

Quarterly Shareholder Report | September 2024

Clinical stage drug development company Syntara Limited (ASX: SNT) is pleased to provide a summary of its activities for the quarter ended 30 September 2024.

- **Phase 2 blood cancer trial recruitment target achieved as 15th patient dosed with 12 patients exceeding one month treatment – we plan to release interim results in December 2024**
- **Researchers at Heidelberg University to take SNT-5505 into the clinic for the blood cancers myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML) with A\$2.5m funding from Deutsche Krebshilfe (German Cancer Aid)**
- **Tim Luscombe appointed Chief Financial Officer**
- **\$5 million raised to provide essential funding for the Company's Phase 2 clinical trials**

Syntara's CEO Gary Phillips commented: "It was a productive period for the company from a clinical, operational and financial perspective. Our lead program, the Phase 2 trial of SNT-5505 targeting myelofibrosis, reached full recruitment and before the end of the calendar year we plan to announce interim data and present it at the American Society of Haematology (ASH) annual conference in San Diego held from 7-10 December. We expect we will seek a meeting with the FDA in 1H 2025 once we have enough data to fully characterise the safety and efficacy profile of the drug.

It was also pleasing to broaden out the scope of SNT-5505 with the awarding of the A\$2.5m grant in Germany for a new Phase 1b/2 trial for high risk MDS and CMML patients, beginning next quarter. This study and a further study in low/intermediate risk MDS that has received funding from the Australian government is expected to start recruitment in 1H 2025. These are clinically and commercially important studies given the relatively poor outcomes for patients in this disease and a corresponding interest from pharmaceutical companies.

I want to again take the opportunity to thank the new and existing shareholders that supported our capital raising during the quarter, which has put us on a strong financial footing. We've supplemented this with investor relations activities to continue to increase awareness of the compelling opportunity we see in Syntara and subsequently introduce new investors to the register.

We look forward to updating the market with the SNT-5505 data and other developments in due course."

Phase 2 blood cancer trial fully recruited – interim results planned to be released in December 2024

In July, Syntara announced that it completed recruitment for the last cohort in its Phase 2 trial of SNT-5505, which is being tested in combination with ruxolitinib to treat myelofibrosis, a bone marrow cancer. The cohort dosed its 15th patient, reaching its recruitment target, with 12 patients having already completed more than one month of treatment at the time. This exceeds the minimum threshold agreed upon with the FDA for safety evaluation. To date in this final cohort, there have been no drug-related withdrawals or serious adverse reactions, and the trial has continued without safety concerns.

The trial is being conducted at 19 sites across the United States, Australia, South Korea, and Taiwan. SNT-5505, a pan-LOX inhibitor, is the lead candidate in Syntara's drug development pipeline. Based on data from earlier trials, the drug has shown potential to address the unmet needs in myelofibrosis treatment, a market estimated to be worth over \$1 billion annually.

Syntara plans to release interim data from the study in December 2024 at the ASH Annual Meeting. This and subsequent data collected as patients get extended exposure to SNT-5505 will inform potential further discussions with the FDA regarding the design of a pivotal study, with those talks expected in the first half of 2025. Full 12-month data of the existing study is anticipated by the third quarter of 2025.

SNT-5505 has also shown potential in preclinical studies when combined with standard treatments for other cancers, such as myelodysplastic syndrome and solid tumours, including hepatocellular carcinoma and pancreatic cancer.

New indication for SNT-5505 as German MDS study group awarded A\$2.5m grant to conduct phase 2 blood cancer trial

Syntara also announced that Heidelberg University's Medical Center Mannheim has received a A\$2.5 million grant from Deutsche Krebshilfe (German Cancer Aid) to conduct a Phase 1b/2 clinical trial of SNT-5505 in patients with high-risk myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML). This study, known as the AZALOX trial, is expected to begin in the first half of 2025, running parallel to a previously announced Australian Phase 1c/2 study that will focus on low-to-intermediate-risk MDS patients.

The trial will be conducted at seven specialist centres in Germany, which have agreed to participate, and it has been prioritised by the German MDS Study Group. The trial will first involve a dose-escalation phase, with up to 12 patients receiving two doses of SNT-5505 in combination with the hypomethylating agent 5-azacitidine over six months. This will be followed by an expansion phase where 30 patients will receive the selected dose for another six months. Syntara will provide supplies of SNT-5505 for the study.

This research follows earlier preclinical collaboration between Syntara and Heidelberg University, which demonstrated improved responses to standard therapy when combined with SNT-5505, as published in *Nature Communications*. MDS and CMML are forms of blood cancer that often progress to acute myeloid leukemia (AML). Current treatments, such as 5-azacitidine, have limited long-term efficacy, with many patients relapsing after initial response, highlighting the need for new therapies.

CORPORATE

Syntara appoints new CFO

During the quarter the Company the appointment of Tim Luscombe as Chief Financial Officer (CFO). Tim succeeds David McGarvey, who retired after over 20 years in the role. Mr

McGarvey will continue as Company Secretary and also focus on completing the financial and legal aspects related to the sale of Syntara's mannitol business unit (MBU).

Tim Luscombe is a Director at Bio101 Financial Advisory and has over a decade of experience in finance and commercial roles, working with both public and private companies in the biotechnology and healthcare sectors. He holds a Bachelor of Commerce from the University of Melbourne, a Certificate in Governance Practice from the Governance Institute of Australia, and is a Chartered Accountant.

