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Memphasys Limited

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Share Price: A$0.051

ASX: MEM

Sector: Health Care Equipment & Services

9 July 2020

An innovative medical device company

Memphasys (ASX: MEM) is an Australian biotechnology company, focussed on cell separation technology. Its most advanced program, the separation of sperm cells for human IVF, is currently in commercial development and has the potential to improve in vitro fertilisation clinical outcomes. It is also advancing research into the application of its technology for the animal artificial reproductive technologies market.

Memphasys' revolutionary IVF technology

The company's patented technology helps in the separation of cells using electrophoresis and size-exclusion membranes. Memphasys' technology has shown great promise in sperm cell separation studies in domestic animals such as horses and cattle. It has been tested for separation of various subtypes of cells isolated from blood. Backed by these results, Memphasys is in the final stages of commercialising the technology for use in human sperm cell separation in human artificial reproductive technologies and develop its 'Felix' device to address male infertility. We believe the global IVF market will continue to have a strong growth potential underpinned by declining fertility rate across nations and shifting social paradigms.

Felix to be commercialised by Q4 2020

Memphasys currently undertakes global clinical assessments headed by key opinion leaders across several regions. The company stands to leverage opportunities across a multitude of countries and benefit from a liberal regulatory environment in the initial target markets of Canada, India, Japan and New Zealand. Despite that the overall product development program will be delayed due to the impact of COVID-19, the company expects that those delays are not likely to impact expected first sales of the Felix device, which are projected to occur in Q4 2020.

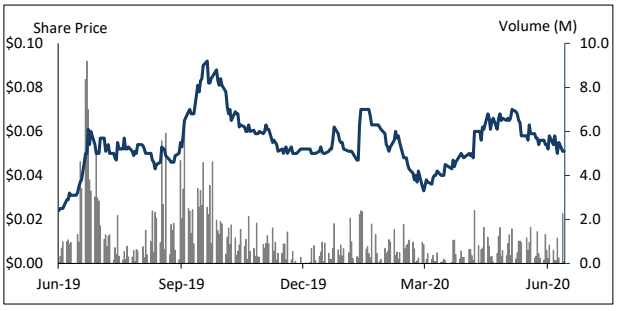
Memphasys is undervalued on our numbers

Memphasys is undervalued as per our numbers. We value Memphasys at A$0.15 base case and A$0.24 per share optimistic case using a DCF approach. We see Memphasys being re-rated towards our valuation range on the back of improved sentiment for the Felix device, as the company works towards first commercial sales in Q4 2020.

Market Cap. (A$ m)	38.5
# shares outstanding (m)	754.0
# share fully diluted	792.2
Market Cap Ful. Dil. (A$ m)	40.4
Free Float	57.5%
12 months high/low	0.095 / 0.030
Average daily volume (x1,000)	1,140.5
Website	www.memphasys.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	0.15 – 0.24
WACC	14.3%
Assumed terminal growth rate	2.0%

Source: Pitt Street Research

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Introducing Memphasys

Memphasys is a Sydney-based biotechnology company focussed on developing sperm separation technologies for in vitro fertilisation (IVF). The company (previously known as NuSep Holdings Limited) rebranded itself as Memphasys Limited in July 2016. Its prime focus now is on developing and commercialising electrophoresis-based technology products.

The company's patented technology is powered by a combination of electrophoresis and size-exclusion membranes. These membranes utilise patented hydrogels and other polymer membranes to support high-value cell separations. In addition to application for separation of sperm cells for human IVF Memphasys' technology has shown great promise in sperm cell separation studies in domestic animals such as horses and cattle. The technology has also been tested for separation of various subtypes of cells isolated from blood. Backed by these results, Memphasys has plans to commercialise the technology for use in human sperm cell separation in human artificial reproductive technologies (ART) and develop its 'Felix' device to address male infertility.

A revolutionary cell separation technology with widespread application in the IVF market

The Felix device (Figure 1) facilitates separation of sperm cells on the basis of the high net negative charge on the surface of high-quality sperm cells. High-quality sperm cells have a well-defined cyto-skeleton, which is indicative of intact DNA in the cell nucleus. Further, using the size-exclusion membranes, the device enables separation of cells based on size and facilitates removal of unwanted debris such as white blood cells (WBCs).

Figure 1: Memphasys' Felix device

Source: Company

With potential widespread application across the human and animal ART markets, along with significant cost-saving potential, Memphasys' sperm cell separation technology is positioned to gain traction from both the healthcare and agriculture sectors. With the aim to promote global market access in IVF, Memphasys is targeting high-income countries (e.g., Australia, Japan, Canada and the US) and medium-income countries (e.g. relatively high-income populations in India and China). IVF clinics are likely to want to adopt this technology to gain a cost advantage and improve clinical IVF outcomes. We believe that the company's technology has the potential to cater to global markets and generate revenues across many geographies.

Key reasons to consider Memphasys

1) **Strategic focus on IVF segment.** The company has evaluated its technology for both the human IVF and animal reproductive markets. The prime focus remains on the lucrative human IVF market due to the larger market opportunity and manageable commercialisation process.
2) **Technological edge over current processes.** Felix has shown superior sperm cell separation across initial assessments vis-à-vis long-standing sperm separation technologies, such as density gradient centrifugation (DGC) and swim-up. Further, the automated device reduces manual intervention and processing time, providing opportunities to save costs.
3) **Significant potential to tap 'global' footprint.** Declining fertility rates are a global cause of concern, and this offers Memphasys the opportunity to target a multitude of countries for technology commercialisation.
4) **Favourable regulatory environment across initial markets of interest**. Liberal regulations related to the approval of laboratory equipment utilised for IVF procedures bode well for Memphasys in these markets. This will assist smooth commercialisation of its technology across target markets.
5) **Accelerated commercialisation timelines.** With various key opinion leaders (KOLs) already on board to conduct technology assessments across key markets, Memphasys expects commercial revenue generation by late 2020.

Memphasys will emerge as a key technology provider for the global IVF market

6) **Strong management driving company's vision.** The leadership team has extensive entrepreneurial expertise in commercialisation of innovative technologies across diverse industries. Alison Coutts, the Executive Chairman since March 2014[1], has helped in the commercialisation of biotechnology entrepreneurial ventures such as Mariposa Healthcare Pty Ltd (2009) and Micro-X Ltd (2010).
7) **High potential for critical partnerships in IVF space.** Post the commercialisation of Felix, the company's technology is likely to be sought by all major IVF companies to improve clinical outcomes.
8) **Memphasys is undervalued on our numbers.** We value Memphasys at A$0.15 base case and A$0.24 optimistic case using a DCF approach. We see Memphasys being re-rated towards our valuation range on the back of the various commercialisation milestones being met for selling the Felix device in a number of different geographic markets.

