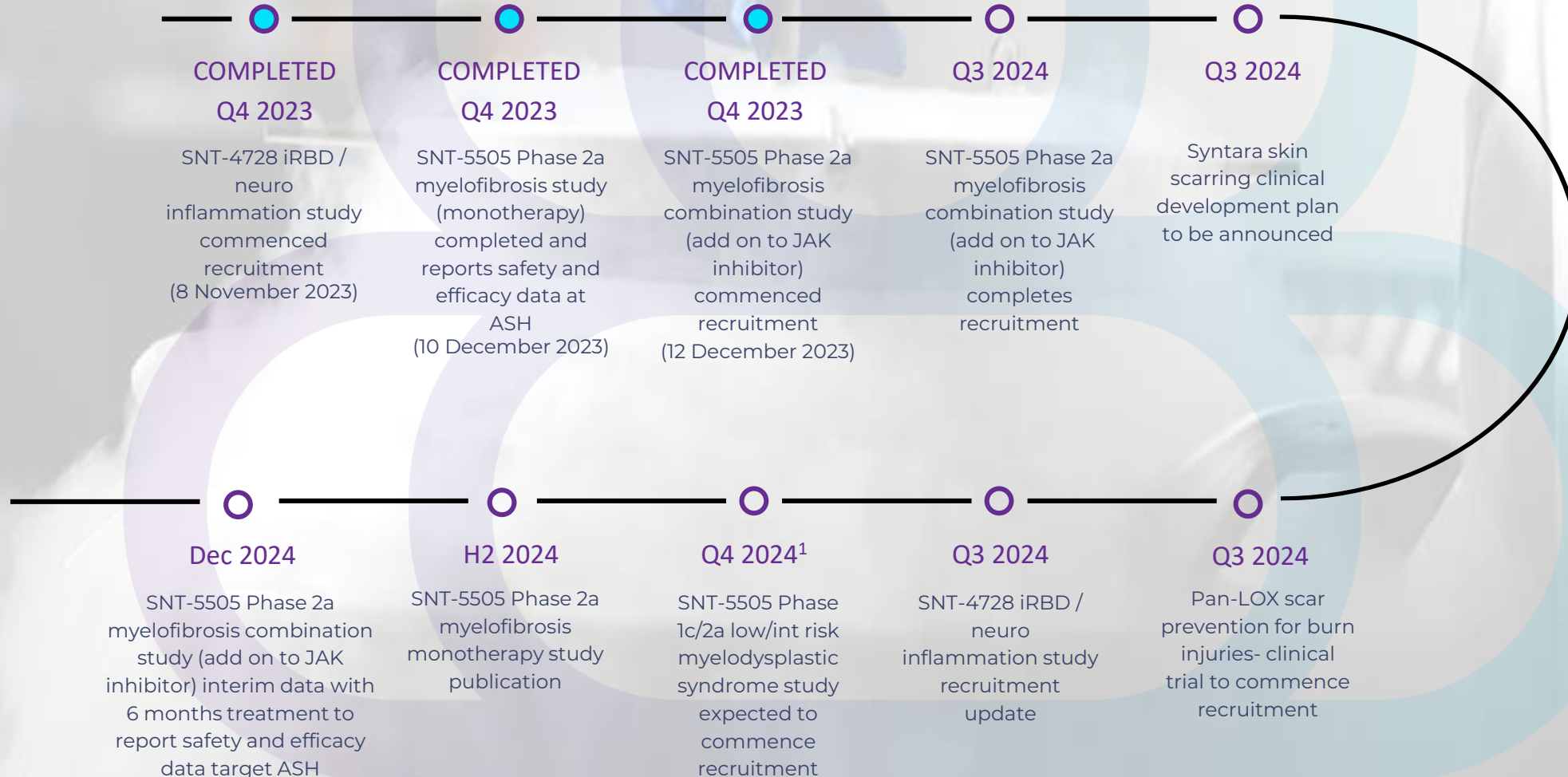
4) Scar modification: Addressable market, Global Scar Market 2020 page 40 and 71. Total scar treatment market in 2019 exceeded US\$19b. Keloid and hypertrophic scar segment ~US\$3.5b

5) 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**



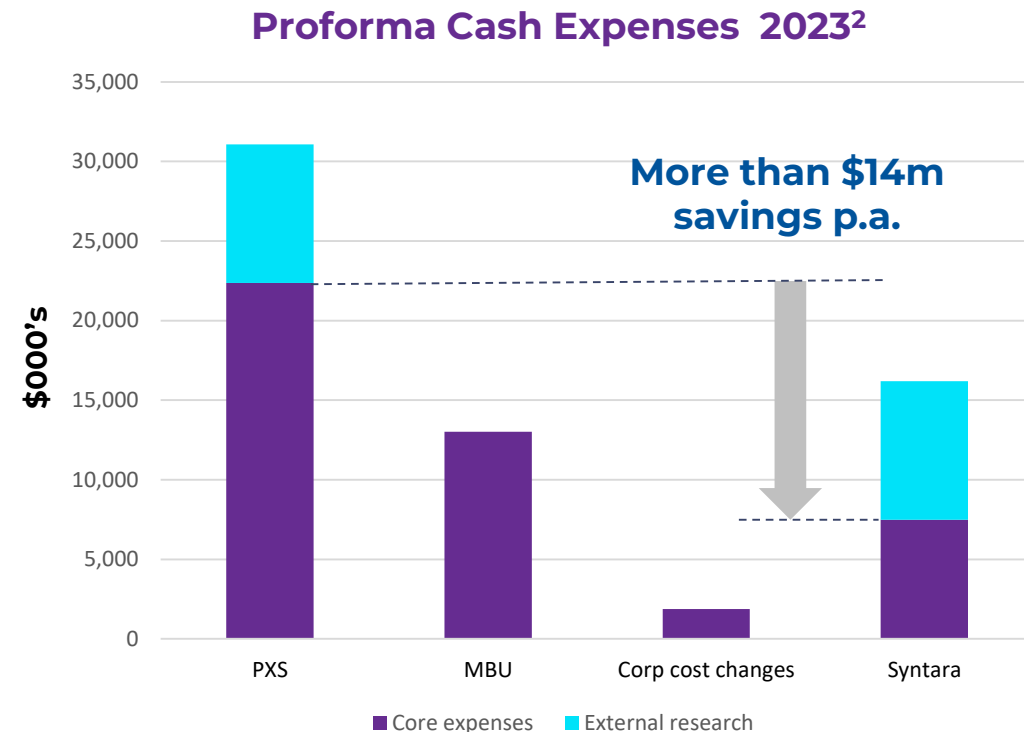
# Evolution from Pharmaxis to Syntara<sup>1</sup>: Cost savings and clear clinical focus

