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Press Release

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Strategy update: Leapfrogging to the decentralization of IndiTreat® testing through full focus on automation

2cureX, a company pioneering the use of 3D tumoroids for drug sensitivity prediction in patients with cancer, announces that it will focus all resources on making IndiTreat® testing available at hospitals worldwide by accelerating the development of an automated IVD system. To support the implementation of this strategy, the company has proposed Tonni Bülow-Nielsen as new Chairman of the Board, to be confirmed by the Extraordinary General Meeting on November 14th. Expectations for 2023 have been revised, to adapt to the new strategic focus on automation.

Leapfrogging to a new business model

2cureX Board of Directors and Management Team have decided to focus its efforts in accelerating the development of an automated system – a combination of instrument, reagents, consumables, and software – that can be placed in a standard customer lab anywhere in the world and operated by their own staff to run the IndiTreat® test.

By enabling in-house testing at customer's labs, 2cureX aims at leveraging its first mover advantage and building a global leader position in an emerging segment that is expected to become a multi-billion USD per year market.

This decision is a consequence of the insight the company has gained through the interaction with hundreds of hospitals across Europe, in conferences, face-to-face discussions and market surveys, indicating that the business model of being a service provider out of a centralized lab location – is not suitable for mainstream use as it disrupts the hospital workflows and requires too complex logistics.

Full focus of the company's resources

The development of an automated system will require the company to fully focus on the activities that support this project. Specifically, this will mean:

- Concentrating all internal resources in the activities that support the development of an automated IndiTreat® system for multiple tumor entities – leveraging our ongoing efforts in ovarian and pancreatic cancer – and preparing the launch of the system.
- Reducing by 30% all operating expenses not related to this project.
- Continue to run clinical studies to generate additional evidence and build trust in the IndiTreat® technology among healthcare professionals.
- Leveraging our unique customer reach to keep learning about the market, creating awareness, establishing relationships with oncologists, and identifying customers to become evaluators and early users of the automated system.
- Engaging hospitals in our network to be first movers conducting IndiTreat® testing on-site.

- Seeking additional funding both from investors and grants, to support the activities throughout the automated system development project.

Revised goals for 2023 and new set of goals for 2024

The company had previously announced 2023 goals in revenue (6M SEK), commercial rollout (25 countries) and number of samples tested (500). Due to the issues in scaling up with the current business model, and the re-prioritization that comes with the new strategy, the revised estimate is that at the end of the year revenues will be at 3M SEK, number of samples tested will be 125 and the commercial rollout will stay at the current 20 countries.

For 2024, a new set of goals will be defined, focusing on the milestones associated with the new focus of the company.

Building on strong knowledge and experience

In 2020 the company partnered with Hahn-Schickard Institute in Freiburg to develop an instrument prototype that has seen several versions. Before that, the company had developed internally a proprietary consumable concept ("drug cartridge") that will be key to the recurrent revenue model.

"It has been fantastic to see the automation project developing over the last years. All this work will now be the basis for developing the new IVD system that we will also make suitable for other tumor entities like pancreatic and ovarian cancer", said **Ole Thastrup, CSO and Founder**.

The next step is to "industrialize" the system, meaning it needs to be re-designed and developed for useability, serviceability, reliability, and manufacturing scalability, and doing it in compliance with IVD-R so it can be CE-marked at the end. For this, the company is planning to engage a Contract Development and Manufacturing Organization (CDMO), an organization providing end-to-end development and manufacturing services for medtech companies. The use of CDMOs is a common industry practice, even for the largest players.

Uniquely positioned to seize the opportunity

The emerging field of Functional Drug Sensitivity Testing represents a market opportunity that exceeds 1Bn EUR per year but is impaired by the logistic and organizational complexity of the current business model, that requires samples with living cells to travel to a central testing location.

2cureX is uniquely positioned to be the first mover with an automated system and leverage that advantage. Over the years the company has developed and matured the base technology and created IP protection for key elements. It has clinically validated the concept through a prospective interventional trial with results that are unmatched. It has established a "pre-commercial" network, to build strong relationships with Key Opinion Leaders and understand the real-life conditions of the IndiTreat® use. And finally, has attracted a strong, experienced, and highly motivated team to realize the vision.

"We are convinced that focusing the company on the development of the automated system is the right move to unlock the full potential of the emerging Functional Drug Sensitivity Testing segment and make 2cureX its global leader", says **Fernando Andreu, CEO**. "Our efforts of the last years are converging in this important project, and such a system will create multiple opportunities for partnering with the big players in the industry and provide the type of value creation pathway that current and future shareholders are expecting. We are grateful to them for their continued support, which we expect to keep in this new phase".

Strengthening the Board of Directors

The Board of Directors has called an **Extraordinary General Meeting** on November 14th seeking authorization to resolve to issue of new shares, convertible loan notes and / or warrants and also proposing the election of Tonni Bülow-Nielsen as new member of the Board of Directors.

Tonni Bülow-Nielsen has extensive Medical Device and Life Science experience, both as an executive – having worked for ELA Medical, a part of the Sanofi Group, St. Jude Medical, Guidant and others – and as an investor through more than 16 years in top management positions at Vækstfonden – currently EIFO (Export and Investment Fund of Denmark). Tonni is a Partner in the Medtech and Life Science team in EIFO, managing a significant portfolio of investments through Board positions, value creation and transactions.

"In the last months I have assisted 2cureX in evaluating the company's assets and designing the next step for its development. Decentralizing the testing is the logical next step to realize the potential of this new technology and I am truly impressed with the achievements of the company so far, and the network they have built with Key Opinion Leaders", said **Tonni Bülow-Nielsen**. "I see great potential for the company and for cancer patients and I am excited having been proposed as Chairman of the Board of Directors at the upcoming Extraordinary General Metting".

This important addition to the Board will provide the company with competences in funding, company scaling and M&A that will be critical in this new phase of the company.

Investor event: October 26, 20:00 CET

2cureX will hold a **webinar** on October 26th, 20:00 CET hosted by **Stokk.io** to discuss the results of Q3 2023 and to present the newly focused strategy on upscaling and decentralization of IndiTreat. Questions can be placed in advance through the link: **Q3 Investor Update**.

For more information about 2cureX:

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About 2cureX

2cureX is a leader in cancer drug sensitivity testing and has developed the IndiTreat® (Individual Treatment) family of tests. Starting from a sample of the patient's tumor, IndiTreat® creates thousands of 3D replicas (tumoroids) and predicts the tumor response to the different available drugs, providing the physician with valuable information to make the treatment decisions.

The first three IndiTreat® tests are aimed at optimizing treatment decisions in patients with metastatic colorectal cancer (IndiTreat® Start for first line of therapy, IndiTreat® Extend and Explore for third line). Additional tests are under development to cover other stages of colorectal cancer as well as other gastrointestinal cancers.

According to several reports, the total yearly expenditure in cancer-related In Vitro Diagnostic (IVD) tests exceeds 17.5Bn USD worldwide, from which 2.5 Bn USD are tests directly related to therapy decision making, with a CAGR of 12.7%. Despite this, only one third of all cancer treatments are supported by one of these tests. IndiTreat® aims at filling this gap and making Precision Oncology available to all cancer patients.

The company is listed on Nasdaq First North Growth Market in Stockholm (symbol: "2CUREX"). For more information about 2cureX visit www.2cureX.com

Certified Adviser: Redeye AB

This information is information that 2cureX is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-10-26 18:30 CEST.

Image Attachments

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Attachments

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