[1] The appointment was originally interim but became permanent in June 2015.

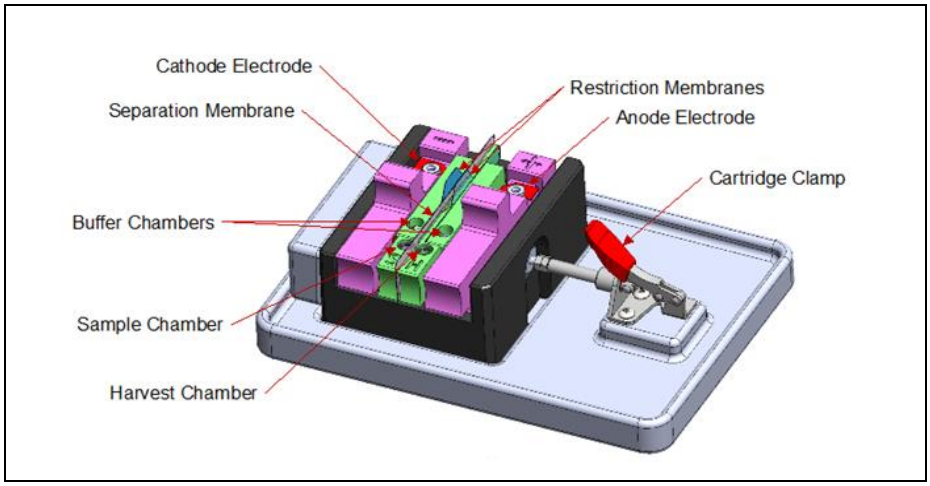
Memphasys' IVF technology to tilt balance in its favour

Felix device combines electrophoresis and filtration to deliver superior sperm separation compared with conventional processes

Memphasys' Felix offers an automated lab instrument to isolate sperm from a semen sample in human IVF clinics. Electrophoresis is the underlying technology behind Felix that enables this separation. While the technology leverages a filtration membrane to separate sperm from other semen components based on their size, it also relies on the characteristic of good-quality sperm possessing a net electronegative charge due to the rich presence of sialic acid on the terminal end of the glycoproteins that form the outer edge of the cell membrane.

The device (Figure 2) comprises two chambers – sample and harvest chambers – bound by restriction hydrogel membranes with small labyrinthine pore sizes. These membranes facilitate free circulation of the buffer ions, but not the cells. The chambers are divided by a separation membrane, which allows only the sperm to migrate to the harvest chamber. On application of an electric field, the most highly negatively charged sperm are drawn towards the anode (the positive electrode) in the harvest chamber. After processing by Felix, they are simply pipetted out of that chamber and are immediately ready to inseminate eggs to create embryos.

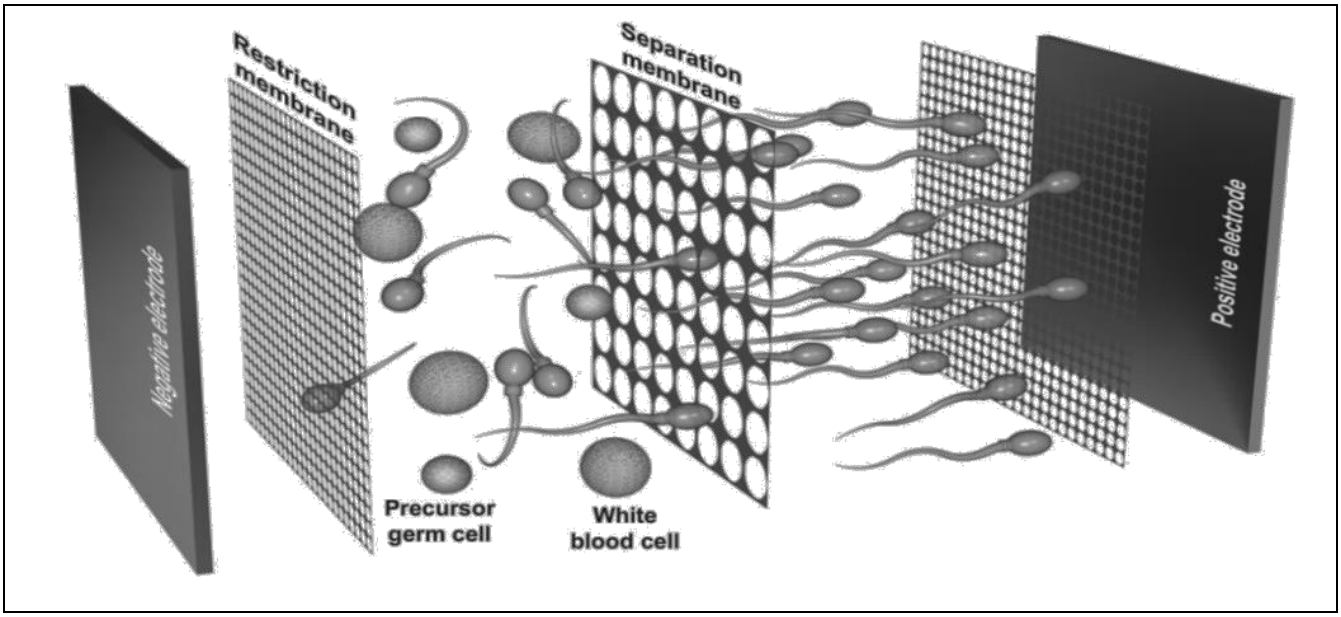
Figure 2: Device components



Source: Company

The company has developed the next-generation single-use cartridge comprising biocompatible membranes made from a biocompatible proprietary copolymer mix (Figure 3). that keeps the sperm away from the electrodes but enables the free flow of ions during electrophoresis.