## The main factors impacting cash from separation of the mannitol business unit (MBU) are:

- Employee numbers dropped from ~67 to ~26 FTEs
- Much reduced space requirement - research labs and small office area
- Downsized Corporate and Administration requirements
- Removal post transition of all direct and indirect costs associated with operating a manufacturing and global pharma distribution business

## Core expenses (excluding external clinical trial and drug discovery costs) cut by more than 60%<sup>2</sup>

- Cash expenses excluding clinical trials drops from ~\$22m to \$8m



**Core expenses include employee costs, rent, utilities, manufacturing, regulatory and admin expenses**

1. Change of name from Pharmaxis Ltd to Syntara Limited occurred on 4 December 2023.

2. Indicative based on proforma FY 2023

# Syntara Board under new leadership and downsized

## Significant international pharmaceutical experience



**Dr Kathleen Metters**  
Chair

- Former Senior Vice President and Head of Worldwide Basic Research for Merck & Co. with oversight of the company's global research projects.
- In a subsequent role at Merck & Co she led work on External Discovery and Preclinical Sciences (a).
- Former CEO of biopharmaceutical company Lycera Corp.



**Dr Simon Green**  
Non-Executive Director

- Experienced senior global pharma executive with 30 years' of experience in the biotechnology industry.
- Actively involved in CSL's global expansion over a 17-year period where he held roles as Senior Vice President, Global Plasma R&D and General Manager of CSL's manufacturing plants in Germany and Australia.
- Prior to joining CSL he worked in the USA at leading biotechnology companies Genentech Inc and Chiron Corporation.



**Gary Phillips**  
Chief Executive Officer

- 30+ years' of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia.
- Joined Syntara in 2003 and was appointed Chief Executive Officer in March 2013 at which time he was Chief Operating Officer.
- Previously held country and regional management roles at Novartis – Hungary, Asia Pacific and Australia.



**Hashan De Silva**  
Non-Executive Director

- Experienced life sciences investment professional with extensive knowledge of the biotech, pharmaceutical and medical technology sectors.
- Worked as associate healthcare analyst at Macquarie Group and lead healthcare analyst at CLSA Australia before joining Karst Peak Capital in February 2021 as head of healthcare research.
- Prior to moving into life science investment Hashan worked at Eli Lilly in various roles focused on the commercialisation of new and existing pharmaceuticals.

# Experienced senior management team

Significant global experience in drug development, commercialisation and partnering



**Gary Phillips**  
Chief Executive Officer

- 30+ years' of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia.
- Previously held country and regional management roles at Novartis – Hungary, Asia Pacific and Australia.



**Wolfgang Jarolimek**  
Head of Drug Discovery

- 20+ years' experience in pharmaceutical drug discovery and published more than 40 peer reviewed articles.
- Previously Director of Assay Development and Compound Profiling at the GlaxoSmithKline Centre of Excellence in Drug Discovery in Verona, Italy.



**Kristen Morgan**  
Head of Medical & Regulatory Affairs

- 20+ years' experience in the pharmaceutical industry.
- Previously held a senior role in medical affairs at Sanofi-Aventis, and a commercial sales role at GlaxoSmithKline.



**Jana Baskar**  
Chief Medical Officer

- 20+ years' experience both in clinical medicine and the biopharmaceutical industry.
- Former Medical Director at Novartis Oncology in Australia; former Medical Director for IQVIA in Australia and New Zealand.



**David McGarvey**  
Chief Financial Officer

- 30+ years' experience building Australian based companies from inception to globally successful enterprises.
- Previously Chief Financial Officer of the Filtration and Separations Division of US Filter (1998-2002), and Memtec Limited (1985-1998).



**Dieter Hamprecht**  
Head of Chemistry

- 20+ years' experience with small molecule and peptide drug discovery, contributed to greater than 10 drug candidates brought to development and co-inventor of 50 patent families, co-author of 30+ scientific publications.
- Previously Managing Director – Boehringer Ingelheim's research group in Milan.

## Scientific excellence

- Global leaders in amine oxidase chemistry and biology – key to inflammatory and fibrotic diseases
- 3 Nature publications with collaborators in last 2 years

## Drug development expertise

- 6 drugs through preclinical and phase 1 / IND eligible since 2015
- 5 of these drugs went on to successfully clear phase 1
- 3 drugs completed Phase 1c/2 patient clinical proof of concept studies with acceptable safety and signs of efficacy

## Commercial acumen

- Three licensing / asset sale deals worth ~\$100m in cash receipts
- Extensive Pharma industry networks

# Terms of sale of MBU to Arna Pharma (acquiror)

## Key terms of sale

- **Sale completed 18 October 2023. Business sale agreement amended effective 31 January 2024**
- **Transition period (18 October 2023 to 31 January 2024)**
  - SNT retained facility lease and MBU employees to support the manufacture mannitol products under the direction of the acquiror
  - Majority of MBU employees commenced with the acquiror 1 February 2024
  - Acquiror recently signed a new lease over facility effective 21 June 2024
- **Deal financials**
  - SNT continued to be responsible for rent until May 2024 for employees until 31 January 2024 and certain operational costs of the leased facility until 31 January 2024.
  - The sale agreement includes a number of payments from the acquiror to Syntara
    - Fixed payments
    - Payments for inventory
    - Reimbursement of various operating and other costs over and beyond the transition period
  - Royalties on the net profits from the sale of: (i) Bronchitol and Aridol (for a seven year period commencing on the second anniversary of completion of the MBU); (ii) products manufactured using the spray drier sold as part of the sale other than Bronchitol or Aridol (for a 10 year period from first commercial delivery of such product); and (iii) other products manufactured in the Rodborough Rd facility (for an 8 year period commencing on the date of first sale of such products)

