

SEPTEMBER 2023 QUARTERLY ACTIVITY REPORT AND APPENDIX 4C – MEMPHASYS LIMITED (ASX: MEM)

Memphasys Limited (**ASX: MEM**) is a reproductive biotechnology company developing novel medical devices, diagnostics, and media with application to assisted reproduction technologies in humans and animals.

MEM's most advanced product, the Felix™ System, which is now being sold commercially in Japan, is a patented, automated device for quickly and gently separating sperm from a semen sample for use in human IVF procedures. In addition, MEM is undertaking several other projects, most notably RoxSta and AI-Port, in conjunction with MEM's research partner, the University of Newcastle (UoN) to extend its product pipeline.

Memphasys encloses its Appendix 4C cash flow statement for the quarter ended 30 September 2023 (**Q1 2024**), along with the following update.

BUSINESS ACTIVITIES IN THE SEPTEMBER QUARTER (Q1 2024)

There was no change in the activities of the Company during Q1.

The most significant change in the cash flow of the Company in Q1 compared with the prior quarter is the general decrease in payments of creditors due to the late receipt of the \$1.3m R&D tax refund. This delay had a substantial impact on the Company's cash flow management and the company sourced bridging loans from related parties to cover the short-term funding gaps. The R&D tax refund was received in October.

Administration and Corporate costs include the payment of director fees of \$40,643 and salaries and super of \$91,915, paid to MEM's Managing Director.

FELIX COMMERCIAL ROLL-OUT

VITROLIFE DISTRIBUTION AGREEMENT IN JAPAN

In Q1 2024, MEM signed an exclusive five-year distribution agreement with Vitrolife Japan KK (Vitrolife KK) to sell and distribute Felix™ in Japan, one of the top five addressable markets globally in terms of sales for Felix™ with a potential market opportunity exceeding A\$100 million.

Vitrolife is a subsidiary of the listed Vitrolife Group (Vitrolife AB), which has a market capitalisation of approximately A\$3.06 billion. Vitrolife AB is a world-leading, Swedish-based global provider of medical devices, consumables and genetic testing services dedicated to the human IVF and reproductive health market.

As part of the agreement, Vitrolife KK will provide marketing, sales, and training with an initial focus on key clinicians and high-volume clinics in Japan's private health sector. It will also work with MEM to build clinical data sets over time to position Felix™ to receive full insurance coverage in Japan in the future.

During Q1 2024, Vitrolife KK placed its first order for 150 Felix™ cartridges to supply five high volume Key Opinion Leader (KOL) fertility clinics in Japan. The sale was in addition to previous Felix™ direct sales in Japan to an ART clinic in Kobe.

Post quarter end, Memphasys received a second order of 150 Felix cartridges for roll out to the next 5 KOL clinics. The Kobe clinic which had ordered directly prior to Memphasys signing the distribution agreement with Vitrolife KK is now re-ordering through Vitrolife KK.

Under the terms of the distribution agreement, Vitrolife and Memphasys commenced discussions to implement a standing ordering system to smooth manufacturing and inventory to accommodate the anticipated growth in Felix™ uptake and commercial sales in 2024.

OTHER EARLY ACCESS JURISDICTIONS

MEM is continuing to discuss distribution in other early access jurisdictions (NZ and Canada) with various potential distributors, including Vitrolife.

India

India is a substantial and growing commercial market, with a potential addressable market in terms of sales exceeding A\$50 million. It is one of the top five addressable markets globally for Felix™.

Before regulatory changes were introduced by the Indian regulator, the Central Drugs Standard Control Organisation (CDSCO) in August 2022, MEM made a substantial number of Felix cartridge sales to the Coimbatore Women's Hospital (CWH). These cartridges were clinically used to make embryos which were subsequently frozen for future implantation. Embryo freezing is an increasingly common practice in IVF clinics globally.

Following the introduction of the regulatory changes, MEM temporarily suspended sales in India. MEM has taken action to address the regulatory changes brought in last year. As an initial strategy, it has submitted a voluntary product registration with CDSCO to sell non-commercial quantities in India, which is pending; it has also sought regulatory advice on importing the Felix™ into India for special test purposes. MEM is further investigating this option.

In the September quarter, CWH successfully recorded ten new live births using Felix™. This brings total live births to date to eleven following the first live birth of a baby using Felix™ in the 2023 financial year. All patients had previously failed IVF and the males had high levels of sperm DNA fragmentation, a known cause of infertility. The results confirmed the positive impact of Felix™ on sperm selection in a highly challenged patients, especially in males with high levels of sperm DNA damage. Dr Ramya Jayaram from CWH, one of MEM's KOL partners, presented the paper titled: *'First Recorded Normal Live Birth after ICSI with Electrophoretically Isolated Spermatozoa Using the Felix™ System'* in September at the ASPIRE Congress in Adelaide. Dr Jayaram is an internationally recognised specialist in reproductive medicine.

China

China is one of the top five addressable markets globally for Felix™ with a potential market opportunity in terms of sales of approximately A\$140 million.

MEM completed the submission of its two applications to China's regulatory authority, the National Medical Products Administration (NMPA) in the second half of the 2023 financial year. NMPA provided an initial review of submissions and responded to MEM with a series of technical and clinical questions in June 2023 which MEM is addressing.

Australia

While not a top five target market in terms of sales, Australia is MEM's home market and is important to obtaining regulatory clearance for Felix™, not only for Australian access, but also for access to other markets, notably India and various Asian and Middle Eastern countries.

