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EVE Advances Reformulated Drugs Targeting Global Markets

New reformulations targeting sexual health and cardiovascular therapies

- Research and development completed on several reformulated pharmaceutical candidates using EVE's proprietary drug delivery and solubilisation technologies
- Candidates target established pharmaceutical markets including erectile dysfunction, premature ejaculation and anticoagulation therapies
- Combined addressable global markets estimated to exceed US\$30 billion¹
- Intellectual property filings in preparation to protect novel formulations and delivery methods
- Programs support EVE's strategy of reformulating established medicines approaching patent expiry for improved delivery and patient convenience
- These programs significantly expand EVE's reformulation pipeline and create multiple potential licensing opportunities across large established pharmaceutical markets.

EVE Health Group Limited (ASX: EVE, EVE or the Company) is pleased to announce the completion of research and development work on several reformulated drug candidates targeting sexual health and cardiovascular therapies across large global pharmaceutical markets.

The programs utilise the Company's proprietary drug delivery and solubilisation technologies to improve the delivery and usability of established medicines. EVE's approach focuses on reformulating well-known pharmaceutical compounds that have established safety profiles, while developing novel delivery methods and intellectual property protection.

Initial validation of EVE's delivery technologies has been demonstrated through the Company's lead product programs Dyspro®, a cannabinoid-based pastille targeting dysmenorrhoea, and Libbo™, an oral dissolving film formulation targeting erectile dysfunction. Building on this foundation, the Company has expanded its pipeline to include additional reformulated drug candidates addressing significant therapeutic markets.

These programs form part of the Company's broader strategy of reformulating approved pharmaceutical compounds with known safety profiles to deliver improved bioavailability, faster onset of action, and enhanced patient usability. The completion of these programs significantly expands EVE's commercial pipeline across multiple high-value therapeutic areas.

Strategic Rationale: Targeting the Pharmaceutical Patent Cliff

EVE's research and development strategy focuses on reformulating established pharmaceutical compounds that suffer from limitations such as poor solubility, slow onset of action, or suboptimal administration formats. By targeting drugs approaching or entering patent expiry, the Company

¹ Various publicly available pharmaceutical market analyses and company disclosures.



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aims to develop differentiated formulations that can be commercialised through licensing or supply partnerships with established pharmaceutical distribution networks.

This approach offers meaningful advantages over traditional drug discovery:

- Known safety profiles reduce clinical development risk
- Large, established markets with predictable demand
- Shorter development timelines compared to novel drug development
- Potential for improved delivery formats that address unmet patient needs

New Men's Sexual Health Spray Formulations

EVE has successfully completed research and development on three proprietary oral spray formulations targeting major conditions in the global men's sexual health market, which is estimated to exceed US\$7 billion annually and continues to grow due to increasing awareness, ageing populations, and expanding access to treatment.²

Vardenafil Erectile Dysfunction Spray

A rapid-delivery alcohol-free spray formulation of vardenafil designed to provide faster onset and improved patient convenience and efficacy, while avoiding alcohol-based delivery systems used in some spray formulations. Vardenafil, the active ingredient in Levitra®, is a well-established PDE5 inhibitor with a proven safety and efficacy record. A spray formulation has the potential to improve bioavailability, effectiveness and reduce time to onset, addressing a key limitation of tablet formulations.

The global erectile dysfunction treatment market is estimated at approximately US\$5 billion annually.²

Dapoxetine Premature Ejaculation Spray

A reformulated spray formulation of dapoxetine targeting premature ejaculation through improved delivery characteristics and ease of administration. Dapoxetine (sold under the name Priligy) is the only short-acting selective serotonin reuptake inhibitor specifically approved for premature ejaculation in multiple markets however requires administration three hours prior to sexual intercourse to be effective. A spray format may overcome the limitations of Priligy enabling faster absorption and more predictable dosing.

The global premature ejaculation treatment market is estimated at approximately US\$3 billion.³

Combination Vardenafil + Dapoxetine Dual-Molecule Spray

A novel dual-active spray formulation combining vardenafil and dapoxetine in a single delivery system, targeting patients experiencing both erectile dysfunction and premature ejaculation, conditions that frequently co-occur. This formulation represents a differentiated approach to combination therapy, offering potential for improved compliance and patient experience compared to administering two separate products.

² Coherent Market Insights, Erectile Dysfunction Market Analysis, available at: <https://www.coherentmarketinsights.com/market-insight/erectile-dysfunction-market-200>

³ IMARC Group, *Premature Ejaculation Market: Global Industry Trends and Forecast*, available at: <https://www.imarcgroup.com/premature-ejaculation-market>

All three formulations are now being prepared for patent lodgement ahead of progression through commercialisation pathways. The development of these spray-based delivery systems leverages EVE's proprietary solubilisation and reformulation technologies.

