

Memphasys Limited

ABN 33 120 047 556

Financial Year Ended 30 June 2021

Appendix 4E: Performance Commentary**PRINCIPAL ACTIVITIES**

Memphasys is focused on commercialising high value reproductive biotechnology and proprietary cell separation technologies. The Company is developing novel medical devices, diagnostics, and media with application to assisted reproduction technologies, including IVF in humans and artificial insemination in animals.

The Company's most advanced product is the Felix device which utilises a technology known as electrophoresis, combined with size-exclusion membranes to select the best quality cells for improved IVF treatments.

The Company is also in the process of developing several other technologies. These include its Stallion Fertility Test, a rapid in vitro diagnostic device to detect the probability of the stallion being able to fertilise a mare, which is currently in the prototype phase. They also include various media projects to extend the longevity of semen without the need for freezing; new, innovative methods of sperm separation and novel analytical methods to detect causes of infertility.

REVIEW OF OPERATIONS

Over the twelve months to 30 June 2021, Memphasys has continued its focused on reproductive biotechnology and proprietary cell separation techniques.

Personnel and Awards

In August 2020 Memphasys announced global fertility expert Professor John Aitken has increased his commitment to Memphasys via entering into an employee agreement with a view to progressing the Felix Device as well as pursuing new product initiatives as rapidly as possible¹.

Professor Aitken's involvement with Memphasys has continued to deepen throughout this period and post year-end, Professor Aitken has been employed by the Company as Research Director.

¹ See ASX Announcement dated: 17 August 2020

The employment of Professor Aitken by the Company, which will be for a time commitment of 50%, follows his retirement from the position of Distinguished Laureate Professor of Biological Sciences within the School of Environmental and Life Sciences at the University of Newcastle (“UoN”) on 30th June 2021.

Post retirement, Professor Aitken will also assume the lifetime title of Distinguished Emeritus Laureate Professor of Biological Sciences at UoN, where he will maintain access to the university laboratory and research staff to enable him to continue his ground-breaking work with Memphasys.

This deepening commitment to Memphasys reflects the compelling opportunities presented and demonstrates the capability of the Company to work with internationally recognised leaders in reproductive biology.

Professor Aitken has become the top ranked world expert in spermatozoa and sperm capacitation (the physiological changes sperm must undergo to be able to penetrate and fertilise an egg) as well as a leader in Australian research grant success.

In 2012, Professor Aitken was named as NSW Scientist-of-the-year and in 2016 was presented with the prestigious Carl G. Hartman Award for reproductive biology. This award is one of the most prestigious international accolades in reproductive science and, at the time of the award, Professor Aitken was only the second researcher working outside of North America to have been honoured with this distinction. More recently, Professor Aitken was also awarded the 2021 Distinguished Andrologist award by the American Society of Andrology (“ASA”).

Throughout the period, Memphasys and its product development partner, Hydrix Services Pty Ltd (“Hydrix”), have also jointly received two Australian 2020 Good Design Awards for the Felix™ Device during the year².

The device received a Gold Good Design Award for engineering design and a Good Design Award for product design in the medical and scientific category.

² See ASX Announcement dated: 9 September 2020



Felix device console and single-use cartridge

Verification & Validation (“V&V”) activities

Verification and validation are essential activities in the final stages of product development and require the test articles to be manufactured to the quality of a commercial device.

During the latter stages of the Validation process on the Felix Device, Memphis identified an engineering flaw that is likely to have reduced the effectiveness of the Felix system in use by the Company’s KOL partners³.

The KOL data collected to date showed that the device was generally performing the function of separating good quality sperm. However, after remediation of the device, the sperm separation process is expected to improve. The engineering issue has required a minor modification of the device and is not an issue with the Felix core technology or science.

Most of the Felix verification work has been unaffected by this modification. However, some verification tasks were required to be redone and post year-end have been successfully completed⁴. Some validation work previously performed by development partners is also in the process of being re-performed with the final device.