# Sale of Mannitol Business Unit to Arna Pharma

## Current status

- After amounts already paid by the acquiror (~\$2.5m), the amounts currently claimed by SNT at 30 June 2024 are:
  - Fixed payments: ~\$3.3m
  - Inventory: ~\$0.4m
  - Reimbursement of transition & other SNT costs: ~\$1.4m
  - Total: ~\$5.1m
- Acquiror has recently challenged amounts claimed by SNT primarily related to the fixed payments
- Other contractual payment obligations are in dispute
- While SNT is confident in its position, the acquiror's approach creates some uncertainty as to the timing and recoverability of certain amounts owing
- SNT has appointed external counsel to actively pursue legal remedies, if required

# Equity Raising

# Equity Raising Summary

## Offer Size and Structure

- The **Offer**: \$5.0m two tranche placement (**Placement**) comprising the issue of 178.6 million new fully paid ordinary shares (**New Shares**):
  - Tranche 1 to raise approximately A\$2.7m within the Company's existing placement capacity under ASX Listing Rule 7.1; and
  - Tranche 2 to raise approximately A\$2.3m within the Company's existing placement capacity under ASX Listing Rule 7.1
- Tranche 2 will include a A\$1.5m investment by KP Rx, a fund managed by a director of the Company, which is subject to shareholder approval at a General Meeting (**GM**) expected to be convened for late August or early September 2024

## Offer Price

- New Shares to be issued under the Equity Raising at a fixed offer price of A\$0.028 per New Share, which represents a discount of:
  - 30.0% to the Company's last traded price on 26 July 2024<sup>1</sup>;
  - 28.7% discount to the 5-day volume weighted average price (**VWAP**);
  - 31.4% discount to the 10-day VWAP; and
  - 15.4% discount to the 30-day VWAP.

## Ranking

- New shares issued under the Offer will rank pari passu with existing shares on issue.

## Lead Manager

- Canaccord Genuity is acting as Lead Manager and Bookrunner to the Placement.

1. Last traded price of A\$0.040 per share



# Sources and Use of Funds

## Funds including proceeds raised under the Placement will be used to fund:

### MF combination clinical trial

- Phase 2 study to deliver interim results expected Dec 2024 triggering FDA discussions on pivotal study design and expected interest from strategics H1 2025

### iRBD/Parkinson's and scar trials

- Phase 2 trials in areas of high unmet need expected to deliver clinical proof of concept data H2 2025

### Drug development

- Protection of existing patent positions and next generation of inflammation / fibrosis drugs

### Employee research costs

- Funding of team with global track record in scientific research, drug development and commercialization

### General working capital<sup>3</sup> and costs of the offer

Note 1) Does not include other amounts that may be recovered from Arna Pharma in connection with the sale of the MBU.

Note 2) Covers period 1 July 2024 to 30 June 2025

Note 3) Includes legal costs associated with issues relating to the sale of the MBU

Not for release to US wire services or distribution in the United States

Anticipated Sources of Funds <sup>1,2</sup>	A\$m
Existing cash as at 30 June 2024	\$3.5
R&D tax credits (FY24)	\$3.6
Cash from returned security deposits and sale of assets	\$0.9
Parkinson's UK grant for iRBD study	\$1.7
Amounts due but not previously disputed by Arna Pharma <sup>1</sup>	\$0.4m
Placement proceeds (net)	\$4.7
<b>Total Sources</b>	<b>\$14.8</b>

Targeted Uses of Funds	A\$m
MF combination clinical trial	\$4.0
iRBD/Parkinson's trial	\$2.4
MDS clinical trial – SNT support	\$0.7
Drug development and scar trials	\$0.9
Employee research costs	\$3.8
General working capital and costs of Offer	\$3.0
<b>Total Uses</b>	<b>\$14.8</b>

# Indicative Timetable

Event	Time (AEST) / Date
Announce completion of Placement, trading halt lifted and recommencement of trading	Tuesday, 30 July 2024
Settlement of Tranche 1	Monday, 5 August 2024
Tranche 1 New Shares commence normal trading	Tuesday, 6 August 2024
GM to approve Tranche 2	Late August / Early September 2024
Tranche 2 New Shares allotted	Late August / Early September 2024
Tranche 2 New Shares commence normal trading	Late August / Early September 2024

Note: The above timetable is indicative only and subject to change. Subject to the requirements of the Corporations Act, the ASX Listing Rules and any other applicable laws, Syntara in consultation with the Lead Manager, reserves the right to amend this timetable and withdraw the offer at any time

# Program Update

A blurred background image of a laboratory setting. A person in a blue lab coat is visible in the upper left, and another person in a white lab coat is partially visible on the right. The scene is brightly lit, suggesting a clean, professional environment.

# Myelofibrosis (MF)

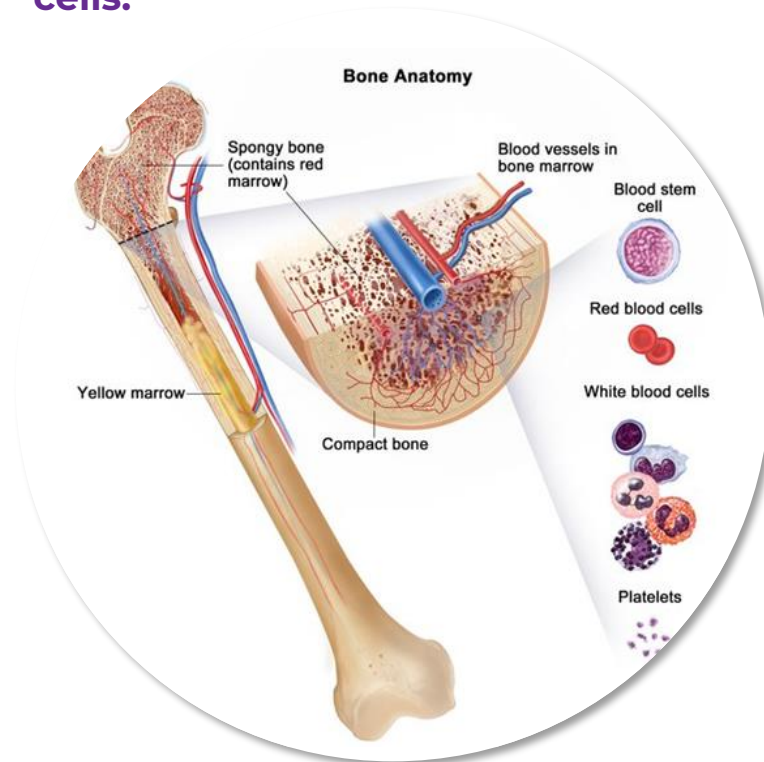
# Myelofibrosis

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

## Key Facts

- Affects ~15 in 1m people worldwide
- 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
- Spleen increases blood cell production and becomes enlarged
- Other common symptoms include fever, night sweats, and bone pain.

