

# INOVIQ TO DEVELOP A SUBB2M-BASED TEST ON NICOYA'S DIGITAL SPR PLATFORM

- Contract Research Agreement signed with Nicoya to transfer, develop and evaluate a SubB2M-based Surface Plasmon Resonance (SPR) test on the Alto™ Digital SPR instrument
- Nicoya has commercialised Alto, a next-generation benchtop SPR instrument for the highly sensitive detection of analytes such as proteins, antibodies, nucleic acids and sugars
- Nicoya's Alto has the potential to deliver in vitro diagnostic tests for use in pathology laboratories worldwide
- The SubB2M-based SPR test measures Neu5Gc levels and will initially be developed for use as a cancer risk assessment test

**Melbourne, Australia, 13 October 2022:** INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**) is pleased to announce that it has signed a contract research agreement with Nicoya Lifesciences Inc (Nicoya) to transfer, develop and evaluate a prototype SubB2M-based test on the next generation Alto digital SPR instrument.

## SubB2M technology and pipeline

INOVIQ's SubB2M technology is based on an engineered protein that binds to the pan-cancer biomarker Neu5Gc that is elevated in multiple human cancers including breast, ovarian, prostate and others. INOVIQ is developing SubB2M-based diagnostics for multi-cancer detection and monitoring.

The SubB2M-based SPR test measures Neu5Gc and will initially be developed as a cancer risk assessment test for potential inclusion in a general health panel. Increased Neu5Gc levels in the blood may provide an early warning that an individual requires follow-up investigation for the presence of cancer such as breast, ovarian, prostate, melanoma and others.<sup>1</sup>

The SubB2M-based SPR test has the potential to be developed as a multi-cancer detection test that first detects the Neu5Gc cancer signal and then applies a biomarker panel to determine its origin.

## Contract research agreement with Nicoya

Under the contract research agreement, Canadian-based [Nicoya Lifesciences Inc](#) will provide services to transfer, develop and evaluate a SubB2M-based SPR test on its Alto instrument.

[Alto](#) is the world's first high-throughput, benchtop surface plasmon resonance (SPR) system to be powered by digital microfluidics (DMF) technology. With its ability to provide industry-leading data quality while using up to 200 times less sample and minimal hands-on time, Alto revolutionizes real-time interaction analysis. Alto is currently being sold to researchers and pharmaceutical companies worldwide for the identification of biomarkers and to accelerate drug discovery.



Nicoya Alto

Nicoya CEO and Founder Ryan Denomme said: "While Alto is a critical tool in drug development with its unprecedented sample throughput and automation capabilities, it's also broadly applicable in

<sup>1</sup> Griffith University SPR and INOVIQ IHC initial data

*many other impactful areas of disease research that align with our mission to improve human life. There is significant potential to leverage the Alto platform as a clinical diagnostic tool for many diseases, including cancer detection. We are excited to partner with INOVIQ in the development of this novel in-vitro diagnostic test and bring together our unique technologies to commercialize this life-changing innovation.”*

The statement of work includes technology transfer, assay development and initial evaluation of assay throughput, analytical and clinical performance of a SubB2M-based test for detection of Neu5Gc on the Alto SPR instrument. The project aims to demonstrate effective discrimination between cancer and cancer-free blood samples on the Alto instrument. INOVIQ will pay (non-material) agreed costs for the work undertaken and the project is expected to complete within six months from commencement date.

On successful completion, INOVIQ will need to conduct additional studies to further develop and validate the SubB2M-based SPR test for risk assessment of multiple cancers. Additionally, INOVIQ and Nicoya intend to enter a commercial arrangement enabling INOVIQ to commercialise the SubB2M-based SPR test on the Alto instrument for detection and monitoring of multiple cancers.

### Previous SubB2M SPR test results

Previous proof-of-concept studies conducted at Griffith University demonstrated a SubB2M-based SPR test (performed on the Biacore SPR instrument<sup>2</sup>) detected breast and ovarian cancers across all stages with over 95% sensitivity and 100% specificity compared to healthy controls.

Recently, INOVIQ advised (ASX: 29 July 2022) that it had expanded its feasibility program for a highly sensitive SubB2M-based SPR test with a Canadian-based life sciences company on its next-generation high-throughput benchtop SPR instrument. An initial feasibility study was conducted with Nicoya to determine if INOVIQ’s SubB2M-based SPR test was compatible with the Alto instrument. Initial data from this feasibility program were positive concluding the SubB2M-based SPR test previously performed on the Biacore SPR instrument could be transferred to the Alto SPR instrument.