Figure 3: Felix membrane technology



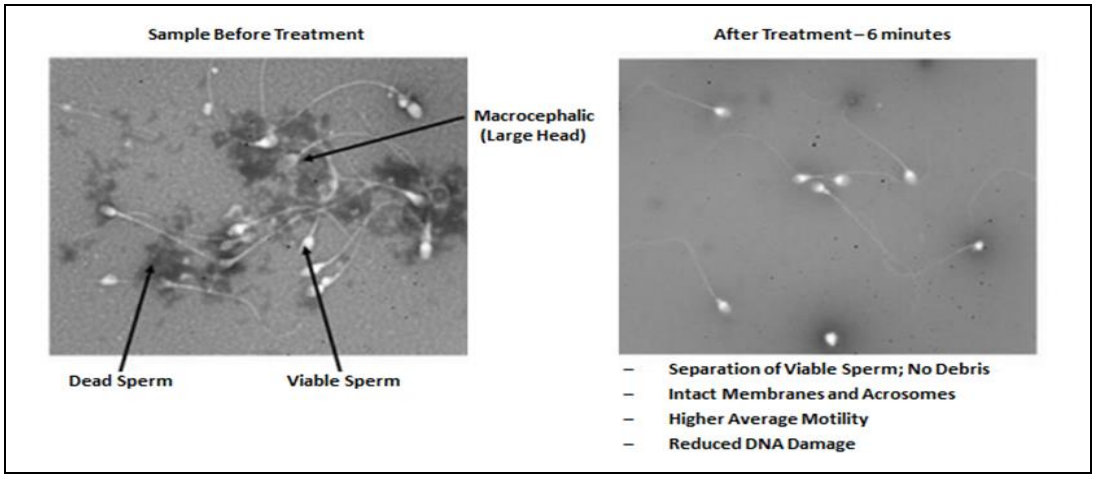
Source: Company

Felix is significantly superior to the conventionally used technologies

Felix isolates sperm from other constituents in a semen sample based on both size and charge (Figure 3), thus offering a number of advantages over presently available conventional sperm separation technologies – swim-up and DGC. These include the following:

- **Prevention of sperm damage:** It can separate sperm from leukocytes, which damage sperm by causing undesired lipid peroxidation and DNA damage.
- **Faster:** It takes less than a quarter of the time required to conduct DGC for a single semen sample.
- **High purity:** The isolated samples are free from debris and comprise viable sperm with higher average progressive motility and less DNA damage.
- **Suitability for patients having poor sperm motility:** Unlike the swim-up technology, electrophoresis is independent of sperm motility.

Figure 4: Felix prototype cartridge performance results on healthy human ejaculate



Source: Company

Felix helps isolate functional sperm without DNA damage. Less DNA damaged sperm has been shown to increase the rate of fertilisation and implantation, while reducing the chances of miscarriage and recurrent pregnancy loss and improving the chances of successful pregnancy and the birth of healthy progeny. Figure 4 shows Felix prototype cartridge performance results on healthy human ejaculate.

Road to commercialisation

Memphasys has partnered with innovative suppliers to add value to its product and speed up its commercialisation timelines

The development of Memphasys' Felix device is being done in collaboration with its inventor Professor John Aitken and his research team (University of Newcastle). The company has made crucial investments to get the right partners on-board. Some of them are **Hydrix,** a Melbourne-based engineering company that works as a key product development partner, and **Monash IVF Group** for assistance in product development and commercialisation of the Felix device.

Further, recommendations from Monash IVF Group, pertaining to design changes in the Felix device, were incorporated by Memphasys in 2019. Design modifications included reduction of clinical sample volume (from 1.8 ml to 1 ml) and usage of single-pipetting methods for cartridge loading.

Memphasys has partnered with innovative companies to ensure commercialisation of its technology. It has also selected **W&S Plastics (W&S)** as its cartridge manufacturing partner. W&S will manufacture components for the cartridges, assembling, packaging and labelling of Felix devices.

Both Hydrix and W&S have played critical roles in product development and have suggested several design and manufacturing process improvements, resulting in the need for fewer components; this subsequently helped Memphasys reduce manufacturing costs and increase automation. Key modifications included replacement of the expensive platinum-coated titanium electrodes with cost-effective carbon-printed film on plastic substrates.

Memphasys will initially manufacture hydrogel membranes for the KOL study and then transfer the technology to W&S during commercial-stage production.

Rigorous march towards gaining edge in IVF services market

Global KOL assessments are underway to validate clinical performance of Memphasys' technology

Memphasys has inked multiple KOL agreements across key markets[2] and the company continues to develop clinical assessment protocols in collaboration with Professor John Aitken to evaluate Felix device's performance in comparison with two conventional sperm processing techniques (DGC and swim-up) used for IVF procedures. Memphasys expects to initiate commercial sales by late 2020.

Memphasys does not face stringent regulatory requirements across its initial markets of interest. However, the level of regulatory oversight varies across the different regions. For the EU and China, the regulatory hurdles are highest. For the US, Australia and The Middle East[3] the regulatory hurdles are 'medium'. For India, Canada, Japan, and New Zealand the hurdles are considered low.

Some of the key regulatory pathways are listed below.

Benign regulatory environment across major target markets will help in achieving commercialisation timelines

- The approval for IVF-related laboratory equipment is more challenging in the EU, China, the US and Australia than in early target countries (India, Canada, Japan and New Zealand). However, these regulations tend to be more lenient than regulations for approval of complex medical devices (Class III and Class IV) in the same regions.
- The US Food and Drug Administration Agency (FDA) categorises equipment used in IVF equipment[4] as a 'Class II (special controls)' medical device. The regulatory pathway for Felix is the 'De Novo' pathway since there is no 'substantially equivalent' device. The company intends to have a pre submission meeting with the FDA during which it will put its case of what level of clinical testing should be required. Felix will probably be required to undergo a clinical trial to prove its equivalence in safety and efficacy against current ways of processing semen for IVF, namely DGC and swim up.
- Regulations across India, Canada, NZ and Japan indicate there will be lower market barriers to sell the Felix device in these markets. In some of these jurisdictions it will be considered laboratory equipment, and will simply have to show that it has passed the requisite design and manufacturing quality controls and to satisfy the key opinion leaders in these jurisdictions, who will have already tested the performance of the device against swim up and DGC, that it is a viable alternative method for processing sperm for IVF.

Memphasys has implemented a quality management system (QMS) and utilises "Greenlight Guru", a specialised online software system for medical device development, in preparation for obtaining ISO 13485 certification, which is likely to be applied for in Q1 CY2021.

[2] Tokyo, (Japan), Toronto (Canada), Boston, New York and Denver (USA), Clermont (France), Gothenburg (Sweden), Munster (Germany), Isfahan (Iran), Ahmedabad (India), Shanghai (China), Melbourne (Australia) and Auckland (New Zealand).

[3] Memphasys had expected Iran would be low but now believes that the hurdles are medium as that country will require either TGA, FDA or CE mark approval before Memphasys can market there.

[4] Assisted reproduction labware is defined as laboratory equipment/supplies that are intended to be used to prepare, store, manipulate or transfer human gametes/embryos for assisted reproduction procedures such as IVF and gamete intra-fallopian transfer.

Commercialisation of Felix remains on track despite COVID-19

Positive data received from initial KOL sites

In a market update on 16 June 2020, Memphasys reported that positive Felix data have been received from initial KOL sites, with additional data expected in coming weeks as more KOL sites begin to recommence accepting patients and continuing Felix assessments post the COVID-19 interruption.

Following the Australian Government's recent decision to allow elective surgeries to recommence, Monash IVF has resumed IVF services and Felix testing. The resumption of this activity will allow Monash IVF to continue its collaboration with Memphasys.

