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Ã¢â?¬Å?Despite advances, access to innovative treatments can be limited, particularly for rare cancersÃ¢â?¬Â•

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Specialised in the discovery and development of novel cell signalling small molecules to treat complex medical conditions, Australian life sciences company QBiotics is currently focusing on novel treatments for cancer and debilitating chronic wounds, along with an early-stage antibiotics programme. While the company is known for its lead product, tigilanol tiglate, which is undergoing clinical trials for various cancers, QBiotics is also actively preparing for a potential IPO on the Australian Securities Exchange (ASX) within this calendar year. To find out more about how QBiotics is tackling some of the most pressing and underserved challenges in global health, BioSpectrum Asia spoke to Stephen Doyle, Chief Executive Officer at QBiotics.



What are the major challenges that QBiotics is addressing through its research projects within Australia and globally?

Many solid tumours, especially rare cancers like soft tissue sarcomas (STS), lack effective, targeted therapies. Existing standards of care – surgery, radiation, and chemotherapy – are often associated with significant morbidity and limited efficacy. Through our tigilanol tiglate programme, we aim to provide a novel, minimally invasive treatment option with the potential to improve patient outcomes and quality of life.

Chronic wounds represent a silent epidemic, affecting millions worldwide, and placing immense strain on healthcare systems. Approximately 10 per cent of chronic wounds fail to heal, and with only one new wound healing drug approved in the US in more than two decades, innovation is urgently needed. EBC-1013, our first-in-class small molecule, is designed to activate multiple tissue repair pathways, offering hope for true healing rather than mere wound management.

Our early-stage antibiotics programme addresses the growing threat of drug-resistant infections, a looming crisis with profound public health implications. By focusing on these areas, QBiotics is positioned to deliver transformative therapies that address critical gaps in current medical practice, worldwide.

What are the major research projects taking place at QBiotics in 2025? Please share details.

In 2025, we are advancing several pivotal research programmes, each targeting areas of urgent unmet medical need, including:

Soft Tissue Sarcoma (STS) – Phase IIa Human Clinical Trial (QB46C-H07): Our lead oncology asset, tigilanol tiglate, is currently being evaluated in a Phase IIa trial for patients living with soft tissue sarcoma. Stage 1 of this trial, conducted at Memorial Sloan Kettering Cancer Center in New York, delivered encouraging results. 8 out of 10 evaluable patients experienced either complete ablation (100 per cent reduction in tumour volume) or partial ablation (?30 per cent reduction). In February 2024, tigilanol tiglate was granted Orphan Drug Designation by the US FDA for STS, underscoring its potential to address a critical unmet need.
Stage 2 of this trial is scheduled to commence in Q3 2025, further evaluating efficacy and safety in a broader cohort.

Head and Neck Cancer – Phase II Efficacy Trial (QB46C-H08): We are also conducting an open-label, single-arm Phase II study assessing tigilanol tiglate in up to 37 patients with various solid tumours in the head and neck region. Recruitment is ongoing at leading clinical sites across the UK and Australia, with the aim of expanding therapeutic options for these challenging cancers.

Wound Healing – Phase I Dose Escalation Trial (QB1013C-H201): Our wound healing candidate, EBC-1013, is currently being evaluated in a first-in-human, placebo-controlled, multi-centre Phase I clinical trial in Australia. This study is assessing the safety and tolerability of EBC-1013 in patients living with venous leg ulcers – a chronic, debilitating condition with limited, effective therapies.

Early-Stage Antibiotics Programme: Recognising the global threat of antimicrobial resistance, QBiotics is advancing an early-stage antibiotics programme, currently in lead optimisation. This initiative reflects our commitment to addressing emerging health challenges beyond oncology and wound care.

What are the company's future plans for the next 5 years?

Our core business strategy is to advance drug candidates through early human trials (up to proof-of-concept Phase IIb), thereby de-risking assets before seeking strategic partnerships for late-stage development and commercialisation.

We are actively preparing for a potential IPO on the Australian Securities Exchange (ASX) within this calendar year. Jefferies (Australia) Pty Ltd and Bell Potter Securities Limited have been appointed as Joint Lead Managers to guide this process.

We will continue to expand the clinical development of tigilanol tiglate across multiple tumour types, and progress EBC-1013 through clinical trials for chronic wounds and burns, targeting both regulatory approval and commercial readiness.

QBiotics aims to secure licensing or co-development agreements for our lead assets, facilitating global commercialisation. These partnerships are expected to generate upfront, milestone, and royalty payments, providing sustainable revenue streams for reinvestment in our R&D pipeline.

How much revenue was generated in 2024? How much growth are you expecting this year?

As a research-driven biotechnology company, QBiotics' primary focus is on advancing novel therapeutics through early-stage clinical development. While we are not yet reliant on human pharmaceutical sales, we have established a revenue stream through our approved veterinary product, STELFONTA, indicated for the treatment of canine mast cell tumours.

For the financial year ending June 30, 2024, QBiotics recorded revenue of A$ 1,284,777, attributed to sales of STELFONTA. We anticipate continued growth in STELFONTA sales as global veterinary adoption increases. However, our primary value inflection points in the coming years will be driven by clinical milestones, regulatory approvals, and strategic partnerships for our human health assets.

How many funds have you raised so far? Are you planning to raise more funds this year or beyond?

To date, QBiotics has raised a total of A$194 million. We are actively exploring additional capital raising opportunities, including a potential IPO on the ASX in the near term. This will provide the resources necessary to advance our clinical programmes, expand our pipeline, and accelerate global commercialisation efforts.

What is the current scenario of the oncology market in Australia, including the challenges and opportunities?

Australia's oncology sector is characterised by world-class research infrastructure, a skilled clinical workforce, and robust regulatory frameworks. However, significant challenges remain, particularly in the treatment of rare, aggressive, and refractory cancers.

There is a strong appetite for novel therapies, especially those that can address unmet needs in rare cancers and improve patient-centric outcomes. Australia's collaborative research environment fosters partnerships between academia, industry, and healthcare providers, accelerating clinical translation.

Despite advances, access to innovative treatments can be limited, particularly for rare cancers. Early-stage biotech companies face challenges in securing sustained funding for high-risk, high-reward research.

QBiotics is leveraging these opportunities by advancing tigilanol tiglate in clinical trials for soft tissue sarcoma and head and neck cancers, with the aim of delivering new treatment options and setting new standards of care.

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