December 19, 2022

ProPhase Labs Acquires Rights to Novel Esophageal Cancer Test

GARDEN CITY, NY, Dec. 19, 2022 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. "ProPhase" (NASDAQ: PRPH), a growth oriented and diversified diagnostics, genomics and biotech company, today announced that it has entered into an asset purchase agreement to acquire from Stella Diagnostics, Inc. ("Stella") world-wide exclusive rights to Stella's BE-Smart Esophageal Pre-Cancer diagnostic screening test and related intellectual property assets for approximately $4.5 million dollars, comprised of approximately $3.5 million in cash and $1 million in ProPhase common stock. Under the terms of the agreement, an additional $2 million of Company common stock may be issued to Stella in the future upon the achievement of a revenue-based commercial milestone within the five-year period following the closing. Stella will also receive a 5% royalty based on adjusted gross margin generated from the commercialization of the intellectual property acquired from Stella. The transaction is subject to approval by Stella shareholders and is expected to close in early January 2023. ThinkEquity acted as advisor to ProPhase Labs in the transaction.

The BE-Smart test is aimed at early detection of esophageal cancer. It has already been tested by an independent test lab, mProbe, Inc. on over 200 human samples and has shown greater than 99% sensitivity and specificity to detect protein expressions in cells that are at high risk of becoming cancerous [1]. mProbe, Inc., a precision health and medicine company utilizing clinical proteomics in the oncology space in conjunction with Dr. Christopher Hartley of the prestigious Mayo Clinic, has been utilizing a small sample of tissue collected during endoscopies to confirm and optimize the BE-Smart Test. The initial data appears to demonstrate accuracy and reproducibility as well as identification of potential biomarkers for therapeutic drug discovery to treat esophageal cancer.

According to the National Institute of Health, over 20 million endoscopies are performed every year in the United States [2]; approximately 2 million of these procedures are done on patients with Barret's Esophagus, which is a condition in which the flat pink lining of the swallowing tube that connects the mouth to the stomach (esophagus) becomes damaged by acid reflux, which causes the lining to thicken and become red. In patients with Barrett's Esophagus, one in two hundred will develop esophageal adenocarcinoma. Esophageal cancer is highly lethal and deemed as the sixth cause of cancer death worldwide. The overall five-year survival rate is less than 20% [3].

The BE-Smart test is intended to provide health care providers and patients with data to help determine treatment options, including whether patients not believed to be at risk for esophageal cancer should continue to be monitored or, alternatively, to provide patients who might otherwise have been undiagnosed early treatment before esophageal cells become cancerous. The goal of widespread adoption of the BE-Smart diagnostic test would allow health care providers to initiate potentially lifesaving early treatment processes such as an ablation procedure to remove the precancerous cells. This diagnostic test could also

significantly reduce unnecessary endoscopies as well as offer peace of mind to patients who are suffering with Barret's syndrome who are at greater risk of esophageal cancer.

"We are excited to continue the study and relationship with ProPhase Labs," said Sheeno Thyparambil, Senior Director of Research and Development at mProbe, Inc. "The initial testing of the BE-Smart system shows significant early detection and is extremely promising. ProPhase's commitment to continuing the study allows us to complete the testing that we started more than a year ago and help get this important product to market."

"We have built a great platform at ProPhase with valuable assets that we believe have significant current and future potential, infrastructure, experience, expertise, and unlike most other development stage life sciences companies, revenues with positive earnings and cash flow," stated Ted Karkus, CEO of ProPhase Labs. "The two-year bear market for biotech and life sciences companies has created some tremendous opportunities to leverage the ProPhase platform. We believe that the IP that we have either licensed or acquired to date, including the Stella Diagnostics Esophageal Cancer Test that we are acquiring, can be efficiently developed and that we can easily fund the near-term development of such IP out of a small portion of our current working capital. After exploring more than 50 potential opportunities this past year, the Stella Diagnostics Esophageal Cancer Test is exactly the kind of asset that we have been looking for to continue to build our portfolio of IP that has the potential to generate significant returns."

Mr. Karkus continued, "We believe, but cannot assure, that the BE-Smart diagnostic tool has the potential to be commercialized within approximately 18 months based on the completion of testing of a total of 1,000 specimens with mProbe Inc. in coordination with specimens provided by the Mayo Clinic."

"ProPhase will be working on clinical validation as a laboratory developed test (LDT) in parallel with this ongoing study. The prevalence of Barrett's Esophagus in the general population could be as high as 3.0 - 6.0 million people in the United States. [4] And some sources suggest that this prevalence is even higher. Our goal is to pursue reimbursement rates in a range of $1,000 - $3,000 per test, based on CPT codes of similarly complex tests [5], which equates to a multi-billion dollar target market for those with Barret's esophagus in the United States alone. An estimated 20 million endoscopies are carried out each year in the United States. [2] Once we complete our testing cycle, we will pursue the adoption of the BE-Smart diagnostic test as a standard health care test that could be utilized in conjunction with every endoscopy to accurately predict the risk of esophageal cancer. We will, of course, pursue global distribution of this important and potentially lifesaving test, concluded Mr. Karkus."

About ProPhase Labs

ProPhase Labs, Inc. (Nasdaq: PRPH) ("ProPhase") is a growth oriented and diversified diagnostics, genomics and biotech company that seeks to leverage its CLIA lab services to provide whole genome sequencing and research direct to consumers and build a genomics database to be used for further research. The Company provides traditional CLIA molecular laboratory services, including COVID-19 testing. The Company also operates a contract manufacturing subsidiary and offers the TK Supplements line of dietary supplements, which are distributed in food, drug and mass stores throughout the country.