As the extent of the COVID-19 outbreak differs among each country, the company expects that KOL Felix assessment data will likely be first received from KOL clinics located in markets such as China and Japan ahead of USA, Canada, Europe, India and Iran.

Memphasys progresses with its Felix verification & validation process

Memphasys has also reported significant progress with its Felix verification and validation (V&V) process, an important internal testing process that is required to be completed before sales can be made in highly regulated markets. The Felix cartridge production cleanroom at W&S Plastics has now been completed. All equipment is scheduled to be installed and cleanroom certification to ISO7 and ISO8 expected by end of July 2020. The company expects to undertake Felix V&V validation test using final production devices on clinical samples at Monash IVF in Q3 2020. After completing requisite V&V processes, the cartridges will be ready for commercialisation in early markets. Also note that V&V runs in parallel to the Felix KOL assessment trial.

First Felix sales still expected to occur in Q4 2020

Despite that COVID-19 has caused delays on the overall product development program, Memphasys expects that those delays will not materially impact on their anticipated timing of the first sales of the Felix device, which remains on track for Q4 2020.

Memphasys' technology has potential to transform the IVF market

As part of its strategy to focus on the development of the Felix device, Memphasys has the potential to revolutionise the IVF market. Memphasys' cell separation technology is anticipated to overcome challenges associated with conventional sperm processing methods (DGC and swim-up) and pave the way for improved clinical success rates whist simultaneously reducing costs.

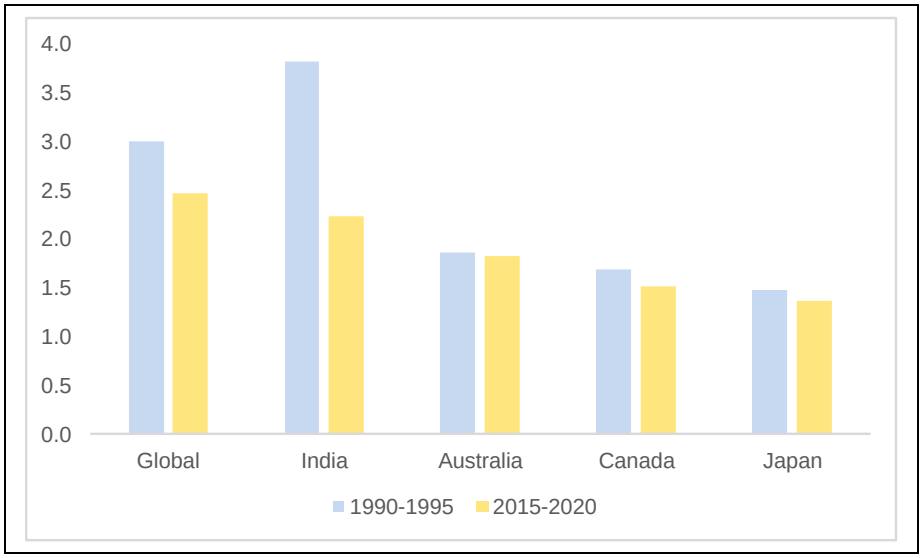
The company will also benefit from ongoing and projected industry developments. Some key market drivers are as follows:

– **Declining global fertility rate** to increase demand for technologies that will improve process efficiencies and reduce the cost of the overall IVF treatment. As per the United Nations (UN) World Population Prospects 2019 estimates, the total fertility rate (Figure 5) has declined from 3.01 (1990–1995) to 2.47 (2015–2020)[5,6]. Memphasys' early-stage focus

[5] Total Fertility rate is defined as the average number of live births a hypothetical cohort of women would have at the end of their reproductive period if they were subject during their whole lives to the fertility rates of a given period and if they were not subject to mortality. It is expressed as live births per woman.
[6] Data sourced from the UN World Population Prospects database on 14 January 2020.

markets, such as Australia/New Zealand, Canada, India and Japan, are facing significant declines in the total population fertility rate.

Figure 5: Total fertility rate – by region (1990–2020)



Source: UN Department of Economic and Social Affairs, Population Division (2019)

Declining fertility rate, coupled with shifting social paradigms to drive IVF market growth

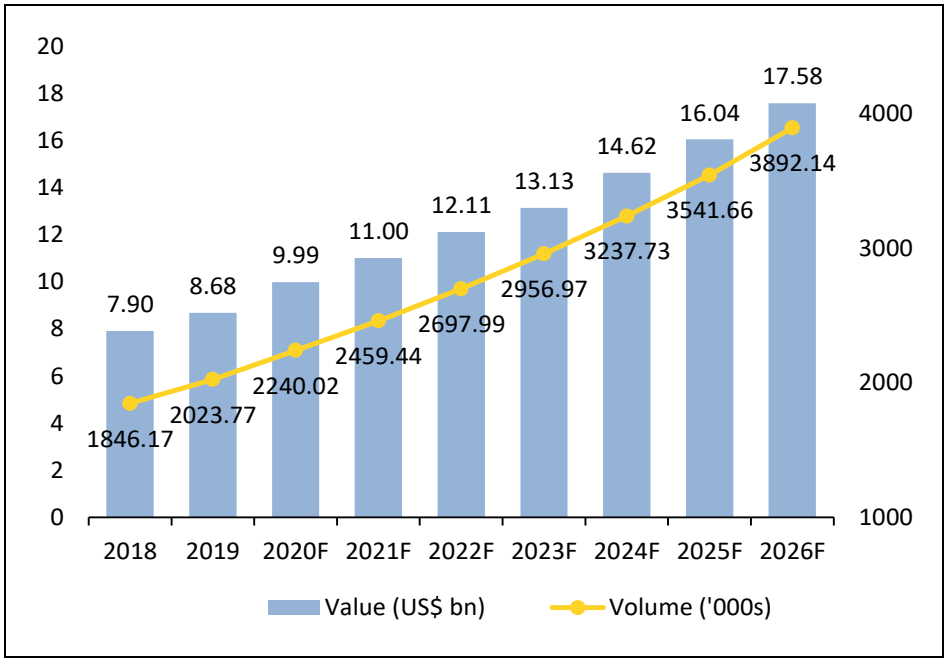
– **Rising focus on technological advancements** to improve IVF success rate by reducing the average number of IVF cycles needed for live child birth. As per the 2018 European Society of Human Reproduction and Embryology[7], since 1978, more than 8 million babies globally have been born due to IVF and other advanced fertility treatments[3]. Conventional sperm separation technologies, in particular, DGC, are associated with DNA damage to sperm and this increases the risk of IVF treatment failure. This is driving focus on developing innovative technologies to improve the IVF success rate and reduce IVF treatment costs.

