Memphasis Limited
ABN 33 120 047 556
Financial Year Ended 30 June 2019
Appendix 4E: Performance Commentary

Principal activities

Memphasys has patented technology combining electrophoretic separations with size exclusion-based membranes using patented hydrogels and other polymer membranes. Memphasys is using this technology for high value cell separations.

The first and major commercial opportunity for the Company is the selection of very high-quality sperm cells from semen for human IVF treatments. The technology has also been proven to work in various domestic animal sperm separations, notably in horses and cattle and in addition it has demonstrated an ability to separate various cell populations and subtypes of these populations from blood.

For the primary application, human artificial reproductive technologies ("ART"), Memphasys has developed a unique device, "Felix", to address male factor infertility. The Felix device is positioned to be used in IVF clinics globally and is close to commercialisation. The key basis of the separation is the high net negative change on the surface of the best sperm cells, which indicates a well formed cyto-skeleton, which in turn indicates intact DNA in the cell nucleus. The cells are also separated on the basis of their size, with unwanted debris including white blood cells left behind, as they are unable to get through the size exclusion membrane.

Memphasys is developing the Felix device with its engineering development partner, Melbourne-based Hydrix, and with the inventor of the sperm separation technology, Professor John Aitken and his research team at the University of Newcastle. In addition, Memphasys has an ongoing collaborative agreement with Monash IVF Group. Monash IVF Group personnel, led by Professor Michelle Lane, are providing crucial clinical testing and technical, clinical and regulatory advice to assist Memphasys in bringing the product to market. For its initial work with Memphasys, in April 2019, Monash IVF Group was issued 4 million ordinary Memphasys shares, priced at 2 cents per share.

The collaborations with both Professor John Aitken's team at University of Newcastle and with Professor Michelle Lane at Monash IVF Group are ongoing.Memphasys' platform technology enables efficient and cost effective separation of valuable cells and proteins from biological.

Review of operations

The Felix Device for Human Assisted Reproductive Technologies ("ART")

Over the twelve months to June 30, 2019, the main focus of the Company has been the commercial development of the Felix device for use in the human IVF market.

The Felix device gently and efficiently separates sperm in around 5 minutes in a simple, single, automated process. This is a marked improvement on the current sperm preparation and separation processes, density gradient centrifuge ("DGC") and/or "swim up" that are currently used in IVF clinics. These processes have been used since the advent of IVF some 40 years ago. Both techniques are laborious, variable depending on the operator (not automated), take up 30 to 40 minutes and they do not necessarily select the most viable sperm with least DNA damage and fertilising potential. In addition, these processes can create oxidative damage to the sperm and/or damage the sperm's DNA.

Felix Product Development

Over the year, Memphasys carried out extensive work on refining the design and operating performance of the single use cartridge – the most complex part of the device - in preparation for making Felix a commercial product for routine human clinical use in IVF clinics globally.

Feedback from Monash IVF, a subject matter expert in the IVF sector, highlighted a number of design characteristics that could be implemented to facilitate a simpler user process and improved user experience, including reducing the 1.8 ml volume to the usual 1 ml clinical sample volume and allowing the use of a single rather than dual pipetting method to be used to load the cartridge. These two suggestions, now incorporated, necessitated changes to the cartridge chamber geometry and the development of a dry hydrogel membrane for use within the cartridge.

Felix Production

Memphasys completed the Felix requirements specification and built the first Felix machined single use cartridge prototypes to this specification and then extensively tested the prototypes at the University of Newcastle and Monash IVF.

Initial hand-assembled manufacturing runs of the Felix device took place in 2019 in preparation for the Key Opinion Leader ("KOL") study and clinical validation. Memphasys has now chosen the product suppliers for all Felix components for the final product.

The major manufacturer appointed is W&S Plastics ("W&S"), with other suppliers also selected for other components. W&S will manufacture the plastic components and other parts of the cartridges, assemble, pack and label the cartridges, then send cartridges for external gamma sterilisation. W&S provided an improved design to support an improved manufacturing process with an over-mould instead of using silicon gaskets to seal the cartridge chambers. This results in fewer components, a product that is easier to assemble, decreased manufacturing costs and increased automation to enable larger runs. The design of the separation membrane has been improved, resulting in a more efficient process and less wastage. The electrodes were also modified to enable the use of a far cheaper carbon printed film on a plastic substrate, replacing the expensive platinum coated titanium electrodes that were used in the original prototype.

