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): November 7, 2024

PROPHASE LABS, INC.
(Exact name of registrant 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**

Not Applicable
(Former name or former address, if changed since last report)

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 8.01. Other Events.

Underwritten Public Offering

On November 7, 2024, ProPhase Labs, Inc., a Delaware corporation (the "Company") issued a press release announcing that it intends to offer to sell shares of its common stock (and/or pre-funded warrants ("Pre-Funded Warrants") in lieu thereof) in an underwritten public offering (the "Underwritten Public Offering"). The Company intends to grant the underwriters of the offering a 45-day option to purchase up to an additional 15% of the number of shares of common stock and/or Pre-Funded Warrants sold in this offering to cover over-allotments, if any. All of the shares of common stock (and/or Pre-Funded Warrants) are being offered by the Company. The offering is subject to market conditions and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

On November 7, 2024, the Company filed a preliminary prospectus supplement with the U.S. Securities and Exchange Commission (the "SEC") under its effective shelf registration statement on Form S-3 (Registration Statement No. 333-260848), or the Preliminary Prospectus Supplement, in connection with the proposed registered Underwritten Public Offering.

The Preliminary Prospectus Supplement contains information relating to recent developments concerning the Company's business and includes the following disclosure:

Overview

DNA Complete

The Company offers whole genome sequencing and related services through its wholly-owned subsidiary, DNA Complete, Inc. ("DNA Complete"). DNA Complete sequences specimens at Nebula Genomics, Inc. ("Nebula"), another wholly-owned subsidiary of the Company, as well as at other laboratories.

DNA Complete focuses on genomics testing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in deoxyribonucleic acid ("DNA"). The data obtained from genomic sequencing may help to identify inherited disorders and tendencies, predict disease risk, identify expected drug response, and characterize genetic mutations, including those that drive cancer progression. The Company currently offers DNA Complete's whole genome sequencing products direct-to-consumers online with plans to sell in food, drug and mass ("FDM") retail stores and to provide testing for universities conducting genomic research. DNA Complete offers three tiers of DNA testing, Essential, Pro, and Elite, which differ in the amount of DNA analyzed (1x whole genome sequencing ("WGS"), 30x WGS, and 100x WGS, respectively), the level of accuracy, the number of reports per month that consumers would receive, and the total of personalized health reports included (more than 175 reports, more than 250 reports, and more than 350 reports, respectively). The DNA Complete tests include the first year of membership. The DNA Complete platform offers both ancestry and personalized health reports covering a number of health dispositions, such as longevity, mental health, cancer, and more. In addition, DNA Complete offers subscription services to ensure ongoing customer engagement by providing regular updates and new insights.

DNA Complete also offers DNA Expand, a platform that allows consumers to upload their DNA data from previous DNA tests obtained from other service providers to discover 50x more data points derived from over 35 million genetic variants, and to obtain in-depth health and wellness reports that are based on the latest scientific discoveries. DNA Expand's database was created from WGS tests that were obtained from 130 countries and are equivalent to roughly 150 million ancestry single nucleotide polymorphisms based tests.

BE-Smart Esophageal Pre-Cancer Diagnostics Screening Test

In March 2023, the Company announced a collaboration with mProbe and Dr. Christopher Hartley of Mayo Clinic for the continued development of our BE-Smart Esophageal Pre-Cancer diagnostic screening test. Currently, the Company plans to commercialize the BE-Smart test as a Laboratory Developed Test ("LDT"). However, on April 29, 2024, the United States Food and Drug Administration ("FDA") released a final rule that classified LDTs as in vitro diagnostics that are regulated by FDA as medical devices under the federal Food, Drug, and Cosmetic Act. Under this approach, FDA proposed to phase out its general enforcement discretion approach for LDTs under a four-year period subject to certain continuing enforcement discretion policies. The final rule was published on May 6, 2024, and in the absence of a successful legal challenge, will become effective after a year, after which medical device regulatory requirements such as medical device reporting, registration and listing, quality system regulation requirements, and premarket authorization requirements, among others, will become applicable eventually. The Company plans to comply with such requirements, including that of premarket authorization, in partnership with Forward Healthcare Consultants ("FHC"), as described below, if the final rule is not modified or rescinded.

In August 2024, the Company announced a collaboration with FHC to assist in the approval and commercialization of BE-Smart. The experts at FHC will assist with securing market access by focusing on clinical validation and commercialization planning, to include coverage, pricing, and coding. Additionally, FHC will bring its vast relationships with physician networks to drive commercialization success. FHC has already completed the first two phases of its plan for advancing towards commercialization. This plan includes publishing a peer reviewed paper as well as a comprehensive dossier on the BE-Smart test. In addition, the Company has initiated certain discussions in coordination with FHC with respect to a potential strategic partnership or sale for the BE-Smart test.

