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Healthy 3Q24 post mannitol exit

NEED TO KNOW

- \$7.2m cash; \$5.4m net operating cash outflow in 3Q
- SNT-5505 combination MF study: hits 50% recruitment in Phase 2, interim results expected December 2024
- SNT-5505 in MDS to start Phase 2 trial in 2HCY24

Key financials: Syntara announced 3Q results. Cash balance was \$7.2m and net operating cash outflow was \$5.4m; notably, this included \$1.2m in costs for the mannitol business, sold in December 2023. SNT estimates this sale will yield \$14m in total savings p.a.

Lead asset SNT-5505 combination with JAK inhibitor (myelofibrosis [MF]) – new study arm coming: Syntara's Phase 2 clinical trial evaluating the efficacy and safety of SNT-5505 in combination with ruxolitinib to treat MF has achieved 50% recruitment. This open-label study, initiated in December 2023, aims to enrol a total of 15 patients. By early April, 8 patients had received their first dose of the drug combination. This swift recruitment pace suggests the trial may reach its target enrolment by end-1HCY24. The successful recruitment milestone significantly advances the development of SNT-5505 as a potential therapeutic for MF, warranting further investigation into its clinical efficacy.

SNT-5505 (myelodysplastic syndrome [MDS]) – Phase 2 trial in 2HCY24: A Phase 2 clinical trial evaluating a combination treatment of SNT-5505 + chemo in low-/intermediate-risk MDS is expected to begin recruitment in 2HCY24.

Investment Thesis

Overall focus on dysfunction of the extracellular matrix (ECM), a key element in many diseases with high unmet need: *The ECM is a network of fibres, collagen and other proteins that link cells to form tissues; it also provides key signals to cells and regulates the movement of molecules between them.* Syntara is working to develop powerful inhibitors of enzymes that affect the ECM, using amine oxidase chemistry and other technologies, in order to develop new medicines for blood cancers and inflammatory and fibrosis-related conditions. Many of these diseases have high unmet need.

Deep clinical pipeline: Syntara's most advanced clinical asset, SNT-5505, is in Phase 2 clinical trials for primary MF (a rare bone marrow cancer involving fibrosis) and will begin Phase 2 for MDS later in 2024. SNT-5505 is a novel small molecule and irreversible inhibitor to key enzymes involved in forming collagen, specifically the lysyl oxidase (LOX) family of proteins, whose overproduction is implicated in many conditions of chronic inflammation and pathological fibrosis.

Lots of results coming in the foreseeable future: The recent addition of the MDS trial means that Syntara is now conducting four Phase 2 trials; thus, the next 18 months should see strong newsflow from the trial results.

Valuation/Risks

We value Syntara at A\$234m, or A\$0.20/share on a fully diluted basis, using a risk-adjusted NPV-based SOTP (sum-of-the-parts) approach. Our valuation is most sensitive to clinical risk associated with the SNT-5505 at this point.

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Pharmaxis is a clinical-stage drug discovery company developing novel small molecule drugs for inflammatory and fibrotic diseases with major unmet medical need. It is a leader in mechanism-based inhibitors of amine oxidases. It is targeting cancers (e.g., myelofibrosis, pancreatic and liver cancer), diseases of organs including the liver (NASH, liver fibrosis), lungs (pulmonary fibrosis) and kidneys (chronic kidney disease), and fibrotic scarring from burns and other trauma. www.parmaxis.com.au

Valuation	A\$0.20 (unchanged)
Current price	A\$0.02
Market cap	A\$18m
Cash on hand	A\$7.2m (31 March 2024)

Upcoming Catalysts / Next News

Period	
2HCY24	SNT-5505 MDS Phase 2 trial starts recruitment
Dec 2024	SNT-5505, MF: Interim results for Phase 2 combination trial

Share Price (A\$)



Source: FactSet, MST Access

Financials

Figure 1: Income statement

	A\$000's	3Q24	3Q23	Year to date (FY24)	Year to date (FY23)
Revenue					
Grants		260	97	638	456
Interest		9	31	85	72
R&D tax incentive		-	-	12	53
Other		118	111	353	338
Total Revenue		387	239	1,088	919
Expenses					
Employee costs	-	1,759 -	1,611 -	5,242 -	4,800
Administration & corporate	-	826 -	633 -	2,181 -	1,692
Occupancy & utilities	-	116 -	138 -	255 -	352
Clinical trials	-	1,242 -	2,026 -	3,906 -	4,559
Drug development	-	624 -	712 -	1,270 -	1,600
Other	-	14 -	72 -	155 -	227
Depreciation & Amortisation	-	139 -	26 -	218 -	78
Foreign currency exchange gains & losses	-	48	53	426 -	983
Finance costs	-	3 -	63 -	354 -	63
Total expenses	-	4,675 -	5,228 -	13,155 -	14,354
Profit (loss) before tax - continuing operations	-	4,288 -	4,989 -	12,067 -	13,435
Profit (loss) before tax - discontinued operations	-	150 -	73	1,980	3,497
Income tax expense	-	-	-	-	-
Net profit (loss)	-	4,138 -	5,062 -	10,087 -	9,938

Source: Syntara

Figure 2: Cash flow statement (abbreviated)

	A\$000's	3Q24	Year to date (FY24)
Cash inflow/(outflow) from			
Operations - continuing	-	4,216 -	6,003
Operations - discontinued	-	1,162 -	4,085
Investing activities		-	194
Financing activities		6,773	7,782
total cash generated /(used)		1,395 -	2,112
Cash at bank		7,145	7,145

Source: Syntara

3Q24 cash flow - key items

The company conducted a capital raising in the quarter and raised:

- \$7.6m received upon completion of a \$10m placement
- \$303,000 raised through the share purchase plan.