The initial hydrogel membranes for the KOL study are being manufactured at Memphasys but will be transferred later to W&S for production.

Regulatory Strategy and Submissions

Memphasys updated its regulatory strategy, in conjunction with specialist consultants.

The Company also implemented a quality management system ("QMS") and an online software system, Greenlight Guru, in preparation for achieving an ISO 13485 certification.

Marketing and Key Opinion Leader assessment program

In order for the Felix device to receive market support, testing and endorsement of KOLs will be vitally important. To this end, Memphasys has recruited 13 KOLs situated in key markets around the world to participate in in-vitro assessment of Felix.

Memphasys developed clinical assessment protocols in conjunction with Prof. John Aitken to evaluate Felix device's performance against the two current processes of preparing sperm for IVF procedures, DGC and Swim Up.

Animal ART work

Memphasys continued to research the use of its prototype benchtop reusable device for the separation of both fresh bull and stallion sperm from semen. The device can handle semen from different species through the use of different buffers, membranes and operating conditions. Various electrical parameters, buffers and membranes were used to determine optimum conditions for separations. The current device was proven

to work to separate high quality sperm, for both species, but only at small scale. It would be adequate for IVF procedures but not artificial insemination ("AI"), which requires much larger sperm quantity and ability to handle larger volumes of ejaculate.

Next Gen Research

During the period research was conducted into using the electrophoretic process and membrane technology for separating other high value cells, apart from sperm cells, for the biomedical sector. The performance of cells, for example T-cells from blood during the separation process, were investigated with promising results.

A multichannel flat-bed electrophoresis device was designed to better understand the electrophoretic process, the behaviour of individual cells and improvement of their separation. This work is continuing to further enhance the potential of Memphasys' separation techniques.

Intellectual Property

Memphasys has registered a number of new patents pertaining to the electrophoretic process and device component configuration. Memphasys has also registered the use of the Felix name for its sperm separation device.

Outlook for 2020

The major focus in 2020 for Memphasys will be:

- Preparing Felix for commercial human IVF treatments
- Improving Felix performance in a next generation device, both for human and animal ART use.

Felix for Human IVF Treatments

Over the coming months, Memphasys will prepare for pre-submission meetings with regulatory bodies in key jurisdictions. Memphasys will also continue to monitor and evaluate regulatory environment changes, including the new Medical Device Regulations ("MDR") which will come into effect in the EU in May 2020, and Memphasys will update its plans where necessary.

The build of cartridges for KOL assessment will be transferred to W&S, who will also manufacture additional cartridges for clinical testing and ultimately for commercial marketing.

Memphasys will also be focusing on maintaining and updating the QMS system and will prepare for final ISO 13485 certification, which will assist with regulatory submissions in a number of target markets. The QMS system also enables Memphasys to handle any issues from KOL feedback, to report external clinical evaluation of the Felix device and to document remedial action taken.

Memphasys personnel have ongoing communications with the KOLs and are preparing them to participate in a Felix clinical assessment. KOL studies are anticipated to commence in late September 2019. The outcomes of the international KOL studies are important to Memphasys as they will provide further evidence as to the technical capabilities and clinical benefits of the Felix device, provide significant user examples of range of use and further define the commercialisation strategy of the Company.

Next Generation Device for both human and animal ART use

Memphasys intends to investigate next generation Felix designs that will address unforeseeable issues or restrictions that arise from the KOL study and clinical evaluations. The next generation device will also focus on a design that removes the reliance on the very fine pipette tips used currently for handling the semen sample. Memphasys also aims to provide more efficient separations and higher yields, enabling us to do more intrauterine insertion ("IUI") in humans, with semen samples that would not currently provide sufficient yield for IUI, and artificial insemination ("AI") in animals.

Most focus will remain on Felix and for improvement in the current human first generation device, but there will also be an extension into larger animals, starting with the horse. Memphasys plans to engage with external research collaborators who possess extensive experience in animal reproduction, to scale up the current device and tackle any species-specific issues. Given that the device already works to separate good quality sperm from both stallion and bull ejaculates it has high potential for fractionating high quality sperm from other species' semen that have similar reproduction, semen and sperm characteristics to horses and cows.