Recent Events

Term Note Agreement

On October 22, 2024, the Company entered into a term note agreement with an individual investor for cash proceeds of $500,000 (the "Term Note"). The Term Note has an implicit interest rate of 15%. The Term Note has a term of 12 months and requires the Company to make interest only monthly payments in the amount of $6,250 with a $506,250 balloon payment at end of term. There are no warrants or convertible features associated with this note.

2024 Third Future Receipts Financing

On August 1, 2024, the Company entered into an agreement of sale of future receipts ("Third Future Receipts Financing Agreement") with RDM Capital Funding ("RDM"), by which RDM purchased from the Company its future accounts and contract rights arising from the sale of goods or rendition of services to the Company's customers. The purchase price was $500,000, which was paid to the Company on August 2, 2024, net of $17,500 origination fee. The Company also incurred $17,500 brokerage fee. The Third Future Receipts Financing Agreement requires 32 weekly payments of $21,094 for a total repayment of $675,000 over the term of the agreement.

Neither the disclosures on this Current Report on Form 8-K nor the exhibits hereto shall constitute an offer to sell or the solicitation of an offer to buy the securities described herein and therein, nor shall there be any sale of such securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

2024 Second Future Receipts Financing

On June 27, 2024, the Company entered into an agreement of sale of future receipts ("Second Future Receipts Financing Agreement") with Slate Advance ("Slate") by which Slate purchased from the Company its future accounts and contract rights arising from the sale of goods or rendition of services to the Company's customers. The purchase price was approximate $1.5 million, which was paid to the Company on June 28, 2024, net of $42,000 origination fee. The Company also incurred $22,000 brokerage fee which was paid subsequently in July 2024. The Second Future Receipts Financing Agreement required 32 weekly payments of $60,718 for a total repayment of approximately $1.9 million over the term of the agreement.

During the three and six months ended June 30, 2024, the Company recognized $9,000 interest expense from the amortization of debt discount using the effective interest rate method, respectively. As of June 30, 2024, the outstanding balance under the Second Future Receipts Financing Agreement was $1.4 million, net of debt discount of $548,000.

On November 5, 2024, the Company entered into an agreement with Slate (the "Amended Second Future Receipts Financing Agreement") pursuant to which the original Second Future Receipts Financing Agreement was amended by increasing the receivables purchased amount to approximately $2.1 million and the purchase price to approximately $1.6 million, less the origination fees of $35,000 and the outstanding balance of approximately $1.0 million under the agreement, resulting in net proceeds to the Company of $527,000. The Amended Second Future Receipts Financing Agreement shall be repaid by the Company in 24 weekly installments of $89,000.

Risk Factors

FDA's finalized regulations on laboratory-developed tests may impact our operations adversely, and we may not be able to comply with the requirements.

We market our genetic tests as laboratory-developed tests ("LDT"), and plan to also initially market our BE-Smart Esophageal Pre-Cancer as an LDT. Until recently, the FDA has exercised enforcement discretion on LDTs that are marketed in the United States, provided that the LDTs can meet certain conditions that the FDA has outlined. However, on May 6, 2024, the FDA issued a final rule aimed at helping to ensure the safety and effectiveness of laboratory developed tests (LDTs). The rule amends the FDA's regulations to make explicit that in vitro diagnostic products ("IVD") are medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA is finalizing a policy under which the FDA will provide greater oversight of IVDs offered as LDTs through a phaseout of its general enforcement discretion approach for LDTs over the course of four years, as well as targeted enforcement discretion policies for certain

categories of IVDs manufactured by laboratories. As a result of the final regulations, premarket review, clearance, or approvals may be required by FDA for the products that we are currently marketing or plan to market as LDTs. Our business and operations may be adversely affected because we may be required to cease sales of such products and be required to expend significant resources into collecting data from clinical trials, ensuring compliance with the applicable requirements for medical devices, and preparing and submitting premarket applications for the FDA's review. We may not be able to complete the required clinical trials to enable marketing of our tests due to resource constraints, or we may not be able to complete them in a timely manner. We also may not be able to comply with the associated regulatory requirements including those of premarket authorization, medical device reporting, quality system regulations, and others. In addition, even if we are able to comply with such requirements or complete the clinical trials in a timely manner, there is no guarantee that FDA will clear or approve our products. FDA may also determine that our tests are not safe or effective, and that they must be removed from the market. The FDA may bring enforcement actions against LDTs that are on the market by sending warning letters, untitled letters, it-has-come-to-our-attention letters, or through other actions such as seizure, recalls, civil monetary penalties, injunction, and import refusals and import alerts, among others. If we cannot obtain the required premarket review, clearance, or approval, we may be forced to stop the marketing of our products, which will impact our operations and financial conditions adversely.