**Primary Myelofibrosis is characterised by a build up of scar tissue (fibrosis) in bone marrow reducing the production of blood cells.**



## Current standard of care (SoC): JAK inhibition

- Symptomatic relief plus some limited survival improvement.
- 75% discontinuation at 5 years
- Median overall survival is 14 – 16 months after discontinuation

## SNT-5505

In contrast to SoC SNT-5505 intervenes at the source, clearing fibrosis from the bone marrow and enabling the production of healthy blood cells to resume

### Clinical positioning

- Distinct mode of action, improved tolerability and a profile suitable for combination with SoC
- In addition to symptomatic relief, potential for disease modification.

### Commercial Opportunity

- Current SoC; revenue ~US\$1b per annum
- Recent history of biotech exits in excess of US\$1.7b

# SNT-5505 Phase 2a trial part 1; Monotherapy in JAK inhibitor treatment failures

**Demonstrates improvements in fibrosis grade, excellent safety profile and promising signs of clinical activity**

Study Design	Endpoints	Trial Outlooks
<ul style="list-style-type: none"> <li>• IND approved Q3 2020</li> <li>• Open label Phase 2a</li> <li>• 200mg BD dose (&gt;90% inhibition of LOX enzyme)</li> <li>• 21 trial sites in Australia, South Korea, Taiwan and USA</li> <li>• Recruited 24 patients who were non responsive or inappropriate for JAKi treatment</li> <li>• 13 patients completed 24 weeks of treatment</li> </ul>	<ul style="list-style-type: none"> <li>• SNT-5505 has been well tolerated</li> <li>• Majority of AEs were mild and not related to treatment</li> <li>• 11 patients dropped out of the study, none due to treatment related AEs</li> </ul>	<ul style="list-style-type: none"> <li>• 5/11 evaluable patients had improved bone marrow fibrosis scores of <math>\geq 1</math> grade</li> <li>• 5/13 had an improvement in symptom score of &gt;20%</li> <li>• 9/13 had stable/improved hemoglobin (Hb) counts</li> <li>• 10/13 had stable/improved platelet counts</li> <li>• No spleen volume response (SVR35) was identified</li> </ul>

# Phase 2a study; SNT-5505 in patients on a stable dose of JAK inhibitor

Fastest route to meaningful data with no dose escalation and utilising existing trial infrastructure

Design	Treatment Cohort	Endpoints
<p>FDA reviewed interim monotherapy data and combination therapy protocol Q3 2023</p> <p>Open label Phase 2a</p> <p>52 week treatment period</p> <p>15 patients</p> <p>SNT-5505 200mg BID + stable dose of RUX</p>	<p>Int-2/high risk PMF or post-ET/PV MF</p> <p>Treated with RUX <math>\geq</math>12 weeks (stable dose for <math>\geq</math>8 weeks) and not achieved complete remission per IWG criteria</p> <p>Population enriched with patients who reach predetermined thresholds in bone marrow fibrosis and symptom score</p>	<p><b>PRIMARY</b> Safety</p> <p><b>SECONDARY</b> PK/PD BMF Grade IWG Response SVR Hematology Symptom score Platelet response RUX dose modifications</p>

**ClinicalTrials.gov ID NCT04676529**

\* JAKi – Janus Kinase inhibitor, RUX – Ruxolitinib, MF myelofibrosis, ET Essential Thrombocythaemia, PV polycythaemia vera, INT intermediate, BMF bone marrow fibrosis, PK pharmacokinetics, PD pharmacodynamics, SVR spleen volume response, IWG International Working Group Myeloproliferative Neoplasms

### Safety Monitoring Committee (SMC) – 30 May 2024

- SMC consists of all Study Investigators, CRO Medical Monitor and Sponsor representative.
- 10 patients reviewed, 5/10 at 3 months
- Unanimous agreement from all voting members to continue the study

### Study Plan

- 19 clinical trial sites
- Recruitment started 13 Dec 2023
- **14/15 recruited**
- Full recruitment scheduled for Q3 2024

**Interim 6 months data targeted for Dec 2024 at American Society of Hematology**

- Top line data expected mid 2025

**Interim data to drive FDA discussion on pivotal study design and potential partnering interest**

# Strong interest in myelofibrosis assets from strategics



Date of Announcement	Feb-2024	June-2023	July-2022
Drug Name	Pelabresib	Pacritinib	Momelotinib
Lead Indication / Phase (at transaction)	Myelofibrosis (Successful Phase 3 studies)	Myelofibrosis (Marketed)	Myelofibrosis (FDA Filed – June)
Deal Type	Acquisition	Acquisition	Acquisition
Upfront / Milestones (USD)	US\$2.9B	US\$1.7B	US\$1.9B
Earnout Payments / Royalty Rate (%)	Subject to regulatory approvals	None	None



A background image of a scientist in a white lab coat and safety glasses, looking down at a piece of equipment. The image is overlaid with large, semi-transparent blue and purple circular shapes.

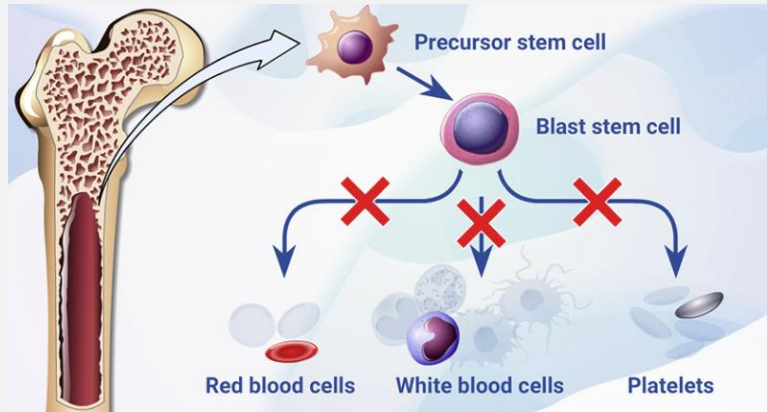
# Myelodysplastic Syndromes (MDS)

# Myelodysplastic syndrome (MDS) is a blood cancer

Diverse bone marrow disorders characterized by inadequate production of healthy blood cells

