



## Oncocyte Enters the Rapidly Growing Immune Therapy Monitoring Market with the Closing of the Acquisition of Chronix Biomedical, Inc.

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*Oncocyte gains proprietary capabilities for immune therapy monitoring and transplant rejection testing, both from a standard blood sample*

*Oncocyte's technologies may provide more precision to the selection of appropriate immune therapies and monitoring for treatment response in real time allowing physicians to personalize treatment more effectively*

*Establishes a European beachhead to launch Oncocyte's full suite of tests*

IRVINE, Calif., April 19, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NASDAQ: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, has completed its acquisition of Chronix Biomedical, a privately held molecular diagnostics company developing blood tests for use in cancer treatment and organ transplants. The acquisition includes the intellectual property and technology for Chronix's TheraSure™-Copy Number Instability (CNI) Monitor test for immune therapy monitoring. The Chronix CNI test is a patented, novel blood-based test that is differentiated from current methods because it requires no upfront tumor tissue sample. With the acquisition, Oncocyte also gains the organ transplant technology and the associated patent portfolio developed by Chronix.

"We believe the acquisition of Chronix will provide Oncocyte a distinct competitive advantage as the first and only company to potentially offer a continuum of tests, from selecting patients for immune therapy treatment, to monitoring the effectiveness of the treatment," said Ron Andrews, President and Chief Executive Officer of Oncocyte. "Once available, we believe the CNI test will allow physicians to begin monitoring patients for treatment efficacy more quickly given the CNI test requires only a blood sample. In contrast, getting a result from the emerging tests for monitoring can take significantly longer as these tests start with the time consuming and costly genetic sequencing of a patient's tissue sample. According to our voice of customer work, many later stage cancer biopsies do not provide enough tissue available to complete the analysis. These challenges are particularly amplified in lung cancer, where most later stage patients have very limited tissue from a fine needle biopsy sample and thus, quite often, have too little sample to perform tissue-based testing, including personalized MRD testing. Even in cases where sufficient tissue is available, preserving precious sample to enable other tests will be an added benefit of Oncocyte's fully blood-based approach. Assuming the data published to date continues to be validated in future studies, the CNI test will be able to deliver timely results on progression using blood only, with no need for tissue biopsies, at the second treatment cycle. This time frame will deliver valuable information to physicians much faster than currently seen with imaging or tissue-informed technologies."

The addition of the CNI test to Oncocyte's portfolio of diagnostic products marks the Company's entry into blood-based immune-therapy monitoring, a market that is estimated at \$3 billion in the United States alone. Ownership of Chronix's intellectual property portfolio helps establish the foundation for Oncocyte to potentially build additional applications to address an estimated \$6 billion U.S. recurrence monitoring market. Further, as approximately 40%-60% of patients fail to see a sustained response to immune checkpoint inhibitors, it is estimated that by 2025, more than \$60 billion a year could be misspent on treatments that may never benefit patients.

The acquisition, which includes Chronix's lab in Germany and its EU-based development and business team, establishes a footprint for the continued development and potential commercial launch of Oncocyte's proprietary tests in the European market. The Company expects to launch the CNI test as a pharma service in Europe from Germany by the end of the current quarter. After the tech transfer to its U.S. facilities, Oncocyte plans to launch the test for research use only in domestic immune therapy clinical trials during the fourth quarter of this year. The anticipated first indication for use will be in lung cancer, followed by expansion to other cancer types. Further, as the path to reimbursement is already established, Oncocyte plans to demonstrate the comparability of the CNI test to existing reimbursed tests.

Also included in the acquisition are tests and a patent estate for the use of digital PCR to detect transplant rejection in recipients as well as enabling the absolute amount of tumor or donor cell-free DNA, which eliminates the influence of changes in cell-free DNA caused by unrelated reasons making the technique more specific for monitoring. The Company plans to explore the use of the patented methodologies and combine with digital PCR for development of super-sensitive detection of tumor-derived DNA in blood to monitor for long-term recurrence as well as explore licensing this technology and patent estate for transplant to potential partners.

Dr. Ekkehard Schuetz, former CEO and Chief Medical Officer of Chronix and now General Manager and CMO of Oncocyte Europe said, "By becoming part of Oncocyte, we believe our CNI monitoring test, together with DetermalO, has the potential to become a much more powerful tool for oncologists as they will have a comprehensive solution for two of the biggest challenges in immune therapy: better identifying patients who are most likely to respond to treatment, and then monitoring for treatment efficacy and the development of resistance. The combination of Oncocyte's proprietary immune therapy selection test and their commercial experience with Chronix's rich portfolio of tests and IP make the deal clearly a case of the sum of the parts being greater than the whole."

