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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 000-21617

ProPhase Labs, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**23-2577138**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
711 Stewart Avenue, Suite 200 **Garden City, New York**	**11530**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0005 par value per share	**PRPH**	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was $151,728,652 as of June 30, 2022, based on the closing price of the common stock on The Nasdaq Capital Market on such date.

As of March 24, 2023, there were 17,182,841 shares outstanding of the registrant's common stock, par value $0.0005 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2023 annual meeting of stockholders (the "2023 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2023 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical facts, included in this Annual Report, including statements related to future events and our future financial performance are forward-looking statements. Forward-looking statements typically are identified by use of terms such as "anticipate", "believe", "plan", "expect", "intend", "may", "will", "should", "estimate", "predict", "potential", "continue" and similar words although some forward-looking statements are expressed differently. Forward-looking statements include, but are not limited to, statements concerning:

- our strategic plans for our businesses, product candidates and research programs;
- our anticipated timelines for clinical trials, regulatory filings and regulatory approvals for our product candidates, dietary supplements and diagnostics;
- the beneficial characteristics, therapeutic effects, and potential advantages of our product candidates, dietary supplements and diagnostics;
- anticipated developments related to our competitors and our industry;
- estimates regarding the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements; and
- our anticipated use of our existing resources, capital requirements, and timing and needs for additional financing.

You are cautioned that forward-looking statements are not guarantees of performance and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance, achievements or prospects to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. Many of these factors are beyond our ability to predict.

You should also consider carefully the statements under other sections of this Annual Report, including the Risk Factors included in Item 1A, which are summarized below, which address risks that could cause our actual results to differ from those set forth in any forward-looking statements. Our forward-looking statements speak only as of the date of this Annual Report. We undertake no obligation to publicly update or review any forward-looking statements, whether as a result of new information, future developments or otherwise except as otherwise required by law.

SUMMARY OF RISK FACTORS

You should consider carefully the risks described under the "Risk Factors" section and elsewhere in this Annual Report. These risks, which include the following, could materially and adversely affect our business, financial condition, operating results, cash flow, and prospects, which could cause the trading price of our common stock to decline and could result in a partial or total loss of your investment:

Risks Related to Our Business Generally

- Our failure to manage our growth successfully could harm our growth and operating results.
- Our businesses are subject to significant competitive pressures.
- Disruptions to our supply chain or increases in the price of testing supplies, equipment and raw materials needed for our businesses could materially and adversely affect our business, financial condition and results of operations.
- The adulteration of key testing materials and raw materials needed for our businesses could materially and adversely affect our business, financial condition and results of operations.
- We may be subject to product liability claims.
- We may require additional capital to support our businesses and additional funding may not be available to us on acceptable terms, or at all.
- System failures, security breaches or cyberattacks could adversely affect our results of operations and financial condition.
- Our success is dependent on key personnel.

Risks Related to Our Diagnostics Business

- We may be unable to continue to successfully offer, perform or generate revenues from our lab diagnostic services, particularly if demand for COVID-19 testing becomes no longer necessary and we are unable to generate sufficient profits from other RPP Molecular tests.
- Any delay in transmitting and collecting claims, or failure to accurately bill for testing services, could have an adverse effect on our revenue.
- The loss of sales to any one or more of our large diagnostic services customers could have a material adverse effect on our business operations and financial condition.
- If we fail to comply with the complex federal, state, local and foreign laws and regulations, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition.
- Our products could become subject to regulation as medical devices by the FDA or other regulatory agencies even if we do not elect to seek regulatory clearance or approval to market our products for diagnostic purposes, which would adversely impact our ability to market and sell our products and harm our business.
- Any disputes relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Risks Related to Our Personal Genomics Business

- Our success in this industry will depend, in large part, on our ability to establish our presence in the personal genetics market, provide customers with a high level of service at a competitive price, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products, and services to offer to our customers.
- The total addressable market for personal genomic services and the potential for market growth may prove to be inaccurate.
- Concerns regarding consumer privacy concerns and the use of genetic information accessed from other genetic databases by law enforcement and governmental agencies may decrease the overall consumer demand for personal genetic products and services, including ours.
- If we lose a significant or sole supplier, our business and operations could be materially adversely affected.
- Any significant disruption in service on our website, mobile applications, or in our computer or logistics systems could harm our reputation and may result in a loss of customers.
- Our personal genomics business is subject to seasonal fluctuations.

Risks Related to our Contract Manufacturing and Dietary Supplement Business

- Disruptions at our PMI manufacturing facilities or any loss of manufacturing certifications could materially and adversely affect our business, financial condition, results of operations and customer relationships.
- Our PMI manufacturing business is subject to seasonal fluctuations.
- Our contract manufacturing and dietary supplement businesses are subject to extensive governmental regulation.
- Our product development and commercialization efforts may be unsuccessful.
- If our products do not have the effects intended or cause undesirable side effects, our business may suffer.

Risks Related to Our Drug Development Operations

- It will be many years before our wholly owned subsidiary, ProPhase BioPharma, Inc. (PBIO) is able to commercialize a product candidate, if ever.
- We may expend our resources to pursue particular product candidates or indications while failing to capitalize on other product candidates or indications that may be more profitable, or for which there is a greater likelihood of commercial success.
- If we experience delays or difficulties enrolling patients in the clinical trials for our product candidates, our ability to advance our product candidates through clinical development and the regulatory process could be delayed or prevented.
- Clinical trials are expensive, time consuming, and subject to uncertainty.
- Our preclinical studies or clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates and the development of our product candidates may be delayed or unsuccessful.
- If our product candidates cause serious adverse events or undesirable side effects, including injury and death, their commercial potential may be limited or extinguished.
- Even if we complete the necessary preclinical studies and clinical trials, we may be unable to obtain the regulatory approvals necessary for the commercialization of our product candidates or may face delays.
- If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.
- Our products may not gain market acceptance and the market opportunities for our product candidates may be smaller than we currently believe.
- Even if we are able to commercialize our product candidates, such products may be subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which could harm our business.

Risks Related to Our Intellectual Property

- Failure to protect our trademarks and other intellectual property could impact our business.
- If our licensors are unable to maintain effective patents or we are unable to maintain our license rights for approved products, product candidates or any future produce candidates, or if the scope of the patent or license rights are not sufficiently broad, we may not be able to compete effectively in our markets.
- Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.
- Our reliance on third parties requires us to share our trade secrets or confidential proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets confidential proprietary information will be misappropriated or disclosed.

Risks Related to Governmental Regulation

- Laws and regulations regarding direct selling may prohibit or restrict our ability to sell our products in some markets or require us to make changes to our business model in some markets.
- We depend on third parties to provide services critical to our businesses and we depend on them to comply with applicable laws and regulations.
- We must comply with complex and overlapping laws protecting the privacy and security of health information and personal data.

Risks Related to Our Common Stock, Internal Controls and Governance Matters

- Future sales of shares of our common stock in the public market could adversely affect the trading price of shares of our common stock and our ability to raise funds in future offerings.
- If securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.
- Our Chief Executive Officer and Chairman of the Board of Directors owns a substantial amount of our common stock.
- Our Certificate of Incorporation and By-laws contain certain provisions that may be barriers to a takeover.
- Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, executive officers, or employees.
- We have agreed to indemnify our officers and directors from liability.

PART I

Item 1. Business

Overview

We are a growth oriented and diversified company focused on diagnostic and genomic products and services, the development and commercialization of novel drugs, dietary supplements, and compounds, and contract manufacturing.

We offer a broad array of COVID-19 related clinical diagnostic and testing services including polymerase chain reaction ("PCR") testing for COVID-19 and Influenza A and B through our wholly-owned subsidiary, ProPhase Diagnostics, Inc. ("ProPhase Diagnostics"). We also offer rapid antigen testing for COVID-19.

We offer whole genome sequencing and related services through our wholly-owned subsidiary, Nebula Genomics, Inc. ("Nebula Genomics").

Our wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO") is focused on the licensing, development and commercialization of novel drugs, dietary supplements, and compounds.

Our wholly-owned subsidiary, Pharmaloz Manufacturing, Inc. ("PMI"), is a full-service contract manufacturer and private label developer of a broad range of non-GMO, organic and natural-based cough drops and lozenges and OTC drug and dietary supplement products.

We also develop and market dietary supplements under the TK Supplements® brand.

ProPhase Diagnostics

Our wholly-owned subsidiary, ProPhase Diagnostics, which was formed in October 2020, offers a broad array of COVID-19 related clinical diagnostic and testing services including PCR testing for COVID-19 and Influenza A and B at its two Clinical Laboratory Improvement Amendments ("CLIA") certified laboratories, located in Old Bridge, New Jersey and Garden City, New York. We also offer rapid antigen testing for COVID-19. We are also in the process of validating for regulatory panel, viral panel, bacteria panel and monkey pox.

Following receipt of the necessary validations, our testing capabilities are expected to include:

- Chemistry and Immunoassay: general chemistry, diabetes, toxicology, therapeutic drug monitoring, auto-immune diseases, cardiac function, reproductive, endocrinology, STI and oncology.

- Hematology: complete blood county automated/manual, individual cell diferrential, retic analsyis and platelet assay.

- Hemostasis: coagulation function testing, including platelet count, bleeding time, partial thromboplastin time, prothrombin time and Factor Assays.

- Urinalysis: fully automated microscopic and complete urinalysis solution.

Nebula Genomics

Nebula Genomics focuses on genomics 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. We currently offer Nebula Genomics 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.

Nebula Genomics provides consumers access to affordable and secure whole genome sequencing. It also provides customers with access to over 300 personalized reports based on their genomic profile. These reports are created utilizing the latest scientific research and provide individual genetic commentary on a broad range of traits and characteristics. Customers can access their reports via Nebula Genomic's secure online portal. As new scientific discoveries are made, customers receive new reports, as well as regular updates to their existing reports, through Nebula Genomic's subscription model. In addition to the personalized reports, Nebula Genomics provides customers with access to a suite of exploration tools including a gene browser and a gene analysis tool. These tools allow customers to browse their data, search for genetic variants, and analyze their genes.

Nebula Genomic's solution is powered by the innovations of George Church, Ph.D., Professor of Genetics at Harvard Medical School and Chairman of Nebula Genomic's Scientific Advisory Board. Dr. Church has pioneered the development of multiple DNA sequencing methods, including molecular multiplexing approaches that enable next generation sequencing (NGS) as well as nanopore sequencing.

Nebula's whole genome sequencing DNA test decodes approximately 6.4 billion base pairs of the human genome, generating significant amounts of data, which exceeds the amount and quality of data widely offered by most competing services. Through the use of additional tools, the data that is generated can help identify rare genetic mutations and provide consumers other valuable insights into their genes and overall health and wellness. Nebula Genomics also provides consumers with weekly educational content to further their knowledge about the use of their genetic data.

Nebula Genomics was the first company to bring the cost of sequencing a human genome below $300 and became one of the largest direct-to-consumer whole genome sequencing companies. Our goal is to dramatically increase Nebula Genomic's sales by decreasing price, decreasing turnaround times and increasing distribution to both businesses and consumers, including universities conducting genetic research. We plan to accomplish this by integrating Nebula Genomics' genomic sequencing into our CLIA-certified labs.

We are also actively collaborating with G42 Healthcare, a leading Abu Dhabi-based artificial intelligence (AI) health-tech company, to explore several collaborative opportunities including, but not limited to, genomic sequencing, artificial intelligence, sharing of genomic data insights, and obtaining certain advanced certifications.

ProPhase BioPharma

We formed PBIO in June 2022 for the licensing, development and commercialization of novel drugs, dietary supplements and compounds. Licensed compounds under development currently include Equivir (dietary supplement) and Equivir G (Rx), two broad-based anti-virals, and Linebacker LB-1 and LB-2, two small molecule PIM kinase inhibitors. We also own the exclusive rights to the BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets.

Equivir (dietary supplement) and Equivir G (Rx)

We have exclusive worldwide rights to develop and commercialize Equivir (dietary supplement) and Equivir G (Rx) pursuant to a license agreement with Global BioLife, Inc. ("Global BioLife"), a wholly-owned subsidiary of DSS, Inc.

Equivir is a blend of polyphenols, which are substances found in many nuts, vegetables and berries. The composition, which contains polyphenols that we believe are Generally Recognized as Safe (GRAS), is projected to come in capsule form and be taken much like a multivitamin. The composition is believed to work by helping to improve proper immune function. We plan to pursue commercialization of Equivir as a dietary supplement, leveraging our distribution in over 40,000 food, drug and mass (FDM) retail stores and online direct to consumers.

In March 2023, we commenced patient enrollment in a randomized, placebo-controlled clinical trial of Equivir to evaluate its effect on upper respiratory tract infections. Vedic Lifesciences, a leading clinical research organization, is contracted to conduct the combination prophylactic and therapeutic study, which will be conducted at 12 sites. We currently anticipate trial completion in the third quarter of 2023 and anticipate launching Equivir (dietary supplement) in the United States toward the end of 2023.

Equivir G is a blend of polyphenols similar to Equivir (dietary supplement) with the addition of Gallic acid. We are in the process of formulating its composition and preparing clinical studies. We are pursuing the development of Equivir G as a prescription based antiviral treatment based on data related to the polyphenol formulation in Equivir. Evidence suggests that the blend of polyphenols in Equivir has the potential to block the entry of a virus into host cells, thereby preventing infection and replication in those host cells. Through our development of Equivir G, we believe a similar polyphenol formulation can be developed for the treatment of infection caused by various serotypes of influenza and Rhinovirus, a common viral infectious agent predominantly associated with the common cold in humans. We believe this formulation may also have the potential to block the entry of Ebola virus into host cells, which could prevent Ebola Virus Disease (EVD) and Ebola Hemorrhagic fever (EHF). These diseases are rare, but severe and often fatal in humans, particularly in sub-Saharan Africa. Ebola has a 90% death rate, according to the World Health Organization. Equivir has also shown in in-vitro studies to combat SARS-COV2. We plan to apply for an Investigational New Drug Application ("IND") for Equivir G as a prescription-based antiviral treatment. Planned antiviral applications include SARS-COV2, Influenza and Ebola, among others.

Linebacker (LB-1 and LB-2)

We have exclusive worldwide rights 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, pursuant to a license agreement with Global BioLife.

LB-1 and LB-2 were initially developed by Global BioLife in partnership with Global Research and Development Group Sciences ("GRDG"). GRDG and Global BioLife created Linebacker, a multi-faceted therapeutic platform targeting metabolic, neurologic, cancer, and infectious diseases, to mirror the Panacea Project, a U.S. Defense Advanced Research Projects Agency (DARPA) program that provides novel, multi-target therapeutics for unmet physiological needs. Linebacker is a modified polyphenol. Linebacker compounds are modified Myricetin, which is a common plant-derived flavonoid. Myricetin exhibits a wide range of activities that include strong antioxidant, anticancer, antidiabetic and anti-inflammatory activities. It displays activities that are related to the central nervous system. Anecdotal evidence suggests that it may be beneficial to protect against diseases such as Parkinson's and Alzheimer's.

LB-1 is being developed as a potential co-therapy to down-regulate PIM (proviral integration site for moloney murine leukemia virus) kinase, which plays a key role as an oncogene in various cancers including myeloma, leukemia, prostate and breast cancers. In preclinical laboratory studies, LB-1 inhibited PIM, which could potentially slow the growth of the cancer and allow for better efficacy of the co-therapy drug or treatment being used.

Chemotherapy drugs alone, like TAXOL® (paclitaxel) injection, kill healthy cells alongside tumorous ones. LB-1 is being developed to focus directly on the PIM expressions potentially rendering the cancer cell transcription and replication significantly less effective, so that chemotherapy drugs such as paclitaxel can effectively kill the existing tumor cells. LB-1 may also be developed as a potential standalone post therapy to ensure cancer cells do not regenerate.

Our initial focus for LB-1 is as a potential co-therapy for the following four drugs:

- *Paclitaxel*: a drug used to treat breast, ovarian, lung, bladder, prostate, melanoma, esophageal, as well as other types of solid tumor cancers.

- *Doxorubicin*: a drug used to treat used to treat various forms of cancer, including breast cancer, bladder cancer, Kaposi's sarcoma, lymphoma, and acute lymphocytic leukemia.

- *Topotecan*: a drug used to treat ovarian cancer.

- *Cisplatin*: a drug used to treat testicular, ovarian, bladder, head and neck, lung and cervical cancer.

In vitro studies from the initial LB-1 cell line demonstrated the following findings:

- *LB-1 Co-Therapy with Paclitaxel*
    - LB-1 alone inhibited cell proliferation at 69.94% at 100uM
    - TAXOL alone inhibited cell proliferation at 41.96% at 200nM
    - LB-1 and TAXOL combined inhibited cell proliferation at 75.5% (100uM of LB1 + 200nM Taxol)

- *LB-1 Co-Therapy with Doxorubicin*
    - LB-1 alone inhibited cell proliferation at 69.66% at 100uM
    - Doxorubicin alone inhibited cell proliferation at 51.6% at 2000nM
    - LB-1 and Doxorubicin combined inhibited cell proliferation at 86.95% (100uM of LB1 + 2000nM Doxorubicin)

- *LB-1 Co-Therapy with Topotecan*
    - LB-1 alone inhibited cell proliferation at 69.54% at 100uM
    - Topotecan alone inhibited cell proliferation at 58.27% at 2000nM
    - LB-1 and Topotecan combined inhibited cell proliferation at 97.18% (100uM of LB1 + 2000nM Topotecan)

- *LB-1 Co-Therapy with Cisplatin*
    - LB-1 alone inhibited cell proliferation at 72.33% at 100uM
    - Cisplatin alone inhibited cell proliferation at 22.74% at 30uM
    - LB-1 and Cisplatin combined inhibited cell proliferation at 82.48% (100uM of LB1 + 30uM Cisplatin)

Additional preclinical studies of the Linebacker portfolio with each of the four drugs described above is currently being conducted by a major U.S. university.

In January 2023, REPROCELL completed an independent review of LB-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.

PBIO is also party to a two-year collaborative agreement with Dana-Farber Cancer Institute and Harvard Medical School to further the research LB-1. This collaboration provides for year 1 and year 2 research plans. 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.

Additionally, selection has been confirmed for animal studies. Dana-Farber/Harvard will deploy two animal xenograft models, with and without radiation. The current goal for completion of the animal studies is the end of second quarter of 2023, with data expected to be published in the third quarter of 2023. Initial Good Manufacturing Practices ("GMP") for LB-1 is expected to commence in the third quarter of 2023, in tandem with toxicology studies.

We currently anticipate initiating the preclinical requirements for an IND application submission for LB-1 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; and
- *Large Animal Studies*: combined therapy studies on large animals according to study protocol.

We aim to submit our IND application for LB-1 in mid-2024. We plan to operate our own Phase 1 safety study for LB-1 and will seek a strategic partner for future development following Phase 1.