## Key Facts

12–20k new cases are reported every year in the US (87k p.a. worldwide)



- Prognosis and overall survival depend upon multiple factors including the severity of cytopenias (low blood counts)
- Therapy for low-risk MDS patients is aimed at improving cytopenia(s) to prevent complications
- 25–30% have high-risk MDS with average survival of ~ 1 year
- 1 out of 3 MDS patients progress to acute myeloid leukemia (AML)

## Treatment of MDS

### Current standard of care: Hypomethylating agents (HMAs)

- First line therapy: HMAs such as azacytidine (5-AZA) or decitabine,
- Adverse effects of HMAs include low blood counts, risk of infections, nausea, vomiting, diarrhea or constipation, weakness and fatigue
- Only ~50% of patients respond to HMAs and most responders eventually progress; median overall survival 4–6 months

### Drugs in development

- Other investigational products in Phase 3 trials (eg. venetoclax, sabatolimab, magrolimab) have demonstrated encouraging response rates in combination with 5-AZA in Phase 1b studies<sup>1</sup>
- However, these results are offset by greater toxicity (e.g. neutropenia, thrombocytopenia, anemia) that are likely to result in frequent dose interruptions and treatment discontinuation.
- Sabatolimab and magrolimab have recently failed in phase 3

Market Opportunity in ~US\$3.2bn p.a.

1. Platzbecker U, 2021, Leukemia 2021

# Phase 1c/2a study in low and intermediate risk MDS

Grant funded Australian investigator study with specialist CRO to deliver first results by mid 2025

Study Population	Design	Treatment Cohort	Endpoints	
<ul style="list-style-type: none"> <li>Low/intermediate risk MDS patients</li> <li>Transfusion dependent</li> </ul>	Phase 1c/2a open label study to evaluate safety, PK/PD, and efficacy	<p><b>Dose escalation:</b> SNT-5505 200mg BID + two different doses of a HMA n = 9 subjects; 3 months</p> <p><b>Dose expansion:</b> SNT-5505 200mg BID + HMA, n = 30 subjects; 6 months</p>	<b>PRIMARY</b> Safety	<p><b>SECONDARY</b> PK/PD</p> <p>Reduction in transfusion dependency</p> <p>Haematological parameters</p> <p>Quality of life</p>

## Study organisation

- \$0.83m grant from the Australian Medical Research Future Fund (MRFF).

- Investigator study run by University of Newcastle and the Australasian Leukaemia and Lymphoma Group
- ### Study Plan

- 10 Australian clinical trial sites
- Recruitment expected to commence Q4 2024 (or Q1 2025 depending on timing of third party drug supply)

- Interim data for ~9 patients with 3 months dose escalation data scheduled for Mid 2025**

\*MDS Myelodysplastic Syndrome, PK pharmacokinetics, PD pharmacodynamics, HMA Hypomethylating Agent

# Phase 1c/2a study in high-risk MDS/CMML study

German investigator study with specialist CRO – Grant Pending

Study Population	Design	Treatment Cohort	Endpoints	
Patients >18 years of age <ul style="list-style-type: none"> <li>Confirmed intermediate-2 or high risk MDS</li> </ul> or <ul style="list-style-type: none"> <li>Intermediate to high risk CMML</li> </ul>	Multicentre Phase 1/2a open label study to evaluate safety, PK/PD and efficacy	<p><b>Dose escalation:</b> SNT-5505 150mg and 200mg BID +5-AZA (HMA) n = 3-12 subjects; up to 6 months</p> <p><b>Dose expansion:</b> SNT-5505 + 5-AZA n = 30 subjects; 6 months</p>	<p><b>PRIMARY</b> Safety</p>	<p><b>SECONDARY</b> Haematological improvements Disease progression Survival Quality of life Transfusion independence Cytogenetic/molecular response</p>

## Study organisation

- Grant pending
- Syntara to provide free drug supply
- Clinical trial protocol received a top rating from the German MDS clinical trial group <https://d-mds.de/>

## Study Plan

- 10 German clinical trial sites
- Safety confirmation and potential for efficacy signals from 3 month dose escalation**

1. CMML: chronic myelomonocytic leukemia

A background image of a man with a beard and glasses, wearing a white lab coat, looking down at a piece of equipment in a laboratory setting. The image is overlaid with a large, semi-transparent graphic consisting of two overlapping circles and a horizontal bar, in shades of blue and purple.

# Skin Scarring

# Hypertrophic and keloid scarring

Cutaneous scarring following skin trauma or a wound is a major cause of morbidity and disfigurement

## Key Facts

01

100m patients develop scars in the developed world alone each year as a result of elective operations and operations after trauma

02

Hypertrophic scars and keloids are fibroproliferative disorders that may arise after any deep cutaneous injury caused by trauma, burns, surgery, etc.

03

Hypertrophic scars and keloids are cosmetically and functionally problematic significantly affecting patients' quality of life



*"In (preclinical) models of scarring we found that topical application of SNT-6302 reduces collagen deposition and cross-linking and improves scar appearance without reducing tissue strength. This is a unique way of modulating a critical stage in scar formation and maintenance and holds out great promise for the treatment of scars."*

**Dr Mark Fear  
UWA**

- **Mechanisms underlying scar formation are not well established; prophylactic and treatment strategies remain unsatisfactory**
- **Current standard of care includes:**
  - Corticosteroids
  - Surgical revision
  - Cryotherapy
  - Laser therapy
  - 5-fluorouracil
- **Pre clinical evidence**
  - Treatment with SNT-6302 monotherapy demonstrates cosmetic and functional improvements to scarring in pre clinical models<sup>1</sup>
- **Clinical evidence**
  - 1 month phase 1c in healthy volunteers demonstrates good tolerability and strong inhibition of LOX in skin.
  - 3 month phase 1c placebo controlled study in patients with established scars demonstrates unprecedented reduction in scar collagen content.

