



Quarterly Shareholder Report | June 2024



Dear shareholder,

The June quarter of 2024 was an exciting period for the company as we rapidly closed in on our recruitment targets for the Phase 2 multinational study targeting myelofibrosis (MF). 14 out of 15 patients have been recruited and the last review of the data coming from this open label study by the Safety Monitoring Committee resulted in a unanimous vote to continue the study. The committee is made up of the principal investigators from all of the active sites, a representative from the contract research organisation running the study and Syntara's chief medical officer. The safety profile of SNT-5505 continues to look reassuringly good and we believe we will have a meaningful amount of data ready to present at the American Society of Hematology in December this year.

SNT-5505 in blood cancers remains our key focus and we concluded the quarter with progress made in protocol development for the upcoming low / intermediate risk myelodysplastic syndrome (MDS) phase 1c/2 study, that will be conducted in Australia with the Australasian leukemia and lymphoma group, and in the high risk MDS trial proposed for the MDS clinical network in Germany. MDS is a very important add-on indication for SNT-5505 with a patient population 3 times larger than MF and with very few promising drugs in development. It says a lot about the quality of the program and the researchers that we are working with that the Australian study has already attracted significant funding from the Australian Government, and that the German high risk MDS study has progressed through grant evaluation with a decision pending. Delivering additional value for shareholders with non-dilutive funding from grant bodies has been a stand-out achievement of our scientific and clinical leadership team in FY 2024.

Elsewhere we have added a second trial site for the phase 2 study examining the impact of LOX inhibition on scar development after burns injuries to increase recruitment capacity. We

expect to see results from this study in the second half of 2025 and in the meantime have held further discussions with trial leader Prof Fiona Wood and her team about progressing our topical LOX inhibitor in keloid scarring later this year. This remains a very exciting prospect and we are focused on ensuring the next development steps correctly balance the commercial opportunity with clinical trial feasibility and regulatory parameters.

The final parts of the exit from the mannitol business unit and the associated manufacturing facility were completed in the June quarter with the acquiring business, Arna Pharma, taking full responsibility for all aspects including the lease of the facility. The dramatic cost savings and ability to focus on developing Syntara's clinical pipeline have already delivered significant benefit to the company. In an unexpected turn of events, Arna Pharma has recently challenged amounts claimed by Syntara including a number of fixed payment obligations that are contained in the agreement signed by both parties in October 2023. Arna Pharma's approach created an unacceptable level of uncertainty around funding of our active clinical trial programs – hence the announcement made earlier this week of a successful share placement raising \$4m. I am grateful for the strong support of our shareholders to ensure that we can continue to deliver key data from our phase 2 programs and the multiple opportunities that flow from that.

In the meantime, Syntara has appointed external counsel to actively pursue a legal resolution with Arna Pharma.

Further detail on all the above points is included in the body of this update. We look forward to bringing you further news through the rest of 2024.

Gary Phillips - Chief Executive Officer

Clinical pipeline at a glance

Disease/target	Drug	Status
Myelofibrosis (oral pan-LOX inhibitor) - monotherapy	SNT-5505	Phase 2a completed
Myelofibrosis (oral pan-LOX inhibitor) – combination with JAK inhibitor	SNT-5505	Phase 2a recruited 14/15
Myelodysplastic syndrome – low/intermediate risk (MDS) (oral pan-LOX inhibitor)	SNT-5505	Phase 1c/2 expected to commence H2 CY 2024
Myelodysplastic syndrome – high risk (MDS) (oral pan-LOX inhibitor) –	SNT-5505	Phase 1c/2 expected to commence H1 CY 2025 subject to grant funding
Established skin scars (Topical pan-LOX inhibitor)	SNT-6302	Phase 1c IIS ¹ reported
Scar prevention (oral pan-LOX inhibitor)	SNT-5505	Phase 2 IIS ¹ recruiting
Neuro inflammation - isolated Rapid Eye Movement Sleep Behaviour Disorder (SSAO/MAOB inhibitor)	SNT-4728	Phase 2 recruiting
Chronic fibrotic diseases (LOXL2 inhibitor)	SNT-5382	Phase 1 completed

1. Investigator initiated study

New drug development

Oral pan-LOX inhibitor program (SNT-5505) in myelofibrosis

Syntara's primary drug development initiative is its pan-Lysyl Oxidase (pan-LOX) inhibitor program focused on the rare blood cancer, myelofibrosis. SNT-5505 is an orally taken drug that inhibits the lysyl oxidase family of enzymes and was developed from the Company's amine oxidase chemistry platform.