Financial Performance

The private placement of shares to Peters Investments Pty Ltd and the R&D tax refund funded Memphasys' operations in the first 4.5 months of the financial year. From that point and until the end of March 2019, when the amount of $3.45m was received from the non-renounceable rights issue, the Company was funded with various loans received from Andrew Goodall, adding up to the amount of $1.18m. All of these loans have been either converted to equity in the non-renounceable shares issue in March

2019 or will be converted to equity in the share placement in September 2019. As a result, the Company has reduced its debt to its lowest ever point, keeping a strong financial position which enables the Company to continue to develop its first commercial product, the Felix device for human IVF processes.

Memphasys completed 15:1 share consolidation on 18 August 2018.

Memphasys finalised the financial year with working capital of $1,420,952 (2018: $37,879) and with net assets of $6,071,441 (2018: $3,351,580).

Capitalised expenditure on the two projects in the development stage, as allowed by accounting standards, was as follows:

- Felix, which received an investment of $1,944,900 (2018: $1,080,943); and
- New membranes for the Felix device, which received an investment of $396,764 (2018: $225,498).

Memphasys incurred a $1,044,578 loss from continuing operations (2018: loss of $401,159). The main reason for the increase in the loss in 2019 was that in 2018 there was the abnormal gain of $896,232 from the settlement of debt with PrIME Biologics Private Limited. This was partially offset by finance costs decreasing by 83% from $276,988 to $47,334 and the General & Administration expenses reducing by 10%.

The tax refund on R&D activities granted by the Federal Government ("Tax Incentive") continues to be the Company's sole source of regular revenue. A R&D tax refund of $1,103,264 has been approved by AusIndutry for R&D expenditure incurred in the current financial year.

Board and management

Memphasys appointed Nick Gorring as Operations Manager on 15 April 2019.

There was no change in the Board of Directors during the financial year. However, post reporting date, Shane Hartwig joined the board in July 2019.

Matters subsequent to the end of the financial year

The following events occurred subsequent to end of the financial year:

- On 12 July 2019 the Company received the first tranche of the placement of shares organised by its corporate finance advisors, Patersons Securities Limited, for the amount of $1,516,533 net of brokerage fees. The second tranche of this placement, for an amount of $2,138,490 net of brokerage fees and net of debt of $293,038 to be converted to equity by Andrew Goodall, is estimated to be received at the end of September 2019.
- On 29 July 2019 the Company lodged the R&D tax claim for an amount of $1,103,264 which was approved by AusIndustry on 2 August 2019 and is expected to be received from the ATO in September 2019.

Memphasys Limited

Appendix 4E

Preliminary final report

Name of entity

Memphasys Limited

ABN or equivalent company reference	Financial year ended ('current period')
33 120 047 556	30 JUNE 2019 (Comparisons to 30 June 2018)

For announcement to the market

				$A'000
Revenue from continuing ordinary activities	**Remained**		**at**	**0**
Total income from continuing ordinary activities	**Increased**	**32%**	**to**	**87**
Loss from continuing operations	**Increased**	**160%**	**to**	**(1,045)**
Loss from ordinary activities after tax attributable to members	**Increased**	**160%**	**to**	**(1,045)**
Net Loss for the period attributable to members	**Increased**	**160%**	**to**	**(1,045)**

Dividends (distributions)	Amount per security	Franked amount per security
Final dividend	Nil	Nil
Previous corresponding year	Nil	Nil

Record date for determining entitlements to the dividend, N/A

For a brief explanation of any of the figures reported above see notes below and also refer to the attached market announcement.