ProPhase BioPharma has formed an advisory board with Daryl Thompson as its founding member. Daryl Thompson is President and Director of Scientific Initiatives at GRDG and is a biochemist twice nominated for the Nobel Prize in 2015 and 2016 for his work in cutting-edge organic and carbohydrate chemistry.

BE-Smart Esophageal Pre-Cancer Diagnostics Screening Test

We also own the worldwide exclusive rights to the BE-Smart Esophageal Pre-Cancer diagnostics screening test and related intellectual property assets. The BE-Smart test is aimed at early detection of esophageal cancer. It remains under development but has already been tested by an independent test lab, mProbe, Inc. ("mProbe"), 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. 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 help us 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.

In March 2023, we announced a collaboration with mProbe and Dr. Christopher Hartley of Mayo Clinic for the continued development of its BE-Smart Esophageal Pre-Cancer diagnostic screening test. We are pursuing initial commercialization of the BE-Smart test as an LDT (Laboratory Developed Test) and RUO (Research Use Only) for the third quarter of 2023 with full commercialization backed by insurance expected by mid-2024.

According to the National Institute of Health, over 20 million endoscopies are performed every year in the United States; 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%.

The BE-Smart test is being developed 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 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, once fully validated, 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.

Pharmaloz Contract Manufacturing

Our wholly-owned subsidiary, PMI, is a full-service contract manufacturer and private label developer of a broad range of non-GMO, organic and natural-based cough drops and lozenges and OTC drug and dietary supplement products. PMI provides consumer product development, pre-commercialization services, production, warehousing and distribution services for its customers. Our manufacturing facility, which is located in Lebanon, Pennsylvania, is registered with the U.S. Food and Drug Administration (the "FDA") and is certified organic and kosher.

As part of the sale of our former Cold-EEZE® business in March 2017, PMI entered into a manufacturing agreement with Mylan Consumer Healthcare Inc. (formerly known as Meda Consumer Healthcare Inc.) ("MCH") and Mylan Inc. (together with MCH, "Mylan") to supply various Cold-EEZE® lozenge products to Mylan following the sale for a period of five years with annual renewal options. Pursuant to the terms of the manufacturing agreement, Mylan (or an affiliate or designee) purchased the inventory of the Company's Cold-EEZE® brand and product line, and PMI agreed to manufacture certain products for Mylan, as described in the manufacturing agreement, at prices that reflect current market conditions for such products and include an agreed upon mark-up on our costs. On May 1, 2021, the manufacturing agreement was assigned by Mylan to Meda Consumer Healthcare, Inc. ("Meda") in connection with Meda's acquisitions of certain assets from Mylan, including the Cold-EEZE® brand and product line. In November 2022, Meda provided a notice to extend the original agreement for another year through March 2024.

In February 2023, we announced the acquisition of new equipment, which is expected to double our current capacity for pouch packaging by the second quarter of 2023, to meet the growing demand for our products and services. PMI is also planning for expansion of its lozenge manufacturing business. PMI had two new customers enter full production in 2022, resulting in the addition of over 3.5 million units, mostly in the fourth quarter of 2022. PMI formulated and launched seven new products for new and existing customers, totaling 1.75 million units in 2022. Additionally, PMI added three new customers, which are expected to enter full production in 2023, representing an estimated 1.0 million additional units.

TK Supplements

Our TK Supplements® product line is dedicated to promoting better health, energy and sexual vitality. Each of our herbal supplements is researched to determine the optimum blend of ingredients to ensure our customers receive premium quality products. To achieve this, we formulate with the highest quality ingredients derived from nature and ingredients enhanced by science. Our TK Supplements® product line includes Legendz XL®, a male sexual enhancement and Triple Edge XL®, an energy and stamina booster.

Legendz XL® has distribution in Rite Aid, Walgreens and other retailers, and via ecommerce, and is now achieving broader distribution at CVS and Walmart. Triple Edge XL®, is now gaining retailer acceptance as well.

In 2022 we restaged Triple Edge XL from a 56ct to a 20ct at CVS making the retail price more in line with competition. The result has been a double digit increase in consumer sales and a 40% expansion increase in the number of stores carrying the item. Based on performance Triple Edge XL is being reviewed for authorization in other major pharmacies.

Fluctuations in our Business

Our diagnostic services revenues are subject to fluctuations in COVID-19 testing demand. The demand for COVID-19 tests has been, and ProPhase expects it to continue to be, highly volatile, primarily driven by the emergence and severity of new variants, which are unpredictable.

Our personal genomics kit sales are impacted by seasonal holiday demand. We expect to generate greater revenues from this business during the first quarter of our fiscal year. While kits sales increase during the holiday season (fourth quarter), we will generally recognize revenue when the customer sends in their kit to our laboratory for processing and a genetic report is delivered, which we expect will occur in the following fiscal quarter.

Our contract manufacturing revenues are subject to seasonal fluctuations. As the majority of products that we manufacture for our customers are OTC healthcare and cold remedy products, our revenues tend to be higher in the first, third and fourth quarters during the cold season. Generally, a cold season is defined as the period from September to March when the incidence of the common cold rises as a consequence of the change in weather and other factors. Revenues are generally at their lowest levels during the second quarter when contract manufacturing demand generally declines.

Intellectual Property

We do not currently own any patents. We maintain various trademarks for our TK Supplements® products including Legendz XL® and Triple Edge XL®. We maintain a trademark for our genomic testing, Nebula Genomics®.

Licensing Agreements

Licensing Agreement with Global BioLife, Inc. for Equivir and Equivir G

We are party to a license agreement with Global BioLife, dated March 17, 2022, pursuant to which we acquired from Global BioLife a worldwide exclusive right and license (the "Equivir License") under certain patents identified in the license agreement and know-how (collectively, the "Equivir Licensed IP") to exploit any product comprising or containing Equivir Licensed Compound (as defined in the license agreement) ("Equivir Licensed Products") for all uses (the "Equivir Field").

Under the terms of the license agreement, Global BioLife reserves the right, solely for itself to use the Equivir Licensed IP to research and develop, including modify, enhance, improve, Equivir Licensed Products in the Equivir Field.

Subject to certain conditions set forth in the license agreement, we may grant sublicenses to our rights under the license agreement to any of our affiliates or any third party. We may assign our rights under the license agreement without consent (i) to our affiliates or (b) to an acquirer of all or substantially all of our assets to which this agreement relates. Under the terms of the license agreement, we or our affiliates have a fully-paid up, irrevocable, exclusive right of first refusal to obtain exclusive global rights to certain patents identified in the license agreement.

Licensing Agreement with BioLife, Inc. for Linebacker LB-1 and LB-2

We are also party to a license agreement with Global BioLife, dated July 19, 2022, pursuant to which we acquired from Global BioLife a worldwide exclusive right and license under certain patents identified in the License Agreement (the "Linebacker Licensed Patents") and know-how (collectively, the "Linebacker Licensed IP") to exploit any compound covered by the Linebacker Licensed Patents (the "Linebacker Licensed Compound"), including Linebacker LB-1 and LB-2, and any product comprising or containing a Linebacker Licensed Compound ("Linebacker Licensed Products") in the treatment of cancer, inflammatory diseases or symptoms, memory-related syndromes, diseases or symptoms including dementia and Alzheimer's Disease (the "Linebacker Field"). Under the terms of the license agreement, Global BioLife reserves the right, solely for itself and for GRDG Sciences, LLC ("GRDG") to use the Linebacker Licensed Compound and Linebacker Licensed IP solely for research purposes inside the Linebacker Field and for any purpose outside the Linebacker Field.

Subject to certain conditions set forth in the license agreement, we may grant sublicenses (including the right to grant further sublicenses) to our rights under the license agreement to any of our affiliates or any third party with the prior written consent of LiGlobal BioLife, which consent may not be unreasonably withheld. Either party to the license agreement may assign its rights under the license agreement (i) in connection with the sale or transfer of all or substantially all of our assets to a third party, (b) in the event of a merger or consolidation with a third party or (iii) to an affiliate; in each case contingent upon the assignee assuming in writing all of the obligations of its assignor under the license agreement.

Under the terms of the license agreement, we were required to pay to Licensor a one-time upfront license fee of $50,000 within 10 days of the effective date and must pay an additional $900,000 following the achievement of a first Phase 3 study which may be required by the FDA for the first Linebacker Licensed Product and an additional $1 million upon the receipt of regulatory approval of a New Drug Application ("NDA") for the first Licensed Product.

During the term of the license agreement, we are also required to pay to Global BioLife 3% royalties on Net Revenue (as defined in the license agreement) of each Linebacker Licensed Product, but no less than the minimum royalty of $250,000 of Net Revenue per year minus any royalty payments for any required third party licenses.

Under the terms of the license agreement, the development of the Linebacker Licensed Compound and the first Linebacker Licensed Product for the United States will be governed by a clinical development plan, including anticipated timeline goals in connection with the clinical trials for the first Linebacker Licensed Product (the "Linebacker Development Plan"). The Linebacker Development Plan may be amended by the mutual written agreement of the parties to the Linebacker License Agreement based upon results of preclinical studies or clinical trials, including safety and effectiveness, guidance by the FDA, or upon the agreement of the parties.

The license agreement will expire automatically on a country-by-country basis upon the last to occur of the expiration of the last to expire Linebacker Licensed Patents (the "Term"). Following the expiration of the Term, and on a country-by-country basis, the license will become non-exclusive, perpetual, fully-paid, unrestricted, royalty-free and irrevocable.

The license agreement may be terminated by us for any reason or for convenience in our sole discretion: (i) on a Linebacker Licensed Product-by-Linebacker Licensed Product or a country-by-country basis or (ii) in its entirety, in either case ((i) or (ii)) for convenience upon 180 days prior written notice to Global BioLife. Global BioLife may terminate the license agreement solely for a material breach of the license agreement by us, which is not cured within 60 days' of written notice to us of such breach.

Government Regulation

Our business is subject to extensive governmental regulation by various federal, state, and local agencies as described below.

U.S. Food and Drug Administration

Diagnostic Testing Services

The FDA has regulatory responsibility for diagnostic testing instruments, test kits, reagents and other devices used by clinical laboratories. The FDA enforces laws and regulations that govern the development, testing, manufacturing, performance, labeling, advertising, marketing, distribution and surveillance of diagnostic products, including COVID-19 diagnostics authorized by the FDA under and EUA, and it regularly inspects and reviews the manufacturing processes and product performance of diagnostic products.

Since 2014, there have been ongoing discussions and advocacy between stakeholders, including the clinical laboratory industry, the FDA, and Congress, about potential FDA regulation of laboratory-developed tests (LDTs), which are assays developed and performed in-house by clinical laboratories that can be made available to the public without pre-market review by the FDA (although COVID-19 LDTs are currently subject to FDA pre-market requirements, as a consequence of the national health emergency). Various regulatory and legislative proposals are under consideration, including some that could increase general FDA oversight of clinical laboratories and LDTs. The outcome and ultimate impact of such proposals on our business is difficult to predict at this time.

Pharmaceutical Regulation

The manufacturing and distribution of pharmaceutical products are subject to extensive regulation by the federal government, primarily through the FDA and the Drug Enforcement Administration ("DEA"), and to a lesser extent by state and local government agencies. The Food, Drug, and Cosmetic Act ("FFDCA") and other federal statutes and regulations govern or influence the manufacture, labeling, testing, storage, record keeping, approval, advertising and promotion of OTC pharmaceutical products.

Facilities used in the manufacture, packaging, labeling and repackaging of drug products, including OTC drug products, must be registered with the FDA and are subject to FDA inspection to ensure that drug products are manufactured in accordance with current Good Manufacturing Practice ("cGMPs").

FDA approval is required before any "new drug" may be marketed, including new formulations, strengths, dosage forms and generic versions of previously approved drugs. Generally, to obtain FDA approval of a "new drug" a company must file a NDA or Abbreviated New Drug Application ("ANDA").

Under the OTC monograph system, selected OTC drugs are generally recognized as safe and effective and do not require the submission and approval of an NDA or ANDA prior to marketing.

The FDA OTC monographs include well-known ingredients and specify requirements for permitted indications, required warnings and precautions, allowable combinations of ingredients and dosage levels. Drug products marketed under the OTC monograph system must conform to specific quality, formula and labeling requirements; however, these products can be developed and marketed without prior FDA approval unlike products requiring a submission and approval of an ANDA or NDA. In general, it is less costly to develop and bring to market a product regulated under the OTC monograph system. From time to time, adequate information may become available to the FDA regarding certain prescription drug products that will allow the reclassification of those products as no longer requiring the approval of an ANDA or NDA prior to marketing. For this reason, there may be increased competition and lower profitability related to a particular OTC-switch product should it be reclassified to the OTC monograph system.

Noncompliance with applicable requirements can result in product recalls, seizure of products, injunctions, suspension of production and/or distribution, refusal of the government or third parties to enter into contracts with us, withdrawal or suspension of the applicable regulator's review of our drug applications, civil penalties and criminal fines, and disgorgement of profits.

Dietary Supplement Regulation

The FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and OTC). Under the Dietary Supplement Health and Education Act (the "DSHEA"), which was passed in 1994, dietary supplements that were in commerce prior to 1994 are broadly presumed safe. For these supplements, manufacturers do not need to register their products with the FDA nor get FDA approval before producing or selling them. Manufacturers must make sure that product label information is truthful and not misleading. For these products, the FDA is responsible for taking action against any unsafe or misbranded dietary supplement product after it reaches the market. All new ingredients marketed within dietary supplements after 1994 that are not found in food must meet a stricter set of regulations and notification prior to release in the marketplace.

In June 2007, pursuant to the authority granted by the FFDCA as amended by DSHEA, the FDA published detailed cGMP regulations that govern the manufacturing, packaging, labeling, and holding operations of dietary supplement manufacturers. The cGMP regulations, among other things, impose significant recordkeeping requirements on manufacturers. The cGMP requirements are in effect for all manufacturers, and the FDA is conducting inspections of dietary supplement manufacturers pursuant to these requirements. The failure of a manufacturing facility to comply with the cGMP regulations renders products manufactured in such facility "adulterated" and subjects such products and the manufacturer to a variety of potential FDA enforcement actions.

In addition, under the Food Safety Modernization Act, (the "FSMA"), which was enacted on January 2, 2011, the manufacturing of dietary ingredients contained in dietary supplements are subject to similar or even more burdensome manufacturing requirements. The FSMA requires importers of food, including dietary supplements and dietary ingredients, to conduct verification activities to ensure that the food they might import meets applicable domestic requirements. The FSMA also expands the reach and regulatory powers of the FDA with respect to the production and importation of food, including dietary supplements. The expanded reach and regulatory powers include the FDA's ability to order mandatory recalls, administratively detain domestic products, require certification of compliance with domestic requirements for imported foods associated with safety issues and administratively revoke manufacturing facility registrations, effectively enjoining manufacturing of dietary ingredients and dietary supplements without judicial process. The regulation of dietary supplements may increase or become more restrictive in the future.

Under FFDCA, dietary supplements are subject to both adulteration and misbranding provisions. Adulterated products are those that contain unlisted ingredients or are not prepared or packaged under the FDA cGMPs for dietary supplements and misbranded products are those with false or misleading labels. Adulterated or misbranded products are subject to the full range of civil and criminal enforcement measures under the FFDCA and all violations of FFDCA are subject to criminal enforcement at the FDA's discretion.

We are also subject to the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which was passed in 2006 to amend the FFDCA with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, among other things. The law requires that the manufacturer, packer or distributor of a dietary supplement or OTC drug notify the FDA of all serious adverse events it receives associated with their dietary supplement or OTC product within 15 business days. Serious adverse events are defined as those that result in death, a life-threatening experience, in-patient hospitalization, a persistent or significant disability or incapacity, congenital anomaly or birth defect, as well as situations where medical/surgical intervention is required to prevent the previously listed events.

Consumer Product Safety Commission

Under the Poison Prevention Packaging Act ("PPPA"), the Consumer Product Safety Commission ("CPSC") has authority to require that certain dietary supplements and certain pharmaceuticals have child-resistant packaging to help reduce the incidence of accidental poisonings. The CPSC has published regulations requiring iron-containing dietary supplements and various pharmaceuticals to have child resistant packaging and has established rules for testing the effectiveness of child-resistant packaging and for ensuring senior adult effectiveness. The manufacturer of any product that is subject to any CPSC rule, ban, standard or regulation must also certify that, based on a reasonable testing program, the product complies with CPSC requirements.

Federal Trade Commission

Advertising of our products in the United States is subject to regulation by the Federal Trade Commission (the "FTC") under the Federal Trade Commission Act (the "FTC Act"). Under the FTC's Substantiation Doctrine, an advertiser is required to have a "reasonable basis" for all objective product claims before the claims are made. Failure to adequately substantiate claims may be considered either deceptive or unfair practices. Pursuant to this FTC requirement, we are required to have adequate substantiation for all material advertising claims that we make for any products sold in the United States.

In recent years, the FTC has initiated numerous investigations of and actions against companies that sell dietary supplements. The FTC has issued guidance to assist companies in understanding and complying with its substantiation requirement. We believe that we have adequate substantiation for all material advertising claims that we make for our products in the United States, and we believe that we have organized the documentation to support our advertising and promotional practices in compliance with these guidelines. However, no assurance can be given that the FTC would reach the same conclusion if it were to review or question our substantiation for our advertising claims in the United States.

The FTC may enforce compliance with the law in a variety of ways, both administratively and judicially, using compulsory process, cease and desist orders, and injunctions. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, divestiture of assets, rescission of contracts, and such other relief as the agency deems necessary to protect the public. Violation of these orders could result in substantial financial or other penalties. Although we have not been the subject of any action by the FTC, no assurance can be given that the FTC will not question our advertising or other operations in the United States in the future. Any action in the future by the FTC could materially and adversely affect our ability to successfully market our products in the United States.

Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

The performance of laboratory diagnostic services is subject to extensive U.S. regulation, and many of these statutes and regulations have not been interpreted by the courts. CLIA extends federal oversight to virtually all physician practices performing clinical laboratory testing and to clinical laboratories operating in the United States by requiring that they be certified by the federal government or, in the case of clinical laboratories, by a federally approved accreditation agency. Standards for testing under CLIA are based on the complexity of the tests performed by the laboratory, with tests classified as "high complexity," "moderate complexity," or "waived." Laboratories performing high-complexity testing are required to meet more stringent requirements than moderate-complexity laboratories. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties.

State and Laboratory Licensure

We are subject to regulation under state law. State laws, including those of New Jersey and New York, require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. For example, New York laws and regulations establish standards for: quality management systems; qualifications, responsibilities, and training; facility design and resource management; pre-analytic, analytic (including validation and quality control), and post-analytic systems; and quality assessments and improvements. The New York state laboratory laws and regulations are more stringent than CLIA. New York law mandates proficiency testing for laboratories licensed under New York law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York State Department of Health, or NYSDOH, may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. NYSDOH also must approve laboratory developed tests before the test is offered in New York. Should we be found out of compliance with New York or any other applicable laboratory standards of practice, we could be subject to such sanctions, which could harm our business. Applicable statutes and regulations could also be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly.