Myelofibrosis is a cancer with a poor prognosis and limited therapeutic options.

Syntara believes that the current treatments can be augmented by the concurrent use of a pan-LOX inhibitor. The combination with standard of care should be disease modifying in a market that is conservatively worth US\$1 billion per annum.

A second arm of the Phase 2 trial (named MF-101; ClinicalTrials.gov Identifier: NCT04676529), evaluating SNT-5505 in combination with ruxolitinib in patients with myelofibrosis commenced recruitment in December 2023 and has enrolled 14 out of the targeted 15 patients with full recruitment expected to be achieved in coming weeks.

Read more [here](#).

Monotherapy arm of MF-101

The initial, monotherapy arm of the trial reported at the 2023 American Society of Hematology (ASH) meeting and aimed to demonstrate that SNT-5505 was safe and well tolerated as a monotherapy in myelofibrosis patients who are intolerant, unresponsive or ineligible for treatment with approved JAK inhibitor drugs.

The trial has additional secondary endpoints to explore the impact of inhibiting lysyl oxidase enzymes on a number of important disease parameters such as bone marrow fibrosis, cytopenia and spleen volume.

The trial protocol called for 24 patients to be treated twice a day for 6 months. A total of 20 sites in Australia, South Korea, Taiwan and the United States participated in the monotherapy arm of the trial.

The presentation at ASH included data from 23 patients. Eleven patients had completed the full 24 weeks of treatment at that time.

- Safety endpoints:
 - SNT-5505 was well tolerated with no serious treatment related adverse events reported
 - The majority of adverse events were mild and not related to treatment
 - 11 patients dropped out of the study, none treatment related.
- Efficacy endpoints:
 - five out of ten evaluable patients had improved bone marrow fibrosis scores of ≥ 1 grade
 - four out of five fibrosis responders demonstrated stable haematological parameters
 - three out of five patients reported symptomatic improvement
 - four patients had an improvement in symptom score of $>20\%$
 - seven patients had stable/improved hemoglobin (Hb) counts
 - eight patients had stable/improved platelet counts; three of these eight patients entered the study with Grade 4 (potentially life-threatening) thrombocytopenia

- no spleen volume response (SVR35) was identified. It was noted that:
 - patients had a relatively smaller spleen size at baseline
 - the majority of patients stopped JAK inhibitor treatment less than 1 month before commencing treatment

The last patient finished the 6 month treatment in early May allowing completion of analysis and submission for publication later in the year.

Read the interim update [here](#).

Watch an interview with CEO Gary Phillips outlining the study data [here](#).

Combination arm of MF-101:

The combination arm of MF-101 commenced dosing in December 2023 under the FDA's Investigational New Drug (IND) scheme.

This second arm of the Phase 2 trial MF-101 aims to demonstrate that SNT-5505 is safe and effective in myelofibrosis patients whose disease is sub-optimally controlled by the market leading JAK inhibitor, ruxolitinib. The trial has recruited 14 out of the targeted 15 patients with full recruitment expected to be achieved in coming days. The trial is being conducted in 19 clinical trial sites in Australia, South Korea, Taiwan and the USA.

Secondary end points include:

- characterize pharmacokinetic and pharmacodynamic parameters
- determine reduction in bone marrow fibrosis
- determine response rates as defined by International Working Group (IWG)-Myeloproliferative Neoplasms Research and Treatment criteria
- evaluate efficacy of SNT-5505 in spleen size reduction measured by CT or MRI scan
- evaluate the efficacy of SNT-5505 on MF related symptoms based on MF-SAF scores (Myelofibrosis Symptom Assessment Form)
- evaluate platelet response
- explore the impact of SNT-5505 on ruxolitinib dosing
- explore the correlations between biomarkers of disease burden and high-molecular risk genes

Syntara anticipates reporting on 6-month results of the trial in an interim data update at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2024. The interim data is expected to allow Syntara to engage with the FDA and discuss pivotal study design in Q1 2025, with the full 12-month data set to be available by mid-2025. The outcome of the

trial will drive regulatory discussions and hopefully garner strategic interest.