1. Consolidated Statement of Profit or Loss and Other Comprehensive Income

	Continuing operations	For the year ended 30 June 2019 $	For the year ended 30 June 2018 $
1.1	**Revenue**		
	Revenue from sales or services	**-**	-
	Gross profit	**-**	-
	Grant income	**83,736**	**63,178**
	Finance income	**2,876**	**2,363**
	Net gain on settlement of debt	**-**	**896,232**
	General & administration	**(886,955)**	**(986,781)**
	Research & development	**(196,901)**	**(181,109)**
	Finance cost expense	**(47,334)**	**(276,988)**
	Foreign exchange gain / (loss)	**-**	**81,946**
1.2	**Loss before income tax**	**(1,044,578)**	**(401,159)**
1.3	Income tax	-	-
1.4	**Loss after tax from continuing operations**	**(1,044,578)**	**(401,159)**
1.5	**Discontinued operations**		
	Loss from discontinued operations net of tax	**-**	**-**
1.6	**Net loss for the year**	**(1,044,578)**	**(401,159)**
1.7	**Net loss attributable to members of parent**	**(1,044,578)**	**(401,159)**
1.8	**Other comprehensive income / (expense)**		
	Items that may be reclassified subsequently to profit or loss		
	Exchange translation difference	**-**	**-**
	Total other comprehensive income / (expense) for the year	**-**	**-**
1.9	**Total comprehensive expense for the year**	**(1,044,578)**	**(401,159)**

Consolidated accumulated losses

	30 June 2019 $	30 June 2018 $
1.10 Accumulated losses at the beginning of the financial year	**(37,759,344)**	**(37,358,185)**
1.11 Net loss attributable to members (*item 1.7*)	**(1,044,578)**	**(401,159)**
1.12 Accumulated losses at end of the financial year	**(38,803,922)**	**(37,759,344)**

2. Consolidated Statement of Financial Position

		As at 30 June 2019 $	As at 30 June 2018 $
	Current assets		
2.1	Cash and cash equivalents	873,573	201,807
2.2	Other current assets	1,280,035	659,454
2.3	**Total current assets**	**2,153,608**	**861,261**
	Non-current assets		
2.4	Property, plant and equipment	27,514	22,732
2.5	Intangible assets	4,655,316	3,333,180
2.6	**Total non-current assets**	**4,682,830**	**3,355,912**
2.7	**Total assets**	**6,836,438**	**4,217,173**
	Current liabilities		
2.8	Trade & other payables	308,618	222,428
2.9	Interest bearing liabilities	-	471,736
2.10	Non-interest bearing liabilities	319,372	26,334
2.11	Lease liabilities	3,768	3,552
2.12	Tax liabilities	7,436	10,146
2.13	Short term provisions	93,462	89,186
2.14	**Total current liabilities**	**732,656**	**823,382**
	Non-current liabilities		
2.15	Lease liabilities	2,975	6,746
2.16	Long term provisions	29,366	35,465
2.17	**Total non-current liabilities**	**32,341**	**42,211**
2.18	**Total liabilities**	**764,997**	**865,593**
2.19	**Net assets**	**6,071,441**	**3,351,580**
	Equity		
2.20	Issued capital	43,424,091	40,095,314
2.21	Reserves	1,451,272	1,015,610
2.22	Accumulated losses	(38,803,922)	(37,759,344)
2.23	**Total equity**	**6,071,441**	**3,351,580**

3. Consolidated Statement of Cash Flow

		For the year ended 30 June 2019 $	For the year ended 30 June 2018 $
	Cash flows from operating activities		
3.1	Receipts from customers	-	52,769
3.2	Payments to suppliers and employees	(1,183,854)	(1,548,506)
3.3	Government grants	592,734	831,529
3.4	Finance costs	(116,352)	(74,211)
3.5	**Net cash flows used in operating activities**	**(707,472)**	**(738,419)**
	Cash flows from investing activities		
3.6	Interest receipts	2,876	2,613
3.7	Payment for Increase of security term deposit	-	(4,800)
3.8	Payment for purchases of property, plant and equipment	(13,702)	(2,405)
3.9	Payment for purchases of other non-current assets	(2,115,859)	(1,229,505)
3.10	**Net cash flows used in investing activities**	**(2,123,685)**	**(1,234,097)**
	Cash flows from financing activities		
3.11	Proceeds from issues of securities	2,703,594	2,344,349
3.12	Share issue costs	(380,028)	(350,169)
3.13	Proceeds from third party loans	50,000	660,000
3.14	Repayment of third party loans	(114,982)	(545,156)
3.15	Proceeds from related party borrowings	1,294,339	286,330
3.16	Repayment of related party borrowings	(50,000)	(223,380)
3.17	**Net cash flows from financing activities**	**3,502,923**	**2,171,974**
3.18	**Net (decrease)/increase in cash held**	**671,766**	**199,458**
3.19	Cash at beginning of year	**201,807**	**2,349**
3.20	**Cash and cash equivalents at end of year** *(see reconciliation of cash)*	**873,573**	**201,807**