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act ("HIPAA") was designed to address issues related to the security and confidentiality of health information and to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions. These regulations apply to health plans and healthcare providers that conduct standard transactions electronically and healthcare clearinghouses (covered entities). Six such regulations include: (i) the Transactions and Code Sets Rule; (ii) the Privacy Rule; (iii) the Security Rule; (iv) the Standard Unique Employer Identifier Rule, which requires the use of a unique employer identifier in connection with certain electronic transactions; (v) the National Provider Identifier Rule, which requires the use of a unique healthcare provider identifier in connection with certain electronic transactions; and (vi) the Health Plan Identifier Rule, which required the use of a unique health plan identifier in connection with certain electronic transactions. We believe that we are in compliance in all material respects with each of the HIPAA Rules identified above.

The Privacy Rule regulates the use and disclosure of protected health information ("PHI") by covered entities. It also sets forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, such as the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. The Privacy Rule requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves the creation, receipt, maintenance, or transmission of PHI. We believe that we are in compliance in all material respects with the requirements of the HIPAA Privacy Rule.

On December 12, 2018, HHS issued a request for information (RFI) seeking input from the public on how the HIPAA regulations and the Privacy Rule, in particular, could be modified to amend existing, or impose additional, obligations relating to the processing of PHI. Subsequent to the RFI, on January 21, 2021, HHS published a notice of proposed rulemaking ("NPRM") containing potential modifications to the Privacy Rule addressing standards that may impede the transition to value-based health care. We are monitoring the NPRM process. If modifications to the Privacy Rule are adopted, they may impact our compliance obligations under HIPAA.

The U.S. Health Information Technology for Economic and Clinical Health Act ("HITECH"), which was enacted in February 2009, with regulations effective on September 23, 2013, strengthened and expanded the HIPAA Privacy and Security Rules and their restrictions on use and disclosure of PHI. HITECH includes, but is not limited to, prohibitions on exchanging PHI for remuneration and additional restrictions on the use of PHI for marketing. HITECH also fundamentally changes a business associate's obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. Moreover, HITECH requires covered entities to provide notice to individuals, HHS, and, as applicable, the media when unsecured PHI is breached, as that term is defined by HITECH. Business associates are similarly required to notify covered entities of a breach. We believe our policies and procedures are fully compliant with HIPAA as modified by the HITECH requirements.

The administrative simplification provisions of HIPAA mandate the adoption of standard unique identifiers for healthcare providers. The intent of these provisions is to improve the efficiency and effectiveness of the electronic transmission of health information. The National Provider Identifier Rule requires that all HIPAA-covered healthcare providers, whether they are individuals or organizations, must obtain an NPI to identify themselves in standard HIPAA transactions. NPI replaces the unique provider identification number and other provider numbers previously assigned by payers and other entities for the purpose of identifying healthcare providers in standard electronic transactions. The Company believes that it is in compliance with the HIPAA National Provider Identifier Rule in all material respects.

The Health Plan Identifier ("HPID") is a unique identifier designed to furnish a standard way to identify health plans in electronic transactions. The Centers for Medicare and Medicaid Services ("CMS") published the final rule adopting the HPID for health plans required by HIPAA on September 12, 2012. Effective October 31, 2014, CMS announced a delay, until further notice, in enforcement of regulations pertaining to health plan enumeration and use of the HPID in HIPAA transactions adopted in the HPID final rule. On October 28, 2019, CMS published a final rule rescinding the adopted standard unique HPID and implementation specifications and requirements for its use and other entity identifier and implementation specifications for its use, effective December 27, 2019. This delay remains in effect. We will continue to monitor future developments related to the HPID and respond accordingly.

Violations of the HIPAA provisions could result in civil and/or criminal penalties, including significant fines and up to 10 years in prison. HITECH also significantly strengthened HIPAA enforcement by increasing the civil penalty amounts that may be imposed, requiring HHS to conduct periodic audits to confirm compliance and authorizing state attorneys general to bring civil actions seeking either injunctions or damages in response to violations of the HIPAA privacy and security regulations that affect the privacy of state residents.

The total cost associated with meeting the ongoing requirements of HIPAA and HITECH is not expected to be material to our operations or cash flows. However, future regulations and interpretations of HIPAA and HITECH could impose significant costs on us.

In addition to the HIPAA regulations described above, numerous other data protection, privacy and similar laws govern the confidentiality, security, use, and disclosure of personal information. These laws vary by jurisdiction, but they most commonly regulate or restrict the collection, use, and disclosure of medical and financial information and other personal information. In the U.S., some state laws are more restrictive and, therefore, are not preempted by HIPAA. Penalties for violation of these laws may include sanctions against a laboratory's licensure, as well as civil and/or criminal penalties.

Congress and state legislatures also have been considering new legislation relating to privacy and data protection. For example, on June 28, 2018, the California legislature passed the California Consumer Privacy Act ("CCPA"), which became effective January 1, 2020. The CCPA created new transparency requirements and granted California residents several new rights with regard to their personal information. In addition, in November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative, which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the CPPA. The amendments introduced by the CPRA went into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. We have implemented processes to manage compliance with the CCPA and continue to assess the impact of the CPRA on our business as additional information and guidance becomes available.

Effective August 14, 2020, the Substance Abuse and Mental Health Services Administration of HHS ("SAMHSA") announced the finalization of proposed changes to the Confidentiality of Substance Use Disorder Patient Records regulation, 42 Code of Federal Regulations Part 2. This regulation protects the confidentiality of patient records relating to the identity, diagnosis, prognosis, or treatment that are maintained in connection with the performance of any federally assisted program or activity relating to substance use disorder education, prevention, training, treatment, rehabilitation, or research. Under the regulation, patient identifying information may only be released with the individual's written consent, subject to certain limited exceptions. The latest changes to this regulation seek to better facilitate care coordination, while maintaining more stringent confidentiality of substance use disorder information. We have adopted changes to our policies and procedures necessary for compliance.

Genetic Privacy and Testing Laws

We are subject to myriad laws designed to establish safeguards regarding the conduct of genomic testing and analysis and to protect against the misuse of genetic information and human biological specimens, collectively, "samples", from which genetic information can be derived. These laws vary in their scope and in the nature of their requirements and restrictions. For example, certain genetic privacy laws prohibit the retention of samples after performing a genomic analysis in addition to prohibiting the use or disclosure of genetic information for certain purposes, such as research, without appropriate informed consent from the individual or without sufficient anonymization. The applicability of such informed consent requirements may also depend on the identifiability of the genetic information or sample and the purposes of which it is used. Other laws may impose additional requirements, including requirements regarding institutional review board review and approval for certain research uses of genetic information or samples requirements to implement certain security controls in connection with the transfer of genetic information. We must comply with such genetic privacy and testing laws in our collection, use, disclosure, and retention of genetic information and samples.

Other Regulatory Oversight

We are also subject to regulation under various state, local, and international laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising, and distribution of dietary supplements and OTC drugs. For example, Proposition 65 in the State of California is a list of substances deemed to pose a risk of carcinogenicity or birth defects at or above certain levels. If any such ingredient exceeds the permissible levels in a dietary supplement, cosmetic, or drug, the product may be lawfully sold in California only if accompanied by a prominent warning label alerting consumers that the product contains an ingredient linked to cancer or birth defect risk. Private attorney general actions as well as California attorney general actions may be brought against non-compliant parties and can result in substantial costs and fines.

Reimbursement

Billing for diagnostic services is complex and subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payers, such as patients, insurance companies, Medicare, Medicaid, other government agencies and employer groups. Failure to accurately bill for our services could have a material adverse effect on our business.

We bill third-party payors, both commercial and government, using Current Procedural Terminology ("CPT") codes, which are published by the American Medical Association ("AMA"). In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are priced and paid under Medicare. On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for an advanced diagnostic laboratory test ("ADLT")), private payor payment rates and volumes for clinical diagnostic laboratory tests, or CDLTs. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We do not believe that any of our tests meet the current definition of ADLTs. We therefore report private payor rates for our tests every three years.

As required under PAMA, CMS uses the data reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates. For tests furnished on or after January 1, 2019, Medicare payments for CDLTs are based upon reported private payor rates. For a CDLT that is assigned a new or substantially revised CPT code, the initial payment rate is assigned using the gap-fill methodology, as under prior law.

On December 20, 2019, President Trump signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act ("LAB Act"). The LAB Act delayed by one year the reporting of payment data under PAMA for CDLTs that are not ADLTs until the first quarter of 2021. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was signed into law on March 27, 2020, delayed the reporting period by an additional year, until the first quarter of 2022. On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (S. 610) further delayed the reporting requirement. On December 29, 2022, Section 4114 of Consolidated Appropriations Act, 2023 again delayed the next data reporting period for CDLTs that are not ADLTs. The next data reporting period of January 1, 2024 through March 31, 2024, will be based on the original data collection period of January 1, 2019 through June 30, 2019.

In addition, under PAMA, as amended by the LAB Act, any reduction to a particular payment rate resulting from the new methodology is limited to 10% per test per year in 2020 and to 15% per test per year in each of the years 2021 through 2023. The CARES Act delayed the 15% cut scheduled to take effect on January 1, 2021, for one year.

Fraud and Abuse Laws and Regulations

Existing U.S. laws governing federal healthcare programs, including Medicare and Medicaid, as well as similar state laws, impose a variety of broadly described fraud and abuse prohibitions on healthcare providers, including clinical laboratories. These laws are interpreted liberally and enforced aggressively by multiple government agencies, including the U.S. Department of Justice, OIG and various state agencies. Historically, the clinical laboratory industry has been the focus of major governmental enforcement initiatives. The U.S. government's enforcement efforts have been conducted under regulations such as HIPAA, which includes several provisions related to fraud and abuse enforcement, including the establishment of a program to coordinate and fund U.S., state and local law enforcement efforts, and the Deficit Reduction Act of 2005, which includes requirements directed at Medicaid fraud, including increased spending on enforcement and financial incentives for states to adopt false claims act provisions similar to the U.S. False Claims Act. Amendments to the False Claims Act, and other enhancements to the U.S. fraud and abuse laws enacted as part of the ACA, have further increased fraud and abuse enforcement efforts and compliance risks. For example, the ACA established an obligation to report and refund overpayments from Medicare or Medicaid within 60 days of identification (whether or not paid through any fault of the recipient); failure to comply with this requirement can give rise to additional liability under the False Claims Act and Civil Monetary Penalties statute.

The U.S. Anti-Kickback Statute prohibits knowingly providing anything of value in return for, or to induce the referral of, Medicare, Medicaid or other U.S. healthcare program business. Violations can result in imprisonment, fines, penalties, and/or exclusion from participation in U.S. healthcare programs. The OIG has published "safe harbor" regulations that specify certain arrangements that are protected from prosecution under the Anti-Kickback Statute if all conditions of the relevant safe harbor are met. Failure to fit within a safe harbor does not necessarily constitute a violation of the Anti-Kickback Statute; rather, the arrangement would be subject to scrutiny by regulators and prosecutors and would be evaluated on a case-by-case basis. Many states have their own Medicaid anti-kickback laws, and several states also have anti-kickback laws that apply to all payers (*i.e.*, not just government healthcare programs).

From time to time, the OIG issues alerts and other guidance on certain practices in the healthcare industry that implicate the Anti-Kickback Statute or other fraud and abuse laws. OIG Special Fraud Alerts and Advisory Opinions relevant to the Company set forth a number of practices allegedly engaged in by some clinical laboratories and healthcare providers that raise issues under the U.S. fraud and abuse laws, including the Anti-Kickback Statute. These practices include: (i) providing employees to furnish valuable services for physicians (other than collecting patient specimens for testing) that are typically the responsibility of the physicians' staff; (ii) offering certain laboratory services at prices below fair market value in return for referrals of other tests that are billed to Medicare at higher rates; (iii) providing free testing to physicians' managed care patients in situations where the referring physicians benefit from such reduced laboratory utilization; (iv) providing free pickup and disposal of biohazardous waste for physicians for items unrelated to a laboratory's testing services; (v) providing general-use facsimile machines or computers to physicians that are not exclusively used in connection with the laboratory services; (vi) providing free testing for healthcare providers, their families and their employees (i.e., so-called "professional courtesy" testing); (vii) compensation paid by laboratories to physicians for blood specimen processing and for submitting patient data to registries; and (viii) the provision of discounts on laboratory services billed to customers in return for the referral of U.S. healthcare program business.

In addition to the Anti-Kickback Statute, in October 2018, the U.S. enacted the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"). EKRA is an all-payer anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. As drafted, an EKRA prohibition on incentive compensation to sales employees is inconsistent with the federal anti-kickback statute and regulations, which permit payment of employee incentive compensation, a practice that is common in the industry. Only one court has addressed the application of EKRA. That case was decided by the United States District Court of Hawaii and involved a lawsuit between a laboratory and an employee. The Court ruled that the commission-based compensation provisions of the laboratory employee's contract did not violate EKRA. Although this may be a favorable interpretation of EKRA for laboratory compensation structures, we cannot be assured that courts in our jurisdiction will reach the same conclusion or that the decision will not be overturned if there is an appeal. Significantly, EKRA permits the U.S. Department of Justice to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but such regulations have not yet been issued. We are working through our trade association to address the scope of EKRA and are seeking clarification or correction.

Enrollment and re-enrollment in U.S. healthcare programs, including Medicare and Medicaid, are subject to certain program integrity requirements intended to protect the programs from fraud, waste, and abuse. In September 2019, CMS published a final rule implementing program integrity enhancements to provider enrollment requiring Medicare, Medicaid, and Children's Health Insurance Program ("CHIP") providers and suppliers to disclose on an enrollment application or a revalidation application any current or previous direct or indirect affiliation with a provider or supplier that (1) has uncollected debt; (2) has been or is subject to a payment suspension under a federal health care program; (3) has been or is excluded by the OIG from Medicare, Medicaid, or CHIP; or (4) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked. This rule permits CMS to deny enrollment based on such an affiliation when CMS determines that the affiliation poses an undue risk of fraud, waste, or abuse. CMS is phasing in this new affiliation disclosure requirement.

Under another U.S. statute, known as the Stark Law or "physician self-referral" prohibition, physicians who have a financial or a compensation relationship with a commercial laboratory may not, unless an exception applies, refer Medicare or Medicaid patients for testing to the laboratory, regardless of the intent of the parties. Similarly, laboratories may not bill Medicare or Medicaid for services furnished pursuant to a prohibited self-referral. There are several Stark Law exceptions that are relevant to arrangements involving clinical laboratories, including: (i) fair market value compensation for the provision of items or services; (ii) payments by physicians to a laboratory for commercial laboratory services; (iii) ancillary services (including laboratory services) provided within the referring physician's own office, if certain criteria are satisfied; (iv) physician investment in a company whose stock is traded on a public exchange and has stockholder equity exceeding $75.0 million; and (v) certain space and equipment rental arrangements that are set at a fair market value rate and satisfy other requirements. Many states have their own self-referral laws as well, which in some cases apply to all patient referrals, not just government reimbursement programs.

In December 2020, the OIG and CMS published final rules to amend the regulations implementing the Anti-Kickback Statute and the Stark Law, respectively. The amendments are primarily intended to alleviate perceived impediments to coordinated care and value-based compensation arrangements through new safe harbors to the Anti-Kickback Statute and new exceptions to the Stark Law and have varying degrees of applicability to laboratories. The CMS final rule incorporates laboratories and permits support for value-based arrangements, under certain conditions for purposes of the Stark Law. However, the OIG final rule excludes laboratories from protection under the Anti-Kickback Statute safe harbors for value-based arrangements.

There are a variety of other types of U.S. and state fraud and abuse laws, including laws prohibiting submission of false or fraudulent claims. We seek to conduct our business in compliance with all U.S. and state fraud and abuse laws. We are unable to predict how these laws will be applied in the future, and no assurances can be given that our arrangements will not be subject to scrutiny under such laws. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid, and other U.S. or state healthcare programs, significant criminal and civil fines and penalties, and loss of licensure. Any exclusion from participation in a U.S. healthcare program, or material loss of licensure, arising from any action by any federal or state regulatory or enforcement authority, would likely have a material adverse effect on our business. In addition, any significant criminal or civil penalty resulting from such proceedings could have a material adverse effect on our business.

Competition

Our principal competition for our lab diagnostic services are commercial laboratories, such as Quest Diagnostics Incorporated and Laboratory Corporation of America Holdings, both of which have significant infrastructures and resources to support their diagnostic processing services. In addition, we compete with large, multispecialty group medical clinics and health systems. Academic medical university-based clinics may also provide in-house clinical laboratories offering COVID-19 and other RPP Molecular tests. Additionally, we compete against regional clinical laboratories providing diagnostic services, including Interpace Biosciences, Inc.

The number of companies entering the personal genomics market has increased in recent years. We face competition from other companies attempting to capitalize on the same, or similar, opportunities as we are, including those with existing diagnostic, laboratory services and other companies entering the personal genetics market with new offerings such as direct access and/or consumer self-pay tests and genetic interpretation services. Some of our current and potential competitors have longer operating histories and greater financial, technical, marketing and other resources than we do. These factors may allow our competitors to respond more quickly or efficiently than we can to new or emerging technologies. These competitors may engage in more extensive research and development efforts, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies, which may allow them to build larger customer bases than we will be able to achieve. Our competitors may develop products or services that are similar to our products and services or that achieve greater market acceptance than our products and services. This could attract customers away from our services and reduce our market share.

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include major multi-national pharmaceutical established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staffs, established manufacturing capabilities and facilities, and experienced marketing organizations with well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies that have greater resources. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated on our competitors. Competition may increase further as a result of advances in the commercial applicability of genome editing or other new technologies and greater availability of capital for investment in these industries. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment for participation in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, have broader acceptance and higher rates of reimbursement by third-party payors, or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, new technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitor products. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, and availability of reimbursement.

We compete with other contract manufacturers of OTC drug and dietary supplement products. These suppliers range widely in size. We compete primarily on the basis of price, quality and service. Management believes that our manufacturing capacity and abilities offer a significant advantage over many of our competitors in the full-service contract development and manufacturing industry. We have over 20 years of manufacturing experience and industry know how in large scale batch production of OTC lozenge products. To the extent that any of our competitors are able to offer better prices, quality and/or services, however, we could lose customers and our sales and margins may decline.

The OTC healthcare products and dietary supplements industries are highly competitive. Many of the participants in these industries have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, and distribution experience than we do. We believe that our ability to continue to compete in these industries will depend on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support. However, our failure to appropriately and timely respond to consumer preferences and demand for new products could significantly harm our business, financial condition and results of operations. Furthermore, unfavorable publicity or consumer perception of products we develop and commercialize could have a material adverse effect on our business and operations.