– **Shifting social paradigms** are resulting in individuals' choice to have children later in life, thereby leading to a higher social acceptance of IVF globally.

Further, industry reports valued the global IVF market for fresh IVF cycles[8] (Figure 6) at US$7.9bn in 2018 and forecast the market to cross US$17.6bn by 2026. The market growth is majorly driven by declining global fertility rate and rising focus on technological advancements. However, high costs of IVF treatments continue to dampen market growth.

[7] 'More than 8 million babies born from IVF since the world's first in 1978', European Society of Human Reproduction and Embryology (July 2018).
[8] A fresh IVF cycle involves transvaginal harvesting of eggs using ovulation-inducing medications followed by fertilisation using fresh sperm.

Figure 6: Global IVF market for fresh IVF cycles – by value and volume (US$ bn, '000s; 2018–2026F)



Source: Company

Medium-income countries such as India and Iran are key markets for Felix device commercialisation

Additionally, Memphasys has decided to initially target countries with significant market potential (Figure 7). The favourable regulatory macro-environment in these target markets is anticipated to speed up Memphasys' commercialisation timelines. The company is poised to revolutionise the market and witness wider adoption among global IVF players for improving clinical success rate and reducing overall costs.

Figure 7: IVF market for fresh IVF cycles – by volume (2018–2026F)

Region	Fresh IVF Cycles		CAGR
	2018	2026F	(2018–2026F)
Canada	6,360	21,140	34.96%
India	169,800	489,840	39.57%
Japan	269,110	699,110	43.37%
New Zealand	5,300	11,190	52.00%

Source: Company

Uses beyond animals

Memphasys's first application is human fertility. However, it is reasonable to expect this technology to ultimately be applied to animal breeding as well. We see considerable upside from such applications to Memphasys:

- **Pigs**: Up until recently, around 100 million tonnes of pork were produced p.a. However, pork production dropped in 2019[9] because of the outbreak of African swine fever, which caused Chinese herd numbers to fall by 40%[10] and may cause the world's total stock of pigs to decline by 25%[11]. In many countries pork producers use artificial insemination intensively[12], but there is a need to rebuild herd numbers globally and this will provide impetus in the search for new technologies to improve breeding success rates.
- **Horses**. Artificial insemination in the breeding of thoroughbred racehorses is banned in most countries, including Australia, by the International Federation of Horseracing Authorities (IFHA), of which Racing Australia is a member[13]. However, breeding of horse other than those used in horse racing would be a legitimate use of this technology. Horses traditionally have the lowest reproductive efficiency of all species of domestic livestock, with the typical foaling rates only 50-60% of mares bred[14]. America alone has around 9 million horses that are not used in horse racing.
- **Dairy cattle.** There are about 250 million dairy cattle worldwide[15] and breeders are always on the lookout for tools that can improve milk yield, at a time when global dairy demand is rising sharply thanks to increased Chinese consumption. Farmers have noticed a decline in the fertility of their herds in recent decades[16].
- **Beef cattle**. There are probably in excess of a billion beef cattle in herds today[17]. Until recently artificial insemination was not applied to beef as intensively as to dairy cattle but that is changing as cattle producers grapple with rising meat demand

Memphasys has estimated that the market for artificial insemination consumables for horses alone is > US$200m. Memphasys will seek to partner the global distribution of the animal applications of its technology when these applications are ready to be marketed.

[9] Source: Statista.
[10] See *Quarter of world's pig population 'to die due to African swine fever'* by Bibi van der Zee, The Guardian, 1 November 2019.
[11] See *'Not enough pork in the world' to deal with China's demand for meat* by Bibi van der Zee, The Guardian, 24 November 2019.
[12] Acta Scientiae Veterinariae. 37(Supl 1): s61-s71, 2009.
[13] There was an unsuccessful Federal Court challenge to this ban in Australia in 2012 – see *Court upholds racehorse insemination ban* by Jamelle Wells, ABC, 19 December 2012.
[14] Source: Equimed.
[15] Source: Compassion in World Farming.
[16] Animal. 2008 Aug; 2(8): 1104–1111.
[17] Estimated from FAO data.

Valuing Memphasys

We value Memphasys based on a DCF model using what we think are conservative assumptions. Our key assumptions are as follows:

- **Time horizon**: We used a 10-year time horizon in our DCF followed by terminal value growth of 2% beyond 10 years.
- **Volume**: We used a market share approach to forecast cartridge and device volumes. We applied market shares assumptions of the Felix technology on the expected fresh IVF cycles across the global markets to arrive at the number of cartridges and devices sold per region over the next 10 years. Also, our modelling factored in growth in the underlying market shares of the Felix technology across our 10-year forecast horizon.
- **Price per cartridge**: We assumed the initial price of each cartridge to be ~A$200, basing off competitor pricing[18]. Memphasys's product is a single-use disposable cartridge and will be the main source of revenue for the company. We have increased the pricing in our base case model by an average of ~4% over the forecast horizon.
- **Revenue from devices:** Besides the cartridge, the company will be earning revenue from the devices sold along with the cartridge. We have assumed the initial price per device to be ~A$1,000 and have increased the price by an average of ~4% over the forecast horizon.
- **Pathway to commercialisation:** Based on company guidance, we expect Memphasys to realise its first sales in FY2021. The markets in which we expect that the company will realise its initial sales are countries with a lenient regulatory framework, including Japan, India, Canada, Iran and New Zealand. In FY2022 and beyond, we assumed the company to expand its technology offering to the rest of the global IVF market.
- **Amortisation:** We expect capitalised development costs to be amortised from FY2021 as the company realises its first sales. We assumed the estimated useful life of intangibles to be 20 years.
- **Tax Rate**: We have assumed a corporate tax rate of 30%. As the company has significant amount of tax losses to carry forward, our base case modelling expects Memphasys to begin paying cash tax in FY2025.
- **Discount rate**: We used a WACC of ~14.3%, appropriate in our view for a 'Speculative' risk rating[19]. Memphasys is in pre-revenue phase and is more risky than other more commercialised Life Sciences ventures.

Based on the above key assumptions, we arrive at intrinsic values of A$0.15 and A$0.24 for Memphasys, based on base case and bull case assumptions, respectively. The DCF valuations in both the cases have been summarised in Figure 8. Figure 9 provides our sensitivity analysis by varying terminal growth rate and discount rate. Figure 10 shows sensitivity analysis by varying pricings on cartridge and device.

[18] DxNow has Zymot, an automated swim up device with microfluidic chambers. DxNow is attempting to charge around US$200 per cartridge.

[19] For a relevant discount rate, we use varying WACCs depending on the risk for Life Science companies. We start with an RFR of the Australian ten year bond rate (1.6%) and an ungeared beta of 1.1 but use a variable MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies). Ordinarily we regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'. We have used a Speculative risk rating for Memphasys considering it is at a pre revenue stage.