Oral pan-LOX inhibitor program (SNT-5505) in myelodysplastic syndrome (MDS)

Syntara has ongoing preclinical collaborations with the University of Heidelberg, Germany and the University of Newcastle, Australia, investigating the role of lysyl oxidase enzymes in the treatment of myelodysplastic syndrome (MDS).

MDS comprises a group of blood cancers that share clinical and pathologic features with acute myeloid leukemia (AML). Abnormal tissue growth leads to bone marrow failure, often featuring low blood counts leading to infections, transfusion dependence and risk of progression to acute myeloid leukemia (AML), a more aggressive form of blood cancer. Overall 5-year survival rate for transfusion dependent MDS is only 37%. MDS occurs most commonly in older adults with an annual incidence thought to be as high as 75 cases/100,000.

The current standard of care for high risk MDS is treatment with hypomethylating agents (HMAs) such as 5-AZA and decitabine. Although approximately 50% of MDS patients initially respond to HMAs, subsequent relapse is almost certain, highlighting an urgent need for compounds that significantly improve the beneficial effects of HMAs.

A recent issue of Nature Communications published peer-reviewed data from the University of Heidelberg collaboration investigating the role of lysyl oxidase enzymes in MDS and the effect of combining 5-azacytidine (5-AZA) with Syntara's pan-lysyl oxidase inhibitor, SNT-5505.

Read more [here](#).

Last quarter the Company announced a new Phase 2 trial evaluating combination treatment of SNT-5505 with chemotherapy in patients with low and intermediate risk MDS. The trial, to commence later this year (or Q1 2025 depending on timing of third party drug supply), will be led by Associate Professor Anoop Enjeti at Australia's University of Newcastle, and will be conducted under the clinical trial framework of the Australasian Leukaemia and Lymphoma Group (ALLG), the leading investigator run national blood cancer trials network with more than 160 trials undertaken. The Australian Medical Research Future Fund (MRFF) has awarded a \$0.83 million grant to support the trial.

This trial will feature a dose escalation phase where up to 9 MDS patients who are transfusion dependent will be treated with a fixed dose of

SNT-5505 and two different doses of a hypomethylating agent followed by a dose expansion phase where 30 patients will be treated for 6 months on the dose combination selected in the first phase based on tolerability and efficacy. Endpoints will include safety and the reduction in transfusion dependency, haematological parameters and quality of life. Results from the dose escalation phase are anticipated mid-2025.

The grant from the MRFF and the support of University of Newcastle and the ALLG enables Syntara to expand the haematology indications for SNT-5505 beyond the current international myelofibrosis study and into another area of high unmet need and commercial value.

Syntara's contribution to the MDS study is estimated to be \$1.1 million over the three years the dose escalation and expansion phases are expected to run, as well as supplying the study drug and LOX assays on tissue samples taken during the study.

Read more [here](#)

Subject to a pending grant, the Company's collaborators at the University of Heidelberg, are planning to conduct a new Phase 2 trial evaluating combination treatment of SNT-5505 with chemotherapy in patients with high risk MDS. If the grant funding is successful the trial is expected to commence in the first half of CY 2025.

The clinical trial protocol received a top rating from the German MDS clinical trial group and is planned to be conducted at 10 German sites.

This trial will feature a dose escalation phase (up to 12 MDS patients) for up to six months and a dose expansion phase (30 patients) for six months. Endpoints will include safety, haematological improvements, disease progression, survival, quality of life, transfusion independence and cytogenetic/molecular response. Safety confirmation and potential efficacy signals are expected from the 3-month dose escalation phase.

Syntara's contribution to the trial will be to supply the study drug and LOX assays on tissue samples taken during the study.