Human Capital Management

We consider talent attraction, development, engagement and retention a key driver to our business success. We are committed to developing a comprehensive, cohesive and positive company culture and employee experience. At December 31, 2022, we employed 129 full-time employees, of which 47 were engaged in our contract manufacturing operations and 82 employees were providing diagnostic services.

We emphasize a number of measures and objectives in managing our human capital assets, including, among others, employee safety and wellness, talent acquisition and retention, employee engagement, development and training, diversity and inclusion, and compensation. None of our employees are represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

We are committed to fostering an environment where all employees can grow and thrive. A diverse workforce results in a broader range of perspectives, helping drive our commitment to innovation. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our cash and equity incentive plans are to attract, retain and reward personnel through the granting of cash-based and stock-based compensation awards, in order to increase stockholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

The success of our business is fundamentally connected to the well-being of our employees. We understand that good health leads to better performance. We provide our employees and their families with access to a variety of flexible and convenient health and wellness programs, health reimbursement accounts and retirement savings plan Our health and wellness programs include benefits that provide support to manage events that may require time away from work or that impact their financial well-being and that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. We regularly evaluate our benefits package to make modifications that are aligned with the competitive landscape, legislative changes, and the unique needs of our business and culture.

Corporate Information

ProPhase was initially organized in Nevada in July 1989. Effective June 18, 2015, we changed our state of incorporation from the State of Nevada to the State of Delaware. Our principal executive offices are located at 711 Stewart Avenue, Suite 200, Garden City, New York 11530 and our telephone number is 215-345-0919.

Where You Can Find Other Information

We file periodic and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). We make available on our website (www.ProPhaseLabs.com) free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to or exhibits included in those reports as soon as reasonably practical after we electronically file such materials with or furnish them to the SEC. Information appearing on our website is not part of this Annual Report. In addition, the SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements regarding issuers that file electronically with the SEC, including the Company.

Item 1A. Risk Factors

The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from our expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below and in other sections of this Annual Report and in our subsequent filings with the SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial, may also affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report.

Risks Related to Our Business Generally

Our failure to manage our growth successfully could harm our growth and operating results.

Since the sale of our Cold-EEZE™ business in March 2017, we have been actively exploring new product technologies, applications, product line extensions and other new product and business opportunities.

In October 2020, we purchased our first CLIA licensed laboratory in Old Bridge, New Jersey, where we offer a variety of important medical tests, including, among others, COVID-19 diagnostic testing and Influenza A and B. In December 2020, we expanded our diagnostic services to a second location in Garden City, New York. In August 2021, we acquired Nebula, a privately-owned personal genomics company. We are in the process of integrating Nebula's whole genome sequencing services with the clinical diagnostic services already offered at our CLIA-certified molecular testing laboratories. In March 2022, we formed ProPhase Biopharma, Inc. for the licensing, development and commercialization of novel drugs, dietary supplements, and compounds. We may in the future consider and pursue investments and acquisitions in other sectors and industries.

We have and will continue to incur significant expenses as we grow our new businesses. In order for us to be profitable, we must generate sufficient revenue to cover our expenses. There can be no assurance that our different business lines will succeed or that we will be successful in initiating or acquiring any new lines of business in the future, or that any such new business lines will achieve profitability. As of December 31, 2022, we had working capital of approximately $40.7 million, which we believe is a sufficient level of working capital to support our businesses for at least the next twelve months.

Our businesses are subject to significant competitive pressures.

Our principal competition for our lab diagnostic services are commercial laboratories, such as Quest Diagnostics Incorporated and Laboratory Corporation of America Holdings, both of which have significant infrastructures and resources to support their diagnostic processing services. In addition, we compete with large, multispecialty group medical clinics and health systems. Academic medical university-based clinics may also provide in-house clinical laboratories offering COVID-19 and other RPP Molecular tests. Additionally, we compete against regional clinical laboratories providing diagnostic services, including Interpace Biosciences, Inc. If we are unable to compete effectively, our earnings may be significantly negatively impacted.

The number of companies entering the personal genomics market has increased in recent years. We face competition from other companies attempting to capitalize on the same, or similar, opportunities as we are, including those with existing diagnostic, laboratory services and other companies entering the personal genetics market with new offerings such as direct access and/or consumer self-pay tests and genetic interpretation services. Some of our current and potential competitors have longer operating histories and greater financial, technical, marketing and other resources than we do. These factors may allow our competitors to respond more quickly or efficiently than we can to new or emerging technologies. These competitors may engage in more extensive research and development efforts, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies, which may allow them to build larger customer bases than we will be able to achieve. Our competitors may develop products or services that are similar to our products and services or that achieve greater market acceptance than our products and services. This could attract customers away from our services and reduce our market share.

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include major multi-national pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staffs, established manufacturing capabilities and facilities, and experienced marketing organizations with well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies that have greater resources. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated on our competitors. Competition may increase further as a result of advances in the commercial applicability of genome editing or other new technologies and greater availability of capital for investment in these industries. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment for participation in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, have broader acceptance and higher rates of reimbursement by third-party payors, or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, new technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitor products. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, and availability of reimbursement.

We compete with other contract manufacturers of OTC drug and dietary supplement products. These suppliers range widely in size. We compete primarily on the basis of price, quality and service. Management believes that our manufacturing capacity and abilities offer a significant advantage over many of our competitors in the full-service contract development and manufacturing industry. We have over 20 years of manufacturing experience and industry know how in large scale batch production of OTC lozenge products. To the extent that any of our competitors are able to offer better prices, quality and/or services, however, we could lose customers and our sales and margins may decline.

The OTC healthcare products and dietary supplements industries are highly competitive. Many of the participants in these industries have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, and distribution experience than we do. We believe that our ability to continue to compete in these industries will depend on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support. However, our failure to appropriately and timely respond to consumer preferences and demand for new products could significantly harm our business, financial condition and results of operations. Furthermore, unfavorable publicity or consumer perception of products we develop and commercialize could have a material adverse effect on our business and operations.

Disruptions to our supply chain could materially and adversely affect our business, financial condition and results of operations.

Disruptions to our supply chain, including our access to testing supplies and personal protective equipment for our diagnostic services business, materials and equipment (such as our saliva collections kits) necessary for our personal genomics business, and raw materials and product components necessary for our manufacturing operations, could have a material impact on our business, financial condition and results of operations.

We do not have long-term contracts with most of our suppliers. Although we maintain relationships with suppliers with the objective of ensuring that we have adequate supply for the delivery of our products and services, increases in demand for such items and services can result in shortages and higher costs. Our suppliers may not be able to meet our delivery schedules. Further, we may experience shortages in certain items as a result of limited availability, increased demand, pandemics (such as the COVID-19 pandemic), epidemics or other infectious disease outbreaks, weather conditions and natural disasters, global economic conditions, as well as other factors outside of our control.

The COVID-19 pandemic adversely impacted, and it or another pandemic, epidemic or infectious disease outbreak may in the future adversely impact, third parties that are critical to our businesses, including vendors, suppliers, and business partners. While our businesses have not been significantly negatively impacted up to this point by the COVID-19 pandemic, it is difficult if not impossible to predict whether and how we could be impacted by the COVID-19 pandemic, or another pandemic, epidemic or infectious disease outbreak, in the future.

Increases in the price of testing supplies, equipment and raw materials needed for our businesses and costs associated with doing business could materially and adversely affect our business, financial condition and results of operations.

We purchase testing supplies and personal protective equipment for our diagnostic services business, and certain materials and equipment (such as our saliva collections kits) for our personal genomics business. We must also purchase certain key raw materials and product components for our manufacturing operations.

If the price of these testing supplies, equipment, raw materials, and components were to increase significantly, we may not be able to pass on such increases to customers who use our services or purchase our products, which could have a material adverse impact on our business, financial condition and results of operations.

Our freight costs may also increase due to factors such as limited carrier availability, increased fuel costs, increased compliance costs associated with new or changing government regulations, pandemics (such as the COVID-19 pandemic), epidemics or other infectious disease outbreaks, or inflation. Higher prices for natural gas, propane, electricity and fuel may also increase our production and delivery costs. The prices charged for our products may not reflect changes in our packaging material, freight, tariff and energy costs at the time they occur, or at all.

The adulteration of key testing materials and raw materials needed for our businesses could materially and adversely affect our business, financial condition and results of operations.

We are reliant upon the supply of diagnostic and genomics testing materials and raw materials that meet our specifications and the specifications of third parties for whom we manufacture. If any diagnostic or genomics testing material or raw material is adulterated and does not meet our specifications or third parties' specifications, it could significantly impact our ability to perform diagnostic or genomic services or manufacture products and could materially and adversely impact our business, financial condition and results of operations.

We may be subject to product liability claims.

As a direct marketer and manufacturer of products designed for human consumption, we are subject to product liability claims if the use of our products or the products that we manufacture for third parties are alleged to have resulted in injury or to include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. Our current products and the products that we currently manufacture for third parties are not subject to pre-market regulatory approval in the United States and could contain contaminated substances.

While we currently maintain product liability insurance, a successful claim brought against us related to our branded products or products that we manufacture for third parties in excess of, or outside of, our existing insurance coverage, could result in increased costs and could adversely affect our reputation with customers, which could in turn materially adversely affect our business, financial condition and results of operations.

We may require additional capital to support our growing diagnostic services business, personal genomics business, product development and commercialization programs, and biopharmaceutical business, but additional funding may not be available to us on acceptable terms, or at all.

The amount of capital that may be needed to support our various businesses will depend on many factors which may include, but are not limited to (i) the revenue we generate from our diagnostic services, personal genomics products and services, drug and dietary supplement lines, and contract manufacturing services; (ii) the expenses we incur in growing these businesses and services; (iii) the cost involved in applying for and obtaining FDA, international regulatory or other technical approvals, if required; and (iv) whether we elect to establish partnering or other strategic arrangements for the development, sales, manufacturing and marketing of our products and services.

Income from our various businesses may not generate all the funds we need to support the growth of these businesses. To the extent that we do not generate sufficient cash from operations, we may, in the short and long-term, seek to raise capital through the issuance of equity securities or through other financing sources. To the extent that we seek to raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may include financial and other covenants that could restrict our use of the proceeds from such financing or impose other business and financial restrictions on us. In addition, we may consider alternative approaches such as licensing, joint venture, or partnership arrangements to provide long-term capital. Additional funding may not be available to us on acceptable terms, or at all.

Adverse credit market conditions may significantly affect our access to capital, cost of capital and ability to meet liquidity needs.

Disruptions, uncertainty or volatility in the credit markets could adversely impact the availability and cost of credit to us in the future. For example, the credit and financial markets may be adversely affected by the war in Ukraine and measures taken in response thereto. If the credit markets are not favorable, we may be forced to delay raising capital or pay unattractive interest rates, which could increase our interest expense, decrease our profitability and significantly reduce our financial flexibility. Longer-term disruptions in the capital and credit markets as a result of uncertainty, changing or increased regulation, reduced alternatives or failures of significant financial institutions could adversely affect our access to liquidity needed for our business. Any disruption could require us to take measures to conserve cash until the markets stabilize or until alternative credit arrangements or other funding for our business needs can be arranged. Such measures could include deferring capital expenditures or other discretionary uses of cash. Overall, our results of operations, financial condition and cash flows could be materially adversely affected by disruptions in the credit markets.

System failures could adversely affect our results of operations and financial condition.

Like many companies, our business is highly dependent upon our information technology infrastructure (websites, accounting and manufacturing applications, and product and customer information databases) to manage effectively and efficiently our operations, including order entry, customer billing, accurate tracking of purchases and volume incentives and managing accounting, finance and manufacturing operations. The occurrence of a natural disaster, security breach or other unanticipated problem could result in interruptions in our day-to-day operations that could adversely affect our business. A long-term failure or impairment of any of our information systems could have a material adverse effect on our results of operations and financial condition.

We will face legal, reputational, and financial risks if we fail to protect our customer data from security breaches or cyberattacks. Changes in laws or regulations relating to privacy or the protection or transfer of data relating to individuals, or any actual or perceived failure by us to comply with such laws and regulations or any other obligations relating to privacy or the protection or transfer of data relating to individuals, could adversely affect our business.

We receive and store a large volume of personally identifiable information, genetic information, and other data relating to our customers, as well as other personally identifiable information and other data relating to individuals such as our employees. Security breaches, employee malfeasance, or human or technological error could lead to potential unauthorized disclosure of our customers' personal information. Even the perception that the privacy of personal information is not satisfactorily protected or does not meet regulatory requirements could inhibit sales of our solutions and any failure to comply with such laws and regulations could lead to significant fines, penalties or other liabilities.

A security compromise of our information systems or of those of businesses with whom we interact that results in confidential information being accessed by unauthorized or improper persons could harm our reputation and expose us to regulatory actions, customer attrition, remediation expenses, disruption of our business, and claims brought by our customers or others for breaching contractual confidentiality and security provisions or data protection laws. Breaches of health information and/or personal data may be extremely expensive to remediate, may prompt federal or state investigation, fines, civil and/or criminal sanctions and significant reputational damage. Monetary damages imposed on us could be significant and not covered by our liability insurance. Techniques used by bad actors to obtain unauthorized access, disable or degrade service, or sabotage systems evolve frequently and may not immediately produce signs of intrusion, and we may be unable to anticipate these techniques or to implement adequate preventative measures. In addition, a security breach could require that we expend substantial additional resources related to the security of our information systems and providing required breach notifications, diverting resources from other projects and disrupting our businesses. If we experience a data security breach, our reputation could be damaged, and we could be subject to additional litigation, regulatory risks and business losses.

Our failure, or the failure by our third-party providers on our platform, to comply with applicable laws or regulations or any other obligations relating to privacy, data protection, or information security, or any compromise of security that results in unauthorized access to, or use or release of personally identifiable information or other data relating to our customers, or other individuals, or the perception that any of the foregoing types of failure or compromise have occurred, could damage our reputation, discourage new and existing customers from using our platform, or result in fines, investigations, or proceedings by governmental agencies and private claims and litigation, any of which could adversely affect our business, financial condition, and results of operations. Even if not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition, and results of operations.

Our success is dependent on key personnel.

Our success depends, in part, upon the continued service of key personnel, such as Mr. Ted Karkus, Chairman and Chief Executive Officer, and certain managers and strategists within the Company. The loss of the services of any one of them could have a material adverse effect on us.

In order to be successful, we must retain and motivate executives and other key employees, including those in managerial, technical, marketing and health product positions. In particular, our product generation efforts depend on hiring and retaining qualified health and science professionals. Competition for skilled employees who can perform the services that we require is intense and hiring, training, motivating, retaining and managing employees with the skills required is time-consuming and expensive. If we are not able to hire sufficient professional staff to support our operations, or to train, motivate, retain and manage the employees we do hire, it could have a material adverse effect on our business operations or financial results.

Risks Related to Our Diagnostics Business

There can be no assurance that we will be able to continue to successfully offer, perform or generate revenues from our lab diagnostic services.

Our diagnostic services business is subject to substantial risks and uncertainties. To address these risks and uncertainties, we must, among other things, successfully execute our business strategy, respond to competitive developments, and attract and retain qualified personnel. We cannot assure you that we will continue to operate profitably or that our business strategy will be successful in the long-term. Our ability to continue to generate revenues from COVID-19 and other RPP molecular testing, and to continue to generate profits from our diagnostic services business, will depend on a variety of factors, including:

- the level of demand for COVID-19 testing in light of widespread and effective vaccination and other successful containment efforts;
- the level of demand for other diagnostic testing;
- the price we are able to receive for performing our testing services, and the length of time for which that demand persists;
- the availability of COVID-19 and other diagnostic testing from other laboratories;
- the ability of our laboratories to maintain status as authorized laboratories to perform COVID-19 and other diagnostic testing and related services and to respond to any changes in regulatory requirements;
- the potential for supply disruptions and our reliance on certain single-source suppliers;
- the potential for disruption in the delivery of patient samples to our laboratories;
- the capacity of our laboratories to satisfy both COVID-19 testing and other testing demands;
- the extent to which we choose to allocate limited laboratory capacity, supplies and other resources to areas of our business other than COVID-19 testing;
- the complexity of billing for, and collecting revenue for, our testing services;
- our ability to maintain laboratory operations during the COVID-19 pandemic or during another pandemic, epidemic or other infectious disease outbreak and to perform our tests accurately and punctually;
- our ability to expand and or diversify our diagnostic services; and
- the ease of use of our ordering and reporting processes.

In addition, the process of expanding our diagnostic services business may divert resources and distract management's attention from other areas of our business that may be more profitable or strategic. If we are unable to successfully provide diagnostic services while continuing to operate our existing genomics business, contract manufacturing business and/or dietary supplements business, our results of operations, financial position and reputation may suffer.

If demand for COVID-19 testing becomes no longer necessary and we are unable to generate sufficient profits from other RPP Molecular tests, our business could be materially adversely affected.

We launched our diagnostic service business in October 2020. Fluctuations in profits from our diagnostic business have occurred and may occur in the future due to of a variety of factors, including, among others, the amount and timing of sales of billable tests, the prices we charge for our tests due to changes in product, customer or payor mix, general price degradation for tests or other competitive factors, future pandemics, epidemics or other infectious disease outbreaks, the rate and timing of our billings and collections, the timing and amount of our commitments and other payments, as well as the other risk factors discussed in this Annual Report. Our results have been, and may in the future be, impacted by events that may not recur regularly, in the same amounts or at all in the future.

For the year ended December 31, 2022, we saw a significant increase in our net revenues due to our substantial COVID-19 testing volumes during that time, particularly during the first, second and third quarters of 2022. In the fourth quarter of 2022, testing volumes significantly decreased as COVID-19 testing demand slowed. The FDA has approved multiple COVID-19 vaccines for administration to the public. There can be no assurance that demand for our COVID-19 testing services will continue to exist in the future due to the widespread and effective vaccination of a majority of Americans against COVID-19 and successful containment efforts. If there is no demand for our COVID-19 testing services, and we are unable to generate sufficient profits from other RPP Molecular tests, our business could be materially adversely affected.

On January 31, 2023, President Biden issued a Statement of Administration Policy indicating that the administration intends for the COVID-19 national emergency and public health emergency to end on May 11, 2023. When the public health emergency ends, the FDA will continue to have the authority to issue Emergency Use Authorizations (EUAs) until that authority is formally terminated by the Secretary of HHS through a separate process. Upon termination, our laboratories will no longer be permitted to perform COVID-19 testing under an existing EUA. All subsequent COVID-19 testing would need to occur through our own laboratory developed test or an COVID-19 diagnostic test that has been approved or cleared by FDA.

Billing and collections processing for our diagnostic tests is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on our revenue.

Billing for our diagnostic tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we may bill different parties for our tests. This includes billing customers directly, as in the case of our hospital and other medical institution customers, as well as billing through Medicare, Medicaid, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts due to the complexities of these billing requirements, including long collection cycles and lower collection rates, which could adversely affect our business, results of operations and financial condition.