### Commercial Opportunity

- Total scar treatment market in 2019 exceeded US\$19b.
  - Keloid and hypertrophic scar segment ~US\$3.5b

1. Chaudhari et al, Topical application of an irreversible small molecule inhibitor of lysyl oxidases ameliorates skin scarring and fibrosis, Nature communications 2022  
<https://doi.org/10.1038/s41467-022-33148-5>

# SNT-6302 phase 1c Trial in established skin scars (Solaria 2); Top line results



## SNT-6302 well tolerated and demonstrated a good safety profile.

- No serious adverse events reported
- Two patients withdrew from the placebo controlled study; reversible rash



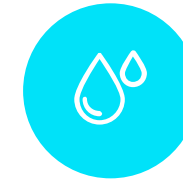
## Mean inhibition of LOX activity 66% compared to baseline and placebo (p<0.001)

- LOX inhibition measured 2 days post final dose
- LOX is responsible for the cross linking of collagen fibres implicated in adverse scarring.



## Meaningful changes in the composition of the scars

- Patients in the active arm had a mean reduction in collagen<sup>1</sup> of 30% compared to placebo after three months treatment. (p<0.01).



## Longer study required to show appearance and physical improvements

- No significant differences in the overall POSAS<sup>2</sup> score were seen between active and placebo groups after three months of treatment.

*“SNT-6302 leads directly to an unprecedented change to the scar composition that we have not seen with any other form of treatment.”*



### Professor Fiona Wood

Burns Service of Western Australia  
 Director of the Burn Injury Research Unit  
 University of Western Australia

1. Collagen content quantified via hydroxyproline assay

2. POSAS: Patient and Observer Scar Assessment Scale

# Syntara skin scarring clinical development plan

Incidences of skin rash with SNT-6302 in Solaria trial suggest potential development limitations. IND-enabling studies with backup candidate completed with progression to phase 1 funding dependent.

**Unprecedented structural changes** effected by 3 months treatment with SNT-6302 open up a wide vista of potential skin fibrosis indications for clinical development. For example:

- Younger scars
- Scar prevention post surgery
- Keloids
- Dupuytren's
- Surgical adhesions

**Scar prevention** with oral pan-LOX inhibitor progressing in Q3 2024; SNT-5505 being used to establish fastest clinical proof of concept

**Collaboration** with Professor Fiona Wood and University of Western Australia extended

**Pilot phase 1c study** with SNT-6302 in Keloid scars planned



A background image of a scientist in a white lab coat and safety glasses, looking down at a piece of equipment. The image is overlaid with a semi-transparent blue filter and large, overlapping blue circles.

# APPENDIX

# Risks

The Company's business is subject to a number of significant risks and uncertainties both specific to its business and of a general nature, some of which are summarised below.

As such, potential investors should be aware that investing in the Company's securities involves a high degree of risk and an investment in the Company should be regarded as a speculative investment.

Prior to deciding whether to apply for securities, potential investors should read and carefully consider this presentation and relevant announcements made by the Company to ASX in order to gain an understanding of the Company, its activities, operations, financial position and prospects and the risks and uncertainties associated with the Company. You should carefully consider these risks in light of your financial and investment objectives, financial situation and particular needs and seek advice from a qualified professional adviser.

If any of these risks were to occur, the future operating and financial performance and prospects of the Company as well as the value of its securities could be materially and adversely affected and you could lose part or all of your investment in the Company. Whilst some of the risk factors may be mitigated by appropriate commercial action, many are either wholly or in part outside of the control of the Company and its directors.

No guarantee as to maintenance of or appreciation in value, the payment of dividends or return of capital of the Company's securities is provided. Further, there can be no guarantee that the Company will achieve its stated objectives or that any forward-looking statement will eventuate.

The following sets out some of the risks associated with the Company.

For specific risks related to the issues arising from the sale of the mannitol business unit, please refer to the Risk section under the heading "Mannitol business unit".

# Key business risks

## **(a) Overview**

The Company' business success is currently substantially dependent on its ability to successfully advance the clinical development of SNT-5505, SNT-6302 (and related back up compounds) and SNT-4728 in a timely manner. There is a risk that the clinical development of all or some of these product candidates or any of our other product candidates that it may develop in the future, may not be successful, may be delayed or may cost more than anticipated.

The Company's strategy involves advancing a pipeline of development assets through clinical development to the point where it is able to enter into collaborative partnerships deals and strategic alliances with other lifescience companies to advance the programs and enable us to maintain our financial and operational capacity. There is a risk that the Company may not be able to enter into these sorts of collaborative partnership deals, on acceptable terms, or at all.

There is a risk that the product candidates may not receive the regulatory approvals required to commercialise them, or that such regulatory approval may be delayed. Even if regulatory approval is obtained, there is a risk that the products are not a commercial success.

## **(b) The clinical development of the Company's product candidates may not be successful**

Before obtaining regulatory approval for the commercial sale of any of the product candidates the Company is developing, it is necessary to complete preclinical development and extensive clinical trials in humans to demonstrate the safety and efficacy of the relevant product. Clinical trials are subject to extensive regulation, are expensive, time consuming, subject to delay and their outcome uncertain. Failure can occur at any stage of the clinical testing or approval process. Phase I clinical trials are not primarily designed to test the efficacy of a product candidate but rather to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and schedules. Negative or inconclusive results or adverse medical events during a clinical trial could cause the clinical trial to be delayed, redone or terminated. Success in pre-clinical and early clinical trials is not a guarantee of future results nor does it ensure that later large scale trials will be successful.

The Company's clinical trial program is described in this presentation. The trials proposed by the Company (and future clinical trials) may not show sufficient safety or efficacy to:

- warrant progressing to the next phase of development;
- enable the Company to secure a collaborative partnership deal with a lifesciences company to enable the continued clinical development of any given product candidate to continue; or
- obtain regulatory approval to sell the product.

This may mean that the Company is unable to continue the development of one or more of its product candidates or generate revenue from those product candidates.

# Key business risks

## **(c) The time and cost to undertake clinical trials and obtain regulatory approval may be significantly more than expected**

The length of time and the cost necessary to complete clinical trials and to submit an application for marketing approval may vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors. Due to the Company's reliance on contract research organisations, hospitals and investigators to conduct clinical trials, the Company is unable to directly control the timing, conduct and expense of its clinical trials. There are numerous factors that could affect the timing of the commencement, performance and completion of clinical trials which may delay the clinical trials or prevent the Company from completing these trials successfully, which include:

- any inability to secure a collaborative partnership deal at the appropriate time to enable the clinical development of any given product candidate to continue;
- delays in securing clinical investigators or trial sites for the Company's clinical trials, delays in obtaining approvals for trials;
- slower than anticipated recruitment of patients who meet the trial eligibility criteria or the loss of patients during the course of the clinical trials;
- the requirement to repeat clinical trials or undertake additional large clinical trials;
- unforeseen safety issues or adverse side effects or fatalities;
- shortages of available product supply of the necessary standard; and
- problems with investigator or patient compliance with the trial protocols.

