



*Eradicating disease through capital investment*

13th December 2021

Announcements  
National Stock Exchange of Australia  
1 Bligh St  
Sydney NSW 2000

### **Market announcement – FDA Breakthrough Devices Designation Application to Fastrack Rapid Saliva Glucose Test**

iQX Limited (NSX: IQX), on behalf of Life Science Biosensor Diagnostics Pty Ltd (LSBD), a life sciences and medical technology company, and fully owned subsidiary of The iQ Group Global Ltd (NSX: IQG) and iQX Limited, in which IQX holds 19% equity position, today announced it has filed an application with the U.S Food and Drug Administration (FDA) for Breakthrough Device Designation.

The FDA Program will provide LSBD with an expedited path toward regulatory approval for its non-invasive, real-time Saliva Glucose test.

The iQ Group Global, through LSBD and its commercial subsidiaries and licensees, BioSensX Global Inc. and GBS Inc., are developing a suite of 150 different diagnostic point-of-care tests, including a salivary quantitative SARS-CoV-2 test, allergen panels, and saliva-based glucose; for patients living with diabetes; using the Biosensor Platform.

The Biosensor is a small organic thin-film transistor diagnostic test, developed at Newcastle University, that enables accurate salivary glucose measurement in real-time at point-of-care.

The FDA's Breakthrough Devices Program allows expedited approval for medical devices and products that provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions, like diabetes. The purpose of the Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review.

"We are looking forward to working with the FDA so we can commence clinical trials as soon as possible and make this innovative device accessible to the people who need it globally. The Biosensor Platform unlocks extraordinary opportunities not only for the patient, but also for the healthcare industry," CEO and Chairman of The iQ Group Global, Dr. George Syrmalis, said.

"There are more than 400 million people living with various stages of diabetes globally that have no alternative other than a painful and invasive blood glucose test, that often has to be administered multiple times per day. Our technology negates the need for this often-traumatic experience by using saliva instead of blood."

#### **About Life Science Biosensor Diagnostics Pty Ltd (LSBD)**

Life Sciences Biosensor Diagnostics Pty Ltd (LSBD) is the company that owns and manages the intellectual property of the diagnostic Biosensor Platform

#### **About iQX Limited (NSX:IQX)**

iQX Limited is an NSX listed investment funds management company specialising in the bioscience sector that is committed to eradicating disease through capital investment. IQX Limited is a core member of The iQ Group Global.

#### **About The iQ Group Global**

The iQ Group Global is a group of companies that find, fund and develop bioscience discoveries to create life-changing medical innovations. Recognised by The Australian Financial Review for the second consecutive year as one of the country's Most Innovative Companies in 2020, The iQ Group Global's flagship innovations include the Biosensor Platform and TEX Core, a first-in-class oncology drug platform with the ability to develop a pipeline of novel oncology compounds. Visit our website: [theiqgroupglobal.com](http://theiqgroupglobal.com)