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): March 1, 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)

Company'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 March 1, 2023, ProPhase Labs, Inc. (the "Company") issued a press release announcing its collaboration with mProbe, Inc. and Mayo Clinic for the continuing development of the BE-Smart Esophageal Pre-Cancer Diagnostic Screening Test and outlining its roadmap for commercialization. A copy of this 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 of 1933, as amended, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press Release dated March 1, 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/ Robert Morse*
Robert Morse
Controller (principal financial officer and principal accounting officer)

Date: March 1, 2023

Exhibit 99.1

ProPhase Labs Announces Collaboration with mProbe, Inc. and Mayo Clinic for the Continuing Development of BE-Smart Esophageal Pre-Cancer Diagnostic Screening Test

Company Outlines BE-Smart Test Roadmap for Commercialization in the U.S.

Company in Early Stages of Exploring Development for Commercialization in Other Countries

Garden City, NY, March 1, 2023 (GLOBE NEWSWIRE) — ProPhase Labs, Inc. (NASDAQ: PRPH) ("ProPhase"), a growth oriented and diversified diagnostics, genomics and biotech company, today announced a collaboration with mProbe, Inc. ("mProbe"), a precision health and medicine company utilizing clinical proteomics in the oncology space, and Dr. Christopher Hartley of Mayo Clinic for the continued development of its BE-Smart Esophageal Pre-Cancer Diagnostic Screening test.

mProbe plans to continue testing specimens provided by the Mayo Clinic in the first quarter of 2023. ProPhase Labs intends to pursue initial commercialization of the BE-Smart test as a laboratory developed test (LDT) and for research use only (RUO) in the third quarter of 2023, once 500 specimens have been tested by mProbe. Clinical validation of the BE-Smart test for mass spectrometry for non-insurance payers is estimated to commence in the third quarter of 2023. Full commercialization backed by insurance is expected to commence by mid-2024.

The BE-Smart test has been previously tested on over 200 human samples to date by mProbe in conjunction with Dr. Christopher Hartley and Mayo Clinic and has shown an area under curve of greater than 99% in distinguishing highly impactful histologic classifications.[1] The initial protein-histologic correlations have also been redemonstrated in an unrelated RNA sequencing data set. Additional pilot findings include 100% accuracy in predicting invasive carcinoma in biopsy specimens that were otherwise uninformative about invasion histologically. The assay's performance in this regard was confirmed with subsequent resection or synchronous endoscopic ultrasound findings.

Ted Karkus, ProPhase Lab's Chief Executive Officer, commented, "We are excited to announce this continued collaboration and outline our development and early commercialization strategy for the BE-Smart diagnostic test, which we believe could become an important and potentially lifesaving test. Approximately 83% of esophageal adenocarcinoma (EAC) patients die of this terrible disease within six months to five years of diagnosis.[2] If diagnosed potentially years earlier with our diagnostic test, an ablation procedure may destroy the pre-cancerous cells before developing into cancer. With partners like mProbe and Dr. Hartley of the Mayo Clinic, we are optimistic that we can meet our commercialization goals for this potentially life-saving test. We are also in preliminary discussions to license, develop and ultimately commercialize our BE-Smart test in other countries."

Mr. Karkus continued, "ProPhase is ahead of schedule in hiring an expert consultant to initiate its evaluation and cost benefit analysis toward obtaining CPT codes. The Company expects to pursue reimbursement rates in the range of $1,000 to $2,000 per test, based on CPT codes of similarly complex tests[3] and with gross profit margins approaching 75% as volumes grow. Our initial target market is 2 million endoscopies performed annually on patients with Barrett's esophagus, which equates to a $2 billion to $4 billion potential market just in the U.S. mProbe and Mayo Clinic aim to study 1,000 specimens in total by the end of 2023, which will enable ProPhase to pursue full commercialization as an LDT."

ProPhase Labs has also begun to establish various touchpoints with key opinion leaders (KOLs) and will continue to do so throughout 2023 to increase awareness of the Company's ongoing development of the BE-Smart test and lay the groundwork for its eventual adoption once fully validated and commercially available.

About the BE-Smart Test

The BE-Smart Esophageal Pre-Cancer Diagnostic Screening 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 an area under curve of greater than 99% in distinguishing highly impactful histologic classifications.[1] ProPhase Labs plans to pursue initial commercialization of the BE-Smart test as an LDT and RUO. 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.

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 Pharmaloz, a rapidly growing 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 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 rapidly growing and 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. The Company also owns the exclusive rights to the BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets. The BE-Smart test remains under validation as a LDT. The 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.

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.

References

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. https://jgo.amegroups.com/article/view/53833/html

3. 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 anticipated timeline for developing and commercializing the BE-Smart diagnostic test, our estimates regarding the target market for esophageal cancer, 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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Source: ProPhase Labs, Inc.

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