MEMPHASYS
REPRODUCTIVE BIOTECHNOLOGY

DECEMBER 2022 QUARTERLY ACTIVITY REPORT AND APPENDIX 4C – MEMPHASYS LIMITED (ASX: MEM)

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

MEM is commercialising the Felix™ System, which is a patented, automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures. In addition, it has several research and development projects being undertaken in conjunction with MEM's research partner, the University of Newcastle (UoN).

MEM is prioritising projects with the highest/quickest commercial return and on this basis, the top three projects are the Felix™, ROSA and AI-Port.

Memphasys is pleased to provide its Appendix 4C cash flow statement for the quarter ended 31 December 2022 (**Q2**), along with the following update.

BUSINESS ACTIVITIES IN THE DECEMBER QUARTER (Q2)

There was no change in the activities of the Company during Q2.

The most significant change in the cash flow of the Company in Q2 was the receipt of the R&D Incentive grant for $1.49m.

On the cash out-flows side, the most significant changes compared with the prior quarter were:

- a decrease of 64 percent on R&D expenditure, mainly due to payment in Q1 of three instalments relating to the research agreement with the UoN, versus no payments made in Q2;
- an increase of 279 percent on Product Manufacturing, due to manufacturing 1,600 Felix™ cartridges in Q2, versus none in Q1; and
- a decrease of 56 percent on Administration and Corporate costs, mainly due to payment of the D&O insurance, year-end audit fees and legal fees (in relation to the court application for the failure to lodge cleansing notices in the past) in Q1, versus no one-off payments made in Q2.

Administration and Corporate costs include the payment of:

- non-executive director fees for a total of $50,333; and
- salaries and super of $87,800, paid to MEM's Managing Director and Chief Executive Officer, Ms Alison Coutts.

MATERIAL DEVELOPMENTS

The Felix™ System

Estimated addressable market size: $670m (for top 5 markets only: Europe, China, Japan, USA, India)

Regulatory plan

Strong regulation enables market stability and clarity, provides more certainty around the opportunities in target markets and is positive for the development of business. Regulatory compliance and approval are essential and necessary components of commercialising a medical product for the market.

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INDIA

The Indian regulator, the Central Drugs Standard Control Organisation (CDSCO), introduced changes to improve IVF processes in Q1 FY23. The changes cover the regulation of all Assisted Reproductive Technology (ART) clinical processes undertaken in India and also, of all medical devices sold in India, not just those used for ART.

During Q2 FY23, MEM addressed these changes by:

- consulting and seeking advice with an Indian-based regulatory adviser on the changes;
- submitting a voluntary product registration with CDSCO as an initial strategy to sell non-commercial quantities in India;
- engaging other parties affected by the changes including Indian Key Opinion Leader ("KOL") partners, consultants, Indian medical device manufacturers and distributors for advice on the regulatory changes; and
- investigating the option of manufacturing in India, which is likely to reduce the Felix™ System production costs, will negate import duties and import agent fees, and potentially enable the Felix™ System to receive priority by CDSCO for granting a license to sell domestically.

CHINA

In Q2 FY23, MEM completed the submission of its two applications to China's regulatory authority, the National Medical Products Administration (NMPA). The first submission requested a device classification for the Felix™ System; the second submission sought the Felix™ System's eligibility for the fast-tracked 'Green Channel' regulatory pathway for innovative medical products.

JAPAN and CANADA

In Q2 FY 23, MEM held face to face meetings with its KOL partners from Japan and Canada at the American Society of Reproductive Medicine Conference in the USA and discussed next commercialisation steps for these markets. Both KOLs agreed that *in vivo* clinical trials to evaluate Felix's performance against their current sperm separation protocols were necessary prior to the KOL making a purchasing decision. Discussions with both KOLs are continuing, with a small Japanese clinical trial about to commence and with the protocol for a trial being agreed with the Canadian KOL.

AUSTRALIA

The timing of MEMs clinical trial with Monash IVF Group Ltd (MVF) was pushed back into 2023. This is due to lower-than-expected participation rates across clinical trial sites post-COVID and patients failing to meet the trial's stringent entry criteria.