Our projections of future performance may not be indicative of actual results

From time to time, we may provide statements to the marketplace in the form of press releases that contain projections related to our future performance. These include statements relating to our projected revenues, our projected collection of receivables, our estimates of future operating and financial results and our planned strategic initiatives including our potential discussions regarding strategic partnerships and M&A activity. Although this information reflects the good faith expectations and estimates of our management based on the information available at the time that such statements were made, there can be no assurance that our actual performance and results will not differ materially from those contained in these projections. Investors are cautioned not to place undue reliance on any projections that may be provided by us.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Current Report on Form 8-K other than statements of historical fact are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the Company's business, strategy, plans, objectives and initiatives, including statements related to the expected completion of the offering described herein. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and the negative of such terms or other similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Such forward-looking statements are based on the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those projected in any forward-looking statements due to numerous risks and uncertainties. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that the Company files from time to time with the SEC. These forward-looking statements are made as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibits are being filed herewith:

No.	Description
99.1	Press Release of the Company, dated November 7, 2024
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/ Ted Karkus*
Ted Karkus
Chairman of the Board and Chief Executive Officer

Date: November 7, 2024

Exhibit 99.1

ProPhase Labs Announces Proposed Public Offering of Common Stock

GARDEN CITY, NY, November 7, 2024 (GLOBE NEWSWIRE) — ProPhase Labs, Inc. (NASDAQ: PRPH), a next-generation biotech, genomics and diagnostics company, today announced that it intends to offer to sell shares of its common stock (and/or pre-funded warrants ("Pre-Funded Warrants") in lieu thereof) in an underwritten public offering. The Company expects to grant the underwriters a 45-day option to purchase up to an additional 15% of the number of shares of common stock and/or Pre-Funded Warrants sold in this offering to cover over-allotments, if any. All of the shares of common stock (and/or Pre-Funded Warrants) are being offered by the Company. The offering is subject to market conditions and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

ProPhase intends to use the net proceeds from this offering for working capital and general corporate purposes, which may include capital expenditures, product development and commercialization expenditures, and acquisitions of companies, businesses, technologies and products within and outside the diagnostic services, genomics and consumer products industry.

ThinkEquity is acting as sole book-running manager for the offering.

The securities will be offered and sold pursuant to a shelf registration statement on Form S-3 (File No. 333-260848), including a base prospectus, filed with the U.S. Securities and Exchange Commission (the "SEC") on November 5, 2021 and declared effective on November 12, 2021. The offering will be made only by means of a written prospectus. A preliminary prospectus supplement and accompanying prospectus describing the terms of the offering has been or will be filed with the SEC on its website at www.sec.gov. Copies of the preliminary prospectus supplement and the accompanying prospectus relating to the offering may also be obtained from the offices of ThinkEquity, 17 State Street, 41st Floor, New York, New York 10004. Before investing in this offering, interested parties should read in their entirety the preliminary prospectus supplement and the accompanying prospectus and the other documents that the Company has filed with the SEC that are incorporated by reference in such preliminary prospectus supplement and the accompanying prospectus, which provide more information about the Company and such offering.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of the prospectus supplement and accompanying prospectus forming a part of the effective registration statement.

About ProPhase Labs

ProPhase Labs, Inc. (Nasdaq: PRPH) ("ProPhase") is a next-generation biotech, genomics and diagnostics company. Our goal is to create a healthier world with bold action and the power of insight. We believe we are revolutionizing healthcare with industry-leading Whole Genome Sequencing solutions, while developing potential game changer diagnostics and therapeutics in the fight against cancer. This includes a potentially life-saving cancer test focused on early detection of esophageal cancer and potential breakthrough cancer therapeutics with novel mechanisms of action. Our world-class CLIA labs and cutting-edge diagnostic technology provide wellness solutions for healthcare providers and consumers. We develop, manufacture, and commercialize health and wellness solutions to enable people to live their best lives. We are committed to executional excellence, smart diversification, and a synergistic, omni-channel approach. ProPhase Labs' subsidiaries and their strategic synergies highlight our potential for long-term value.

For more information, visit www.ProPhaseLabs.com

Forward Looking Statements

This press release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms and similar expressions intended to identify forward-looking statements. These statements include statements related to the expected completion of the offering described herein and the intended use of proceeds. The Company cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to, risks related to whether the Company will consummate the proposed offering of common stock on the expected terms, or at all; the anticipated use of the net proceeds from the offering; and the fact that the Company's management will have broad discretion in the use of the proceeds from any sale of common stock. Management believes that these forward-looking statements are reasonable as and when made. The Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws.

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