## **(d) The Company may be unable to enter into collaborative partnership deals**

An important element of the Company's strategy involves advancing a pipeline of product candidates through clinical development to the point where it is able to enter into collaborative partnerships deals and strategic alliances with other lifescience companies that can advance our programs and enable us to maintain our financial and operational capacity. These collaboration partners may be asked to assist with or take full responsibility for the clinical development, regulatory approval and commercialisation of a product or alternatively to assist with funding or performing clinical trials, manufacturing, regulatory approvals or product marketing. Generally, the Company will seek to enter into such partnership arrangements before entering into a phase III trial, but it may seek to do so earlier or later depending on the circumstances. The Company may not be able to negotiate these sorts of deals on acceptable terms, if at all, and cannot guarantee that any such partners will perform as required and meet commercialisation goals.

Even if the Company is successful in entering into such deals, these arrangements may result in the Company receiving less revenue than if it sold such products directly, may place the development and commercialisation of its products outside its control, may require it to relinquish important rights or may otherwise be on terms unfavourable to it.

The Company has demonstrated the value of the strategy when Boehringer Ingelheim acquired the development asset BI 1467335 from the Company in 2015. However, even after such success, ongoing risks remain. In that case, in 2019 Boehringer Ingelheim determined to cease development of BI 1467335 and returned the asset to the Company. As a result, the Company is no longer receiving payments in connection with that transaction and the development prospects of that asset in NASH have ceased.

# Key business risks

## **(e) The Company may not be successful in developing or securing new product candidates**

Although the Company already has an extensive product candidate pipeline, it continues to spend limited resources developing new product candidates. From time to time it also considers in-licensing potential new product candidates. There is a risk that its research and development programs may not yield, or that it may not be able to in-license, additional product candidates suitable for further investigation through clinical trials.

## **(f) Early stage company with limited revenue**

Even though the Company has been in existence for some time, it remains at an early stage of its development as a clinical stage drug development company. Historically, the Company's source of ongoing product sales income was from Aridol and Bronchitol but in October 2023 the Company restructured its operations and sold the mannitol business unit as the revenue generated by the business unit were not sufficient to cover its costs.

The Company's ability to generate sufficient revenue in the future depends on a number of factors, including:

- the successful clinical development of its product candidates;
- its ability to secure collaborative partnership deals;
- the ability of the Company or its partners to obtain all necessary regulatory marketing authorisations for the products in a timely manner as well as other approvals concerning pricing and reimbursement;
- the ability to manufacture sufficient quantities of products to the required standard and at acceptable cost levels;
- the commercial success of products developed by the Company and its partners; and
- ongoing success in researching and developing new product candidates.
- the Company's research activities being eligible for the Australian government R&D tax incentive and the Company meeting other eligibility criteria.

There is a risk that The Company will continue to incur losses from its operations and may not achieve or maintain profitability. The Company expects its expenses to increase in the short term in connection with continuing conduct of research and development projects and clinical trials. Over the longer term, The Company's costs will fluctuate, primarily dependent on the number, type and size of clinical trials, preclinical development and research projects being undertaken.

## **(g) Capital requirements**

The intended use of funds raised under this offer are set out elsewhere in this presentation. To achieve its goals, the Company will in the future require substantial additional funds which may be dilutive or that may not be available to the Company on favourable terms or at all. Its future funding requirements and the timing of that funding will depend on many factors, including in particular, the success of its clinical programs and whether it is able to enter into collaborative partnership agreements. If the Company is unable to obtain additional funds when required, the Company may be forced to delay, reduce the scope or eliminate one or more clinical trials or research and development programs or future commercialisation efforts.

The phase II trial of SNT-4728 in severe sleep disorders that leads to neurodegenerative diseases is being mainly funded by Parkinson's UK. The funding is provided at various milestones. If this funding agreement was terminated, including for the Company's unremedied breach of the agreement, the Company would be forced to delay, reduce the scope or eliminate the trial. Funding for the proposed German trial is pending and if it is not received, that trial will not progress.

# Key business risks

## **h) Mannitol business unit**

In October 2023, the Company sold its mannitol business unit. The acquiror has challenged certain amounts claimed by the Company under the sale agreement. The Company has appointed external counsel to actively pursue legal remedies to recover those amounts, if required. While the Company is confident in its contractual position, the acquiror's approach creates some uncertainty as to the timing and recoverability of certain amounts claimed by the Company. Any dispute with the acquiror could be costly and time-consuming and could divert management's attention from our business, and the outcome uncertain. There is a risk that the Company receives less than it has claimed. It is not practicable at this time for the Company to predict the resolution of any dispute and the cost to pursue the Company's remedies, however, the sources and uses of funds tables in this document have been presented without reference to the additional amounts claimed that may be received by the Company from the acquiror. Even if the issues concerning the amounts claimed are resolved, the acquiror (and its guarantor) may subsequently default on any amounts ultimately determined as payable or may otherwise be unable to pay the amounts owed. Additional amounts of deferred consideration are also payable by the acquiror in the future, including royalties. In the event the acquiror defaulted in any of its other future payment obligations, including if it ceased as a going concern, the amount of deferred consideration (including royalties) received by the Company may be impacted. The potential of royalties from the acquiror is inherently uncertain and subject to a range of factors including that the level of sales of Bronchitol and Aridol and certain of the acquiror's other products, over which the Company has no control. Notwithstanding the sale of the MBU, the Company maintains the risks for liabilities arising from the operation of the mannitol business prior to the sale. Additionally, the Company provided the acquiror with customary warranties in connection with the sale, subject to customary caps and limitations. Other disputes or cross claims may arise with the acquiror, which could also be costly and time-consuming and could further divert management's attention from our business.

## **(i) Regulatory approvals**

The process to obtain regulatory authorisation is expensive, complex, lengthy and the outcomes uncertain. Failure can occur at any stage of the clinical testing or approval process. The Company and its partners (if any) may not be able to obtain marketing authorisations for some or all of its product candidates in key jurisdictions, or those authorisations may be delayed or subject to significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use.

