28 July 2023

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

Memphasys Limited (ASX: MEM) ("the Company" "Memphasys"), a reproductive biotechnology company developing novel medical devices, diagnostics, and media for application to ART ("Assisted Reproduction Technology") in humans and animals, is pleased to provide its Operational update and Appendix 4C cash flow statement for the quarter ended 30 June 2023 (Q4).

BUSINESS ACTIVITIES IN THE JUNE QUARTER (Q4)

There was no change in the activities of the Company during Q4.

The most significant change in cash flow in Q4 compared with the prior quarter is the increase in payments for staff costs due to the appointment of two highly experienced executives to the key roles of Director of Business Development and Director of Operations.

The Company expects staff costs to reduce in future quarters as it successfully transitions workloads from consultants to these full-time employees.

Administration and Corporate costs include the payment of:
- non-executive director fees for a total of $50k; and
- salaries and super of $90k, paid to MEM's Managing Director and Chief Executive Officer, Ms. Alison Coutts.

MATERIAL DEVELOPMENTS

Key Opinion Leader (KOL) Research Publications

In Q4 2023, the release of a new study titled '*Analysis of sperm separation protocols for isolating cryopreserved human spermatozoa*' (the Study) revealed that only sperm cells separated using the Felix™ System (Felix™) exhibited significantly lower levels of DNA fragmentation following cryopreservation while maintaining relatively high levels of motility and sperm recovery.[1]

This was the first study globally to compare electrophoretic separation (using Felix™) with the density gradient centrifugation (DGC) and Swim-up sperm isolation techniques on cryopreserved human sperm. The storage of sperm via cryopreservation is extensively used in assisted reproductive technology (ART) for the long-term preservation of male fertility.

The Study was designed, conducted, written, and edited by A Hungerford, a PhD student at the University of Newcastle funded by Memphasys and co-authored by Professor John Aitken and Associate Professor Hassan Bakos. The results of the Study were also released on 5 June 2023 at the annual Fertility Society of Australia of Australia and New Zealand (FSA) 2023 Conference and have also been published in the medical journal 'Reproduction and Fertility'.

Peer reviewed papers and studies underpin the integrity of Felix™, support regulatory filing material and ultimately enhance its commercialisation, which is evidenced by an increased level of "in-bound" enquiry for Felix™ since these papers were published.

[1] Refer to ASX announcement dated 6 June 2023

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Product Pipeline

MEM prioritises the development of its novel reproductive biotechnology products according to their potential to deliver the strongest and/or fastest commercial returns for shareholders. Its product pipeline is categorised into three groups:

- Core: in commercialisation
- Developing: in development and subject to stringent assessment prior to proceeding to commercialisation
- R&D: research to extend and sustain the health of MEM's product pipeline in conjunction with MEM's research partner, the University of Newcastle (UoN) – subject to stringent assessment prior to proceeding to development.

The Felix™ System (Core)

The Felix™ System (Felix™) is a patented, automated device that quickly and gently separates high quality sperm from a semen sample for use in human IVF procedures. It is MEM's first commercial product. Felix™ has an estimated addressable market size (per annum) of A$630 million[2][3] in its top five markets of the European Union, China, Japan, the United States and India.

The addressable market size has been estimated based on multiplying the potential sales of the device by the size of the market that could be accessed, which is substantially less than the total size of the market.

Patents

Subsequent to the end of Q4 FY23, MEM was granted two new patents for Felix™ by the Australian Patent Office[4]. Patents have already been granted for Felix™ in several other jurisdictions.

Title of invention	Electrophoresis device
Patent number	2017344755
Date of grant	18 May 2023
Term of patent	20 years from 20 October 2017
Existing patents (by jurisdiction)	China, Japan, the United States; European Union (pending)

Title of invention	Sperm separation by electrophoresis
Patent number	2017344756
Date of grant	20 years from 20 October 2017
Existing patents (by jurisdiction)	China, Japan, the United States; European Union (pending)

Patents are essential to protecting MEM's unique intellectual property globally as Felix™ is increasingly commercialised across target markets.

Pathway to market

Japan

Japan represents one of the top five addressable markets globally for Felix™ with a potential market opportunity exceeding A$105 million (per annum).

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[2] Total annual potential market for the Felix™ System that MEM could be accessing as sales opportunities within the next five years. Reference: Allied Market Research Global IVF Services Market 2019 & "The Infertility Trap: Why Life Choices Impact Your Fertility & Why We Must Act Now" – Robert John Aitken, Cambridge University Press, 5 May 2022

[3] ART in Australia and NZ, Oct 2022, UNSW, Sydney - in collaboration with Fertility Society of Australia

[4] Refer to ASX announcement dated 13th July 2023

In Q4 FY23, MEM made repeat sales of sterile single-use Felix™ cartridges to the Kobe ART Clinic in Japan[5]. MEM doesn't require regulatory clearance to sell Felix™ in Japan, which has been identified as an Early Access market for Felix™.

