UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 3, 2023

PROPHASE LABS, INC.
(Exact name of Company as specified in its charter)

Delaware	**000-21617**	**23-2577138**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

711 Stewart Avenue, Suite 200 **Garden City, New York** (Address of principal executive offices)	**11530** (Zip Code)

Registrant's telephone number, including area code: **(215) 345-0919**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Company under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0005	PRPH	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On January 3, 2023, ProPhase Labs, Inc. (the "Company") issued a press release announcing that it has completed its previously announced acquisition of the world-wide exclusive rights to the BE-Smart Esophageal Pre-Cancer diagnostic screening test and related intellectual property assets from Stella Diagnostics, Inc. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any registration statement filed under the Securities Act, unless specifically identified therein as being incorporated by reference therein. The furnishing of the information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is not intended to, and does not, constitute a determination or admission by the Company that such information is material, or that investors should consider such information before making an investment or voting decision with respect to the Company.

Item 8.01. Other Events.

On January 3, 2023, the Company acquired the world-wide exclusive rights to the BE-Smart Esophageal Pre-Cancer diagnostic screening test and related intellectual property assets from Stella Diagnostics, Inc.

Item 9.01. Financial Statements and Exhibits.

No.	Description

99.1	Press Release dated January 5, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ProPhase Labs, Inc.

By: */s/ Monica Brady*
Monica Brady
Chief Accounting Officer

Date: January 5, 2023

Exhibit 99.1

ProPhase Labs Closes Acquisition of BE-Smart Esophageal Pre-Cancer Diagnostic Screening Test

GARDEN CITY, NY, Jan. 5, 2023 (GLOBE NEWSWIRE) — ProPhase Labs, Inc. (NASDAQ: PRPH) ("ProPhase"), a growth oriented and diversified diagnostics, genomics and biotech company, today announced it has completed its previously announced acquisition of the world-wide exclusive rights to the BE-Smart Esophageal Pre-Cancer diagnostic screening test and related intellectual property assets from Stella Diagnostics, Inc. ("Stella").

The BE-Smart test is focused on the early detection of esophageal cancer, and is intended to provide health care providers and patients with data to help determine treatment options. 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 and could also significantly reduce unnecessary endoscopies.

According to the National Institute of Health, over 20 million endoscopies are performed every year in the United States.[1] Approximately 2 million of these procedures are done on patients with Barret's Esophagus, 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. The prevalence of Barrett's Esophagus in the general population has been estimated to be as high as 3.0 - 6.0 million people in the United States.[2] It is estimated that one in two hundred patients with Barrett's Esophagus 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 has been tested on over 200 human samples by mProbe, Inc. ("mProbe"), a precision health and medicine company utilizing clinical proteomics in the oncology space in conjunction with Dr. Christopher Hartley of the prestigious Mayo Clinic, and has shown greater than 99% sensitivity and specificity to detect protein expressions in cells that are at high risk of becoming cancerous.[4] The initial data appears to demonstrate accuracy and reproducibility as well as identification of potential biomarkers for therapeutic drug discovery to treat esophageal cancer.

The Company acquired the rights to Stella's BE-Smart Esophageal Pre-Cancer diagnostic screening test and related intellectual property assets for approximately $4.6 million dollars, comprised of approximately $3.6 million in cash and $1 million in ProPhase common stock. Under the terms of the asset purchase 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. ThinkEquity acted as advisor to ProPhase in the transaction.

"We are thrilled to have completed this transaction and look forward to working with mProbe with the goal of bringing this important product to market. We believe, but cannot assure, that we will be able to commercialize the BE-Smart diagnostic tool within approximately 18 months based on the completion of testing of a total of 1,000 specimens with mProbe in coordination with specimens provided by the Mayo Clinic," stated Ted Karkus, CEO of ProPhase.

"We intend to pursue clinical validation of the test as a laboratory developed test (LDT) in parallel with this ongoing study. 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. 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.

Footnotes –

1. 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
2. https://www.thompsoncancer.com/barretts/barretts-esophagus-facts/

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. 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

5. https://bassett.testcatalog.org/catalogs/191/files/6843

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 our estimates regarding the target market for esophageal cancer, the anticipated timeline for developing the BE-Smart diagnostic test, and the reimbursement rates for the BE-Smart diagnostic test we plan to pursue, 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.

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