FINANCIAL

Syntara at the end of the September quarter had a closing cash balance of \$4.34 million, compared to \$3.52 million at 30 June 2024. Subsequently, in October 2024 the company also received:

- \$4.56 million related to its Research and Development Tax Incentive (RDTI) with respect to the financial year ended 30 June 2024,
- The release of its security deposit of \$0.9 million in relation to the terminated lease over its Frenchs Forest facility; and
- \$0.6 million of proceeds from the sale of the MBU.

Therefore, the Company on a pro forma basis had closing cash at the end of the September quarter of \$10.4 million.

The net cash outflow in operating activities during the quarter was \$4.23 million, compared with \$4.24 million for the previous quarter to 30 June 2024.

R&D (\$1.81 million) and staff costs (\$2.03 million) totalling \$3.84 million represented 91% of the Company's total net operating cashflows. Of the \$1.81 million direct R&D expenditure the majority was represented by the company's ongoing major clinical programs:

- the Phase 2a clinical trial in myelofibrosis, and
- the iRBD clinical trial, where the majority of the costs of this trial are funded by a grant from Parkinson's UK.

The Company received payments of \$0.4 million in the September quarter from the acquiror of the MBU.

Amounts owed from the sale of the mannitol respiratory business

Syntara sold its mannitol respiratory business unit (MBU) in the fourth quarter of 2023 to Arna Pharma Pty Ltd, (Arna Pharma). A post completion transition period has now ended and the MBU and Frenchs Forest facility are now fully separated from Syntara. Syntara's research laboratories and corporate offices are now subleased at Frenchs Forest from Arna Pharma.

As previously advised, Arna Pharma challenged the contractual payment obligations claimed by Syntara from the sale. Since that time the parties have made some progress in reconciling the amounts owing and some payments have been made (as outlined above). The Company continues to pursue amounts owing by the acquiror and expects to receive further payments over the course of the financial year. There remains significant uncertainty in relation to the quantum and timing of amounts that will be received.

After amounts already paid by Arna Pharma (~\$2.9m), the amounts currently claimed by Syntara at 30 September 2024 total \$4.5 million (~\$3.9 million as at 28 October 2024).

Two-Tranche Placement to Raise A\$5m

During the quarter, Syntara successfully raised approximately A\$5.0 million through a two-tranche institutional placement. The funds were secured through the issuance of approximately 96.4 million shares in Tranche 1, raising A\$2.7 million, and an additional 82.1 million shares in Tranche 2, raising A\$2.3 million. Both tranches were priced at A\$0.028 per share, 27% higher than the company's previous capital raise in January 2024, when shares were issued at A\$0.022.

The funds raised will provide financial support for the ongoing development of Syntara's lead clinical programs.

Payments to Related Entities

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates Executive and Non-Executive Directors' fees, salaries and superannuation. Total payments made for the quarter are summarised below:

A\$'000	Three months ended 30 September 2024
Non-executive directors' fees	60
Executive director remuneration ¹	259
Total	319

¹ includes short term incentive payment from the year ended 30 June 2024 \$130,488.

#ENDS#

SOURCE:

Syntara Limited (ASX: SNT),
Sydney, Australia
(ABN: 75 082 811 630)

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About Syntara

Syntara Limited (ABN: 75 082 811 630) is a clinical stage drug development company targeting extracellular matrix dysfunction with its world-leading expertise in amine oxidase chemistry and other technologies to develop novel medicines for blood cancers and conditions linked to inflammation and fibrosis.

Syntara is managing three phase 2 clinical studies in diseases of high unmet need with a further two potential phase 1c/2 studies being evaluated for 2024. Lead candidate SNT-5505 is for the bone marrow cancer myelofibrosis which causes a build-up of scar tissue that leads to loss of red and white blood cells and platelets. SNT-5505 has already achieved FDA Orphan Drug Designation and clearance under an Investigational New Drug Application for development in myelofibrosis. After encouraging phase 2a trial results when used as a monotherapy in myelofibrosis, SNT-5505 is now being studied with a JAK inhibitor in a further phase 2 myelofibrosis study with a planned release of interim data in Q4 2024. Protocols for another two phase 1c/2 studies with SNT-5505 in patients with a blood cancer called myelodysplastic syndrome are in development and expected to commence recruitment by Q1 2025.

Syntara is also advancing both oral and topical pan-LOX inhibitors in scar prevention and scar modification programs as part of an ongoing collaboration with Professor Fiona Wood and the University of Western Australia. SNT-4728 is being studied in collaboration with Parkinson's UK as a best-in-class SSAO/MAOB inhibitor to treat sleep disorders and slow progression of neurodegenerative diseases like Parkinson's by reducing neuroinflammation.

Other Syntara drug candidates target fibrotic and inflammatory diseases such as kidney fibrosis, NASH, pulmonary fibrosis and cardiac fibrosis.

Syntara developed two respiratory products available in world markets (Bronchitol® for cystic fibrosis and Aridol®- a lung function test), which it sold in October 2024.

Syntara is listed on the Australian Securities Exchange, code SNT. The company's management and scientific discovery team are based in Sydney, Australia. www.syntaraTX.com.au.

Forward-Looking Statements

Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these 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 partnering any of the products in our pipeline on commercially acceptable terms, in a timely fashion or at all. 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.