Several factors make this billing process complex, including:

- contractual restrictions in our customer contracts that may limit our ability to utilize certain third-party billing service providers;
- differences between the list price for our tests and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid;
- disputes among payors as to which party is responsible for payment;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payors;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We have developed internal systems and procedures to handle these billing and collections functions, but we must continue to make significant efforts and expend substantial resources to further develop our systems and procedures to handle these aspects of our business, which could become increasingly important as we focus on increasing test volumes and establishing coverage and reimbursement policies with third-party payors. As a result, these billing complexities, along with the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve or sustain profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payors on a timely basis, or if we are required to switch to a different provider to handle our processing and collections functions, our revenue and our business could be adversely affected.

Failure to accurately bill for testing services, or to comply with applicable laws relating to government health care programs, could have a material adverse effect on our business.

Billing for diagnostic services is complex and subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payers, such as patients, insurance companies, government groups, Medicare and Medicaid. Effective November 2021, billing for diagnostic services is performed internally by our billing department. Failure to accurately bill for our services could have a material adverse effect on our business. In addition, failure to comply with applicable laws relating to billing government health care programs may result in various consequences, including the return of overpayments, civil and criminal fines and penalties, exclusion from participation in government health care programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third-party claims, all of which could have a material adverse effect on our business. Certain violations of these laws may also provide the basis for a civil remedy under the federal False Claims Act, including fines and damages of up to three times the amount claimed. The *qui tam* provisions of the federal False Claims Act and similar provisions in certain state false claims acts allow private individuals to bring lawsuits against health care companies on behalf of the government.

Although we believe we are compliant, in all material respects, with applicable laws and regulations, there can be no assurance that a regulatory agency or tribunal would not reach a different conclusion. The federal and state governments have substantial leverage in negotiating settlements since the amount of potential damages and fines far exceeds the rates at which services will be reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs. We expect that federal and state governments continue aggressive enforcement efforts against perceived health care fraud. Legislative provisions relating to health care fraud and abuse provide government enforcement personnel with substantial funding, powers, penalties and remedies to pursue suspected cases of fraud and abuse.

Our ability to achieve or sustain profitability depends on our collection of payment for the tests we deliver, which we may not be able to do successfully.

Our customer base for our COVID-19 and influenza tests is principally comprised of governmental bodies, municipalities, and large corporations who pay us directly or through third-party payors. In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted, providing for reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding. Approximately 31.5% and 57.6% of our diagnostic services revenue for the years ended December 31, 2022 and 2021, respectively, was generated from this program for the uninsured. On March 22, 2022, the Health Resources & Services Administrations ("HRSA") uninsured program stopped accepting claims for COVID-19 testing and treatment due to the lack of sufficient funds. Despite requests from the Acting Director of the Office of Management and Budget and the White House Coordinator for COVID-19 Response for additional emergency funding for the uninsured program, emergency funding has not been allocated to the HRSA uninsured program. We continue to perform limited testing for uninsured persons and are incurring the accompanying costs.

Further, healthcare policy changes that influence the way healthcare is financed or other changes in the market that impact payment rates by institutional or non-institutional customers could also affect our collection rates. If we are unable to convince customers of the value and benefit provided by our tests, these customers may slow, or stop altogether, their purchases of these tests. Our collection risks also include the potential for default or bankruptcy by the party responsible for payment and other risks associated with payment collection generally. Any inability to maintain our past payment collection levels could cause our revenue and ability to achieve profitability to decline and adversely affect our business, prospects and financial condition.

The loss of sales to any one or more of our large diagnostic services customers could have a material adverse effect on our business operations and financial condition.

For the year ended December 31, 2022, a significant portion of our revenues came from our diagnostic services business. For the year ended December 31, 2022, three customers accounted for 23.5%, 17.9%, and 11.9% of our 2022 revenues, respectively. The loss of sales to these diagnostic services customers could have a material adverse effect on our business operations and financial condition, unless we are able to increase revenue from other sources.

If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our diagnostic service business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition.

Our diagnostic service operations are subject to extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among other things:

- CLIA, which requires that laboratories obtain certification from the federal government, and state licensure laws;
- CMS and FDA laws and regulations;
- HIPAA, which imposes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general and impose requirements for breach notification;
- state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators;
- the federal anti-kickback law, or the Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;

- the federal Physician Payments Sunshine Act, which requires medical device manufactures to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members;
- Section 216 of the federal Protecting Access to Medicare Act of 2014, which requires applicable laboratories to report private payor data in a timely and accurate manner beginning in 2017 and every three years thereafter (and in some cases annually);
- state laws that impose reporting and other compliance-related requirements;
- state billing laws, including regulations on "pass through billing" which may limit our ability to submit claims for payment and/or mark up the cost of services in excess of the price paid for such services, and "direct-bill" laws which may limit our ability to purchase services from a laboratory and bill for the services ordered;
- similar foreign laws and regulations that apply to us in the countries in which we operate.

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratory's ability to provide or receive payment for our services. Any action taken against us by a governmental entity or private party could, regardless of their outcome, damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payors.

U.S. Food and Drug Administration (FDA) regulation of diagnostic products could result in increased costs and the imposition of fines or penalties and could have a material adverse effect upon our business.

The FDA has regulatory responsibility for instruments, test kits, reagents and other devices used by clinical laboratories. The FDA enforces laws and regulations that govern the development, testing, manufacturing, performance, labeling, advertising, marketing, distribution and surveillance of diagnostic products, including COVID-19 diagnostics authorized by FDA under an Emergency Use Authorization (EUA), and it regularly inspects and reviews the manufacturing processes and product performance of diagnostic products.

Since 2014, there have been ongoing discussions and advocacy between stakeholders, including the clinical laboratory industry, the FDA, and Congress, about potential FDA regulation of LDTs.

In March 2017, a draft bill on the regulation of LDTs, entitled "The Diagnostics Accuracy and Innovation Act" ("DAIA") was released for discussion. In December 2018, the sponsors of DAIA released a new version of the legislation called the "Verifying Accurate, Leading-edge IVCT Development Act" ("VALID Act"). The VALID Act proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test category, which includes LDTs, and a new regulatory structure under the FDA. Similar versions of the VALID Act have since been introduced. In 2022, the VALID Act was incorporated into the Senate user fee bill but was not included in the year-end Consolidated Appropriations Act of 2022. As proposed, the bill would create a precertification program for lower risk tests not otherwise required to go through premarket review. It would grandfather existing tests but would allow the FDA to subject otherwise grandfathered tests to premarket review under certain conditions. Similarly, the Verified Innovative Testing in American Laboratories ("VITAL") Act was introduced in December 2020 and re-introduced in May 2021. In contrast with the VALID Act, the VITAL Act would prevent FDA from regulating LDTs and would instead assign regulatory authority over LDTs entirely to CMS. We cannot predict whether either of these or other draft bills governing LDTs will become legislation and cannot quantify the effect of such draft bills on our business.

While we cannot predict whether the either VALID Act or the VITAL Act as proposed, or any modified version of either act will be enacted into law, it is expected that some form of the acts will be incorporated into a broader health care legislative package. The likelihood that Congress will pass legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time. Until the VALID Act, VITAL Act, or other legislation is passed reforming the federal government's regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval.

Absent congressional legislation to clarify FDA's authorities, the FDA may consider administrative action, such as rule making, to clarify requirements for LDTs. FDA regulation of the diagnostic products we use and services we offer could result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material adverse effect on our business, financial condition, results of operation and cash flows.

Our diagnostic services business could be harmed by the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or interpretations of, the law or regulations of the Clinical Laboratory Improvement Act of 1967, and the Clinical Laboratory Improvement Amendments of 1988 (CLIA), or those of Medicare, Medicaid or other national, state or local agencies in the United States.

The performance of laboratory testing is subject to extensive U.S. regulation, and many of these statutes and regulations have not been interpreted by the courts. CLIA extends federal oversight to virtually all physician practices performing clinical laboratory testing and to clinical laboratories operating in the United States by requiring that they be certified by the federal government or, in the case of clinical laboratories, by a federally approved accreditation agency. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. In addition, we expect to be subject to regulation under state law. State laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Applicable statutes and regulations could be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly.

Our products could become subject to regulation as medical devices by the FDA or other regulatory agencies even if we do not elect to seek regulatory clearance or approval to market our products for diagnostic purposes, which would adversely impact our ability to market and sell our products and harm our business.

We intend to initially launch the BE Smart test as an LDT offered through our own laboratory but also offered for sale to others for research purposes or for "research use only" (RUO). A product sold for RUO, such as a BE Smart RUO test, is not designed or intended to be used as a clinical diagnostic test or as a medical device. RUO products can be sold to academic research institutions, translational research and medicine centers, cancer centers, clinical research laboratories, contract research organizations, and other research companies and providers. Tests that are labeled, promoted, and sold as RUO are not currently subject to regulation as medical devices by the FDA.

However, the FDA could disagree that a test labeled as RUO test is intended for research use only or believe that the sales, marketing and promotional efforts related to a RUO test as being inconsistent with research use only products. On November 25, 2013, the FDA issued Final Guidance "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only." The guidance emphasizes that the FDA will review the totality of the circumstances when it comes to evaluating whether equipment and testing components are properly labeled as RUO. The final guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA's clearance, approval, and other regulatory requirements if the circumstances surrounding the distribution, marketing and promotional practices indicate that the manufacturer knows its products are, or intends for its products to be, used for clinical diagnostic purposes. These circumstances may include written or verbal sales and marketing claims or links to articles regarding a product's performance in clinical applications and a manufacturer's provision of technical support for clinical applications.

In addition, customers who purchase a RUO labeled test could, in theory, independently elect to use a RUO labeled product in their own laboratory developed tests (LDTs) for clinical diagnostic use. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against laboratories offering LDTs. However, as manufacturers develop more complex tests and diagnostic software, the FDA has been pushing for increased regulation of LDTs. Further, the VALID Act, which has been introduced in Congress over the last few sessions, if ever enacted, will establish a new risk-based regulatory framework for in vitro clinical tests (IVCTs), which include IVDs, LDTs, collection devices, and instruments used with such tests, and a technology certification program, among other proposals. The adoption of new restrictions on IVDs, LDTs, or RUOs, whether by the FDA or Congress, could adversely affect our ability to commercialize some of our RUO and diagnostic products. Further, we could be required to obtain premarket clearance or approval from the FDA before we can sell some of these products to certain customers.

If the FDA determines our products or related applications should be subject to additional regulation as in vitro diagnostic devices based upon customers' use of our products for clinical diagnostic or therapeutic decision-making purposes, our ability to market and sell our products could be impeded and our business, prospects, results of operations and financial condition may be adversely affected. In addition, the FDA could consider our products to be misbranded or adulterated under the FD&C Act and subject to recall and/or other enforcement action.

We use potentially hazardous materials, chemicals and patient samples in our business and any disputes relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our lab diagnostic services involve the controlled use of hazardous laboratory materials and chemicals, including small quantities of acid and alcohol, and patient samples. We are subject to U.S. laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste. We could be liable for accidental contamination or discharge or any resultant injury from hazardous materials, and conveyance, processing, and storage of and data on patient samples. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. Further, future changes to environmental health and safety laws could cause us to incur additional expense or restrict operations.

In the event of a lawsuit or investigation concerning such hazardous materials, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials or patient samples that may contain infectious materials. The cost of this liability could exceed our resources. While we expect to maintain broad form liability insurance coverage for these risks, the level or breadth of our coverage may not be adequate to fully cover potential liability claims.

Risks Related to Our Personal Genomics Business

Prior to our acquisition of Nebula, we had no specific experience operating a personal genomics business. Our success in this industry will depend, in large part, on our ability to establish our presence in the personal genetics market, provide customers with a high level of service at a competitive price, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products, and services to offer to our customers. Our failure to achieve any of these outcomes could adversely affect our business.

Prior to our acquisition of Nebula in 2021, we had no specific experience operating a personal genomics business. Our success in this industry will depend, in large part, on our ability to establish and maintain our presence in this market, provide customers with a high level of service at competitive prices, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products and services to offer to our customers. If customers do not perceive our personal genomic reports to be reliable and of high quality, if we fail to introduce new and improved products and services, or if we introduce new products or services that are not favorably received by the market, we may not be able to attract or retain customers.

The growth and expansion of our genomics business and service offerings will place a continuous strain on our management, operational and financial resources. We will be required to manage multiple relationships with various strategic suppliers, customers and other third parties, including regulatory agencies. To effectively manage our growth, we must continue to implement and improve our operational, financial and management information systems and to expand, train and manage our employee base. In the event of further growth of our operations or in the number of our third-party relationships, our supply, systems, procedures or internal controls may not be adequate to support our operations and our management may not be able to manage any such growth effectively.

If our estimates of the total addressable market for personal genomic services and the potential for market growth prove to be inaccurate, our business, financial condition, results of operations and prospects may be negatively affected.

Our estimates and forecasts for the personal genomic service market are based on a number of complex assumptions, internal and third-party estimates, and other business data, including assumptions and estimates relating to our ability to leverage our diagnostic testing facilities to generate revenue from personal genomic services. While we believe our assumptions and the data underlying our estimates are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and indicators. Consequently, our estimates of the total addressable market and our forecasts of market growth and future revenue from our products and services may prove to be incorrect. For example, if the annual total addressable market or the potential market growth for our products and services is smaller than we have estimated or if the key business metrics we utilize to forecast revenue are inaccurate, it may impair our sales growth and have an adverse impact on our business, financial condition, results of operations and prospects.

Media reports have in the past reported on consumer privacy concerns and the use of genetic information accessed from other genetic databases by law enforcement and governmental agencies. These reports may decrease the overall consumer demand for personal genetic products and services, including ours.

Companies offering personal genomic services and products have received a high degree of media coverage in recent years. Unfavorable publicity or consumer perception of our product and service offerings, including consumer privacy concerns related to any of our existing or future collaborations, could adversely affect our reputation, resulting in a negative impact on the size of our customer base, the loyalty of our customers, the percentage of our customers that consent to participate in any future research programs, and our ability to attract new customers.

If we lose a significant or sole supplier, our business and operations could be materially adversely affected.

Currently, we rely on a sole supplier to manufacture our saliva collection kits used by customers who purchase our personal genomics services. Change in the [supplier] or design of certain of the materials that we rely on, in particular the saliva collection kit, could result in a requirement for additional premarket review from the FDA before making such a change.

Any new laboratory or laboratories that are engaged to support our personal genomics business must first be validated in accordance with certain governmental standards before we are able to utilize their services for our U.S. customers. We cannot be certain that we will be able to secure alternative laboratory processing services, materials and equipment, and bring such alternative materials and equipment online and revalidate them without experiencing interruptions in our workflow, or that any alternative materials will meet our quality control and performance requirements of our current contracted laboratories that support our personal genomics business.

Any significant disruption in service on our website, mobile applications, or in our computer or logistics systems, whether due to a failure with our information technology systems or that of a third-party vendor, could harm our reputation and may result in a loss of customers.

Customers purchase our personal genomics testing services and access Nebula offerings through our website or our mobile applications. Our reputation and ability to attract, retain and serve our customers is dependent upon the reliable performance of our and our partners' websites, mobile applications, network infrastructure and content delivery processes. Interruptions to any of these systems, whether due to system failures, computer viruses or physical or electronic break-ins, could affect the security or availability of our or our partner websites or mobile applications, including our databases, and prevent our customers from accessing and using our services.

Our systems and operations are also vulnerable to damage or interruption from fire, flood, power loss, telecommunications failure, terrorist attacks, acts of war, electronic and physical break-ins, earthquake and similar events. In the event of any catastrophic failure involving our or our partner websites, we may be unable to serve our customer web traffic. The occurrence of any of the foregoing risks could result in damage to our systems or could cause them to fail completely, and our insurance may not cover such risks or may be insufficient to compensate us for losses that may occur.

Additionally, our business model is dependent on our ability to deliver testing kits to customers and have kits processed and returned to us. This requires coordination between our logistics providers and third-party shipping services. Operational disruptions may be caused by factors outside of our control such as hostilities, political unrest, terrorist attacks, natural disasters, pandemics, epidemics and other infectious disease outbreaks affecting the geographies where our operations and customers are located. We may not be effective at preventing or mitigating the effects of such disruptions, particularly in the case of a catastrophic event which could cause failure to deliver pre-implantation genetic screening (PGS) kits. Any such disruption may result in lost revenues, a loss of customers and reputational damage, which would have an adverse effect on our business, results of operations and financial condition.

Our personal genomics business is subject to seasonal fluctuations.

Our personal genomics kit sales are impacted by seasonal holiday demand. We expect to generate greater revenues from this business during the first quarter of our fiscal year, due to seasonal holiday demand and the fact that kits that are ordered during the holiday season (which occurs during the fourth quarter of our fiscal year) will generally be recognized as revenue when the customer sends in their kit to the laboratory to be processed and genetic reports are delivered to the customer, which for holiday purchases we expect will occur in the following fiscal quarter. Purchasing patterns of kit sales may also align with other gift-giving and family-oriented holidays such as Mother's Day and Father's Day. This seasonality could cause our operating results to vary considerably from quarter to quarter.

We may also experience an increase in lab processing times and costs associated with shipping orders due to freight surcharges due to peak capacity constraints and additional long-zone shipments necessary to ensure timely delivery for the holiday season. Such delays could lead to an inability to meet advertised estimated lab processing times, resulting in customer dissatisfaction or reputational damage. If too many customers access our website within a short period of time, we may experience system interruptions that make our website unavailable or prevent us from efficiently fulfilling orders, which may reduce the volume of kits sold. Also, third-party delivery and direct ship vendors may be unable to deliver merchandise on a timely basis.

Risks Related to our Contract Manufacturing and Dietary Supplement Business

Disruptions at our PMI manufacturing facilities or any loss of manufacturing certifications could materially and adversely affect our business, financial condition, results of operations and customer relationships.

Any significant disruption at our manufacturing facility for any reason, including regulatory requirements, an FDA determination that the facility is not in compliance with the applicable cGMP regulations, the loss of certifications, power interruptions, destruction or damage to the facility or disruptions related to the COVID-19 pandemic or another pandemic, epidemic or infectious disease outbreak, could disrupt our ability to manufacture products for our contract manufacturing customers and any of our own branded products. Any such disruption could have a material adverse effect on our business, financial condition and results of operations.

Our PMI manufacturing business is subject to seasonal fluctuations and may fluctuate from cold season to cold season.

Because the majority of sales from our PMI manufacturing facility are from cold remedy products, our sales are subject to seasonal fluctuations and influenced by the timing, length and severity of each cold season. Our revenues tend to be higher in the first, third and fourth quarters during the cold season. Generally, a cold season is defined as the period of September to March, when the incidence of the common cold rises as a consequence of the change in weather and other factors.

Our contract manufacturing and dietary supplement businesses are subject to extensive governmental regulation.

Our contract manufacturing and dietary supplement businesses are subject to laws and regulations that cover:

- the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of our products;
- the health and safety of our products;
- trade practice and direct selling laws; and
- product claims and advertising.