The company also has the following anticipated cash inflows:

- Lease deposit: Syntara expects a \$929,000 security deposit to be released upon termination of the lease for the Frenchs Forest facility in May 2024.
- Mannitol Business Unit (MBU) acquisition: Syntara estimates remaining payments from the acquirer of the MBU at \$6m, with \$723,000 already received since 31 March 2024. (The MBU was sold during the December quarter of 2023).

Clinical trials and costs

The company's spending on oral pan-LOX development (MF) for 3QFY24 and the preceding 9 months has been largely dedicated to its ongoing Phase 2a clinical trial in MF. This trial, which remains Syntara's focus, gained momentum in December 2023 with the addition of a new treatment arm that is exploring combination therapy.

External drug development costs this quarter primarily supported the company's ongoing MF program. Prior periods also included funding for pre-clinical research conducted by a European university. This research explored the potential application of SNT-5505 in treating MDS, a related blood disorder. Additionally, past external costs captured the development of other pan-LOX inhibitor candidates.

Figure 3: Allocation of clinical costs

	A\$000's	3Q24	3Q23	Year to date (FY24)	Year to date (FY23)
Clinical trials					
Oral pan-LOX (external costs - MF-101)	-	1,005 -	1,790 -	3,175 -	3,559
Topical pan-LOX (external costs)	-	-	-	46	-
iRBD (Parkinson's)	-	99 -	163 -	539 -	576
Other program external costs	-	138 -	73 -	145 -	424
		1,242 -	2,026 -	3,905 -	4,559

Source: Syntara

Syntara's clinical pipeline at a glance

Syntara has five drug candidates, four of which have reached the Phase 2 clinical trials stage (see Figure 4).

Figure 4: Syntara's clinical pipeline now with four Phase 2 programs

Drug	Indication	Discovery	Pre-clinical	Phase 1	Phase 2	Status
SNT-5505	Myelofibrosis					Phase 2a completed
SNT-5505 <i>combination with JAK inhibitor</i>	Myelofibrosis					Phase 2a >50% recruited
SNT-5505	Myelodysplastic syndrome					Phase 2 to commence 2H24
SNT-5505	Scar prevention - burns					Phase 2 recruiting (investigator initiated study)
SNT-6302	Scar modification					Phase 1c reported (investigator initiated study)
SNT-4728	iRBD/Parkinson's Disease					Phase 2 recruiting
SNT-5382	Chronic fibrotic diseases					Phase 1 completed
SNT-8370	Inflammation					IND-enabling package complete

Source: Syntara

Risks

Syntara is subject to all the risks typically associated with drug development, including the possibility of unfavourable outcomes in clinical trials, regulatory decisions, success of competitors, financing, and commercial decisions by partners or potential partners.

In addition, key stock-specific sensitivities are detailed below.

Clinical risk

The company's medicinal chemistry expertise and proprietary assays underpin substantial drug discovery capabilities and provide significant opportunities to design, test, and optimise potential drug candidates in preclinical settings. This has been demonstrated by the development of a broad portfolio of small molecule amine oxidase inhibitors over the past five years.

However, drug development carries a raft of associated clinical risks including clinical trial delays or failures which could have a significant impact on the progress of individual assets and related candidates in the pipeline. The most important near-term development sensitivity is related to SNT-5505, given its Orphan Drug Designation status, and to a lesser extent SNT-6302. Both assets are pan-LOX inhibitors and are entering Phase 2a and Phase 1c trials, respectively, which are designed to demonstrate efficacy in patients. Clinical asset-specific risk considerations also include:

- **Clinical target risk:** Although SNT-5505 was shown to be well tolerated at the highest dose given and has delivered complete inhibition of the target enzymes, Phase 2a will answer the question of whether the disease-modifying effect seen in animal models can be replicated in patients.
- **Clinical development path risk:** Targeting of keloid scarring using SNT-6302 could face additional challenges from a clinical development perspective given the heterogeneity of these scars, variability in patient and skin types, and the less objective measures available to monitor progress.

As such, success at this stage will determine the next leg of development activities and have a major bearing on partnering and commercialisation prospects for both clinical assets.

Key person risk

This is also a consideration for Syntara, given its reliance on its drug discovery engine and the highly experienced team currently in place.

Regulatory risk

Market approval will depend on satisfying the requirements of multiple regulators. As in the case of Bronchitol®, this can result in additional data requirements and lead to time delays and increased funding needs. However, the company's experience in bringing Bronchitol® to market despite such delays bodes well for future submissions.

Funding risk

Syntara's currently solid cash position should be adequate to meet near-term goals given the prioritisation of clinical programs and strategic partnerships established to date. However, the cost of trials and operational expenses may overrun estimates and require additional capital to be raised.

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Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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Syntara (SNT.AX) | Price A\$0.02 | Valuation A\$0.20;

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