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): February 6, 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 February 6, 2023, ProPhase Labs, Inc. (the "Company") issued a press release providing an update on its Linebacker-1 cancer co-therapy program and development strategy. 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 February 6, 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: February 6, 2023

Exhibit 99.1

ProPhase Labs Provides Update on Linebacker-1 Cancer Co-Therapy Program and Outlines Development Strategy

Garden City, NY, Feb. 06, 2023 (GLOBE NEWSWIRE) — ProPhase Labs, Inc. (NASDAQ: PRPH) ("ProPhase"), a growth oriented and diversified diagnostics, genomics and biotech company, today provided an update regarding its progress and development strategy for Linebacker-1 (LB-1), a small molecule PIM kinase inhibitor that is being developed by the Company's wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO"), as a potential therapy enhancer for traditional chemotherapeutic agents to both increase efficacy and decrease toxicity in current cancer treatments.

"We are excited to provide this update on our progress with the Linebacker-1 cancer co-therapy program, a platform which we believe has multi-billion-dollar potential in oncology as well as significant potential in other areas," commented Ted Karkus, ProPhase Lab's Chief Executive Officer. "We look forward to sharing additional updates on our progress throughout the year as we advance toward a potential IND application submission in mid-2024."

In January 2023, REPROCELL completed its independent review of Linebacker-1, which included testing of 25 cell lines with LB-1 and confirmed previous in vitro studies conducted by Charles River. These cell lines confirmed efficacy of LB-1 on ovarian, kidney, colon and lung adenocarcinoma/small cells.

The two-year research collaboration for Linebacker-1 with Dana-Farber Cancer Institute and Harvard Medical School (which was announced in the third quarter of last year) has officially commenced, with cell culture studies currently ongoing. The ongoing studies are focused on identifying the most effective combination of cancer cell lines and agents with LB-1. Initial focus areas include hepatic, colon and breast cancer, and initial therapy agents include Topotecan and Doxorubicin. Initial results from these cell culture studies are very promising.

Additionally, selection has been confirmed for animal studies; Dana-Farber/Harvard will deploy two animal xenograft models, with and without radiation. The goal for completion of the animal studies is the end of Q2 2023, with data expected to be published in Q3 2023. Initial GMP manufacturing for LB-1 is expected to kick off in the third quarter of 2023, in tandem with toxicology studies.

ProPhase expects to initiate the preclinical requirements for investigational new drug (IND) application submission in the fourth quarter of 2023. These requirements include:

- Study Protocol Design: select optimized co-therapy combo from animal study and complete the protocol design for IND submission
- Toxicity Testing: toxicological studies on small animals according to study protocol
- Dosing Studies: dosing studies on small animals according to study protocol
- Large Animal Studies: combined therapy studies on large animals according to study protocol

ProPhase aims to submit its IND application for Linebacker-1 in mid-2024. The Company plans to operate its own Phase 1 safety study for LB-1 and will seek a strategic partner for future development following Phase 1. The Company estimates that the total cost for development prior to exploring a strategic partner will be $3 - $5 million.

Mr. Karkus continued, “The two-year bear market has led to some phenomenal opportunities in the biotech and life sciences space and for our company in particular. In late 2020, in response to the pandemic, we quickly expanded our business to provide CLIA licensed PCR COVID-19 testing, recognizing record revenues for our company, and rewarding our shareholders through the payment of multiple special cash dividends. The financial success of our diagnostic business has also enabled us to strengthen our company’s core infrastructure, and as COVID-19 testing slows, we are confident that we will be able to leverage our infrastructure and platform to take advantage of other exciting new initiatives with even greater potential, including our development of the Linebacker portfolio. These positive preliminary results from the Linebacker-1 studies continue to bolster our confidence in our diversification strategy. We look forward to providing additional updates in the coming weeks on some of our other new strategic initiatives.”

About Linebacker

LB-1 is designed as an anti-cancer agent to be used as a potential co-therapy that targets PIM (proviral integration site for moloney murine leukemia virus) kinase receptors, a growth factor expressed in cancer. In preclinical laboratory studies, LB-1 inhibited PIM, which could potentially slow the growth of cancer and allow for better efficacy of the co-therapy drug or treatment being used. Under the terms of the license agreement, PBIO has obtained exclusive rights worldwide to develop and commercialize LB-1 and LB-2 for the treatment of cancer, inflammatory diseases or symptoms and memory related syndromes, diseases or symptoms including dementia and Alzheimer’s disease.

Linebacker is a modified polyphenol. Polyphenols are substances found in many nuts, vegetables and berries. Linebacker compounds are modified Myricetin, which is a common plant-derived flavonoid. Myricetin exhibits a wide range of activities that include strong antioxidant, anti-cancer, antidiabetic and anti-inflammatory activities. It displays activities that are related to the central nervous system.

LB-1 is Mono-chlorinated Myricetin with a Chlorine atom substituted for the Hydroxy group at 5’ (position 5 on the B-ring). LB-2 is Di-chlorinated Myricetin with Chlorine atoms substituted for the Hydroxy groups at 5’ and 7 (position 5 on the B-ring and position 7 on the A-ring).

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. In January 2023, the Company acquired exclusive rights to BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets. 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.

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.

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 timeline with respect to the clinical studies, data release, GMP manufacturing and potential IND application submission with respect to LB-1, 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.

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