## **(j) Ongoing regulatory issues**

Even after products receive regulatory authorisation, the Company and its collaborative partners may still face developmental and ongoing regulatory compliance difficulties. Regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Potentially costly follow-ups or post-marketing clinical studies may be required and previously unknown problems may result in restrictions on the marketing of the product and could include product withdrawal.

If the Company fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend the Company or its partner's regulatory authorisation or restrict or change the approved indications for use or impose additional safety reporting requirements;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed;
- impose restrictions on the Company' or its partner's operations; or
- seize or detain products or require a product recall.

In addition, the law or regulatory policies governing pharmaceuticals may change. New regulatory requirements or additional regulations may be enacted that could prevent or delay regulatory approval of the Company' products or that may otherwise impact on the Company's ability to market, distribute and sell product. The Company cannot predict the likelihood, nature or extent of adverse government regulation that may arise.

# Key business risks

## **(k) Even if a product is approved, the product may not warrant launch or even if launched, may not be successful in the market**

There is a risk that the product candidates the Company is developing and future product candidates, even if they receive regulatory approval may not gain adequate market acceptance. The degree of market acceptance will depend on a variety of factors, including: the ability to demonstrate safety and efficacy and the prevalence and severity of any side effects; the level of support from clinicians; the relative convenience and ease of administration; cost-effectiveness compared to other treatments; the availability of reimbursement from national health authorities; the timing of market introduction and clinical profile of competitive products; and the success of marketing and sales efforts. Additionally, it is difficult to determine the portion of the patient population that might use the Company's products and there is a risk that the Company's estimates do not accurately reflect the number of patients in the target markets.

## **(l) Pricing and reimbursement**

The commercial success of any products obtain regulatory approval, is substantially dependent on achieving acceptable pricing and whether acceptable third-party coverage and reimbursement is available from government bodies, private health insurers and other third-parties. This process of obtaining pricing for products is time consuming and the outcomes in certain jurisdictions may not be sufficient to warrant the marketing of products in that jurisdiction.

An inability to obtain or delays in obtaining satisfactory pricing and reimbursement in certain jurisdictions may impair the Company and any partner's ability to effectively commercialize products in those jurisdictions. Even if products receive acceptable pricing and reimbursement, pricing and reimbursement levels are subject to change.

## **(m) Manufacturing**

The Company, its partners' or their contract manufacturers and suppliers, may fail to achieve and maintain manufacturing standards for a number of reasons, which could result in patient injury or death, product recalls or withdrawals, product shortages, delays or failures in product testing or delivery or other problems that could seriously harm the Company's (and its partners') business. Any interruption to the Company's or its collaboration partner's manufacturing capability could result in the cancellation of shipments and loss of product, resulting in delays and additional costs for the conduct of clinical trials.

## **(n) Competition**

The Company conducts business in a highly competitive industry in which there are a number of well established competitors that have significantly greater financial resources, sales and marketing organisations, market penetration and development capabilities, as well as broader product offerings and greater market and brand presence. There can be no assurances given in respect of the Company's ability to compete.

## **(o) Product liability claims and insurance**

The Company and its collaboration partners face product liability exposure with respect to its products and product candidates. Regardless of merit or eventual outcome, liability claims may result in decreased demand for the Company and its partners' products; injury to the Company's and its partners' reputation; withdrawal of clinical trial participants; costly litigation and potential contractual disputes; substantial monetary awards to patients and others; loss of revenues; and an inability to commercialise. The Company and its partners' may not be able to maintain insurance coverage at a reasonable cost nor obtain suitable or reasonable insurance coverage in respect of any liability that may arise and any claim for damages could be substantial.

# Key business risks

## **(p) Patents and trade secrets**

The Company uses patents or trade secrets to protect its technologies from unauthorised use by third parties. The term of patents may expire or may be challenged, invalidated or circumvented. There can be no assurances that the Company' patents will afford it significant commercial protection for its products.

## **(q) Enforcement and infringement of intellectual property**

Third parties may own or control patents or patent applications that the Company or its partners may be required to license to commercialise product candidates, that the Company or its partners may infringe, or that could result in litigation that would be costly and time consuming. As a result of intellectual property infringement claims, or to avoid potential claims, the Company or its collaboration partners might be prohibited from selling or licensing a product; required to expend considerable amounts of money in defending claims; required to pay substantial royalties or license fees; required to pay substantial monetary damages; or required to redesign the product so it does not infringe, which may not be possible or could require substantial funds and time.

## **(r) Dependence upon key personnel**

The key personnel, particularly in the Company's research and development and clinical areas, have a high degree of expertise and the Company is reliant on their continued service to maintain and develop its business. The loss of a key employee or the inability to recruit and retain high caliber staff to manage future anticipated growth could have a material adverse effect on the Company. The additions of new employees and departures of existing employees, particularly in key positions, can be disruptive and could also have a material adverse effect on the Company. Increases in recruitment, wages and contractor costs may adversely impact upon the financial performance of the Company.

## **(s) Litigation**

There has been substantial litigation and other proceedings in the pharmaceutical and biotechnology industries. Defending against litigation and other third party claims would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialisation efforts. If third parties are successful in their claims, the Company might have to pay substantial damages or take other actions that are adverse to the Company business.

## **(t) Change in laws**

The Company's business and the business or the third parties with which it operates are subject to the laws and regulations in a number of jurisdictions. Unforeseen changes in laws and government policy both in Australia, the EU, the US and elsewhere, including material and unforeseen changes to licensing and approval requirements or regulations relating to clinical trials, manufacturing, product approval and pricing could materially impact the Company's operations, assets, contracts and profitability.



# Foreign jurisdiction selling restrictions

This document does not constitute an offer of new ordinary shares (**New Shares**) of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

## **Hong Kong**

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the “SFO”). Accordingly, this document may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

## **New Zealand**

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the “FMC Act”).

The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

# Foreign jurisdiction selling restrictions

## **Singapore**

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the “SFA”) or another exemption under the SFA.

This document has been given to you on the basis that you are an “institutional investor” or an “accredited investor” (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

## **United Kingdom**

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the New Shares.

The New Shares may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to “qualified investors” within the meaning of Article 2(e) of the UK Prospectus Regulation. This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (“relevant persons”). The investment to which this document relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this document.



Syntara Limited ABN 75 082 811 630

**Gary Phillips**

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

**David McGarvey**

Chief Financial Officer  
david.mcgarvey@syntaraTX.com.au

[www.syntaraTX.com.au](http://www.syntaraTX.com.au)