³ See ASX Announcement dated: 8 March 2021

⁴ See ASX Announcement dated: 1 July 2021

Post financial year end there were three remaining validation activities to be conducted. These tests are straight forward to conduct and under normal circumstances would have been completed by 30 September 2021. However, two of these activities are still outstanding due to delays from the effects of COVID-19 on Company suppliers. We are experiencing significant delays across most supplier services. This includes logistics of moving cartridges and supplies to gamma irradiation facilities and other test facilities as well as delays in processing in the irradiation facility itself, and a limitation of semen sample availability at both the University of Newcastle and Monash IVF. The strict lockdown rules in place are severely limiting these activities. We expect that the delays could have the effect of delaying the completion of these final two validation tests beyond end September. The tests are expected to be completed soon thereafter but this will depend on the status of COVID-19 lockdown rules.

One of the major tasks of the V&V process which has been largely unaffected by the updated device is the establishment and validation of the cleanroom, which was completed in November 2020⁵. The updated Felix cartridges are manufactured in the cleanroom, located at the Sydney headquarters of manufacturer W&S Plastics Pty Ltd (“W&S”). The cleanroom, which is for the exclusive use of Memphasys, is key to ensuring the Felix cartridges are manufactured sterile – a regulatory requirement for products used in IVF. The cleanroom was validated to ISO7/ISO8 standards.

W&S has the capacity to produce approximately 100 cartridges per day (26,000 cartridges annually) within the cleanroom, with the ability to scale up substantially, depending on demand.



Cleanroom at W&S Plastics: For manufacture and assembly of Felix cartridges

⁵ See ASX Announcement dated: 19 November 2020

KOL program

As part of the commercialisation of the Felix Device, Memphasys has arranged for assessments of the device to be conducted by Key Opinion Leaders (KOLs) which are internationally leading andrology centres and laboratories in the IVF industry. These KOL partners have been selected for technical and academic expertise as well as geographic market positioning.

An initial 13 KOL sites located in eight countries were chosen and while positive in vitro performance data has been returned from sites in Shanghai (China), Tokyo (Japan), Gothenburg (Sweden), Ahmadabad (India), New York (USA), Melbourne (Australia), and Isfahan (Iran), the assessments have been delayed by COVID-19 and the update to the device engineering.

Updated versions of the Felix Device have been distributed to four early access markets (Japan, NZ, India, and Canada) for them to complete their clinical assessment study⁶.

Once clinical testing of the upgraded Felix device has been completed successfully, sales discussions with KOL partners and other prospects in early access markets will resume.

Based on this, the Company now anticipates initiating commercial sales discussions in early access markets in the latter part of the quarter ending 30 September 2021. However, completion of the KOL studies and first sales will be subject to prevailing local COVID conditions, particularly in the four early access markets.

Regulatory

The global sales plan for Felix is dictated by considerations including market size, ease of access and service and pricing. However, the foremost preliminary consideration is jurisdictional regulatory requirements. The initial four target markets of Canada, Japan, NZ and India have low regulatory requirements which enables the potential for early sales. In addition, the market opportunities are substantial, and they are easy to service initially from Australia, especially NZ (see Table 1).

In Canada and Japan, the Felix device is considered laboratory equipment rather than a medical device which significantly reduces the regulatory requirements for Felix in these jurisdictions. Felix has passed the laboratory equipment requirements, the most important being electromagnetic compatibility and safety requirements for electrical

⁶ See ASX Announcement dated: 27 April 2021

equipment. This standard applies to all four markets (Canada, Japan, NZ and India) and has been passed in all four markets.

In NZ, the device has been registered on NZ's Web Assisted Notification of Devices (WAND) database, a necessary precondition before commercial sales can begin. In India, under the current regulatory standards, Felix may be commercially sold. However, this could change when new regulations are introduced in the future, but this is not expected to occur within at least the next 18 months.