Compliance with these laws and regulations is time consuming and expensive. Moreover, new regulations could be adopted that would severely restrict the products we sell or manufacture or our ability to continue our business. We are unable to predict the nature of any future laws, regulations, interpretations or applications, nor can we predict what effect additional governmental regulations or administrative orders, when and if promulgated, would have on our business in the future. These future changes could, however, require the reformulation or elimination of certain products; imposition of additional record keeping and documentation requirements; imposition of new federal reporting and application requirements; modified methods of importing, manufacturing, storing or distributing certain products; and expanded or different labeling and substantiation requirements for certain products and ingredients. Any or all of these requirements could harm our business.

In July 2011, the FDA issued draft guidance governing the notification of new dietary ingredients ("NDIs") and in August 2016, the FDA issued revised draft guidance. Although FDA guidance is not mandatory, it is a strong indication of the FDA's current views, including its position on enforcement. We believe that the draft guidance, if implemented as proposed, could have a material impact on our operations. FDA enforcement of the NDI guidance as written could require us to incur additional expenses, which could be significant, and negatively affect our business in several ways, including, but not limited to, the detention and refusal of admission of imported products, the injunction of manufacturing of any dietary ingredients or dietary supplements until the FDA determines that those ingredients or products are in compliance, and the potential imposition of penalties for non-compliance.

Our failure to comply with FTC regulations could result in substantial monetary penalties and could adversely affect our operating results.

The FTC exercises jurisdiction over the advertising of dietary supplements and has instituted numerous enforcement actions against OTC drug companies for failure to have adequate substantiation for claims made in advertising or for the use of false or misleading advertising claims. Failure by us to comply with applicable regulations could result in substantial monetary penalties, which could have a material adverse effect on our financial condition or results of operations.

Our product development and commercialization efforts may be unsuccessful.

There are numerous risks associated with dietary supplement product development and commercialization. We may be subject to delays and/or be unable to successfully implement our business plan and strategy to develop and commercialize one or more dietary supplements, including Equivir. The successful commercialization and market acceptance of any products we develop will be subject to, among other things, consumer purchasing trends, health and wellness trends, regulatory factors, retail acceptance and overall economic and market conditions. As a consequence, we may suspend or abandon some or all of our proposed new products before they ever become commercially viable. Even if we successfully develop a new product, if we cannot successfully commercialize it in a timely manner, our business and financial condition may be materially adversely affected.

If our products do not have the effects intended or cause undesirable side effects, our business may suffer.

Although many of the ingredients in our current dietary supplement products are vitamins, minerals, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. While we believe that all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects could be harmed significantly.

Risks Related to Our Drug Development Operations

We are early in our development efforts and it will be many years before our wholly owned subsidiary, ProPhase BioPharma, Inc. (PBIO), is able to commercialize a product candidate, if ever.

We are early in the development of our Equivir G (Rx) product candidate and Linebacker portfolio (LB-1 and LB-2) product candidates. Our ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, will be a result of the successful development and eventual commercialization of these product candidates, which may never occur. Our product candidates may have adverse side effects or fail to demonstrate safety and efficacy. Additionally, our product candidates may have other characteristics that may make them impractical or prohibitively expensive for large-scale manufacturing. Furthermore, our product candidates may not receive regulatory approval or, if they do, they may not be accepted by the medical community or patients or may not be competitive with other products that become available.

We must submit IND applications to the FDA to initiate clinical trials in the United States. The filing of IND applications is subject to additional preclinical research, research-scale and clinical-scale manufacturing, and other factors yet to be identified. In addition, commencing any new clinical trial is subject to review by the FDA based on the acceptability and sufficiency of our chemistry, manufacturing, and controls ("CMC"), and preclinical information provided to support our IND applications. If the FDA or foreign regulatory authorities require us to complete additional preclinical studies or we are required to satisfy other requests for additional data or information, our clinical trials may be delayed. Even after we receive and incorporate guidance from the FDA or foreign regulatory authorities, these regulatory authorities could disagree that we have satisfied all requirements to initiate our clinical trials or they may change their position on the acceptability of our trial design or the clinical endpoints selected. They could impose a clinical hold, which may require us to complete additional preclinical studies or clinical trials. The success of our product candidates will depend on several factors, including the following:

- sufficiency of our financial and other resources;
- completion of preclinical studies;
- clearance of IND applications to initiate clinical trials;
- successful enrollment in, and completion of, our clinical trials;

- data from our clinical trials and support an acceptable risk-benefit profile of our product candidates for our intended patient population and indications and demonstrate safety and efficacy;
- establishment of agreements with CMOs for clinical and commercial supplies and scaling up of manufacturing processes and capabilities to support our clinical trials;
- successful development of our internal process development and transfer to larger-scale facilities;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- receiving regulatory exclusivity for our product candidates;
- establishment, maintenance, enforcement, and defense of patent and trade secret protection and other intellectual property rights;
- not infringing, misappropriating, or otherwise violating third-party intellectual property rights;
- establishing sales, marketing, and distribution capabilities for commercialization of our product candidates, if and when approved, whether by us or in collaboration with third parties;
- maintenance of a continued acceptable safety profile of products post-approval;
- acceptance of product candidates, if and when approved, by patients, the medical community, and third-party payors;
- effective competition with other therapies and treatment options;
- establishment and maintenance of healthcare coverage and adequate reimbursement; and
- expanding indications and patient populations for our products post-approval.

We may not be successful in our efforts to identify and successfully research and develop additional product candidates and may expend our resources to pursue particular product candidates or indications while failing to capitalize on other product candidates or indications that may be more profitable, or for which there is a greater likelihood of commercial success.

Part of our business strategy involves identifying and developing new product candidates. The process by which we identify product candidates may fail to yield successful product candidates for a number of reasons, including:

- we may not be able to assemble sufficient resources to identify or acquire additional product candidates;
- competitors may develop alternative therapies that render new product candidates obsolete or less attractive;
- product candidates we develop or acquire may be covered by third-party intellectual property rights;
- new product candidates may, on further study, be shown to have adverse side effects, toxicities, or other characteristics that indicate that they are unlikely to receive marketing approval or achieve market acceptance;
- new product candidates may not be safe or effective;
- the market for a new product candidate may change so that the continued development of that product candidate is no longer reasonable; and
- we may not be able to produce new product candidates in commercial quantities at an acceptable cost, or at all.

We are focused initially on Equivir G (Rx) and] our Linebacker portfolio (LB-1 and LB-2) product candidates and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to that product candidate.

If we experience delays or difficulties enrolling patients in the clinical trials for our product candidates, our ability to advance our product candidates through clinical development and the regulatory process could be delayed or prevented.

The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may encounter delays in enrolling or be unable to enroll a sufficient number of patients to complete any of our clinical trials and, even if patients are enrolled, they may withdraw from our clinical trials before completion. Any clinical trials for our other product candidates will compete for enrollment of patients with other clinical trials for product candidates that are intended for the same or similar study populations as our product candidates. This competition will reduce the number and types of patients available to us because some patients who might opt to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Additionally, since the number of qualified and experienced clinical investigators for therapeutic areas is limited, some of our clinical trial sites may be also conducting clinical trials for some of our competitors, which may reduce the number of patients who are available for our clinical trials at that clinical trial site.

In addition, the enrollment of patients depends on many factors, including:

- size of the patient population and process for identifying patients;
- design of the clinical trial protocol;
- regulatory hold on clinical trial recruitment because of unexpected safety events;
- design of the clinical trial protocol;
- availability of eligible prospective patients who may also be eligible patients for competitive clinical trials;
- availability and efficacy of approved alternative treatments for the disease under investigation;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of our product candidates;
- efforts by clinical sites and investigators to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- physicians' ability to monitor patients adequately during and after treatment because of patient healthcare access issues, including those caused by COVID-19, other pandemics, epidemics or infectious disease outbreaks;
- proximity and availability of clinical trial sites for prospective patients; and
- interruptions, delays, or staffing shortages resulting from the COVID-19 pandemic, other pandemics, epidemics or infectious disease outbreaks.

Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may develop, which may cause our stock price to decline and limit our ability to obtain additional financing. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate ongoing or future clinical trials, and postpone or forgo seeking marketing approval, any of which would have an adverse effect on our business, financial condition, results of operations, and prospects.

Clinical trials are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, if at all. Issues may arise that could suspend or terminate our clinical trials. A failure of one or more of our clinical trials may occur at any stage of testing, and our future clinical trials may not be successful.

Events that may prevent successful or timely completion of clinical development include:

- FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays or failure to obtain regulatory clearance to initiate our clinical trials, as well as delays or failures to obtain any necessary approvals by the clinical sites;
- delays, suspension, or termination of our clinical trials by the clinical sites;
- modification of clinical trial protocols;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites, as well as possible future breaches of such agreements;
- failure to manufacture sufficient quantities of our product candidates for use in our clinical trials;
- failure by third-party suppliers, CMOs, CROs, and clinical trial sites to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- imposition of a temporary or permanent clinical hold by us, IRBs for the institutions at which such trials are being conducted, or by the FDA or other regulatory authorities for safety or other reasons, such as a result of a new safety finding in a clinical trial on a similar product by one of our competitors, that presents unreasonable risk to clinical trial participants;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which we developed our clinical development plan, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipated;
- insufficient funding to continue clinical trials with our product candidates;
- the emergence of unforeseen safety issues or undesirable side effects;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of our product candidates;
- inability to establish clinical trial endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, that applicable regulatory authorities consider likely to predict clinical benefit;
- regulators withdrawing their approval of a product or imposing restrictions on its distribution; and
- interruptions, delays, or staffing shortages resulting from the COVID-19 pandemic, other pandemics, epidemics or infectious disease outbreaks.

If (i) we are required to extend the duration of any clinical trials or to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate; (ii) we are unable to successfully complete preclinical studies or clinical trials of our product candidates or other testing; (iii) the results of these trials, studies, or tests are negative or produce inconclusive results; (iv) there are safety concerns; or (v) we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:

- abandon the development of one or more product candidates;
- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some jurisdictions and not in others;
- obtain marketing approval with labeling that includes significant use restrictions or safety warnings, including black box warnings;
- be subject to additional post-marketing requirements; or
- have regulatory agencies remove the product from the market or we voluntarily withdraw the product from the market after obtaining marketing approval.

Our preclinical studies or clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates and the development of our product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization.

If we encounter safety or efficacy problems in our preclinical studies or clinical trials, our developmental plans could be delayed or prevented. Product candidates in later stages of clinical trials may fail to show the desired safety profiles and efficacy results despite having progressed through initial preclinical studies and clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulatory agencies may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulatory agencies may not interpret our data as favorably as we do, which may delay, limit, or prevent regulatory approval.

In addition, the design of a clinical trial can determine whether its results will support approval of our product candidates, and flaws in the design of a clinical trial may not be apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial that will support regulatory approval.

From time to time, we may publish initial, interim, or preliminary data from our clinical trials. Initial, interim, or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data at the time of publishing initial, interim, or preliminary data. These data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, initial, interim, and preliminary data should be viewed with caution until the final data are available. Moreover, initial, interim, and preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on study, patient enrollment continues, or, for final data, as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results. Unfavorable differences between initial, interim, or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to decline significantly.

If our product candidates cause serious adverse events or undesirable side effects, including injury and death, or have other properties that could delay or prevent regulatory approval, their commercial potential may be limited or extinguished.

Product candidates we develop may be associated with undesirable or unacceptable side effects, unexpected characteristics, or other serious adverse events, including death. Inadequate recognition or management of the potential side effects of our product candidates could result in patient injury or death. If any undesirable or unacceptable side effects, unexpected characteristics, or other serious adverse events occur, our clinical trials could be suspended or terminated, and our business and reputation could suffer substantial harm.

There can be no assurance that we will resolve any adverse event related to any of our products to the satisfaction of the FDA or any regulatory agency in a timely manner or at all. If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidates, the FDA or other regulatory authorities could order us to cease further clinical trials of, or deny approval of, our product candidates. Even if we demonstrate that such serious adverse events are not product candidate-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete our clinical trials. Moreover, if we elect, or are required, to delay, suspend, or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from these product candidates may be delayed or eliminated.

The FDA or other regulatory agencies may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Although the FDA has found substantial evidence to support approval outside of the traditional phase 1, phase 2, and phase 3 framework for certain therapies, the general approach for FDA approval of a new drug is for the sponsor to provide dispositive data from at least two adequate and well-controlled clinical trials of the relevant biologic in the applicable patient population. Such clinical trials typically involve hundreds of patients, have significant costs, and take years to complete. We do not have agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a NDA.

In addition, the standard of care may change with the approval of new products in the same indications to which our product candidates are directed. This may result in the FDA or other regulatory authorities requesting additional studies to show that our product candidate is comparable or superior to the new products.

Our clinical trial results may also not support marketing approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including:

- the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that our product candidates are safe and effective for their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval, including due to heterogeneity of patient populations;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh the safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or other regulatory authorities to support the submission of a NDA or a similar filing in a foreign jurisdiction or to support commercial reimbursement;
- the FDA or other authorities will review our manufacturing processes and inspect our CMOs' facilities and may not approve our manufacturing processes or CMOs' facilities; and
- the approval policies or regulations of the FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we comply with all FDA requests, we may still fail to obtain regulatory approval. We cannot be sure that we will ever obtain regulatory clearance for our product candidates.

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming, and uncertain, and we may be unable to obtain the regulatory approvals necessary for the commercialization of our product candidates; furthermore, if there are delays in obtaining regulatory approvals, we may not be able to commercialize our products, may lose competitive lead time, and our ability to generate revenues from such products will be materially impaired.

The process of obtaining marketing approvals, both in the United States and in other jurisdictions, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. It is impossible to predict if or when any of our product candidates will prove to be safe and effective in humans or if we will receive regulatory approval for such product candidates. The risk of failure through the development process is high. Any product candidates we may develop, and the activities associated with their development and commercialization, including their manufacture, preclinical and clinical development, safety, efficacy, recordkeeping, labeling, storage, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. PBIO has not received approval or authorization to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of its product candidates or any product candidates it may seek to develop in the future will ever obtain marketing approval or commercialization. PBIO has have not previously submitted a NDA to the FDA or made a similar submission to any foreign regulatory authority. ANDA must include extensive preclinical and clinical data and supporting information to establish a drug product candidate's safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing, and controls for our product. Any drug product candidates we develop may not be effective; may be only moderately effective; or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The FDA and other regulatory authorities have substantial discretion in the approval process and may refuse to accept our NDA applications and decide that our data are insufficient and require additional preclinical studies or clinical trials. The same may happen with review of our drug product candidates by foreign regulatory authorities. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit, or prevent marketing approval of our drug product candidates. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any drug product candidates we may develop, the commercial prospects for those drug product candidates and our ability to generate revenues will be materially impaired and we may lose competitive lead time as similar products enter the market.

If ProPhase Biopharma, Inc. (PBIO) is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

To achieve commercial success for any approved product for which PBIO retains sales and marketing responsibilities, PBIO must develop and build a sales and marketing team or make arrangements with third parties to perform these services. There are risks involved with both establishing internal sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay product launch. PBIO will have to compete with other supplement, pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If the commercial launch of a product for which we have recruited a sales force and established marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which may be costly and our investment will be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, hire, train, and retain adequate numbers of effective sales, marketing, customer service, medical affairs, and other support personnel;
- our inability to equip sales personnel with effective materials, including sales literature, to help them educate physicians and other healthcare providers regarding our product candidates and their approved indications;
- our inability to effectively manage a geographically dispersed sales and marketing team;
- the inability of medical affairs personnel to negotiate arrangements for reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, we will need to enter into arrangements with third parties to perform sales, marketing, and distribution services. In such cases, our product revenue or the profitability to us from these revenue streams is likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over those third parties and they may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, and our business, financial condition, results of operations, and prospects will be materially adversely affected.

Our products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, and others in the medical community.

The use of Equivir G (Rx) for antiviral applications and/or the Linebacker portfolio (LB-1 and LB-2) as potential cancer co-therapies may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. Even with the requisite approvals from the FDA and other regulatory authorities internationally, the commercial success of any product candidates we develop will depend, in significant part, on the acceptance of physicians, patients, and healthcare payors of products as medically necessary, cost-effective, safe, and effective therapies.

Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as safe and effective treatments;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence, identification, or severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including limitations or warnings contained in the product labeling;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment of our product candidates in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket for our product candidates in the absence of coverage;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies, or other therapeutic approaches, are introduced that are more favorably received than our products, are more cost effective, or render our products obsolete.

The market opportunities for our product candidates may be smaller than we currently believe and limited to those patients who are ineligible for or have failed prior treatment, which may adversely affect our business.

Our projections of both the number of patients who have the indications we are targeting, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. New studies may change the estimated incidence or prevalence of these cancers. The number of eligible patients may turn out to be lower than we expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations, and prospects. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Even if we are able to commercialize our product candidates, such products may be subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for our product candidates in a particular country, but then be subject to price regulations that delay our commercial launch of such product candidates, possibly for lengthy time periods, and such delays would negatively impact the revenues we are able to generate from the sale of our product candidates in that country. Pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Uncertainty exists as to the coverage and reimbursement status of any of our products candidates for which we obtain regulatory approval. Additionally, reimbursement coverage may be more limited than the indications for which our products are approved. The marketability of our products may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. Furthermore, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Moreover, eligibility for reimbursement does not imply that our product candidates will be paid for in all cases or at a rate that will cover our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of our product candidate and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products, and may be incorporated into existing payments for other services. Net prices for our product candidates may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where our product candidates may be sold at lower prices than in the United States.

Third-party payors, whether domestic or foreign, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to healthcare systems that could impact our ability to sell our product candidates, if approved, profitably. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of, and containing or lowering the cost of, healthcare. The implementation of cost containment measures that third-party payors and healthcare providers are instituting and any other healthcare reforms may prevent us from being able to generate, or may reduce, our revenues from the sale of our product candidates, if approved, and our product candidates may not be profitable. Such reforms could have an adverse effect on anticipated revenue from product candidates for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. Even if our product candidates are successful in clinical trials and receive marketing approval, we cannot provide any assurances that we will be able to obtain and maintain third-party payor coverage or adequate reimbursement for our product candidates in whole or in part.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain approval of and commercialize our product candidates and could adversely affect our business.

The Affordable Care Act brought significant changes to the way healthcare is financed by both the government and private insurers, and significantly impacted the U.S. pharmaceutical industry, including expanding the list of covered entities eligible to participate in the 340B drug pricing program and establishing a new Medicare Part D coverage gap discount program. We expect that these and other healthcare reform measures in the future, may result in more rigorous coverage criteria and lower reimbursement, and in addition, exert downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may hinder us in generating revenue, attaining profitability, or commercializing our products once, and if, marketing approval is obtained.