### **More about CNI and the CNI Monitor Test**

- Cancer modifies the normal genome of cells by accumulating mutations and variation in the number of copies of genes in the genome.
- Chronix's CNI test measures the collective burden of tumor derived copy number variation (CNV) across the genome in blood as a sensitive, specific and quantifiable measure of tumor burden, i.e., response to therapy or prognosis of cancer.
- CNI is a novel approach to measuring cell-free tumor DNA in blood that does not rely upon sequencing the tumor biopsy specimen (tumor naive vs. tumor informed).
- The proprietary CNI test quantitatively measures the amount of CNV present in blood that has been shed by dying tumor cells.
- The CNI Monitor test monitors the change in CNI over time and is suitable for monitoring patients being treated with chemotherapy, targeted therapy or immunotherapy.
- Multiple publications have demonstrated the accuracy of CNI in identifying response or resistance to therapy prior to the second or third cycle of treatment, including a [study](#) in

## **About the Merger and Principal Transaction Terms**

Under the amended merger agreement, Oncocyte delivered closing consideration and paid off assumed liabilities approximating \$4.25 million in cash and \$3 million of Oncocyte common stock (or approximately 591,000 shares) and agreed to pay an additional \$2.5 million of liabilities by July 2022. The agreement also provides for Oncocyte to pay a revenue share on the net collected revenues for certain tests and services for specific periods, and to pay a combination of cash or Oncocyte common stock of up to \$14 million if certain milestones are achieved over a ten-year timeframe, subject to offset by Oncocyte for liabilities paid in excess of \$8.25 million. Oncocyte issued the shares in a private transaction and intends to register the resale of the shares. Additional information regarding the terms of the transaction will be provided in Oncocyte's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on or about April 19, 2021.

## **About Oncocyte Corporation**

Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the cancer care continuum. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives and improve outcomes by accelerating and optimizing the diagnosis and treatment of cancer. The Company's tests and services present multiple opportunities to advance cancer care while also driving revenue growth for the Company. Oncocyte launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection and predicts benefit from adjuvant chemotherapy. Oncocyte has also launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the Company anticipates launching DetermaTx™, a test to assess mutational status of a tumor to help identify the appropriate targeted therapy, in the second half of 2021. The Company recently completed the acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor test, and also plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide pharmaceutical companies who are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation.

## **About Chronix Biomedical**

Chronix Biomedical, Inc., now part of Oncocyte, was a privately held, U.S.-based molecular diagnostics company developing blood tests for use in cancer treatment and organ transplantation. Chronix's TheraSure™ CNI Monitor for cancer uses proprietary algorithms to derive a copy number instability (CNI) score from the sequencing of circulating cell-free tumor DNA (cfDNA), which can be used in the prognosis, diagnosis and monitoring of therapeutic response to cancer. Chronix TheraSure™ Transplant Monitor quantifies the amount of graft derived cell-free DNA in organ recipients to detect early rejection of organ transplants and better assess the transplant health. TheraSure is a trademark of Chronix Biomedical Inc.

## **Oncocyte Forward Looking Statements**

Oncocyte cautions you that this press release contains forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to the acquisition of Chronix Biomedical,

and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Factors that could cause or contribute to changes in the forward-looking statements include, but are not limited to (i) failure to realize the anticipated benefits of the acquisition, (ii) unexpected expenditures incurred or liabilities assumed as a result of the acquisition, (iii) unanticipated difficulties in conforming business practices, including accounting policies, procedures, internal controls, and financial records of Chronix with Oncocyte, (iv) inability to accurately forecast the performance of Chronix resulting in unforeseen adverse effects on Oncocyte's operating results, (v) synergies between Chronix and OncoCyte being estimates which may be materially different from actual results, (vi) failure to retain or integrate Chronix personnel, (vii) greater than estimated allocations of company resources to develop and commercialize Chronix technologies, or (viii) failure to maintain any laboratory accreditation or certification. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our or any distributor's financial and operational results, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to our or any distributor's supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, greater than estimated allocations of resources to develop and commercialize technologies, or failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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