The plan is to initially obtain regulatory clearance and roll out product sales in low regulatory markets. The first high regulatory market the company will seek approval for the Felix Device is planned to be Australia, followed by USA, China and subsequently Europe, which has a new and more difficult regulatory environment for all medical devices manufacturers to comply with. Memphasys is continuing to advance its regulatory program, especially in Australia, China and the US, noting this will likely take two to three years to complete.

Table 1: IVF market in Canada, Japan, NZ and India

	Canada	Japan	NZ	India
IVF cycles⁷	16,852 (2018) ⁸	689,000 (2020 forecast) ⁹	9,400 (2020 forecast) ¹⁰	302,000 (2020 forecast) ¹¹
CAGR growth rate of IVF Cycles 2019-2026, %	15.2% ¹²	12.3 % ¹³	7.8% ¹⁴	15.1% ¹⁵

Throughout the period Memphasys was also able to receive the successful granting of two additional U.S. patents by the U.S. Patent and Trademark Office (USPTO), bringing the total number of patents granted to four.

⁷ One fresh IVF Cycle requires use of one, single use Felix device cartridge

⁸ Canadian Fertility & Andrology Society (CFAS), 2019

⁹ Allied Market Research Report, 2019

¹⁰ Allied Market Research Report, 2019

¹¹ Allied Market Research Report, 2019

¹² Allied Market Research Report, 2019

¹³ Allied Market Research Report, 2019

¹⁴ Allied Market Research Report, 2019

¹⁵ Allied Market Research Report, 2019

The additional U.S. patents granted are as follows:

- **Sperm separation by electrophoresis (U.S. Patent No. 10,946,346, issued on 16 March 2021):** A method of using at least one physically cross-linked biocompatible polymeric membrane in the separation of sperm by electrophoresis
- **Biocompatible polymeric membranes (U.S. Patent No. 10,962,537 issued on 30 March 2021):** A method of using at least one physically cross-linked biocompatible polymeric membrane in the separation of one or more macromolecules and/or cells by electrophoresis.

The granting of these patents further strengthens Memphasys' comprehensive patent portfolio and supports the Company's unique bio-separations technology. Memphasys also owns several pending patent applications in Australia, Europe, the USA and various Asian countries and has sole licensing rights from the UoN on three further patents granted in Australia, the UK and the USA pertaining to sperm cell separation by electrophoresis.

In addition, Memphasys has registered FELIX as a trademark for its 'Felix' sperm separation devices in Australia, the US, the EU and India. Trademark applications for FELIX have also been filed in Canada, China and Japan.

ARC Linkage Grant

During the period, Memphasys decided to terminate the ARC Linkage grant, jointly awarded to Memphasys and its research partners UNSW and UoN¹⁶. The grant was for assistance from UNSW and UoN on the development of a larger scale device to efficiently separate equine sperm (and subsequently sperm from other animals) for Artificial Insemination ("AI").

Fortunately, much of the initial and crucial work, to view and automate the mapping and analysis of equine sperm movement under the influence of electrophoresis, has now been accomplished with UoN and Hydrix. This work is fundamental to our ability to design an efficient device for animal AI and it is also likely to have benefits for designing a next generation human device, particularly for Intrauterine Insertion ("IUI") procedures, which require more sperm to be processed than for IVF and ICSI processes.

¹⁶ See ASX Announcement dated: 26 February 2021

New product opportunities

In addition to the development of the Felix Device, Memphasys is currently overseeing the development of a portfolio of assisted reproductive biotechnology products in conjunction with global reproductive biology expert, Professor John Aitken.

The new product portfolio is focused on reproduction in both humans and animals (see Table 2) and have potentially high value in the reproductive biotechnology field. As a result, Memphasys is expanding its focus into reproductive biotechnology as well as bioseparations.

Preliminary feasibility studies were completed during the period and all programs were considered worthy of progression to initial product development phase¹⁷.