Oral pan-LOX inhibitor program (SNT-5505) in other cancers

Syntara's drug also has potential in several other cancers including liver cancer and pancreatic cancer where it aims to breakdown the fibrotic tissue in the tumour and enhance the effect of existing chemo and immunotherapies. Syntara has a number of scientific collaborations with centres of excellence across the world who have

shown interest in SNT-5505. The Company is encouraging the use of SNT-5505 in independent investigator-initiated clinical studies wherever possible.

In August 2023 the Company announced publication in the prestigious journal Nature Cancer of preclinical results showing SNT-5505 increases survival by 35% compared to chemotherapy treatment alone in the treatment of pancreatic ductal adenocarcinomas.

Read more [here](#).

Pan-LOX inhibitor program in scarring

Syntara has a second pan-LOX program that is developing both topical and oral drugs to inhibit the enzymes that play a critical role in the development of scar tissue. The program is focused on developing drugs with the potential for use in scar revision, keloid scarring and scar prevention post-surgery.

Syntara is collaborating in this program with Professor Fiona Wood and the University of Western Australia.

The Syntara discovery, SNT-6302 (a topical drug), has shown promising pre-clinical results which have been published in Nature Communications (<https://doi.org/10.1038/s41467-022-33148-5>).

The drug has successfully completed Phase 1a/b clinical trials and encouraging results from a Phase 1c trial, known as SOLARIA2, that treated a total of 50 adult patients for established scars of more than one year in age and greater than 10 square centimeters in size for a period of 3 months.

Read more [here](#).

In conjunction with the University of Western Australia, the company is in discussion to explore the application of SNT-6302 to treat keloid scars; a condition particularly prevalent in darker skin types where the scars continue to grow over time and have very high collagen content. A pilot study that establishes safety and an initial indication of efficacy is planned that will lay the foundation for a larger phase 2 study in this area of very high unmet need.

Furthering its collaboration with Professor Wood and the University of Western Australia, the Company is currently recruiting a clinical trial in scar prevention using its oral pan-LOX inhibitor SNT-5505, to establish the fastest clinical proof of concept. An additional site is expected to start recruitment in Q3 2024 at which time further detail will be provided.

SSAO inhibitor program (SNT-4728) in Parkinson's disease

The Syntara discovery SNT-4728 is a potent inhibitor of the inflammatory enzyme SSAO (semicarbazide-sensitive amine oxidase) and, in the brain, MAOB (monoamine oxidase B).

In November 2023 the Company dosed the first Australian patient in a randomised double-blind placebo-controlled Phase 2 study of patients with isolated Rapid Eye Movement Sleep Behaviour Disorder (iRBD) who are at risk of Parkinson's disease.

Previous research has identified that the development of iRBD, where otherwise healthy people start acting out their dreams, is the strongest predictor for the development of Parkinson's and dementia with Lewy Bodies. A recent multicentre study found that over 70% of iRBD patients transitioned to a neurodegenerative disease.

The study will examine whether targeting inflammation in the brain of people with iRBD will be safe and effective so that a neuroprotective strategy to prevent the disease may emerge.

Working in collaboration, experts from the University of Sydney and the University of Oxford are recruiting 40 patients with iRBD to participate in a 3-month Phase 2 trial to evaluate whether SNT-4728 can reduce neuroinflammation as measured by state-of-the-art nuclear scanning techniques.

iRBD patients have very few treatment options available so this study provides hope for an effective treatment with potential to move towards the longer-term goal of stopping neurodegeneration.

The study has recruited 4 of its targeted 40 patients. With all UK regulatory approval steps now completed the Company expects UK recruitment to shortly commence. Trial results are expected in the second half of CY 2025.

SNT-4728 has passed all long-term toxicity studies and has been well tolerated in all clinical studies including two Phase 2 studies in other indications.

The study is substantially funded by leading charity Parkinson's UK with up to £2.9m (~A\$5m) to be paid to Syntara to run the Phase 2 trial. The Parkinson's Virtual Biotech will receive a return of up to four times its funding from royalties on future revenue Syntara receives from commercialising SNT-4728.

Read a news story from Parkinson's UK about the trial [here](#).

Mannitol respiratory business

Sale of 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 from Arna Pharma.

