

## **NEWS RELEASE**

## iX Biopharma's Wafermine Commences Efficacy Study

- √ Solid balance sheet with S\$31.1 million in cash
- ✓ Robust product pipeline with a new range of nutraceutical products

**Singapore, 23 August 2017** – Specialty pharmaceutical company, **iX Biopharma Ltd** ("iX Biopharma" or "the Group"), has made significant strides in the development of its pipeline of pharmaceutical products and the introduction of its new range of next-generation nutraceutical products during its financial year ended 30 June 2017 ("FY17").

During the year, the Group conducted two pharmacokinetic studies. The first of these, in compliance with US FDA requirements, was a pharmacokinetic study of Wafermine versus intravenous Ketalar® (a reference drug imported from the USA). The second study was to determine the optimal administration when two wafers are required. This involved inserting two wafers under the tongue simultaneously on one occasion, and in sequential order on another. The results of the studies showed that the overall absorption of ketamine was similar, with participants preferring sequential administration.

iX Biopharma has commenced a multi-dose Phase 2 efficacy study with Wafermine (KET010) in the USA. The primary objective is to demonstrate Wafermine's efficacy in suppressing acute pain in patients following bunionectomy surgery. The study is a randomised, double-blind, placebo controlled trial with 135 patients receiving either one of two dose strengths of Wafermine or placebo multiple times over a 12-hour period. The outcome of this study will determine the dosing regimen for the pivotal Phase 3 registration studies.

Opioid addiction has recently been declared by the Trump Administration as a national emergency. Wafermine is a non-opioid drug and will be an effective alternative to opioids for pain management when approved.

The Group has also begun supplying its second pain management drug, BnoX, to hospitals and registered pharmacies in Australia under the Special Access Scheme exemption set out under Schedule 5A of Australia's Therapeutic Goods Regulations. Incorporating the active ingredient buprenorphine, BnoX has demonstrated faster absorption and greater absolute bioavailability than



the marketed sublingual buprenorphine tablet Temgesic, and proposes to be a superior alternative

for the management of moderate to severe pain.

A bioequivalence study for PheoniX, a drug for the treatment of erectile dysfunction, was successfully completed in the first quarter of FY17 and the Group filed for the drug's registration with the Therapeutic Goods Administration of Australia ("TGA") in April 2017. It is currently awaiting the TGA's approval for marketing and commercialisation of this novel product.

Following its expansion into the nutraceutical business, the Group has begun marketing its maiden product, WafeRest, under the "**Entity**" brand. WafeRest, a sublingual melatonin wafer supplement, is for the alleviation of jet lag and improvement of sleep quality. Having launched WafeRest in Singapore, the Group will roll out the product progressively on e-commerce platforms and other regional markets in the months ahead.

Financially, the Group recorded a narrowing of net loss to S\$7.4 million for FY17 on revenue of S\$6.4 million, compared to S\$7.7 million on revenue of S\$5.8 million for the previous financial year ("FY16"). In spite of the increased activities, expenses remained well-managed.

For its fourth financial quarter ended 30 June 2017 ("4Q17"), revenue for the Group amounted to S\$1.8 million, compared to S\$1.7 million for the previous corresponding quarter ("4Q16"). The Group recorded a net loss of S\$3.0 million in 4Q17, compared to a net profit of S\$0.4 million in 4Q16, mainly due to higher research and development ("R&D") tax incentive of S\$3.1 million recognised in 4Q16. The higher R&D tax incentive in 4Q16 took into account certain additional R&D expenditure incurred in both FY16 and the 2015 financial year, as approval for the Group's eligibility for additional incentive was granted only in June 2016. Excluding the R&D incentives, the group would have recorded a net loss of S\$3.2 million in 4Q17, compared to a net loss of S\$2.7 million in 4Q16.

As at 30 June 2017, the Group's cash position remained robust at approximately S\$31.1 million, compared to S\$31.3 million as at 30 June 2016.

Looking ahead, the ensuing months should see increased marketing and manufacturing activities for the Group as it prepares to roll out more Entity-branded nutraceutical products to markets locally and in the region. The Group has also commenced preparations for its marketing campaign for PheoniX.

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## About iX Biopharma Ltd

iX Biopharma Ltd is a Singapore public-listed specialty pharmaceutical company, operating a fully integrated business model from drug development to laboratory testing, manufacturing and supply, with facilities in Australia. The Group is focused on the development and commercialisation of innovative therapies for improving the quality of life of those suffering from pain and other health conditions. The Company leverages its patented sublingual drug delivery technology, **WaferiX**, to develop proprietary products that incorporate pharmacologically active compounds that have been approved by regulatory bodies. Its pipeline of products under development includes **Wafermine** and **BnoX** for pain management, **PheoniX** for erectile dysfunction, and **WafeRest** for improved sleep quality. The Group's nutraceuticals division, Entity Health Limited, is engaged in development and commercialisation of nutraceutical products that address specific conditions and improve quality of life.

## Contact for media:

Alvina Tan

DID: +65 6221 2123 H/P: +65 9787 7267

Email: alvina.tan@arkadvisors.com.sg

Karin Lai

DID: +65 6221 0081 H/P: +65 9837 8136

Email: karin.lai@arkadvisors.com.sg

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