Table 2: MEM Assisted Reproductive Technology Product Opportunities

Product	Application; Target Market
Human Market	
<i>Felix</i>	Sperm separation; for use in IVF clinics
<i>Felix media</i>	Use in Felix to replace 3rd party media; for all markets
Long life media	Long term preservation of sperm without need to freeze; for use in IVF
Semen oxidative stress diagnostic	Semen quality assessment diagnostic; for testing the males in infertile couples
Animal Market	
Stallion Fertility Test (at dismount)	Fertility testing of semen; for use primarily in thoroughbred horse industry
Semen oxidative stress diagnostic	Semen quality assessment diagnostic; for use initially in equine for testing stallion fertility Applies to many animal species
Long life media	Long term preservation of sperm without need to freeze; for use in IVF
EQUUS	2nd-gen sperm separation platform; for use initially in horse but applicable across all species. 2nd gen Felix for humans in longer term

The Stallion Fertility Test (at dismount) is to be the first of the products to be progressed to the next development stage, with the Company announcing in May 2021 that a prototype diagnostic product, is now being developed¹⁸.

¹⁷ See ASX Announcement dated: 17 August 2020

¹⁸ See ASX Announcement dated: 4 May 2021

The stallion dismount diagnostic will be a rapid and easily applied in vitro test used at the breeding shed to detect the probability of the stallion being able to fertilise a mare based on the level of mitochondrial activity in the spermatozoa. The result would be known almost instantly following mating using a very small dismount semen sample.

The Australian thoroughbred industry is a large, high-value market. It is estimated that more than 20,000 matings occur throughout Australia each season, resulting in some 13,000 foals. However, there is a high variability of success which places significant economic stress on the industry. A rapid and accurate test applied at the time of conception would be valuable to determine the chance of pregnancy success and mitigate economic loss.

Corporate

On 26 May 2021, the Company announced two major shareholders Peters Investments Pty Ltd (\$1.65m) and Non-Executive Director Andrew Goodall (\$1.35m) have committed a total of \$3m (before costs) to the Company in the form of a loan to be issued as convertible notes subject to shareholder approval¹⁹. Shareholder approval was obtained at the EGM held on 24 August 2021.

This funding will enable the Company to complete a range of necessary tasks for the upgraded Felix device, ahead of the re-commencement of commercial sales discussions in early access markets during the later stages of the quarter ending September 2021.

The funding will also enable the Company to advance the additional products currently being developed by the Company in conjunction with the UoN.

Throughout the year, Memphasys also received a A\$1,293,092 tax rebate following the submission of its 2020 R&D Tax Incentive claim. The R&D Tax Incentive scheme is a program jointly administered by the Australian Taxation Office and AusIndustry, under which companies can receive a refundable tax offset of eligible expenses on research and development activities.

The Company also reported that it had reached the trigger for a round of performance options to staff and consultants during the year. With satisfaction of all legal and regulatory requirements in the three market jurisdictions of Canada, Japan and NZ completed by 30 June 2020 (for Canada) and by 30 September 2020 (for Japan and NZ), Memphasys' board agreed the milestones were met in the vesting of a set of 16,800,000 performance options²⁰. 12,000,000 of these performance options were

¹⁹ See ASX Announcement dated: 26 May 2021

²⁰ See ASX Announcement dated: 26 February 2021

granted to Executive Chairman, Alison Coutts, after shareholder approval was received for their issue on 21 October 2019. The options expire on 21 October 2021 and are exercisable at a price of \$0.1142.

Financial Performance

Memphasys finalised the financial year with working capital of \$2,831,940 (2020: \$2,971,003) and with net assets of \$8,606,990 (2020: \$9,755,760).

Capitalised expenditure on the three projects in the development stage was as follows:

- Human assisted reproduction technologies (Felix), which received an investment of \$2,401,500 (2020: \$2,703,354);
- Animal assisted reproduction technologies, which received an investment of \$298,014 (2020: \$210,237); and
- New membranes for the Felix device, which received an investment of \$202,926 (2020: \$223,571).