4. Consolidated Statement of Changes in Equity

	Issued capital $	Share options reserve $	Accumulated losses $	Total equity $
Balance at 1 July 2018	40,095,314	1,015,610	(37,759,344)	3,351,580
Movement				
Loss for the year	-	-	(1,044,578)	(1,044,578)
Total comprehensive income for the year	-	-	(1,044,578)	(1,044,578)
Issue of share capital	4,075,891	-	-	4,075,891
Transaction costs on share issue	(747,114)			(747,114)
Share options issued	-	435,662	-	435,662
Balance at 30 June 2019	**43,424,091**	**1,451,272**	**(38,803,922)**	**6,071,441**

	Issued capital $	Share options reserve $	Accumulated losses $	Total equity $
Balance at 1 July 2017	35,019,885	936,060	(37,358,185)	(402,240)
Movement				
Loss for the year	-	-	(401,159)	(401,159)
Total comprehensive income for the year	-	-	(401,159)	(401,159)
Issue of share capital	4,435,434	-	-	4,435,434
Transaction costs on share issue	(360,005)	-	-	(360,005)
Share options issued	-	79,550	-	79,550
Balance at 30 June 2018	**40,095,314**	**1,015,610**	**(37,759,344)**	**3,351,580**

5. Reconciliation of cash

Reconciliation of cash at the end of the year (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	30 June 2019 $	30 June 2018 $
5.1 Cash on hand and at bank	873,573	201,807
5.2 Total cash at end of year *(item 3.20)*	**873,573**	**201,807**

6. Earnings per security (EPS)

		30 June 2019	30 June 2018
6.1	Basic losses per share	(0.0025)	(0.0022)
6.2	Weighted average number of ordinary shares used as the denominator in calculating basic earnings per share	409,925,467	182,734,938*
6.3	Diluted losses per share	(0.0025)	(0.0022)
6.4	Weighted average number of ordinary shares and potential ordinary shares used as the denominator in calculating diluted earnings per share	409,925,467	182,734,938*

* The Weighted average number of shares has been adjusted for the share consolidation on 17 August 2018.

7. NTA backing

		30 June 2019	30 June 2018
7.1	NTA backing per ordinary security	$0.003	$0.000

8. Matters subsequent to the end of the financial year

The following events occurred subsequent to end of the financial year:

- On 12 July 2019 the Company received the first tranche of the placement of shares organised by its corporate finance advisors, Patersons Securities Limited, for the amount of $1,516,533 net of brokerage fees. The second tranche of this placement, for an amount of $2,138,490 net of brokerage fees and net of debt of $293,038 to be converted to equity by Andrew Goodall, is estimated to be received at the end of September 2019.
- On 29 July 2019 the Company lodged the R&D tax claim for an amount of $1,103,264 which was approved by AusIndustry on 2 August 2019 and is expected to be received from the ATO in September 2019.

Annual General Meeting

The annual general meeting will be held as follows:

Place	30 Richmond Road, Homebush West, NSW 2140
Date	Thursday 21st November 2019
Time	11 a.m.
Approximate date the annual report will be available	Monday 9th September 2019

Compliance statement

1 The report has been prepared in accordance with the Corporations Act 2001, the recognition and measurement criteria of Accounting Standards and Urgent Issues Group Interpretations, and complies with other requirements of the law. Accounting Standards, include Australian equivalents to International Financial Reporting Standards "AIFRS". Compliance with AIFRS ensures that the consolidated financial statements and notes of the consolidated entity comply with International Financial Reporting Standards "IFRS".

2 This report, and the accounts upon which the report is based, use the same accounting policies.

3 This report does give a true and fair view of the matters disclosed.

4 This report is based on accounts that have been audited.

6 The entity has a formally constituted Audit Committee.

Signed: 

Name: Alison Coutts
Chairman

Date: 26 August 2019