CEO Dr Learne Hinch said: *“Based upon the compelling SubB2M-based SPR results, INOVIQ is excited by the potential to develop SubB2M-based SPR tests for multi-cancer detection and monitoring. When introducing a new clinical diagnostic, the test must be accurate and reliable, high throughput and compatible with routine pathology workflows. Nicoya’s Alto SPR instrument has the potential to be approved as an IVD device for the delivery of such clinical diagnostics in pathology laboratories worldwide.”*

CSO Dr Greg Rice affirmed: *“The Nicoya Alto is the world’s first digital, high-throughput, benchtop SPR system that has the potential to provide INOVIQ with a competitive advantage in cancer diagnostics. The Alto instrument has revolutionized SPR sample analysis using digital microfluidics and nanotechnology biosensors that are integrated into a disposable microwell plate, making it compatible for high throughput diagnostics. We look forward to advancing our partnership with Nicoya to develop a highly sensitive Neu5Gc test for multi-cancer detection on the Alto instrument.”*

### Global Cancer Diagnostics Market

The global cancer burden is significant with an estimated 50.6 million people living with cancer, 19.3 million new cases and 10.0 million deaths in 2020.<sup>3</sup> The incidence of cancer is expected to rise to 28.4 million new cases by 2040 due to population aging and growth. The most commonly diagnosed cancers worldwide were breast (11.7% of all new cases), lung (11.4%), colorectal (10.0%), prostate

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<sup>2</sup> The Biacore SPR instrument is not routinely used in pathology laboratories.

<sup>3</sup> Sung H et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021. <https://doi.org/10.3322/caac.21660>

(7.3%) and stomach (5.6%) cancers. There remains a clear unmet need for more accurate and reliable tests for earlier detection of cancer.

Diagnostics for earlier detection and monitoring could improve treatment options, patient outcomes and survival. Multi-cancer detection tests are now being developed using various approaches in the fight against cancer.

Authorised by the Company Secretary, Tony Di Pietro.

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## ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) (**INOVIQ**) is developing and commercialising next-generation exosome capture tools and precision diagnostics to improve the diagnosis and treatment of cancer and other diseases. The Company has commercialised the EXO-NET pan-exosome capture tool for research purposes and the hTERT test as an adjunct to urine cytology testing for bladder cancer. Our cancer diagnostic pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast and other cancers. For more information on INOVIQ, see [www.inoviq.com](http://www.inoviq.com).

## ABOUT NICOYA LIFESCIENCES INC AND ALTO

Nicoya is a Canadian biotechnology company specializing in innovative biosensor technology for the academic, biotechnology and pharmaceutical sectors. In their mission to improve human life, Nicoya provides scientists with user-friendly and integrated solutions that accelerate label-free biomolecular analysis, and is now helping hundreds of scientists succeed in over 50 countries.

As the world's only surface plasmon resonance (SPR) system powered by digital microfluidics, Alto<sup>4</sup> revolutionizes real-time interaction analysis by eliminating the need to compromise on data quality and throughput. Alto's 16-channel design and automated ecosystem allows users to go from sample to answer within hours, while providing full kinetics analysis from just 2µL of sample. Designed to take the complexity out of SPR, Alto streamlines the toughest biological applications and empowers teams with high quality data to take their discoveries to the next level. Learn more at [www.nicoyalife.com/products/alto](http://www.nicoyalife.com/products/alto).

## ABOUT SUBB2M TECHNOLOGY AND TESTS

The SubB2M technology is based on an engineered protein that specifically binds the pan-cancer biomarker Neu5Gc that is found at elevated levels in multiple human cancers including breast, ovarian, prostate and others. Previous proof-of-concept studies at Griffith University demonstrated a SubB2M-based SPR test detected breast and ovarian cancers across all stages with over 95% sensitivity and 100% specificity compared to healthy controls.

INOVIQ's SubB2M technology is based on an engineered protein that specifically binds to the pan-cancer biomarker Neu5Gc that is found at elevated levels in multiple human cancers including breast,

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<sup>4</sup> Alto is for research use only

ovarian, prostate and others. INOVIQ is developing SubB2M-based diagnostics for multi-cancer detection and monitoring.

The SubB2M-CA15.3 and SubB2M-CA125 immunoassays detect the Neu5Gc-decorated biomarkers CA15.3<sup>5</sup> and CA125<sup>6</sup>, and have the potential to deliver improved specificity (reduced false positives) over existing cancer monitoring tests for breast and ovarian cancer.

The SubB2M-based SPR test measures Neu5Gc and will initially be developed as a cancer risk assessment test for potential inclusion in a general health panel. Increased Neu5Gc levels in the blood may provide an early warning that an individual requires follow-up investigation for the presence of cancer such as breast, ovarian, prostate, melanoma and others.

The SubB2M-based SPR test has the potential to be developed as a multi-cancer detection test that first detects the Neu5Gc cancer signal and then applies a biomarker panel to determine its origin.

### **FORWARD-LOOKING STATEMENTS**

This announcement contains certain 'forward-looking statements' within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as 'may', 'should', 'expect', 'anticipate', 'estimate', 'scheduled' or 'continue' or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.

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<sup>5</sup> CA15.3 = Cancer Antigen 15.3 biomarker used for the monitoring of breast cancer

<sup>6</sup> CA125 = Cancer Antigen 125 biomarker used for the monitoring of ovarian cancer