The key differences between the base and bull case assumptions pertain to volume (fresh IVF cycles) growth in key geographies and annual price growth of cartridges and devices.

Figure 8: DCF valuation for Memphasys

Valuation (A$)	Base Case	Bull Case
Present value of FCF (m)	51.0	79.8
Present value of Terminal FCF	70.1	110.7
Enterprise Value (m)	**121.1**	**190.5**
Net debt (cash) (m)	(0.5)	(0.5)
Minority interest (m)	-	-
Equity value (m)	121.6	191.0
Share outstanding (Diluted)	792.2	792.2
Implied price (A$)	0.15	0.24
Current price (A$)	0.05	0.05
Upside (%)	**201.1%**	**372.8%**

Source: Pitt Street Research

Figure 9: Sensitivities of our model to WACC and terminal growth rate

Sensitivity Analysis									
WACC	**14.25%**								
Terminal Growth Rate	**2.00%**	**Change in WACC**							
Implied Price (A$)	**0.15**	*14.1%*	*14.2%*	*14.2%*	*14.3%*	*14.3%*	*14.4%*	*14.4%*	*14.5%*
	1.25%	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.14
	1.50%	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
	1.75%	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
Change in Terminal Growth Rate	*2.00%*	0.16	0.16	0.15	**0.15**	0.15	0.15	0.15	0.15
	2.25%	0.16	0.16	0.16	0.16	0.15	0.15	0.15	0.15
	2.50%	0.16	0.16	0.16	0.16	0.16	0.16	0.15	0.15
	2.75%	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.16

Source: Pitt Street Research

Figure 10: Sensitivities of our model to price per cartridge and device

Price per Cartridge	AUD 200								
Price per Device	AUD 1,000	**Change in Price per Cartridge**							
Implied Price (A$)	**0.15**	AUD 50	AUD 100	AUD 150	AUD 200	AUD 250	AUD 300	AUD 350	AUD 400
	AUD 700	0.06	0.08	0.11	0.14	0.16	0.19	0.22	0.24
	AUD 800	0.06	0.09	0.12	0.14	0.17	0.20	0.22	0.25
	AUD 900	0.07	0.10	0.12	0.15	0.17	0.20	0.23	0.25
Change in Price per Device	AUD 1,000	0.07	0.10	0.13	**0.15**	0.18	0.21	0.23	0.26
	AUD 1,100	0.08	0.11	0.13	0.16	0.18	0.21	0.24	0.26
	AUD 1,200	0.08	0.11	0.14	0.16	0.19	0.22	0.24	0.27
	AUD 1,300	0.09	0.12	0.14	0.17	0.20	0.22	0.25	0.27

Source: Pitt Street Research

Re-rating Memphasys

We see the following factors contributing to a re-rating of Memphasys towards our valuation range:

- Successful completion of the process of verification and validation testing for the Felix device
- Favourable results from the clinical assessments headed by KOLs across key regions.
- Achieving sales in early markets e.g. Japan, Canada, NZ, India
- Securing approvals for major jurisdictions from TGA, FDA and CE Mark.
- Faster-than-expected achievement of the commercialisation milestones.
- Entering into partnerships with additional or renowned KOLs.

Risks specific to Memphasys

We see three major risks for Memphasys as a company and as a listed stock:

- **Funding risk**. More funding may be required to support the clinical and commercial development of the Felix device.
- **Clinical risk**. There is the risk that KOL clinical assessments with Felix device will not yield desirable clinical results.
- **Technology risk**. Another risk is associated with direct competitors such as DxNow, which has Zymot, an automated swim up device with microfluidic chambers, which can gain from first-mover advantage and lead to Memphasys not realising the full commercial potential of its Felix device. Interestingly DxNow is attempting to charge around US$200 per cartridge, which is nearly double the price we have modelled for Felix cartridges.

Seasoned leadership to mobilise company growth

Alison Coutts, the Executive Chairman, joined Memphasys in December 2013. Ms. Coutts has >30 years of global experience across multiple industries, including investment banking, strategic consulting and biotechnology. Her biotechnology entrepreneurial ventures – Mariposa Healthcare Pty Ltd (2009) and Micro-X Ltd (2010) – have augmented her technology commercialisation and executive management skills. Leading with these experiences, her role as a CEO is likely to be critical in the successful commercialisation of Memphasys' technologies in the IVF market.

The company has an experienced board, comprising the following executives:

- **Andrew Goodall**, non-executive director, has served as a member of Memphasys' board since March 2012. He is also a member of Memphasys' Audit and Risk, and Nomination and Remuneration committees. Presently, he is the largest shareholder of the company. Andrew has established several businesses across Australia and New Zealand, and is currently managing substantial commercial property interests.
- **Paul Wright**, non-executive director since 13 March 2020, brings a strong background in technology development. For the past two decades, Mr Wright worked as CEO for three leading international Australian technology companies focussed on developing, manufacturing and marketing of medical devices and diagnostic instruments, including: Invetech and Vision BiosSystems, which were acquired by a Fortune 500 company and Universal Biosensors, where Mr Wright developed commercial partnerships with two large multinationals and oversaw the development, commercialisation and manufacturing scale-up of a blood coagulation analyser for world markets. Mr Wright is currently a non-executive director of design, engineering and technology commercialisation company Hydrix Ltd and an advisory board member for unlisted digital wastewater services company, Waterwerx Pty Ltd.
- **Shane Hartwig** is Memphasys' non-executive director. Mr. Hartwig is a Certified Practicing Accountant and Chartered Company Secretary. Mr. Hartwig has 25 years of overall financial experience with exposure to both the debt and equity capital markets. He has worked on multiple initial public offerings, capital fundraising, preparation of prospectus and information memorandum, project management, due diligence reviews, and mergers and acquisitions.

Appendix I – Glossary

Cyto-skeleton – It refers to complex networks of interlinking protein filaments that help cells maintain their shape and internal structure. It facilitates essential functions of cells such as division by offering mechanical support.

Deoxyribonucleic acid (DNA) – It is a molecule that comprises two chains that coil around each other to make a double helix. DNA carries genetic information, which is critical for development, functioning, growth and reproduction of all identified organisms.

Electrophoresis – This involves the movement of dispersed particles relative to a fluid under the influence of a spatially uniform electric field. An electrophoretic system contains two electrodes of opposite charge (anode and cathode) placed in an electrolyte (conducting medium).

Fresh IVF cycle – It involves transvaginal harvesting of eggs using ovulation-inducing medications, followed by fertilisation using fresh sperm.

Felix – Memphasys' cell separation technology combines principles of electrophoresis and size-based separation using patented membranes. It helps in separation of high-quality sperm cells and removal of unwanted debris from semen samples for use in IVF procedures.

