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“The APAC market is expected to witness the fastest growth of any radiopharmaceutical market worldwide”

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Australian firm Telix Pharmaceuticals is pioneering advanced radiopharmaceuticals. Recently, the company achieved remarkable success with the global launch of Illuccix, their first commercial product for prostate cancer imaging in 2022. This milestone led to an impressive AUD$100 million in revenue for Q1 this year. Dr David N Cade, CEO of Asia Pacific of Telix Pharmaceuticals, shares insights into the company's vision, future plans, and the regulatory landscape of the radiopharmaceutical sector.

Can you introduce the field of radiopharmaceuticals and the activities of Telix Pharma?

Telix is an Australian-headquartered commercial-stage radiopharmaceutical company. Our targeted radiation imaging and therapy technologies have the potential to transform the way clinicians can find and manage cancer and a number of important rare diseases, inform treatment decisions and deliver personalised therapy in areas of major unmet medical need globally. We’re a therapy company that believes in the concept of precision medicine.

We launched our first commercial product for prostate cancer imaging, Illuccix, in Australia and the United States in 2022 and are helping thousands of patients around the world each week, with the ability to impact the lives of people with cancer increasing every day through commercial products, clinical trials and compassionate use programmes.

We are also building the foundations for long-term sustainable growth to unlock the value in our world-leading, late-stage ‘theranostic’ (therapeutic and diagnostic) pipeline. With more than 20 clinical studies underway worldwide (including partnered investigator-led studies), Telix’s core pipeline aims to address significant unmet medical needs in prostate, kidney,

brain, and blood cancers as well as a range of hard-to-treat immunologic and rare diseases.

We did our first AUD$100 million in Q1 of this year based on a highly successful commercial launch of Illuccix in the US and continue to see strong growth in the Illuccix business. We're well-funded and have recently become a cash-flow-positive company, which is not always the norm in the Australian biotechnology sector. Really, Telix is making a lot of progress across the board against the backdrop of a market that's growing extremely fast.

Can you discuss any ongoing research and development efforts related to Illuccix and other radiopharmaceuticals in Telix Pharma's pipeline? What future advancements or expansions can we expect in this area?

In line with our growth strategy, we've identified four key areas of focus in 2023 to advance Telix's therapeutic pipeline, grow revenue and help more patients in need:

Global Expansion and Illuccix revenue growth

- The commercial launch of Illuccix in 2022 was a major inflection point and clearly demonstrated Telix's ability to successfully commercialise a first-in-class product.
- In 2023 we're focused on continuing to grow revenue from sales of Illuccix in the US and other commercial markets, including Australia and Canada. In March the US FDA approved an expanded label for Illuccix to include patient selection for PSMA-directed radioligand therapy, and we are also now progressing marketing authorisation applications for Illuccix in the United Kingdom, the European Union and South Korea

Advance regulatory filings for two additional diagnostic imaging agents

- Telix's goal is to establish clear leadership in urologic oncology and bring its technology to other fields of medicine, with the ultimate goal of having a portfolio of multiple commercial-stage imaging agents to help support the development of our therapeutic assets.
- In November last year, we reported positive results from our first Phase III clinical trial for TLX250-CDx, our investigational kidney (renal) cancer imaging agent. We are now focused on preparing the Biologics License Application to the FDA, with the goal of gaining approval and being ready to launch commercially during 2024.
- We are also preparing to file a New Drug Application in the US for our investigational imaging agent for glioma (brain cancer), TLX101-CDx. Although used widely in Europe on a magisterial basis, there is currently no such pathway or commercial supply in the US. It's estimated that more than 13,000 Americans were diagnosed with glioblastoma – the most aggressive form of primary brain cancer – in 2022. We have an opportunity to help these patients and demonstrate commercial leadership in this market.

Deliver on clinical milestones in the core therapeutic pipeline

- Our antibody-based prostate cancer therapy programme is the key focus of reinvesting earnings just now. The ProstACT series of studies are evaluating the efficacy of TLX591 in all stages of prostate cancer, from first recurrence to advanced metastatic disease. This includes a global Phase III trial, which is initiating sites in Australia and New Zealand, and will launch in the United States and in Europe, hopefully, this side of Christmas for the US and early next year in Europe.
- This is a programme with a lot of momentum and a huge amount of key opinion leader interest.
- We are also progressing clinical trials this year across our other core indications (kidney and brain cancers) which will reinforce our positioning as a therapeutic company.

Pipeline expansion and advanced manufacturing

- Telix is focused on the identification of new assets with the potential to drive the next generation of personalised, targeted radiation and create future value.
- Our new manufacturing facility in Belgium opened this month and once fully operational will be used for R&D and production of clinical and commercial products for the Europe, Middle East and Africa region, and globally. We expect this to deliver significant flexibility and reliable supply for our growing commercial production requirements.

What are some of the challenges that Telix Pharma faced so far?

A reliable supply chain and manufacturing are particularly important in radiopharmaceuticals due to the nature of the product, which decays from the moment it is made.