The MBU sale and associated Syntara restructure has resulted in a reduction of annual core costs, excluding external research costs, of more than 60%, saving the company over \$14m per year. This is due in large part to the elimination of costs attached to operating a global pharmaceutical manufacturing and distribution business and a headcount that dropped from approximately 70 to 25. Syntara continues its review and reduction of ongoing core operating costs.

As the MBU has been sold the financial statements below report its current and prior financial performance as a single line item in the income statement.

Amounts owed by Arna Pharma

The sale agreement included a number of payments from Arna Pharma to Syntara.

- Fixed payments
- Payments for inventory
- Reimbursement of various operating and other costs over and beyond the transition period

In addition Syntara will receive 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).

After amounts already paid by Arna Pharma (~\$2.5m), the amounts currently claimed by Syntara at 30 June are:

- Fixed payments: ~\$3.3m
- Inventory: ~\$0.4m
- Reimbursement of transition & other SNT costs: ~\$1.4m
- Total: ~\$5.1m

Arna Pharma has recently challenged amounts claimed by Syntara primarily related to the fixed payments. Other contractual payment obligations are in dispute. While Syntara is confident in its position, Arna Pharma's approach creates some uncertainty as to the timing and recoverability of certain amounts owing.


Syntara has therefore appointed external counsel to actively pursue available legal remedies, if required, but for financial reporting purposes has conservatively provided for the majority of the amount owed to it by Arna Pharma as a doubtful debt.

Syntara investor presentation

Syntara's most recent published investor presentation is available on the Company [website](#).

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Corporate

Syntara announces two-tranche placement of A\$[4] million

On 30 July Syntara announced the receipt of firm commitments to raise approximately A\$5.0 million via a two-tranche placement at \$0.028 per share. The first tranche of the placement of ~\$2.7 million and the second tranche of ~\$2.3 million are being raised under the Company's 15% placement capacity. Tranche 2 includes 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 expected to be convened for late August or early September 2024. The placement received strong support from a small group of leading international and domestic institutional investors.

Syntara website

A new company website was launched late 2023 which provides a fresh overview of the company, its people and objectives. The website includes comprehensive detail on the clinical trials we are conducting and the Syntara pipeline, along with publications and investor information.

<https://syntaratx.com.au>

Recent broker research

MST Access updated their research during the quarter. Copies of analyst reports are available on the Syntara [website](#).

Financials

Key financial metrics

Income Statement

A\$'000	Three months ended		Twelve months ended	
(unaudited)	30-Jun-24	30-Jun-23	30-Jun-24	30-Jun-23
Revenue				
Grants	143	54	781	510
Interest	4	45	89	117
R&D tax incentive	3,591	5,193	3,603	5,246
Other	72	137	425	475
Total revenue	3,810	5,430	4,898	6,349
Expenses				
Employee costs	(1,638)	(1,508)	(6,880)	(6,308)
Administration & corporate	(401)	(502)	(2,582)	(2,194)
Occupancy & utilities	(34)	(236)	(289)	(588)
Clinical trials	(1,507)	(1,125)	(5,413)	(5,684)
Drug development	(390)	(1,436)	(1,660)	(3,036)
Other	(568)	(104)	(723)	(331)
Depreciation & amortisation	(14)	(80)	(232)	(158)
Foreign currency exchange gains & losses	(68)	84	357	(899)
Finance costs	(6)	63	(360)	-
Total expenses	(4,626)	(4,845)	(17,781)	(19,199)
Profit (loss) before tax - continuing operations	(816)	584	(12,884)	(12,851)
Profit (loss) before tax - discontinued operations	(4,853)	(2,006)	(2,873)	1,491
Income tax expense	-	-	-	-
Net profit (loss)	(5,669)	(1,422)	(15,756)	(11,360)

Financial commentary

Clinical trials

A\$'000	Three months ended		Twelve months ended	
(unaudited)	30-Jun-24	30-Jun-23	30-Jun-24	30-Jun-23
Clinical trials				
Myelofibrosis: oral pan-LOX (external costs - MF-101)	(1,220)	(920)	(4,395)	(4,479)
Scarring: topical & oral pan-LOX (external costs)	(143)	(183)	(190)	(183)
iRBD (Parkinson's)	(448)	(118)	(987)	(694)
Other program external costs	-	103	(145)	(321)
	(1,507)	(1,125)	(5,413)	(5,684)

- Oral pan-LOX (MF) expenditure in the current and prior three and twelve months relates to the ongoing Phase 2a clinical trial in myelofibrosis that has commenced a new combination arm in December 2023. This is the major focus of the company.
- The iRBD clinical trial recruited its first patient in October. The majority of the costs of this trial are funded by a grant from Parkinson's UK.