In Q1 2024, MEM's clinical trial with Monash IVF Group Ltd (MVF) steadily gained momentum in the swim-up arm, which is now virtually complete. Based on current indications, MEM expects the trial to be complete by Q3-Q4 2024 and the results analysis and regulatory submission to be filed by Q1-Q2 2025. The results of the MVF clinical study will be filed as a formal regulatory submission with the Therapeutic Goods Administration (TGA).

MEM is evaluating the possibility of adding another institution that predominantly uses DGC. DGC is a common method used by clinics globally, but it is not a common sperm preparation method used by Monash IVF.

During the quarter, MEM continued to:

- Accelerate patient recruitment for the Felix™ clinical trial with Monash IVF in Australia.
- Expand its patent portfolio with the granting of additional patents on Felix™.
- Decrease consultants' costs, given that two senior executives could fill activities previously undertaken by consultants.

NEW PRODUCT DEVELOPMENT

ROXSTA (FORMERLY ROSA)

RoXsta is an in vitro diagnostic that assesses semen and other bodily fluids for the presence of oxidative stress. Oxidative stress is linked to human infertility and is an underlying factor in Alzheimer's disease, diabetes and heart disease. The diagnostic has an estimated addressable market size of more than A\$2 billion just in the human fertility market application.

In Q1 2024, MEM changed the name of the product formerly known as ROSA to RoXsta; this new name is now in the process of being trademarked.

The commercialisation of RoXsta progressed in Q1 2024. MEM's external design partner began building a prototype, which will be validated by University of Newcastle once the build is complete.

Like Felix™, RoXsta's accuracy will also be independently tested and published by MEM's KOLs partners to build a body of clinical data and support MEM's submission for regulatory clearance high access markets. It is anticipated at this stage that clinical trials for research use will begin in Q4 2024.

MEM's initial focus for RoXsta's commercialisation will be the reproductive science research market, which has minimal regulatory hurdles, and early access human fertility markets such as Japan. It is anticipated at this stage that sales for research use will begin in Q4 2024.

MEM applied for a patent for RoXsta in the second half of the 2023 financial year, which is pending.

ARTIFICIAL INSEMINATION-PORT (AI-PORT)

AI-Port stores and transports animal semen for artificial insemination for up to seven days without the harmful effects of freezing sperm used in standard AI procedures in livestock. AI-Port has an estimated addressable beef bovine (non-dairy) market size of nearly A\$2.4 billion.

In Q1 2024, MEM completed preparations for its field trial of AI Port, which is due to commence in November on our partner stud farm. The field trial, which aims to increase pregnancy rate over traditional AI, will incorporate an additional step introduced in Q4 2023 into the AI Port process to remove seminal plasma through a simple centrifuging step. Used in conjunction with MEM's proprietary AI medium, the extra step was found to extend the longevity of the sperm up to seven days, produce a high yield of sperm and enhance the *in vitro* parameters of progressive motility, morphology, and vitality. Industry technicians have endorsed the introduction of the front-end centrifuging step in the lead up to the trial.

Pending a positive outcome to the field trial, MEM plans to initially use a contract manufacturer to make MEM's proprietary medium and then to commence sales of AI-Port to Australian producers in the next Australian breeding season followed by potential sales to overseas markets. Ultimately MEM plans to transfer manufacturing of its AI medium in-house.

This concludes MEM's Quarterly Report for Q1 2024.
Approved for release by the Board of Memphasys Limited

For further information, please contact:

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Memphisys Limited

ABN

33 120 047 556

Quarter ended ("current quarter")

30 September 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	18	18
1.2 Payments for		
(a) research and development	(103)	(103)
(b) product manufacturing and operating costs	(3)	(3)
(c) advertising and marketing	(16)	(16)
(d) leased assets	(47)	(47)
(e) staff costs	(415)	(415)
(f) administration and corporate costs	(349)	(349)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(2)	(2)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other	-	-
1.9 Net cash from / (used in) operating activities	(913)	(913)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	-
3. Cash flows from financing activities			
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	356	356
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	356	356
4. Net increase / (decrease) in cash and cash equivalents for the period			
4.1	Cash and cash equivalents at beginning of period	638	638
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(913)	(913)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	356	356
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	81	81

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	81	638
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	81	638

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	133
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
	<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1	Loan facilities	4,888	4,888
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	4,888	4,888
7.5	Unused financing facilities available at quarter end		-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
	Convertible Note: \$3m principal plus interest \$676,708 (maturing 31 December 2023, coupon rate 8%) R&D Loan: \$855,037 (repayable on receipt of R&D rebate, coupon rate 16%) Related party loans: \$356,000 short-term unsecured loan (\$166,000 repayable on receipt of R&D rebate, balance on completing a capital raising, 12% interest rate) \$855,037 and \$166,000 were repaid in October 2023 after receiving the R&D rebate		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(913)
8.2	Cash and cash equivalents at quarter end (item 4.6)	81
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	81
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.09
	<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: YES. Net operating cash flows is expected to be consistent with that shown in 8.1 above, with the exception of certain creditors not paid in the September 2023 quarter until the company received the R&D tax rebate (received 11 October 2023). There is expected to be an increase in research and development expenditure attached to the RoXsta device (refer to activities report)	
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	Answer: YES. The company received the \$1.3m R&D tax rebate on 11 October 2023; it is seeking bridge financing; and has signed a mandate with corporate finance advisors to undertake a capital raising in the December 2023 quarter.	

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: YES. The business expects to continue its operations and meet its business objectives on the basis it has the necessary licences, agreements and technical personal in place to ensure the company continues to advance the commercialisation of the Felix Device (and other technologies).

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31 October 2023

Authorised by: By the Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.