Glycoprotein – It is a conjugated protein in which the non-protein group is a carbohydrate and is covalently attached to amino acid side chains.

IVF – It involves fertilisation by using sperm and eggs surgically removed from an ovary in a test tube or laboratory dish; this is followed by uterine implantation of one or more of the resulting fertilised eggs.

Phase-inversion – It is a demixing process in which an initially homogeneous polymer solution is converted from a liquid state to a solid state in an organised manner. This is the most frequently used method to produce polymeric porous membranes.

Size-exclusion filtration – It involves the separation of a widespread range of molecules according to size, including proteins, polysaccharides and nucleic acids.

Total fertility rate – The average number of live births a hypothetical cohort of women would have at the end of their reproductive period if they were subject during their whole lives to the fertility rates of a given period and if they were not subject to mortality. It is expressed as live births per woman.

Appendix II – Capital structure

As of 25 June 2020	In million	% of fully diluted	Note
Ordinary fully paid shares	754.0	95.2%	
Options	38.2	4.8%	Only in-the-money options (exercise price of 3.3 cents expiring on 28-Sep-21) considered. Out-of-the-money options worth 30m (exercise price of 11.4 cents expiring on 22-Oct-2021)
Fully diluted shares	**792.2**		

Source: Company

Appendix III – Memphasys' intellectual property

Details of Memphasys' intellectual property:

WO/2002/068100, *Polymeric membranes and uses thereof,* priority date 27 February 2001, invented by Dave Solomon, Marcus Caulfield and Helen Purss.

- This patent application covers an organic polymeric membrane made from polyvinyl alcohols – that are crosslinked via hydroxyl groups with a polyfunctional agent (e.g., glutaraldehyde, malonic dildehyde and succinic dialdehyde) – using a step-growth reaction instead of the conventional free-radical polymerisation. Besides offering good processability, reproducibility and bio-stability, the method helps control pore sizes of the membranes produced by adjusting the ratio of the crosslinking agent and polymers. The membrane can be used for electrophoretic separation of biological samples, wherein a few mentioned application areas include the separation of proteins, peptides, DNA and RNA[20].
- Applications for the patent have been filed in Australia, the US, Europe and Canada. However, it has been granted only in the US and Australia as yet.

WO/2018/071977, *Electrophoresis device,* priority date 20 October 2016, invented by Xing Feng Zhao.

- This application pertains to an electrophoresis apparatus that leverages a sucrose-containing HEPES buffer with a low electrolyte content, which reduces currents by 90%. The substantial reduction in currents helps avoid undesirable temperature/pH increase and gas build-up. The specified buffer composition can be used in sealed chambers and does not require circulation of buffer streams, which typically requires additional tubing, pumps and reservoirs. This reduces equipment costs and simplifies post-use decontamination processes. Additionally, the system utilises separation membranes – made from polyvinyl alcohol and polycarbonates – that are free from toxic acrylamine monomers. The apparatus can be used to separate cells (e.g., sperm and platelets) and macromolecules.
- Applications for the patent have been filed in Australia, the US, Europe, China and Japan. However, it has not been granted in any of these geographies till date.

WO/2018/071978, *Sperm separation by electrophoresis,* priority date 20 October 2016, invented by Xing Feng Zhao and Hani Nur.

[20] Memphasys is no longer using phase inversion to make its restriction membranes and the company has added another polymer to make it a co-polymer. Also, Memphasys now uses its polymeric membranes rather than wet.

- This patent relates to the use of polyvinyl alcohol (PVA) films as electrophoretic membranes. The films – made from PVA, polyethylene glycol and poly (N-vinyl-2-pyrrolidone) – can replace conventional polyacrylamide (PAm) membranes, which contain toxic acrylamide monomers. Toxic monomers can damage or contaminate the sperm being separated. The specific membranes and techniques are suitable for isolating viable sperm for the assisted reproductive technology (ART). The conventional sperm-separation methods for ART include swim-up and density-gradient centrifugation that are not fit for use with patients having poor sperm motility and semen samples contaminated with leukocytes, respectively.
- Applications for the patent have been filed in Australia, the US, Europe, China and Japan but have not yet been granted in any of these geographies.

WO/2017/181240, *Biocompatible polymeric membranes,* priority date 22 April 2016, invented by Hani Nur, Sandra Kentish, Martin Van Koeverden and Vikram Chaudhari.

- This patent application pertains to biocompatible polymeric membranes made from polyvinyl alcohols (PVA) instead of polyacrylamide (PAm). PVA membranes can be produced using alcohol-induced phase inversion, which facilitates scaling up of the process by allowing fast wetting of the substrates during casting. Besides offering good processability, reproducibility and bio-stability, the method helps control pore sizes of the membranes by adjusting the ratio of the crosslinking agent and polymers. The membranes can be used for electrophoretic separation of biological samples, wherein a few mentioned application areas include the separation of proteins, peptides, DNA and RNA.
- Applications for the patent have been filed in Australia, the US and Europe, but have not been granted in any of these geographies.

WO/2004/101117, *Cell Separation,* priority date 15 May 2003, invented by Dennis Rylatt and Sharon Leong.

- This application relates to the use of membrane-based electrophoretic techniques to separate cell samples. It helps replace the conventional affinity-based methods, which may alter cell surface properties due to the use of certain enzymes and chemicals. The method involves the application of electric potential between electrodes until the desired purity level is achieved for a specific cell population. It facilitates the recovery of ~90% viable cells and offers a rapid, efficient and cost-effective method of enriching a cell type. The method can be used to separate cells, such as leukocytes, and cancer, totipotent, multipotent, pluripotent and stem cells.
- Applications for the patent have been filed and granted in Australia and the US.

WO/2000/013776, *Removable cartridge for macromolecule purification,* priority date 7 September 1998, invented by David Ogle.

- This application covers removable cartridges for an electrophoresis apparatus. The cartridges comprise a separation membrane, 2 restriction membranes and 2 grid elements. The grids are designed as thin elements to increase the liquid velocity and reduce electrical power deposition on the buffer, thus preventing a rise in temperature which can damage samples. It drives power efficiencies and reduces costs by facilitating the use of smaller power units. The apparatus is said to be used for purifying macromolecules such as proteins.

– Applications for the patent have been filed in Australia, the US, Europe, Germany, Austria, Canada and Japan. They have been granted in the US, Europe and Australia so far.

WO/2001/078878, *Small separation apparatus,* priority date 18 April 2000, invented by David Ogle and Dennis Rylatt.