In the EU, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU member states. The requirements may differ across the EU member states. In markets outside the United States and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings or other price controls on specific products and therapies.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or those third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Our Intellectual Property

Failure to protect our trademarks and other intellectual property could impact our business.

We will rely on trademark laws to protect our proprietary rights in any products we develop and commercialize. Monitoring the unauthorized use of our intellectual property will be difficult. Litigation may be necessary to enforce our intellectual property rights or to determine the validity and scope of the proprietary rights of others. Litigation of this type could result in substantial costs and diversion of resources, may result in counterclaims or other claims against us and could significantly harm our results of operations. In addition, the laws of some foreign countries do not protect our proprietary rights to the same extent as do the laws of the United States. From time to time, we may apply to have certain trademarks registered. There is no guarantee that such trademark registrations will be granted. The unauthorized reproduction of our trademarks could diminish the value of our brand and its market acceptance, competitive advantages or goodwill, which could adversely affect our business.

If our licensors are unable to maintain effective patents or we are unable to maintain our license rights for our approved products, product candidates or any future product candidates, or if the scope of the patent or license rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

Our success depends in large part on our licensors' ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries, as well as our license rights, with respect to our proprietary technology, products and product candidates.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we in-license may fail to result in issued patents with claims that cover our products or product candidates in the United States or in foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that our licensors were the first to file any patent application related to our products or product candidates, or whether they were the first to make the inventions claimed in their owned patents or pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to such patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, such patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties.

Any successful opposition to any patents licensed to us after patent issuance, or the loss or other impairment of any license rights relating to our products or product candidates, could deprive us of rights necessary for the successful commercialization of any products or product candidates that we may develop. Further, if our licensors encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. In addition, our licensors' patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents.

Our licensors may not have sufficient patent terms to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our products or product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our products that have been approved for sale, and to use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will market products and are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our products or our product candidates. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Our reliance on third parties requires us to share our trade secrets or confidential proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets confidential proprietary information will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets or confidential proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

Protecting and enforcing our intellectual property rights could consume monetary funds needed for other company objectives.

Protecting and enforcing our intellectual property rights and combating unlicensed copying and use of our intellectual property can be difficult and expensive. Litigation filed by Company and excessive legal costs could result in insufficient cash available to continue our business objective. Similarly, reductions in the legal protection of our intellectual property.

We may not be able to prevent disclosure of confidential and proprietary information

We receive confidential and proprietary information from collaborators, prospective licensors and licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims, which can result in significant costs if we are found to have improperly used the confidential or proprietary information of others. Even if we are successful in defending against these claims, litigation could result in substantial costs and diversion of personnel and resources.

Risks Related to Governmental Regulation

Laws and regulations regarding direct selling may prohibit or restrict our ability to sell our products in some markets or require us to make changes to our business model in some markets.

Direct selling companies are subject to laws and regulations by various government agencies. These laws and regulations are generally intended to prevent fraudulent or deceptive practices and to protect consumers. The FTC periodically investigates and brings enforcement actions against direct selling companies based on alleged pyramid selling activity and/or false and misleading claims made by the direct selling company or its independent distributors. Direct selling companies that have been the subject of an FTC enforcement action have generally been required to make significant changes to their business model and pay significant monetary fines. Being the target of an investigation or enforcement action by the FTC could have a material adverse effect on our results of operations and financial condition.

We depend on third parties to provide services critical to our businesses and we depend on them to comply with applicable laws and regulations.

We depend on third parties to provide services critical to our businesses, including laboratory service providers, raw material and equipment suppliers, ground and air transport of clinical and diagnostic services supplies and specimens, research services (including ancestry report generation), and people, among other services. Third parties that provide services to us are subject to similar risks related to security of customer-related information and compliance with U.S., state, local, or international environmental, health and safety, and privacy and security laws and regulations as we are. Any failure by third parties to comply with applicable laws, or any failure of third parties to provide services more generally, could have a material impact on us, whether because of the loss of the ability to receive services from the third parties, our legal liability for the actions or inactions of third parties, or otherwise.

We must comply with complex and overlapping laws protecting the privacy and security of health information and personal data.

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data.

Under the administrative simplification provisions of HIPAA, HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of PHI used or disclosed by health care providers and other covered entities.

The privacy regulations regulate the use and disclosure of PHI by health care providers engaging in certain electronic transactions or "standard transactions." They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered health care provider, including the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. The HIPAA security regulations establish administrative, physical, and technical standards for maintaining the integrity and availability of PHI in electronic form. These standards apply to covered health care providers and also to "business associates" or third parties providing services involving the use or disclosure of PHI. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. As a result, we may be required to comply with both HIPAA privacy regulations and varying state privacy and security laws.

Moreover, HITECH, among other things, established certain health information security breach notification requirements. In the event of a breach of unsecured PHI, a covered entity must notify each individual whose PHI is breached, federal regulators and in some cases, must publicize the breach in local or national media. Breaches affecting 500 individuals or more are publicized by federal regulators who publicly identify the breaching entity, the circumstances of the breach and the number of individuals affected.

These laws contain significant fines and other penalties for wrongful use or disclosure of PHI. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. Adding to the complexity is that our planned operations are currently evolving, and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services or provide services involving the use or disclosure of PHI and incur compliance obligations as a business associate. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

We are also required to collect and maintain personal information about our employees as well as receive and transfer certain payment information, to accept payments from our customers, including credit card information. Most states have adopted laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. The collection and use of such information may be subject to contractual obligations as well. If the security and information systems that we or our outsourced third-party providers use to store or process such information are compromised or if we, or such third parties, otherwise fail to comply with these laws, regulations, and contractual obligations, we could face litigation and the imposition of penalties that could adversely affect our financial performance.

Numerous additional local, municipal, state, federal, and international laws and regulations address privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data, including the California Online Privacy Protection Act, the Personal Information Protection and Electronic Documents Act, the Telephone Consumer Protection Act of 1991, Section 5 of the Federal Trade Commission Act, and effective as of January 1, 2020, the CCPA. These laws, rules, and regulations evolve frequently, and their scope may continually change, through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. For example, the CCPA, which went into effect on January 1, 2020, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. The CCPA provides for fines of up to $7,500 per violation. Aspects of the CCPA and its interpretation and enforcement remain uncertain. The effects of this legislation potentially are far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA has been amended on multiple occasions, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CPRA became operative on January 1, 2023 (and applies to consumer data collected on or after January 1, 2022, (the “lookback period”), with enforcement beginning July 1, 2023. While the CCPA will remain operative and enforceable from now until July 1, 2023, we will continue to monitor developments related to the CPRA. The effects of this legislation potentially are far-reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Additionally, many laws and regulations relating to privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data are subject to varying degrees of enforcement and new and changing interpretations by courts. The CCPA and other changes in laws or regulations relating to privacy, data protection, breach notifications, and information security, particularly any new or modified laws or regulations, or changes to the interpretation or enforcement of such laws or regulations, that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer, or disclosure, could greatly increase the cost of providing our platform, require significant changes to our operations, or even prevent us from providing our platform in jurisdictions in which we currently operate and in which we may operate in the future.

We may face audits or investigations by one or more domestic government agencies or our customers pursuant to our contractual obligations relating to our compliance with these regulations. Complying with changing regulatory requirements requires us to incur substantial costs, exposes us to potential regulatory action or litigation, and may require changes to our business practices in certain jurisdictions, any of which could materially adversely affect our business operations and operating results. Despite our efforts to comply with applicable laws, regulations, and other obligations relating to privacy, data protection, and information security, it is possible that our interpretations of the law, practices, or platform could be inconsistent with, or fail or be alleged to fail to meet all requirements of, such laws, regulations, or obligations.

Risks Related to Our Common Stock, Internal Controls and Governance Matters

If we are unable to maintain effective internal controls over financial reporting or if material weaknesses are discovered in our internal accounting procedures, the accuracy and timing of our financial reporting may be adversely affected, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Any failure to develop or maintain effective internal controls over financial reporting or difficulties encountered in implementing or improving our internal controls over financial reporting could harm our operating results and prevent us from meeting our reporting obligations. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports. If we cannot provide reliable financial reports, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, investors relying upon this misinformation could make an uninformed investment decision, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities or to stockholder class action securities litigation.

Future sales of shares of our common stock in the public market could adversely affect the trading price of shares of our common stock and our ability to raise funds in future offerings.

Future sales of substantial amounts of shares of our common stock in the public market, or the perception that such sales are likely to occur, could adversely affect the prevailing trading prices of our common stock. Moreover, the perceived risk of potential dilution could cause stockholders to attempt to sell their shares and investors to "short" our stock, a practice in which an investor sells shares that he or she does not own at prevailing market prices, hoping to purchase shares later at a lower price to cover the sale. All of these events could combine to make it difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

If securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, products or stock performance, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, the unpredictability of our financial results likely reduces the certainty, and therefore reliability, of the forecasts by securities or industry analysts of our future financial results, adding to the potential volatility of our stock price.

Our Chief Executive Officer and Chairman of the Board of Directors owns a substantial amount of our common stock any may be able to exert significant influence over the outcome of matters submitted to stockholders for approval.

As of March 17, 2023, our Chief Executive Officer and Chairman of the Board of Directors beneficially owned approximately 18.1% of our common stock. As such, our Chief Executive Officer may exert significant influence over the outcome of matters submitted to stockholders for approval. Consequently, he exercises substantial influence over major decisions including major corporate actions such as mergers and other business combinations transactions which could result in or prevent a change of control of the Company. Circumstances may occur in which the interests of our Chief Executive Officer could be in conflict with the interests of other stockholders. Accordingly, a stockholder's ability to influence us through voting their shares may be limited.

Our Certificate of Incorporation and By-laws contain certain provisions that may be barriers to a takeover.

Our Certificate of Incorporation and By-laws contain certain provisions which may deter, discourage, or make it difficult for another person or entity to gain control of the Company through a tender offer, merger, proxy contest or similar transaction or series of transactions, including provisions that:

- authorize our board of directors to authorize "blank check" preferred stock without stockholder approval, which may provide for voting, liquidation, dividend, and other rights superior to our common stock;
- specify that special meetings of our stockholders can be called only by our chairman or the board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder matters to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- expressly authorized our board of directors to make, alter, amend, or repeal our amended and restated bylaws.

These provisions may deter a future tender offer or other takeover attempt which could include a premium over the market price of our common stock at the time. Such provisions could depress the trading price of our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, executive officers, or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Certificate of Incorporation or Bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine shall be the Court of Chancery in the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware). This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933 or the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

Although the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, executive officers, or other employees, which may discourage lawsuits against us and our directors, executive officers, and other employees. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

We have agreed to indemnify our officers and directors from liability.

Our Certificate of Incorporation and our By-laws provide that we will indemnify, to the fullest extent permitted by the Delaware General Corporation Law, any person who is or was made a party to, or is or was threatened to be made a party to, any pending, completed, or threatened action, suit or proceeding because he or she is or was a director, officer, employee or agent of the Company or is or was serving at the Company's request as a director, officer, employee or agent of any corporation, partnership, joint venture, trust or other enterprise. These provisions permit us to advance expenses to an indemnified party in connection with defending any such proceeding, upon receipt of an undertaking by the indemnified party to repay those amounts if it is later determined that the party is not entitled to indemnification. We entered into indemnity agreements with each member of our board of directors. These agreements provide, among other things, that we will indemnify each officer and director in the event they become a party or otherwise a participant in any action or proceeding on account of their service as a director or officer of the Company (or service for another corporation or entity in any capacity at the request of the Company) to the fullest extent permitted by applicable law. The indemnification provisions may reduce the likelihood of derivative litigation against directors and officers and discourage or deter stockholders from suing directors or officers for breaches of their duties to the Company, even though such an action, if successful, might otherwise benefit the Company or its stockholders. In addition, to the extent that we expend funds to indemnify directors and officers, funds will be unavailable for operational purposes.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are located in Garden City, New York. We leased this property commencing in December 2020. Our headquarters are approximately 25,000 square feet and are comprised of lab diagnostic area with storage area and office space. Our second location is approximately 4,000 square feet and is comprised of lab diagnostic area with storage area and office space in Old Bridge, NJ. We leased additional administrative office space of approximately 2,000 square feet in Fort Washington, PA. Our principal manufacturing facility is located in Lebanon, Pennsylvania. The facility was purchased in October 2004. The facility has a total area of approximately 57,500 square feet and is comprised of manufacturing, warehousing and office space. We are currently exploring opportunities to expand our lab operations.

Item 3. Legal Proceedings

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of business. We are not presently a party to any material litigation.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Market Information

Our common stock is currently traded on The Nasdaq Capital Market under the trading symbol "PRPH."

As of March 24, 2023, there were approximately 172 holders of record.

Securities Authorized Under Equity Compensation Plans

See Part III, Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information relating to our equity compensation plans.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total number of shares purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or approximate dollar value) of Shares that May Yet Be Purchased Under the Plans or Programs (2)
October 1 through October 31, 2022	29,323	$ 10.10	29,323	$ 4,553,838
November 1 through November 30, 2022 ...	1,781	$ 10.30	1,781	4,535,493
December 1 through December 31, 2022	66,993	9.94	66,993	3,869,583
	98,097	$ 9.99	98,097	$ 3,869,583

(1) These shares were purchased on the open market pursuant to the Company's stock repurchase program.
(2) The stock repurchase program, which was previously announced by the Company on July 26, 2022, authorized the repurchase of up to $6 million of the Company's common stock. The stock repurchase program expires on February 17, 2023 .

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this Annual Report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report.

General

We are a growth oriented and diversified company focused on diagnostic and genomic products and services, the development and commercialization of novel drugs, dietary supplements, and compounds, and contract manufacturing.

Until late fiscal year 2020, we were engaged primarily in the research, development, manufacture, distribution, marketing and sale of over-the-counter ("OTC") consumer healthcare products and dietary supplements in the United States.

In October 2020, we completed the acquisition of all of the issued and outstanding shares of capital stock of Confucius Plaza Medical Laboratory Corp. ("CPM"), which owned a 4,000 square foot CLIA accredited laboratory located in Old Bridge, New Jersey for approximately $2.5 million, and began offering COVID-19 diagnostic tests through our wholly-owned subsidiary, ProPhase Diagnostics, Inc. ("ProPhase Diagnostics") in December 2020. Also in December 2020, we expanded our diagnostic service business with the build-out of a second, larger CLIA accredited laboratory in Garden City, New York. Operations at this second facility commenced in January 2021. We currently offer a broad array of COVID-19 related clinical diagnostic and testing services including polymerase chain reaction ("PCR") testing for COVID-19 and Influenza A and B through ProPhase Diagnostics, as well as rapid antigen and antibody/immunity testing for COVID-19. Our diagnostic service business is and will continue to be impacted by the level of demand for COVID-19 and other diagnostic testing, how long this demand persists, the price we are able to receive for performing our testing services, our ability to collect payment or reimbursement for our testing services, as well as the availability of COVID-19 testing from other laboratories, our ability to comply with applicable regulatory requirements, and the period of time for which we are able to serve as an authorized laboratory offering COVID-19 testing under various Emergency Use Authorizations.

In August 2021, we acquired Nebula Genomics, Inc. ("Nebula Genomics"), a privately owned personal genomics company, through our wholly-owned subsidiary, ProPhase Precision Medicine Inc. ("ProPhase Precision"). Nebula Genomics focuses on genomics sequencing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic sequencing can be used to help identify inherited disorders and tendencies, help predict disease risk, help identify expected drug response, and characterize genetic mutations, including those that drive cancer progression. Our personal genomics business is and will continue to be impacted by demand for our genetic sequencing products and services, our marketing and service capabilities, and our ability to comply with applicable regulatory requirements.

Our wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO") was formed in June 2022, for the licensing, development and commercialization of novel drugs, dietary supplements 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. We also own the exclusive rights to the BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets.

Our wholly-owned subsidiary, Pharmaloz Manufacturing, Inc. ("PMI"), is a full-service contract manufacturer and private label developer of a broad range of non-GMO, organic and natural-based cough drops and lozenges and OTC drug and dietary supplement products. Our contracting manufacturing business is and will continue to be impacted by demand for our services, which is largely a function of the timing, length and severity of each cold season. Generally, a cold season is defined as the period from September to March when the incidence of the common cold rises as a result of the change in weather and other factors. We generally experience in the first, third and fourth quarter higher levels of net revenues from our contract manufacturing business. Revenues are generally at their lowest levels in the second quarter when customer demand generally declines.

We also develop and market dietary supplements under the TK Supplements® brand. Our TK Supplements® product line includes Legendz XL®, a male sexual enhancement and Triple Edge XL®, an energy and stamina booster. Our consumer sales are and will continue to be impacted by (i) the timing of acceptance of our TK Supplements® consumer products in the marketplace, and (ii) fluctuations in the timing of purchase and the ultimate level of demand for these products.

We continue to actively pursue acquisition opportunities for other companies, technologies and products within and outside the consumer products industry.

We maintain two operating segments: diagnostic services (which includes our COVID-19 and other diagnostic testing services) and consumer products (which includes our contract manufacturing, retail customers, biopharma and personal genomics products and services).

Results of Operations from Operations

December 31, 2022 compared with December 31, 2021

Net revenue for the year ended December 31, 2022, increased $43.6 million, or 55%, to $122.6 million compared to $79.0 million for the year ended December 31, 2021. The increase in net revenue was the result of a $39.8 million increase from diagnostic services, and a $3.8 million increase from consumer products.The increase in net revenue from diagnostic services was due to increased COVID-19 testing volumes performed as a result of the spread of the Omicron variant, which emerged in early 2022. Overall diagnostic testing volume increased from approximately 600,000 tests for the year ended December 31, 2021 to approximately 1,000,000 tests for the year ended December 31, 2022, of which 58% and 29% were reimbursed by the HRSA uninsured program, respectively.

Cost of revenues for the year ended December 31, 2022 was $52.0 million, comprised of $39.9 million for diagnostic services and $12.1 million for consumer products. Cost of revenues for the year ended December 31, 2021 were $37.1 million comprised of $29.4 million for diagnostic services and $7.6 million for consumer products.

We realized a gross profit of $70.7 million for the year ended December 31, 2022, as compared to $42.0 million for the year ended December 31, 2021. The increase for the year ended December 31, 2022, compared to the year ended December 31, 2021 consisted of $28.7 million attributable to an increase in diagnostic services, while consumer products remained flat. For the year ended December 31, 2022, our overall gross margin was 57.6% as compared to 53.1% for the year ended December 31, 2021. Gross margin for diagnostic services was 63.2% and 57.1% for the years ended December 31, 2022 and 2021, respectively. The increase in gross margin was principally due (i) increased efficiencies in our lab processing, (ii) decreased sample collection costs and (iii) a decrease in cost of testing materials. Gross margin for consumer products was 15.5% and 27.1% for years ended December 31, 2022 and 2021, respectively. Gross margin for consumer products has historically been influenced by fluctuations in quarter-to-quarter production volume, fixed production costs and related overhead absorption, raw ingredient costs, inventory mark to market write-downs and timing of shipments to customers.