Following introduction of a new IVF reimbursement scheme in Japan in 2022, MEM, has chosen initially to work exclusively with Japan's substantial private clinical market.

MEM's commercialistion strategy in this market is to identify and evaluate the appointment of a distributor for this market, with a key focus being on choosing a company with an established brand and IVF clinic market share, and a proven capacity in the sales/ marketing of consumables and devices.

MEM has undertaken an extensive process in this regard and is in discussions regarding a distribution agreement (or agreements) for this market. It should be noted that these discussions are confidential and incomplete at this time.

Canada

Canada is another early access market for Felix™. MEM is in discussions with potential distributors who service IVF clinics across Canada and are keen to make the product available to these clinics. These discussions are confidential and incomplete at present.

India

India is a substantial and growing market, with a potential addressable market exceeding A$50 million.

Under the regulatory changes introduced in August 2022 by the Central Drugs Standard Control Organisation (CDSCO), which has now disallowed medical device imports to India unless they have home country approval, MEM continues to investigate the viability of establishing a low-cost manufacturing base for Felix™ in India. This option is likely to reduce the cost of production and supply of Felix™ to markets globally, and to negate import duties and import agent fees, and potentially expedite the regulatory clearance to sell Felix™ in India.

MEM is currently in discussions with regulatory consultants in India regarding Indian commercialisation pathways after a preliminary discussion with CDSCO in New Delhi in July 2023.

In Q4 2023, Indian KOL partner, Coimbatore Women's Hospital Centre, reported the first live birth of a healthy baby boy using the Felix™ System[6], which was available prior to the regulatory changes brought about in August 2022. The clinic, which generally freezes embryos for subsequent transplantation, used Felix™ predominantly for males suffering from high sperm DNA fragmentation, which is common and highly correlated with infertility. A paper on the clinical results has been accepted for presentation by the key Coimbatore clinician responsible for the clinic's work at the Asia Pacific Initiative on Reproduction (ASPIRE) conference, to be held in Adelaide, Australia between 7 and 10 September 2023.

China

China represents one of the top five addressable markets globally for Felix™ with a potential market opportunity exceeding A$140 million.

MEM has two submissions pending with China's regulatory authority, the National Medical Products Administration (NMPA). The first submission requested a device classification for Felix™; the second submission sought the device's eligibility for the fast-tracked 'Green Channel' regulatory pathway for innovative medical products. In Q4 FY23, the NMPA completed its first review of both submissions and has now requested MEM to supply additional technical information.

Australia

[5] Refer to ASX announcement dated 3rd April 2023
[6] Refer to ASX announcement dated 3rd April 2023

Australia, a highly regulated market overseen by the TGA (Therapeutic Goods Association) has an addressable market of around A$15m.

In Q4 2023, there was continued uptake in patients participating in the Felix™ clinical trial with Monash IVF Group Ltd (MVF) following the introduction of initiatives to improve trial participation. The trial is assessing the performance of the Felix™ device against the two commonly used methods, "Swim Up" and "DGC", for preparing sperm for ART (Assisted Reproduction Technologies). As Monash IVF undertakes more Swim Up than DGC, the Swim Up arm of the trial has been proceeding most rapidly and is now nearing completion.

Despite a slow start, DGC recruitment is now increasing and, with the later addition of additional DGC sites in Victoria and recently in Perth, Memphasys is hopeful that the trial will conclude at the end of the calendar year but could potentially extend another quarter. Although actual results won't be known until the double blind is removed at the end of the trial, overall results continue to be positive.

The results of the MVF clinical study will form the basis of the regulatory application that will be filed with the Australian Therapeutic Goods Administration (TGA). They will also be used support MEM's application to sell Felix™ in other jurisdictions.

Rapid Oxidative Stress Assay (Core)

Oxidative stress refers to an imbalance between the production of reactive oxygen species (ROS) and the body's ability to neutralise them through antioxidant defences. ROS are highly reactive molecules containing oxygen that can cause damage to cellular components such as DNA, lipids, and proteins. Under normal circumstances, the body's antioxidant defences effectively counteract the harmful effects of ROS. However, when the balance is disrupted, oxidative stress occurs, leading to damage to cells and tissues, potentially causing a cascade of detrimental effects on overall health.

Oxidative stress plays a crucial role in various disease states, including cardiovascular diseases, neurodegenerative disorders, and cancer. Furthermore, it has been increasingly linked to fertility issues in both men and women. In males, excessive oxidative stress has been associated with sperm dysfunction, DNA damage, and reduced sperm motility, all of which contribute to male infertility. In females, oxidative stress can impair oocyte quality and decrease embryo implantation rates, leading to difficulties in conceiving naturally or through assisted reproductive techniques.

Oxidative stress, a crucial area of scientific and clinical interest, has been at the forefront of research discussions, particularly after Professor John Aitken's thought-provoking presentation at the recent ESHRE annual conference in Denmark. As Laureate Professor of Biological Sciences at the University of Newcastle and Scientific Director of Memphasys Ltd, Professor Aitken highlighted the escalating impact of oxidative stress with age and its significant implications for overall health, particularly in the context of fertility for both humans and animals.