In Q2 FY23, MEM has worked to improve trial participation rates including:

- working with MVF technical and marketing personnel to increase awareness of the trial among fertility specialists;
- increasing the number of local participating sites; and
- broadening patient inclusion criteria.

MEM's novel reproductive biotechnology products

ROSA (Rapid Oxidative Stress Assay)

Estimated addressable market size:>$2 billion (human fertility market application only)

ROSA assesses the presence of oxidative stress in a semen or blood sample. Oxidative stress, the imbalance between reactive oxygen species and antioxidant protection in the body, is an underlying factor in many disease states including Alzheimer's disease, diabetes and heart disease. It is also linked to male and female infertility, and associated issues such as pre-eclampsia, placental failure, preterm birth and recurrent miscarriage in women.

- In Q2 FY23, MEM developed a prototype that utilises a unique reaction, currently under patent application, that occurs in minutes, to measure the concentration of antioxidants in human semen and blood. During the quarter, MEM continued to optimise the conditions of the reaction and started to develop a prototype that will lead to a point of care in vitro diagnostic product.

AI-Port

Estimated addressable market size: $1.8 billion (for top 5 beef cattle AI markets only: Brazil, Europe, USA and Australia)

AI-Port stores and transports animal semen for artificial insemination for up to four days without the harmful effects of freezing sperm used in standard AI procedures in livestock.

- In Q2 FY23, MEM established a proof-of-concept device in combination with use of a novel proprietary medium.
- MEM also held initial and fruitful discussions about the potential for doing a pilot *in vivo* field trial with some studs that produce highly valued beef cattle by AI. The trial would compare the outcome from use of the MEM prototype with the standard freeze/thaw AI procedure to obtain cattle pregnancies.

SemPort

SemPort is a device containing a novel, proprietary medium that stores and transports human semen for up to four days at ambient temperature, without the harmful effects of freezing sperm.

- In Q2 FY23, the Company determined whilst it could not technically develop a device for enabling the semen sample to remain intact for seven days without freezing, which was the original goal, it could preserve the semen for 3-4 days.
- MEM is evaluating the potential use of such a product, for example the potential for a man to provide a semen sample at home and then send to a central laboratory for a full semen analysis, rather than providing the sample on the spot at an andrology clinic/ IVF lab for analysis.

Samson device (for evaluating stallion fertility shortly after mare insemination)

- In Q2 FY23, the Company completed field trials at two thoroughbred horse studs on the Samson device. MEM started evaluating results and those evaluations continued through January 2023. Results are likely to be announced in the half year results.

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

Memphasys Limited

ABN	**Quarter ended ("current quarter")**
33 120 047 556	31 December 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(202)	(760)
	(b) product manufacturing and operating costs	(110)	(139)
	(c) advertising and marketing	(34)	(34)
	(d) leased assets	(45)	(91)
	(e) staff costs	(440)	(940)
	(f) administration and corporate costs	(198)	(646)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	5
1.5	Interest and other costs of finance paid	-	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,496	1,504
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**476**	**(1,098)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(39)	(78)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**(39)**	**(78)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	3,360
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	(24)	(283)
3.5	Proceeds from borrowings	-	440
3.6	Repayment of borrowings	-	(515)
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**	**(24)**	**3,002**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	**1,682**	**269**
4.2	Net cash from / (used in) operating activities (item 1.9 above)	**476**	**(1,098)**
4.3	Net cash from / (used in) investing activities (item 2.6 above)	**(39)**	**(78)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	**(24)**	**3,002**
4.5	Effect of movement in exchange rates on cash held	**-**	**-**
4.6	**Cash and cash equivalents at end of period**	**2,095**	**2,095**

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	**2,095**	**1,682**
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)**	**2,095**	**1,682**

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	138
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** *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.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	**476**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**2,095**
8.3	Unused finance facilities available at quarter end (item 7.5)	**-**
8.4	Total available funding (item 8.2 + item 8.3)	**2,095**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**

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.

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:

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:

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:

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 January 2022

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.