– This patent application pertains to an electrophoresis apparatus for separating small samples. The apparatus leverages 2 polyacrylamide membranes – that offer a sample and barrier surface area ratio of 0.02–1 ml/cm^2 – separated by a distance of 1mm. The design ensures rapid movement of compounds without undesirable increase in temperature, thus eliminating the need for circulating buffers. It also increases the separation efficiency without the need for re-circulating the sample multiple times. Although explicit areas of application have not been claimed, the apparatus can be used to separate samples of 0.02–0.1 ml – comprising plasma, proteins, cell extracts and antigens.

– Applications for the patent have been filed in Australia, the US, Europe, Germany, Canada and Japan. It has been granted in the US and Australia till now.

Appendix IV – Memphasys' non-patent literature

Details of technical papers relevant to Memphasys:

Ainsworth et. al. (2005), *Development of a novel electrophoretic system for the isolation of human spermatozoa*. Hum Reprod. 2005 Aug; 20(8):2261-70. Epub 2005 Apr 14.

– This paper relates to an electrophoretic system comprising two chambers separated by a polycarbonate separation membrane. The chambers are bound by polyacrylamide membranes to facilitate free circulation of HEPES buffer medium during the application of electric current. The semen sample is introduced in the first chamber and the sperm isolate is collected from the adjacent chamber. The isolated sperm are motile, viable, and morphologically normal, and exhibit low levels of DNA damage. Compared with conventional DGC technologies, the electrophoretic system is a faster technique to isolate functional human sperm for improved assisted conception outcomes.

Fleming et. al. (2008), *Prospective controlled trial of an electrophoretic method of sperm preparation for assisted reproduction: comparison with density gradient centrifugation.* Hum Reprod. 2008 Dec;23(12):2646-51. Epub 2008 Sep 1.

– This paper covers a comparative study between electrophoretic filtration and DGC for sperm isolation. Both methods offered similar sperm recovery rates and high-quality embryo yields. However, the electrophoretic technique took 5 minutes for a single semen sample – DGC took 20 minutes – thus proving to be a much faster method to isolate sperm for IVF and intracytoplasmic sperm injection.

Ainsworth et. al. (2011). *The electrophoretic separation of spermatozoa: an analysis of genotype, surface carbohydrate composition and potential for capacitation.* Int J Androl. 2011 Oct;34(5 Pt 2):e422-34. Epub 2011 May 12.

– This paper pertains to the use of PCR and MALDI-TOF for the analysis of sperm isolated using the electrophoretic separation technique. The key parameters tested were genotype, surface carbohydrate composition and the potential for capacitation. Although the separation mechanism proved to be independent of the sperm genotype, it resulted in sperm

preparations enriched in surface glycoproteins due to a net electronegative charge.

Appendix V – Major shareholders

- Peters Investments Pty. Ltd, an investment firm promoted by Bob Peters, a Perth-based business and racehorse owner (27.9%).
- Andrew Goodall, Non-Executive Director of Memphasys and a Sydney-based entrepreneur (23.3%).
- Alison Coutts, Executive Chairman of Memphasys (10.8%).

Appendix VI – Comparable companies

Company	Location	Ticker	Market cap (US$m)	Website
IVF solution providers				
Hamilton Thorne Ltd	US	TSXV:HTL	114.9	www.hamiltonthorne.com
INVO Bioscience	US	OTCPK:IVOB	39.4	www.invobioscience.com
Aytu BioScience Inc	US	NasdaqCM:AYTU	14.7	www.aytubio.com
Diagnostic solution providers				
Yourgene Health Plc	UK	AIM:YGEN	112.8	www.yourgene-health.com
Immunodiagnostic Systems	UK	AIM:IDH	78.5	www.idsplc.com
Concepta Plc	UK	AIM:CPT	4.6	www.conceptaplc.com
Memphasys Ltd	Australia	ASX:MEM	32.1	www.memphasys.com

Source: Pitt Street Research

We have looked at comparable companies to Memphasys in two areas – IVF solutions and diagnostic solutions catering to fertility issues.

IVF solution providers

Hamilton Thorne Ltd (HTL): The company provides precision laser devices and advanced image analysis systems for various end markets including fertility, stem cells and development biology research. Notably, HTL's image analysis system – CASA (Computer Assisted Sperm Analysis) – helps clinicians in analysing sperm motility and other characteristics. The system has various use cases such as human fertility, toxicology and animal applications.

INVO Bioscience Inc: The company's lead product INVOcell, an Intravaginal Culture system, is used for preparing, holding and transferring human gametes or embryos in IVF/IVC procedures. The system also includes an INVOcell Retention Device which ensures the retention of the INVOcell culture device in the vaginal cavity during incubation period.

Aytu BioScience Inc: Aytu is a US-based speciality pharmaceutical company engaged in developing and commercialising novel products for various healthcare concerns. The company's MiOXSYS system is an in vitro diagnostic

semen analysis system used to measure static oxidation reduction potential in human semen.

Diagnostic solution providers

Yourgene Health Plc: Yourgene is a UK-based molecular diagnostic company, engaged in providing gene analysis for prenatal screening. The company's IONA test allows clinicians to carry out in vitro diagnostic non-invasive pre-natal test to screen pregnant women for Down's syndrome, Edward's syndrome and Patau's syndrome. Additionally, Yourgene provides a single workflow solution for molecular diagnosis of Male Factor Infertility.

Immunodiagnostic Systems (IDH): IDH is a UK-based provider of in vitro diagnostic solutions. The company manufactures and markets immunoassays and automated immunoanalyser technologies for diagnosis of various ailments including fertility.

Concepta Plc: Concepta is a UK-based provider of mobile health diagnostic medical devices. The company's flagship product, MyLotus, is a fertility monitor allowing women to monitor their hormone cycles and ovulation profile.

Also worth watching

We note with interest a privately held US company called **DxNow** (Gaithersburg, MD, dxnow.com), which is developing a microfluidic sperm sorting device that is easier to use than comparable devices because o the level of automation, and allows lower DNA fragmentation than standard density-gradient centrifugation. This company is now enjoying early sales from labs who only used to do density-gradient centrifugation. Memphasys believes that Felix is a superior product in that it will be faster, less expensive and useful in traditional IVF as well as Intracytoplasmic Sperm Injection.

Appendix VIII – Analyst's qualifications

Stuart Roberts, lead analyst on this report, has been covering the Life Sciences sector as an analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research specialty at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months in 2015 and 2016 doing Investor Relations for two ASX listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Science companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Science companies.

Cheng Ge is an equities research analyst at Pitt Street Research.

- Cheng obtained a B.Com in Finance and LL.B from University of New South Wales, in 2013, and has passed all three levels of the CFA Program.
- Prior to joining Pitt Street Research, he has worked for several financial services firms in Sydney, where his focus was on financial advice.
- He joined Pitt Street Research in January 2020.

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