With Illuccix we have successfully addressed this by producing our product under the practice of pharmacy, in a nuclear pharmacy very close to the customer – rather than manufacturing centrally like some of our competitors. We now have over 200 nuclear pharmacies dispensing in our US network, which means we don't have to travel very far with our product, the typical driving distance being 20-30 minutes or less to a customer. And so, we can offer a lot of scheduling flexibility around the availability of our product. Our supply chain model is unique and as a consequence, we have a very close relationship with our customers.

What are the most important markets for Telix Pharma and the next steps in the strategy?

After a strong start in the US for Illuccix, we are now looking forward to rolling the product out into new global markets - pending the required regulatory approvals.

We've recently submitted marketing authorisation applications for Illuccix in the EU and UK. In the Asia Pacific region, we are making steady commercial progress with Illuccix in Australia and New Zealand and progressing towards commercialisation in China, Japan and South Korea. So, there's a lot of momentum outside of the United States. Our mission is to make sure these products are available globally, and we think that's a really unique point of differentiation at Telix.

We also believe that TLX250-CDx is the perfect follow-on product to Illuccix and builds on the strong engagement we have established in the urology field. It allows us to utilise the commercial infrastructure Telix has built to service this market. There is a great deal of anticipation for this product given the high unmet need in the diagnosis of renal cell carcinoma where there currently is no reliable imaging method to characterise small renal masses, nor are there currently any – besides ours – in development.

What are your long-term visions for the company?

We have a best-in-class research and innovation programme that is pushing forward into new frontiers such as targeted alpha therapy and driving platform technologies that will enhance and extend the life-cycle of products, particularly Illuccix. We believe that this focus on research and innovation is vitally important to maintaining our competitive advantage in the longer term and future-proofing the company.

We recognised early on that building a depth of capability in urologic oncology was going to be important to the future of the business. With Illuccix successfully launched and the clinical development of our renal cancer product completed, this vision is coming to life. We also have studies exploring the utility of our technology in bladder cancer and the aim to become that 'one-stop shop' for diagnostic imaging in urologic oncology.

This forms the basis of our precision medicine strategy – patient selection for therapeutics and bringing molecular imaging into the operating theatre. Unconventionally, we take a fairly broad view of what a "theranostic" could be – so long as our nuclear medicines are driving successful interventions and patient outcomes, we fulfil our mission. In some cases, we will be informing the surgeon, and in some cases the medical oncologist. In all cases, we believe patients will benefit, including from our own therapeutics.

Cancer therapy has changed dramatically in the last decade, shifting to precision oncology. Can you comment on the emergence of radiopharmaceuticals in this paradigm shift?

Many existing cancer therapies are non-selective, impacting healthy tissue and vital organs at the same time as treating disease. Existing external beam radiation therapy (EBRT) approaches are effective but typically only deliver localised treatment and also cause damage to surrounding tissue. Localised therapeutic approaches rely on the treating physician making assumptions about the extent of disease but missing even small amounts of surviving cancer cells can lead to the cancer recurring over time.

Radiopharmaceuticals deliver targeted radiation to cancer cells with precision, regardless of where the cancer is lurking in the body. Telix intends that imaging and therapy are used together to ‘see and treat’. This theranostic approach is a powerful new way to tackle unmet needs in cancer and rare diseases.

Our goal is to integrate with traditional medical oncology and standard of care, to deliver potentially more targeted and personalised therapy, and patient-friendly dosing regimens. This reflects the multidisciplinary approach to managing cancer and rare diseases.

How competitive is the radiopharmaceutical market in APAC and how does the region compare when it comes to regulations?

The radiopharmaceutical market in the APAC Region is highly competitive, driven by the increasing demand for diagnostic and therapeutic applications in nuclear medicine. The region's growing population, rising incidences of cancer and cardiovascular diseases, and advancements in medical imaging technologies have contributed to the market's expansion.

In fact, the APAC market is expected to witness the fastest growth of any radiopharmaceutical market worldwide. To service this growing demand there are a number of global and local players in the region – including pharmaceutical companies, healthcare providers, local and international research institutions, government agencies and industry bodies.

The regulatory landscape for radiopharmaceuticals in APAC varies from country to country. Some countries have well-established regulatory frameworks governing the manufacturing, distribution, and use of radiopharmaceuticals, while others may have evolving regulations that aren’t designed to accommodate the novel aspects of radiopharmaceuticals or less stringent regulations. For example, Japan has a well-developed regulatory system overseen by the Pharmaceutical and Medical Devices Agency (PMDA). In China, the National Medical Products Administration (NMPA) regulates radiopharmaceuticals.

The Therapeutic Goods Administration of Australia is a sophisticated regulatory authority that is highly regarded in the Asia Pacific region and worldwide. Australia has tremendous nuclear technology and nuclear medicine expertise in both the private and public sectors, including the Australian Nuclear Science and Technology Organisation (ANSTO). ANSTO’s investment in medical isotope production is intended to meet 25 per cent of the global needs of key medical isotopes.

Here in Australia, we are fortunate that the government recognises nuclear medicine as ‘critical to Australia’s health system, touching the lives of thousands of Australians each year’ and provides support through funding and initiatives. The government has pledged to maintain a nuclear medicine sovereign capability that will reduce the risk of unplanned supply disruptions and promote positive health outcomes for Australians, especially in regional areas.

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