These conditions represent a combined global market opportunity estimated to exceed US\$8 billion.

Apixaban Solubilisation

The Company has also developed a reformulated version of apixaban, a widely prescribed anticoagulant used to reduce stroke risk in patients with atrial fibrillation and other blood clotting conditions. Apixaban, the active ingredient in Eliquis®, is one of the world's best-selling pharmaceutical products.

Apixaban is an oral anticoagulant that generated over US\$19 billion in global sales in 2022⁴, with primary patents expiring between 2026 and 2028. Improving its solubility and delivery characteristics may enable development of alternative dosage forms, such as liquid or orally dissolvable formats, that address limitations of conventional tablets, particularly for the estimated 590 million people globally affected by dysphagia (difficulty swallowing), a population that includes many patients requiring anticoagulation therapy.⁵

Intellectual Property

EVE intends to lodge patent applications covering the novel formulations and delivery methods associated with these programs. Patent applications for the spray-based formulations are currently being prepared, and a provisional patent application relating to the apixaban reformulation has already been lodged.

Commercialisation Pathway

EVE's strategy is to develop and protect novel reformulations of established pharmaceutical compounds, and to partner with pharmaceutical companies that have existing regulatory capabilities, manufacturing infrastructure and established distribution networks.

Rather than building its own commercial infrastructure, the Company intends to license each product to organisations that already possess the regulatory relationships, sales networks, and market access required to commercialise at scale. The Company is actively pursuing licensing deals with relevant target partners for each drug or molecule in its pipeline.

According to industry data, several major pharmaceuticals approaching patent expiry, including apixaban, rivaroxaban, and enzalutamide, represent a combined annual global market value exceeding US\$48 billion.⁶ EVE's reformulation platform is designed to identify and develop improved delivery formats for selected compounds within these large and established therapeutic markets.

Next Steps

Following completion of formulation development, EVE intends to advance these programs through further development activities including formulation optimisation, intellectual property protection and preparation for regulatory pathway assessment in relevant jurisdictions.

⁴ Bristol Myers Squibb Company (2023), 2022 Annual Report, Bristol Myers Squibb Company.

⁵ Cichero, J.A.Y. et al. (2017), The prevalence of dysphagia, *Dysphagia Journal*, Springer. Available at: <https://link.springer.com/article/10.1007/s00455-016-9758-y>

⁶ DrugPatentWatch, Predict the Patent Cliff, available at: <https://www.drugpatentwatch.com/blog/predict-the-patent-cliff>

The Company will continue to assess partnership opportunities with pharmaceutical companies interested in licensing reformulated products for specific territories or indications.

The Company intends to prioritise further development and commercialisation pathways based on technical feasibility, regulatory requirements, and potential licensing or distribution opportunities.

EVE Chief Operating Officer, Mr Ben Rohr, said: *"The completion of these research programs marks another significant step in expanding EVE's reformulation pipeline. Our strategy is focused on identifying high-value pharmaceutical compounds approaching patent expiry and developing improved delivery systems that enhance patient usability and clinical outcomes."*

"The addition of multiple men's sexual health formulations, alongside the successful apixaban program and patent lodgement, further validates the versatility and commercial applicability of our technology platform. These programs materially expand the Company's commercial opportunities as we progress toward licensing and partnership discussions."

"These programs strengthen our position as a reformulation and delivery innovation partner for the pharmaceutical industry, and we look forward to providing further updates as we advance through the commercialisation pathway."

Authorised for release by the Board of Directors.

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About EVE Health Group

EVE Health Group (ASX: EVE) is an Australian life sciences company focused on developing and commercialising innovative pharmaceutical solutions in high-growth therapeutic areas. The company's lead assets include Dyspro[®], a fast-acting cannabinoid-based pastille targeting dysmenorrhoea and endometriosis, and Libbo[™], an oral dissolving film for erectile dysfunction designed to deliver rapid onset and improved patient convenience. Both products leverage EVE's proprietary formulation and delivery technologies to enhance bioavailability and clinical outcomes, representing near-term commercial opportunities in large, underserved global markets.

EVE is building a vertically integrated health platform that combines proprietary pharmaceutical products with digital education, patient engagement and prescribing pathways. Through its dedicated information platforms, ReclaimMyCycle.com (women's health) and StiffIssue.com (men's health), the Company provides condition-focused education, reduces stigma and supports earlier engagement with appropriate care. These platforms integrate with telehealth and pharmacy fulfilment networks to enable responsible, scalable access to treatment within a regulated healthcare framework.

For further information, please visit www.evehealthgroup.com.au and follow us on LinkedIn.