Drug development

- The majority of external drug development costs for the quarter related to the Company's MF program, and in prior periods also included pre-clinical work by a German university in relation to the effectiveness of SNT-5505 in myelodysplastic syndrome, and development of additional pan-LOX inhibitors, including new topical drugs.

Mannitol respiratory business

- As noted above the mannitol respiratory business was sold during the December quarter of 2023.
- The operations of the business prior to its sale and the ongoing transition period are disclosed as a single line item in the income statement.
- Based on the uncertainty of the amount and timing of future payments owed to Syntara by Arna Pharma, for financial reporting purposes the Company has conservatively booked a doubtful debt provision of \$4.8 million in relation to the \$5.1 million owed by Arna Pharma at 30 June 2024.
- Further detail will be provided in the Company's 2024 financial report to be available in August.

Other expenses

- Other includes a write off of patent costs in relation to programs not currently being developed.
- Finance costs relate to an R&D tax credit loan received and repaid in the second half of the 2023 calendar year.

Cash

A\$'000	30-Jun-24	31-Mar-24	30-Jun-24
(unaudited)	3 months	3 months	12 months
Statement of cash flows			
Cash inflow/ (outflow) from:			
Operations - continuing	(4,071)	(4,151)	(10,038)
Operations - discontinued	(110)	(1,162)	(4,195)
Investing activities - continuing operations	(7)	-	(7)
Investing activities - discontinued operations	899	-	1,093
Financing activities - continuing operations	-	7,383	9,605
Financing activities - discontinued operations	(345)	(610)	(2,168)
Total cash generated/(used)	(3,634)	1,460	(5,710)
Cash at bank	3,521	7,154	3,521

- The Company finished the period with \$3.5 million in cash.
- The Company expects to receive an R&D tax credit in relation to the 2024 financial year of \$3.6 million before 31 December 2024.
- The Company expects a security deposit of \$929,000 to be shortly released subsequent to termination of the Company's lease over its Frenchs Forest facility in the June quarter.
- During the quarter the Company received MBU operating expense reimbursements of \$761,000 and other contractual payments of \$899,000 from Arna Pharma.
- The Company also expects to receive payments from the acquiror of the MBU over the course of the year, there is currently significant uncertainty in relation to the quantum and timing of amounts that will be received.
- On 30 July 2024 the Company announced the receipt of firm commitments to raise approximately A\$5.0 via a two-tranche placement at \$0.028 per share.

Balance Sheet

Below is a summarized balance sheet at 30 June 2024.

A\$'000 (unaudited)	30-Jun-24	30-Jun-23
Assets		
Cash	3,521	9,230
Receivable from purchaser of MBU (net)	346	-
Trade & other receivables	298	4,490
R&D tax credit receivable	3,603	5,193
Inventory		1,641
Property, plant & equipment	383	1,843
Intangible assets	168	682
Security deposits	976	947
Other	2	-
	9,297	24,026
Liabilities		
Trade and other payables	2,392	3,778
Unearned grant revenue	1,877	939
Borrowings	233	2,043
Liabilities related to discontinued operations	462	-
Other liabilities	-	6,603
Provisions	513	1,104
	5,477	14,467
Net Assets	3,820	9,559

Other ASX Listing Rule required disclosures:

Detail in relation to aggregate amount of payments during the quarter to related parties and their associates disclosed in section 6.1 of the Appendix 4C Quarterly Cash Flow Report:

A\$'000	Three months ended 30 June 2024	Twelve months ended 30 June 2024
Non-executive directors' fees	60	285
Executive director remuneration	138	644
Total	198	929

Authorised for release to the ASX by the Syntara Limited Disclosure Committee.

Contact: David McGarvey, Chief Financial Officer and Company Secretary: T +61 2 9454 7200, E David.McGarvey@syntaratx.com.au