ASX Code: MEM



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Distribution agreement with Vitrolife expands – agreements now in place for Canada & NZ

Highlights:

- Exclusive agreements executed between Vitrolife Group and Memphasys for sale and distribution of the Felix[™] System into Canadian and New Zealand markets
- First orders for Canada and New Zealand under this agreement anticipated in H1 2024
- Agreements are an expansion of current relationship with global IVF leader Vitrolife, following signing of an exclusive distribution agreement with Vitrolife for Japanese market in August 2023¹
- "Pathfinder" sales have been achieved in Japan, with a standing order to maintain and grow supplies in Japan expected in Q1 2024.
- Memphasys monitors progress in Japan as clinical data sets continue to grow with a view to achieving public health insurance coverage within that market

Australian-based reproductive biotechnology company, Memphasys Limited (ASX: MEM), is pleased to announce it has signed an exclusive agreement with Vitrolife Pty. Ltd. New Zealand and Vitrolife Inc. Canada, also 100% subsidiaries of global IVF leader Vitrolife AB (Vitrolife), to sell and distribute the Felix[™] System (Felix[™]) in both New Zealand and Canada.

Canada and New Zealand are two key early access target countries for Memphasys. These markets present a strong opportunity for early commercial access to build the Felix[™] brand and access key opinion leaders to legitimise the product in their landscape. For these reasons entry into markets with lower regulatory hurdles are an essential commercial pathway for products such as Felix[™].

The Felix[™] System consists of a console and single-use cartridges for preparing sperm for human IVF procedures. Felix[™] separates sperm from a semen sample in six minutes using a combination of gentle electric forces (known as electrophoresis) and size exclusion membranes. The separated cells yield sperm which are ideal for improved results from the IVF procedure.

Under the agreements, which are each for a period of five (5) years, Vitrolife will have exclusive rights to sell and distribute Felix[™] in these two markets. Vitrolife will provide marketing, sales and training in the use of Felix[™] with an initial focus on key clinicians and high-volume clinics in both Canada and New Zealand.

These distribution agreements, whilst enabling the fast-tracking of commercial sales process, are strategically important for Memphasys as they solidify and legitimise the commercial value of the Felix[™] brand and avoid unnecessary costs associated with product registration and the establishment of a dedicated in-country sales/ marketing team.

¹ Refer ASX announcement dated 7 August 2023



Canada presents a significant opportunity for the Company, with the market estimated to have undertaken 21,030 cycles throughout the year² (with a cycle being one round of IVF treatment). The Canadian market has been conservatively estimated to support a total addressable market of approximately \$2m annualised revenue.

It should be noted that in preparation for entry into the Canadian market, Memphasys has already established a footprint in Canada through its pre-commercial Key Opinion Leader (KOL) networks.

New Zealand is a smaller market than Canada, supporting an estimated 11,940 cycles in 2023³ with a total addressable market of \$1m annualised revenue. Like Canada it is strategically important for Memphasys given its potential to build the brand, legitimise the product in their landscape and produce sizable volumes of clinical data for the Company's further expansion into more regulated markets.

Vitrolife Group (Vitrolife AB), a publicly listed company on the NASDAQ Stockholm exchange, offers substantial access to many clinics globally. Vitrolife is a world-leading global provider of medical devices, consumables and genetic testing services dedicated to the human IVF and reproductive health market. Founded in 1994, the company employs 1,100 people across 33 countries and its products and services are available in more than 125 countries. It has manufacturing sites in Sweden, Denmark and the USA and a direct presence in 25 countries.

In Canada and New Zealand, Vitrolife are well established and has direct sales access to clinical partners.

Japan Update

Vitrolife is already experienced in selling and distributing the Felix[™] System, with a distribution agreement executed between Memphasys and Vitrolife Japan KK⁴ signed in August 2023 for a period of five (5) years.

Vitrolife Japan KK has successfully incorporated the Felix[™] System into a number of its high-volume clinics in the private health sector. To date 300 cartridges have been sold to these clinics and Memphasys anticipates that now that "pathfinder" sales have been established, a standing order to maintain and grow supplies in Japan is expected in Q1 2024.

The upcoming order and feedback from Japanese clinicians suggest the Felix[™] System has been well received amongst these private clinics. However, there remains room for expansion throughout Japan and a dataset of results will be compiled which is expected to position the Felix[™] System to receive public health insurance coverage in Japan. This will significantly improve the attractiveness of the device to a broader number of clinics as approximately 80% of IVF treatments are covered within the insurance system.

It should be noted that with respect to market penetration, Memphasys is the innovator and manufacturer, and the Company does not drive market penetration and uptake in the market as that uptake is dependent on distribution and numerous market factors. Memphasys is extremely pleased with the current uptake to date as it follows well established commercialisation models used by numerous health organisation across the device and pharmaceutical industry.

² Global IVF services Market Opportunities and Forecasts, 2019 – 2026 by Allied Market Research, 2018

³ Allied Market Research, 2018

⁴ See ASX Announcement dated 7 August 2023



Memphasys Acting CEO and Executive Director Dr David Ali said:

"The steps that a commercial partner take including test marketing, evaluation and launch are important in the early stages of commercialisation as they will determine the initial uptake and success in a market. Thus, it is important to be strategic, get it right and drive this process with a considered yet tactical approach.

"This exclusive agreement with Vitrolife Group for a further two markets are continued proof that Memphasys continues to deepen its relationship with Vitrolife, one of the world's preeminent IVF companies, that is also highly experienced in the introduction of novel, technologically advanced IVF products.

"The deepened support, which first commenced with a distribution agreement to Japan and now expanded to Canada and New Zealand demonstrates significant interest in the Felix[™] System and its potential to revolutionise the preparation of male cells for improved IVF results.

"This exclusive distribution agreement fast-tracks our entry into all three of our identified early-access markets and does so in a way where Memphasys does not need to spend resources establishing an incountry sales team or build networks outside of existing KOL partners.

"I am envisioning first orders from Vitrolife in Canada and New Zealand to occur early in 2024. I am pleased with our progress in Japan with a standing order anticipated in Q1 2024 and note the early stages of plans and support to develop submission for integration into the Japanese public health insurance market when sufficient data has been collected.

"These are critical milestones as Memphasys begins to commercialise its product into early access markets, not only providing a number of opportunities for new sales but also providing the Company with a blueprint for further rollout in higher regulatory markets as the product matures."

This announcement has been approved for release by the board of Memphasys Limited.

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About Memphasys

Memphasys Limited (ASX: MEM) specialises in reproductive biotechnology for high value commercial applications. Reproductive biotechnology products in development include medical devices, *in vitro* diagnostics, and new proprietary media. The Company's patented bio-separation technology, utilised by the Company's most advanced product, the Felix[™] System device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com

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