Activities carried out by the Company have not changed from the prior financial year, except for the research of a new portfolio of novel artificial reproduction products for human and animals with Professor Aitken and his research team at the UoN. Memphasys incurred a \$1,486,432 loss from continuing operations (2020: \$1,133,879). The main reason causing this difference is the additional expenditure on the portfolio of R&D products mentioned at the start of this paragraph.

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. An R&D tax refund of \$1,359,513 has been approved by AusIndustry for R&D expenditure incurred in the current financial year.

Board and management

There was no change in the board and management of the Company.

SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

There were no significant changes in the state of affairs of the group during the financial year.

MATTERS SUBSEQUENT TO THE END OF THE FINANCIAL YEAR

Subsequent to 30 June 2021, the company obtained shareholder approval for the issue of convertible notes.

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

	For the year ended 30 June 2021 \$	For the year ended 30 June 2020 \$
Continuing operations		
1.1 Revenue		
Revenue from sales or services	-	-
Gross profit	-	-
Grant income	211,483	166,607
Finance income	2,543	29,839
Other income	90,569	-
General & administration	(1,235,249)	(1,148,440)
Research & development	(466,264)	(113,288)
Finance cost expense	(89,514)	(68,597)
1.2 Loss before income tax	(1,486,432)	(1,133,879)
1.3 Income tax	-	-
1.4 Loss after tax from continuing operations	(1,486,432)	(1,133,879)
1.5 Net loss for the year	(1,486,432)	(1,133,879)
1.6 Net loss attributable to members of parent	(1,486,432)	(1,133,879)
1.7 Other comprehensive income / (loss) <i>Items that may be reclassified subsequently to profit or loss</i>		
Exchange translation difference	-	-
Total other comprehensive income / (loss) for the year	-	-
1.8 Total comprehensive loss for the year	(1,486,432)	(1,133,879)

Consolidated accumulated losses

	30 June 2021 \$	30 June 2020 \$
1.9 Accumulated losses at the beginning of the financial year	(39,680,991)	(38,803,922)
1.10 Net loss attributable to members (<i>item 1.6</i>)	(1,486,432)	(1,133,879)
1.11 Expired share options transferred to accumulated losses	-	256,810
1.12 Accumulated losses at end of the financial year	(41,167,423)	(39,680,991)

2. Consolidated Statement of Financial Position

		As at 30 June 2021 \$	As at 30 June 2020 \$
	Current assets		
2.1	Cash and cash equivalents	2,002,915	1,967,800
2.2	Inventories	118,794	32,677
2.3	Other current assets	1,567,072	1,557,310
2.4	Total current assets	3,688,781	3,557,787
	Non-current assets		
2.5	Property, plant and equipment	594,237	208,464
2.6	Intangible assets	8,291,264	6,546,093
2.7	Right-of-use asset	2,006,557	986,297
2.8	Total non-current assets	10,892,058	7,740,854
2.9	Total assets	14,580,839	11,298,641
	Current liabilities		
2.10	Trade & other payables	339,749	285,744
2.11	Non-interest-bearing liabilities	181,002	26,344
2.12	Lease liabilities	87,857	106,843
2.13	Tax liabilities	5,050	93
2.14	Provisions	243,183	167,770
2.15	Total current liabilities	856,841	586,784
	Non-current liabilities		
2.16	Lease liabilities	1,924,462	931,053
2.17	Interest bearing liabilities	2,932,339	-
2.18	Non-interest bearing liabilities	231,998	-
2.19	Provisions	28,209	25,044
2.20	Total non-current liabilities	5,117,008	956,097
2.21	Total liabilities	5,973,849	1,542,881
2.22	Net assets	8,606,990	9,755,760
	Equity		
2.23	Issued capital	48,884,176	48,697,744
2.24	Reserves	890,237	739,007
2.25	Accumulated losses	(41,167,423)	(39,680,991)
2.26	Total equity	8,606,990	9,755,760