ProPhase Diagnostics, Inc., a wholly owned subsidiary of ProPhase, offers a broad array of clinical diagnostic and testing services at its CLIA certified laboratories including polymerase chain reaction (PCR) testing for SARS-CoV-2 (COVID-19) and Influenza A and Influenza B. Critical to COVID-19 testing, ProPhase Diagnostics provides fast turnaround times for results. ProPhase Diagnostics also offers best-in-class rapid antigen and antibody/immunity tests to broaden its COVID-19 testing beyond RT-PCR testing. The Company has announced plans for the expansion of the lab to include traditional clinical testing and genomics sequencing.

Nebula Genomics, a wholly owned subsidiary of ProPhase, focuses on genomics sequencing and testing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic sequencing may help to identify inherited disorders and tendencies, help predict disease risk, help identify expected drug response, and characterize genetic mutations, including those that drive cancer progression. The Company currently offers Nebula Genomics whole genome sequencing products direct-to-consumer online, with plans to sell in food, drug and mass (FDM) stores and to provide testing for universities conducting genomic research.

ProPhase BioPharma, Inc. (PBIO), a wholly owned subsidiary of ProPhase, was formed for the licensing, development and commercialization of novel drugs and compounds. Licensed compounds currently include Equivir (OTC/dietary supplement) and Equivir G (Rx), two broad based anti-virals, and Linebacker LB-1 and LB-2, two small molecule PIM kinase inhibitors. The company is collaborating with the Dana Farber Cancer Institute to develop LB-1 as a cancer co-therapy.

ProPhase Labs has decades of experience researching, developing, manufacturing, distributing, marketing, and selling OTC consumer healthcare products and dietary supplements under the TK Supplements® brand and Pharmaloz contract manufacturing subsidiary.

ProPhase actively pursues strategic investments and acquisition opportunities for other companies, technologies, and products.

For more information, visit www.ProPhaseLabs.com.

About Stella Diagnostics

Stella Diagnostics, Inc., Stella DX. Stella DX is a molecular diagnostics-based organization focused on improving patient management strategies for people living with severe esophageal disease. Stella DX is developing first-line diagnostic tools that provide superior molecular information for providers as compared to the current standard screening protocols.

Approximately three - six million people suffer from Barrett's Esophagus "BE", a condition which 10% of the thirty - sixty million people that suffer from gastroesophageal reflux disease (GERD) experience. BE patients are monitored using samples pinched from the over 20 million endoscopies done every year in the United States. Approximately 50,000 BE patients will progress to Esophageal Adenocarcinoma every year [4]. That number continues to grow as more and more people develop GERD.

There have been numerous papers published on the subject and a more definitive presentation will be made in February at the USCAP meeting [1][6][7].

Footnotes –

1. Abdo, J., Wichman, C. S., Dietz, N. E., Ciborowski, P., Fleegel, J., Mittal, S. K., & Agrawal, D. K. (2018). Discovery of Novel and Clinically Relevant Markers in Formalin-Fixed Paraffin-Embedded Esophageal Cancer Specimen. Frontiers in Oncology, 8. https://doi.org/10.3389/fonc.2018.00157
2. Chapter 24: Indications and Outcomes of Gastrointestinal Endoscopy. (2021, December 3). National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/burden-of-digestive-diseases-in-united-states/indications-outcomes-gastrointestinal-endoscopy
3. Thrift, A. P. (2021). Global burden and epidemiology of Barrett oesophagus and oesophageal cancer. Nature Reviews Gastroenterology &Amp; Hepatology, 18(6), 432–443. https://doi.org/10.1038/s41575-021-00419-3
4. https://www.thompsoncancer.com/barretts/barretts-esophagus-facts/
5. https://bassett.testcatalog.org/catalogs/191/files/6843
6. Hartley, C., Hagen, C. E., Mittal, S. K., Abdo, J., Thyparambil, S. P., & Bansal, A. (2022). STLA101 assay for the detection of cancerous progression in Barrett's esophagus: A multi-institutional study. Journal of Clinical Oncology, 40(4_suppl), 249–249. https://doi.org/10.1200/jco.2022.40.4_suppl.249
7. Abdo, J., Agrawal, D. K., & Mittal, S. K. (2017). "Targeted" Chemotherapy for Esophageal Cancer. Frontiers in Oncology, 7. https://doi.org/10.3389/fonc.2017.00063

Forward Looking Statements

Except for the historical information contained herein, this document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our strategy, plans, objectives and initiatives, including statements regarding our ability to fund and develop our intellectual property portfolio, the anticipated timeline for developing the BE-Smart diagnostic test, the reimbursement rates for the BE-Smart diagnostic test we plan to pursue, our estimates regarding the target market for esophageal cancer, , as well as our plans to expand our New York lab to include traditional clinical testing and genomic sequencing, to sell our whole genome sequencing products in food, drug and mass (FDM) stores and to provide testing for universities conducting genomic research, and our ability to develop and commercialize LB-1 as a cancer co-therapy. Management believes that these forward-looking statements are reasonable as and when made.
However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to our ability to obtain and maintain necessary regulatory approvals, general economic conditions, consumer demand for our products and services, challenges relating to entering into and growing new business lines, the competitive environment, and the risk factors listed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any other SEC filings. The Company undertakes no obligation to update forward-looking

statements except as required by applicable securities laws. Readers are cautioned that forward-looking statements are not guarantees of future performance and are cautioned not to place undue reliance on any forward-looking statements.

Media Relations and Institutional Investor Contact:

ProPhase Labs, Inc.
267-880-1111
investorrelations@prophaselabs.com

Retail Investor Relations Contact: Renmark Financial Communications John Boidman
514-939-3989
Jboidman@renmarkfinancial.com

Source: ProPhase Labs, Inc.