Memphasys believes there is a pressing need for the development of a rapid, cost-effective point of care diagnosis to aid healthcare practitioners in providing effective patient advice and follow-up treatments.

The Rapid Oxidative Stress Assay being developed by Memphasys is an *in vitro* diagnostic that assesses semen and blood samples for the presence of oxidative stress. The product has an estimated accessible fertility market of A$2.3 billion in its top six target markets including the European Union, China, the United States, Japan, India, and Australia. MEM's application to patent the diagnostic is pending. There is also a subsequent possible application beyond fertility markets to the detection and monitoring of oxidative stress in other diseases.

Pathway to market

In Q4 FY23, MEM contracted a leading Australian product development company to design and prototype the first 'Go-to-Market' product. Once completed, the 'Go-to-Market' prototype will be tested with MEM's research partners, the University of Newcastle and MVF, before the final 'Go-to-Market' product is built.

The initial focus will be the reproductive science research market, which has no regulatory hurdles, and in Early Access human fertility clinical markets such as Japan.

AI-Port (Developing)

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. The product has an estimated addressable bovine (non-dairy) market size of nearly A$2.4 billion.

In Q4 FY23, MEM completed the initial field trial of AI-Port, which compared the pregnancy performance of the AI-Port sperm separation prototype and MEM's novel long-life ambient temperature medium against conventional frozen thawed semen. Whilst there was a pregnancy from the AI-Port device, MEM determined that seminal plasma toxicity was still too limiting.

MEM subsequently tested its proprietary AI-Port medium and found that by removing the seminal plasma through a quick, single pass DGC step, that the sperm were able to survive well in the novel medium for at least seven days rather than for only four days in the presence of seminal plasma.

Pleasingly, a high yield of viable sperm was achieved, and *in vitro* parameters of progressive motility, morphology and vitality were greatly enhanced.

MEM has received endorsement from AI technicians that a front-end DGC step would be fine to do in the field. MEM is now engaging with multiple studs in preparation for bigger field trials in the first half of FY24.

Conclusion

Memphasys has worked systematically and efficiently in the development of its product pipeline. It has attracted and retained a world-leading research team and developed a highly skilled product development team to drive this activity.

Significant advancements in its product portfolio have occurred during the quarter which sees it now well placed for significant milestones to be achieved within the next two quarters, most notably, a meaningful entry and consolidation into key markets for the Felix™ System and value-added development of the oxidative stress diagnostic and AI-Port.

With the appointment of a Director of Business Development and a Director of Operations, which complement the highly skilled existing executive team, the Company is confident the coming quarter will prove pivotal to its commercialisation aspirations.

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	30 June 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	7	15
1.2	Payments for		
	(a) research and development	(236)	(1,242)
	(b) product manufacturing and operating costs	(83)	(287)
	(c) advertising and marketing	(7)	(53)
	(d) leased assets	(54)	(230)
	(e) staff costs	(516)	(1,865)
	(f) administration and corporate costs	(318)	(1,186)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	13
1.5	Interest and other costs of finance paid	(1)	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,504
1.8	Other	10	13
1.9	**Net cash from / (used in) operating activities**	**(1,195)**	**(3,320)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(45)	(162)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(45)**	**(162)**

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	-	(283)
3.5	Proceeds from borrowings	849	1,289
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**	**849**	**3,851**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	**1,029**	**269**
4.2	Net cash from / (used in) operating activities (item 1.9 above)	**(1,195)**	**(3,320)**
4.3	Net cash from / (used in) investing activities (item 2.6 above)	**(45)**	**(162)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	**849**	**3,851**
4.5	Effect of movement in exchange rates on cash held	**-**	**-**
4.6	**Cash and cash equivalents at end of period**	**638**	**638**

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	**638**	**1,029**
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)**	**638**	**1,029**

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	140
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)	**(1,194)**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**638**
8.3	Unused finance facilities available at quarter end (item 7.5)	**-**
8.4	Total available funding (item 8.2 + item 8.3)	**638**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**0.53**

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: Yes. We expect cash outflow to increase by around 20% in the September quarter mainly due the development of the oxidative stress diagnostic and payment of unbilled fees from the University of Newcastle. This increase in spending will be partially offset by the expected R&D tax refund to be received from the ATO (after payment of the R&D loan).

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 has agreed terms to secure a loan from a director to remain fully funded through to September. The Company is on track to submit the R&D application and tax return to receive the R&D loan in September and we anticipate that the next capital raising is expected will be undertaken around this time.

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 be able to continue its operations to 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).

The Company has the support of its longstanding corporate advisor, which has successfully raised funds for Memphasys several times in the past four years, and major shareholders and is engaged to complete the next capital raise in the September quarter.

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: 28 July 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.