3. Consolidated Statement of Cash Flow

	For the year ended 30 June 2021 \$	For the year ended 30 June 2020 \$
Cash flows from operating activities		
3.1 Payments to suppliers and employees	(1,241,125)	(1,011,857)
3.2 Government grants	1,352,331	1,173,264
3.3 Finance costs	(66,500)	(68,597)
3.4 Net cash flows used in operating activities	44,706	92,810
Cash flows from investing activities		
3.5 Interest receipts	2,543	27,385
3.6 Payment for purchases of property, plant and equipment	(118,073)	(236,280)
3.7 Payment for purchases of other non-current assets	(2,886,019)	(2,901,417)
3.8 Net cash flows used in investing activities	(3,001,549)	(3,110,312)
Cash flows from financing activities		
3.9 Proceeds from issues of securities	192,560	4,543,905
3.10 Share issue costs	(6,128)	(339,901)
3.11 Proceeds from third party loans	1,600,129	-
3.12 Proceeds from related party borrowings	1,374,196	-
3.13 Repayment of related party borrowings	(65,000)	-
3.14 Repayment of lease liabilities	(103,799)	(92,275)
3.15 Net cash flows from financing activities	2,991,958	4,111,729
3.16 Net (decrease)/increase in cash held	35,115	1,094,227
3.17 Cash at beginning of year	1,967,800	873,573
3.18 Cash and cash equivalents at end of year <i>(See reconciliation of cash)</i>	2,002,915	1,967,800

4. Consolidated Statement of Changes in Equity

	Issued capital \$	Share options reserve \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2020	48,697,744	739,007	(39,680,991)	9,755,760
Movement				
Loss for the year	-	-	(1,486,432)	(1,486,432)
Total comprehensive income for the year	-	-	(1,486,432)	(1,486,432)
Issue of share capital	192,560	-	-	192,560
Transaction costs on share issue	(6,128)	-	-	(6,128)
Share options issued	-	151,230	-	151,230
Balance at 30 June 2021	48,884,176	890,237	(41,167,423)	8,606,990

	Issued capital \$	Share options reserve \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2019	43,424,091	1,451,272	(38,803,922)	6,071,441
Movement				
Loss for the year	-	-	(1,133,879)	(1,133,879)
Total comprehensive income for the year	-	-	(1,133,879)	(1,133,879)
Issue of share capital	4,836,944	-	-	4,836,944
Transaction costs on share issue	(346,291)	-	-	(346,291)
Share options issued	-	327,545	-	327,545
Expired share options transferred to equity	783,000	(783,000)	-	-
Expired share options transferred to accumulated losses	-	(256,810)	256,810	-
Balance at 30 June 2020	48,697,744	739,007	(39,680,991)	9,755,760

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 2021 \$	30 June 2020 \$
5.1 Cash on hand and at bank	2,002,915	1,967,800
5.2 Total cash at end of year (item 3.18)	2,002,915	1,967,800

6. Earnings per security (EPS)

	30 June 2021	30 June 2020
6.1 Basic losses per share	(0.0020)	(0.0008)
6.2 Weighted average number of ordinary shares used as the denominator in calculating basic earnings per share	756,698,537	1,388,316,844
6.3 Diluted losses per share	(0.0019)	(0.0008)
6.4 Weighted average number of ordinary shares and potential ordinary shares used as the denominator in calculating diluted earnings per share	789,102,994	1,426,521,301

7. NTA backing

	30 June 2021	30 June 2020
7.1 NTA backing per ordinary security	\$0.0000	\$0.004

8. Matters subsequent to the end of the financial year

Subsequent to 30 June 2021, the company obtained shareholder approval for the issue of convertible notes.

Annual General Meeting

The annual general meeting will be held as follows:

Place	30 Richmond Road, Homebush West, NSW 2140
Date	Thursday 25 th of November 2021
Time	11 a.m.
Approximate date the annual report will be available	Wednesday 1 st September 2021

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:

30 August 2021