Diagnostic expenses for the year ended December 31, 2022 were $12.0 million as compared to $9.2 million of diagnostic expenses for the year ended December 31, 2021. The increase in diagnostic expenses of $2.8 million was primarily due to increased COVID-19 testing volumes performed as a result of the spread of the Omicron variant, which emerged in early 2022, partially offset by a greater proportion of costs allocated to cost of revenues as a result of the nature of agreements with network providers.

General and administration expenses increased $11.9 million for the year ended December 31, 2022 to $34.4 million as compared to $22.5 million for the year ended December 31, 2021 . The increase in general and administration expenses for the year ended December 31, 2022 as compared to the year ended December 31, 2021 was primarily related to an increase in personnel expenses and professional fees associated with our diagnostic services business. Additionally, we recorded a bad debt expense of $5.9 million of trade receivable bad debts that we have determined to be uncollectible.

Research and development costs for the year ended December 31, 2022 were $0.7 million as compared to $0.5 million for the year ended December 31, 2021. The increase in research and development costs in fiscal 2022 as compared to fiscal 2021 was principally due to an increase in personnel expenses associated with our diagnostics services business.

Interest and other income for the years ended December 31, 2022 and 2021 was $0.2 million and $0.6 million, respectively. The decrease in interest income for the year ended December 31, 2022 as compared to the year ended December 31, 2021 was primarily due to the lower account balance of our investment account that bears interest.

Loss from the change in fair value of investment securities for the years ended December 31, 2022 and 2021 was $0.1 million and $0.2 million, respectively, which was due to a decrease in stock price as of December 31, 2022 and 2021.

Impairment of a secured promissory note receivable was $3.75 million for the year ended December 31, 2021. This note was fully written off in 2021 and there was no impact to the year ended December 31, 2022 results from operations.

As a result of the effects described above, net income for the year ended December 31, 2022 was $18.5 million, or $1.17 per share, as compared to $6.3 million, or $0.41 per share, for the year ended December 31, 2021. Diluted earnings per share for the years ended December 31, 2022 and 2021 were $1.02 and $0.40 , respectively.

3Non-GAAP Financial Measure and Reconciliation

In an effort to provide investors with additional information regarding our results of operations as determined by accounting principles generally accepted in the United States of America (“GAAP”), we disclose certain non-GAAP financial measures. The primary non-GAAP financial measures we disclose are EBITDA and Adjusted EBITDA.

We define EBITDA as net income (loss) before net interest expense, income taxes, depreciation and amortization. Adjusted EBITDA further adjusts EBITDA by excluding acquisition costs, other non-cash items, and other unusual or non-recurring charges (as described in the table below).

Non-GAAP financial measures should not be considered as a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. These non-GAAP financial measures do not reflect a comprehensive system of accounting, differ from GAAP measures with the same names and may differ from non-GAAP financial measures with the same or similar names that are used by other companies. We compute non-GAAP financial measures using the same consistent method from quarter to quarter and year to year. We may consider whether other significant items that arise in the future should be excluded from the non-GAAP financial measures.

We use EBITDA and Adjusted EBITDA internally to evaluate and manage the Company's operations because we believe they provide useful supplemental information regarding the Company's ongoing economic performance. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our operating results primarily because they exclude amounts that are not considered part of ongoing operating results when planning and forecasting and when assessing the performance of the organization. In addition, we believe that non-GAAP financial information is used by analysts and others in the investment community to analyze our historical results and in providing estimates of future performance and that failure to report these non-GAAP measures could result in confusion among analysts and others and create a misplaced perception that our results have underperformed or exceeded expectations.

The following table sets forth the reconciliations of EBITDA and Adjusted EBITDA excluding other costs to the most comparable GAAP financial measures (in thousands):

	For the years ended	
	December 31, 2022	December 31, 2021
GAAP net income (1)	$ 18,463	$ 6,273
Interest, net	611	506
Income Tax Expense (Benefit)	4,445	(968)
Depreciation and amortization	4,718	3,233
EBITDA	28,237	9,044
Acquisition costs (2)	—	674
Share-based compensation expense	3,986	3,183
Non-cash rent expense (3)	236	459
Bad debt expense	6,163	3,750
Adjusted EBITDA	$ 38,622	$ 17,110

(1) We believe that net income is the financial measure calculated and presented in accordance with GAAP that is most directly comparable to EBITDA and Adjusted EBITDA. EBITDA and Adjusted EBITDA measure the Company's operating performance without regard to certain expenses. EBITDA and Adjusted EBITDA are not presentations made in accordance with GAAP and the Company's computation of EBITDA and Adjusted EBITDA may vary from others in the industry. EBITDA and Adjusted EBITDA have important limitations as analytical tools and should not be considered in isolation or as substitutes for analysis of the Company's results as reported under GAAP.

(2) Transaction cost related to the Nebula acquisition.

(3) The non-cash portion of rent, which reflects the extent to which our GAAP rent expense recognized exceeds (or is less than) our cash rent payments. For newer leases, our rent expense recognized typically exceeds our cash rent payments, while for more mature leases, rent expense recognized is typically less than our cash rent payments.

Liquidity and Capital Resources

Our aggregate cash and cash equivalents and restricted cash as of December 31, 2022 were $9.1 million as compared to $8.7 million at December 31, 2021. Our working capital was $44.8 million and $45.8 million as of December 31, 2022 and 2021, respectively. The increase of $0.5 million in our cash and cash equivalents for the year ended December 31, 2022 was primarily due to the proceeds from the sale and maturities of marketable debt securities of $8.2 million, proceeds from dispositions of property and other assets of $0.5 million, and $28.7 million in cash provided by operating activities, offset by (i) purchases of marketable securities of $6.8 million, (ii) cash dividend payments of $9.3 million, (iii) repayment of note payable of $7.0 million, (iv) repurchase of common shares for $2.2 million, and (v) capital expenditures of $4.1 million (vi) repayment of common stock for payment of statutory taxes of $7.5 million.

To date the principal sources of capital to fund our operations have been from diagnostic services, product sales, net proceeds from the offering of equity securities, and issuances of promissory notes. Based on management's current business plans, the Company estimates it will have enough cash and liquidity to finance its operating requirements for at least 12 months from the date of filing these consolidated financial statements. However, due to the nature of the diagnostic business and the Company's focus thus far on COVID-19 testing, there are inherent uncertainties associated with managements' business plan and cash flow projections, particularly if the Company is unable to grow its diagnostic testing business beyond COVID-19 testing services and/or grow its other businesses.

During the year ended December 31, 2022, cash from operations provided $28.6 million. To the extent that we do not generate sufficient cash from operations, our cash balances will decline. We may also use our cash to explore and/or acquire new product technologies, applications, product line extensions, new contract manufacturing applications and other new product opportunities. In the event that our available cash is insufficient to support such initiatives, we may need to incur indebtedness or issue common stock to finance our plans for growth. Volatility in the credit markets and the liquidity of major financial institutions, including as a result of inflation, the COVID-19 pandemic and/or the war in Ukraine and measures taken in response thereto, may have an adverse impact on our ability to fund our business strategy through future borrowings, under either existing or newly created instruments in the public or private markets on terms that we believe to be reasonable, if at all.

On May 9, 2022, the board of directors of the Company declared a special cash dividend of $0.30 per share on the Company's common stock, paid on June 4, 2022, in the amount of $4.7 million to holders of record of the Company's common stock as of May 25, 2022.

On February 14, 2022, the board of directors of the Company declared a special cash dividend of $0.30 per share on the Company's common stock, paid on March 10, 2022, in the amount of $4.6 million to holders of record of the Company's common stock on March 1, 2022.

For the year ended December 31, 2021, the Board declared a special cash dividend of $0.30 per share on the Company's common stock to holders of record on May 25, 2021, resulting in the payment of $4.5 million to stockholders on June 3, 2021.

Contractual Obligations and Commitments

Equivir License Agreement

Under the terms of our license agreement with Global BioLife for the worldwide exclusive right and license to Equivir and Equivir G, we are required to pay to Global BioLife a royalty of 5.5% after the date of first commercial sale and during the royalty term. In the event that no valid claim of Equivir Licensed Patents cover a Equivir Licensed Product in a particular jurisdiction, the royalty rate for such Equivir Licensed Product will be reduced by 50%. See Part I, Item 1, "Business - Licensing Agreements" for additional details regarding this agreement.

Linebacker License Agreement

Under the terms of our license agreement with Global BioLife for the worldwise exclusive right and license to Linebacker (LB-1 and LB-2), we must pay Global BioLife $900,000 following the achievement of a first Phase 3 study which may be required by the FDA for the first Linebacker Licensed Product and an additional $1 million upon the receipt of regulatory approval of a New Drug Application (NDA) for the first Linebacker Licensed Product. During the term of the license agreement, we are also required to pay to Global BioLife 3% royalties on Net Revenue (as defined in the license agreement) of each Linebacker Licensed Product, but no less than the minimum royalty of $250,000 of Net Revenue per year minus any royalty payments for any required third party licenses. See Part I, Item 1, "Business - Licensing Agreements" for additional details regarding this agreement.

Stella Asset Purchase Agreement

On December 15, 2022, we entered into an Asset Purchase Agreement (the "Stella Purchase Agreement") with Stella Diagnostics Inc. ("Stella") and Stella DX, LLC ("Stella DX" and, together with Stella, the "Stella Sellers"), pursuant to which, on January 3, 2023, we purchased all of the assets, rights and interests of the Stella Sellers and their affiliates pertaining to the Sellers' BE-Smart Esophageal Pre-Cancer diagnostic screening test and certain clinical assets, including all intellectual property rights (the "Stella Purchased Assets"). As consideration for the Stella Purchased Assets, we (i) paid to the Stella Sellers $3.5 million in cash, minus (a) the Secured Note Amount, if any, (b) the Liability Payoff Amount and (c) the Promissory Note Payoff Amounts (each as defined in the Stella Purchase Agreement), and (ii) issued to Stella DX 100,000 shares of our common stock. (See Footnote 11 to the Consolidated Financial Statements).

We are required to pay to the Stella Sellers for each of the seven calendar years (each, an "Annual Period") during the seven year period commencing on the first day of the calendar year following the date of the Commercialization Event (as defined in the Stella Purchase Agreement), a non-refundable, non-creditable royalty of 5% of the Adjusted Gross Margin (as defined in the Stella Purchase Agreement) for such Annual Period.

JXVII Trust Promissory Note

On January 26, 2023, we issued an unsecured promissory note and guaranty for an aggregate principal amount of $7.6 million (the "JXVII Note") to JXVII Trust ("JXVII"). The JXVII Note is due and payable on January 27, 2026, the third anniversary of the date on which the JXVII Note was funded (the "Note Closing Date"), and accrues interest at a rate of 10% per year from the Note Closing Date, payable on a quarterly basis, until the JXVII Note is repaid in full. We have the right to prepay the JXVII Note at any time after the Note Closing Date and prior to the maturity date without premium or penalty upon providing seven days' written notice to JXVII. Repayment of the JXVII Note has been guaranteed by the Company's wholly-owned subsidiary, PMI.

The JXVII Note contains customary events of default. If a default occurs and is not cured within the applicable cure period or is not waived, any outstanding obligations under the JXVII Note may be accelerated. The JXVII Note also contains certain restrictive covenants which, among other things, restrict our ability to create, incur, assume or permit to exist, directly or indirectly, any lien (other than certain permitted liens described in the JXVII Note) securing any indebtedness of the Company, and prohibits us from distributing or reinvesting the proceeds from any divestment of assets (other than in the ordinary course) without the prior approval of JXVII. (See Footnote 11 to the Consolidated Financial Statements).

COVID-19

The COVID-19 pandemic has not had a material adverse impact on our business to date. We experienced higher than normal net revenue for the year ended December 31, 2022, primarily as a result of increased revenue from our diagnostic services business. The increase in net revenue from diagnostic services was due to increased COVID-19 testing volumes performed as a result of the spread of the Omicron variant, which emerged in early 2022. There can be no assurance that demand for our COVID-19 testing services will continue to exist in the future due to the widespread and effective vaccination of a majority of Americans against COVID-19 and successful containment efforts. If there is no demand for our COVID-19 testing services, and we are unable to generate sufficient profits from other RPP Molecular tests and/or our other businesses, our overall business could be materially adversely affected.

There are still numerous uncertainties associated with the COVID-19 pandemic, including the efficacy of the vaccines that have been developed to treat the virus and their ability to protect against new strains of the virus, people's willingness to receive a vaccine, possible resurgences of the coronavirus and/or new strains of the virus, the extent and duration of protective and preventative measures that may be adopted by local, state and/or the federal government in the future as a result of future outbreaks, including business closures, the ongoing impact of COVID-19 on the U.S. and world economy and consumer confidence, and various other uncertainties all of which could negatively impact our Company as a whole.

The COVID-19 pandemic has had a negative impact on the global capital markets and economies worldwide and could ultimately have a material adverse impact on our ability to raise capital needed to develop and commercialize products.

HRSA Funding

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted, providing for reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding. Approximately 28.0% and 57.6% of our diagnostic services revenue for the years ended December 31, 2022 and 2021, respectively, was generated from this program for the uninsured. At December 31, 2022, there were no uncollected receivables that were due from HRSA included in trade receivables. On March 22, 2022, the Health Resources & Services Administration ("HRSA") uninsured program stopped accepting claims for COVID-19 testing and treatment due to lack of sufficient funds. Despite requests from the Acting Director of the Office of Management and Budget and the White House Coordinator for COVID-19 Response for additional emergency funding for the uninsured program, emergency funding has not been allocated to the HRSA uninsured program. We continue to perform testing for uninsured persons and are incurring the accompanying costs.

At-the-Market Facility

On December 28, 2021, we entered into a Sales Agreement (the "Sales Agreement") with ThinkEquity LLC (the "Sales Agent"), pursuant to which we may offer and sell, from time to time through the Sales Agent, shares of our common stock having an aggregate offering price of up to $100,000,000, subject to the terms and conditions of the Sales Agreement. We are not obligated to make any sales of shares under the Sales Agreement.

We will pay the Sales Agent a fixed commission rate of 2.0% of the aggregate gross proceeds from the sale of any shares pursuant to the Sales Agreement and have agreed to provide the Sales Agent with customary indemnification and contribution rights. We also agreed to reimburse the actual out-of-pocket accountable expenses of the Sales Agent up to $60,000 (of which a $25,000 advance was paid on December 7, 2021), which amount includes the fees and expenses of legal counsel to the Sales Agent up to $50,000, and to pay the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, in an amount not to exceed $3,000.

We will pay the Sales Agent a fixed commission rate of 2.0% of the aggregate gross proceeds from the sale of any shares pursuant to the Sales Agreement and have agreed to provide the Sales Agent with customary indemnification and contribution rights. We also agreed to reimburse the actual out-of-pocket accountable expenses of the Sales Agent up to $60,000 (of which a $25,000 advance was paid on December 7, 2021).

Additionally, we will pay to H.C. Wainwright & Co. ("Wainwright"), a fee equal to 1.0% of the gross proceeds of the sales price of all the shares sold under the Sales Agreement, pursuant to a separate financial services agreement with Wainwright. Wainwright is not a sales agent under the Sales Agreement.

For the years ended December 31, 2022 and 2021, we did not have any sales under the at-the-market facility.

Impact of Inflation

We are subject to normal inflationary trends and anticipate that any increased costs for our contract manufacturing and retail operations would be passed on to our customers; however, any increased costs related to diagnostic services would be absorbed by the Company. Inflation has not had a material effect on our business.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included under Item 8 of this Part II. However, certain accounting policies are deemed "critical", as they require management's highest degree of judgment, estimates and assumptions. These accounting policies, estimates and disclosures have been discussed with the Audit Committee of our Board of Directors. A discussion of our critical accounting policies and estimates, the judgments and uncertainties affecting their application and the likelihood that materially different amounts would be reported under different conditions or using different assumptions are as follows:

Use of Estimates

The preparation of financial statements and the accompanying notes thereto, in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the respective reporting periods. Examples include revenue recognition and the estimation of the variable consideration associated with the diagnostic reimbursement rates, the provision for bad debt and billing discrepancies, sales returns and allowances, inventory obsolescence, useful lives of property and equipment, impairment of goodwill, intangibles and property and equipment, income tax valuations and assumptions related to accrued advertising. The estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

Revenue Recognition and Accounts Receivables

We generate revenue principally through four types of revenue streams: diagnostic services, genomic products and services, contract manufacturing, and retail and other. The process for estimating revenues and the ultimate collection of receivables involves assumptions and judgments.

Revenue from our diagnostic services is recognized when the lab test is complete, and the diagnostic test result is provided to the customer. Revenue from our genomics services is recognized when the sequencing report is provided to the customer. Revenue from our consumer products is recognized when the shipments to contract manufacturing and retailer customers are recognized at the time ownership is transferred to the customer. We bill the providers at standard price and take into consideration for negotiated discounts and an anticipated reimbursement remittance adjustments based on the payer portfolio, when revenue is recorded. We use the most expected value method to estimate the transaction price for reimbursements that may vary from the standard price.

We carry our accounts receivable at cost less an allowance for doubtful accounts. Allowances for doubtful accounts are based upon our judgment regarding collectability. On a periodic basis, we evaluate our receivables and establish an allowance for doubtful accounts, based on a history of past write-offs, collections, current credit conditions or generally accepted future trends in the industry and/or local economy. Accounts are written off as uncollectible at the time we determine that collections are unlikely. The reserve is not intended to address return activity or disputed balances with ongoing customers, as this should be addressed in a reserve for credit memos with a corresponding charge to revenue.

Goodwill and Long-lived Assets

We review our goodwill at least annually for impairment as well as the carrying value of goodwill and our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of these assets may not be fully recoverable. When it is determined that the carrying amount of long-lived assets or goodwill is impaired, impairment is measured by comparing an asset's estimated fair value to its carrying value. The determination of fair value is based on quoted market prices in active markets, if available, or independent appraisals; sales price negotiations; or projected future cash flows discounted at a rate determined by management to be commensurate with our business risk. The estimation of fair value utilizing discounted forecasted cash flows includes significant judgments regarding assumptions of revenue, operating and marketing costs; selling and administrative expenses; interest rates; property and equipment additions and retirements; and industry competition, general economic and business conditions, among other factors.

Income Taxes

Accounting for income taxes requires recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. These deferred taxes are measured by applying the provisions of tax laws in effect at the balance sheet date, including the impact of the Tax Cuts and Jobs Act ("TCJA") enacted on December 22, 2017. The TCJA made broad and significant changes to the U.S. tax code that affects the year ended December 31, 2017, including, but not limited to, a change in the federal rate from 35% to 21% effective January 1, 2018.

We recognize in income the effect of a change in tax rates on deferred tax assets and liabilities in the period that includes the TCJA enactment date. We utilize the asset and liability approach which requires the recognition of deferred tax assets and liabilities for the future tax consequences of events that have been recognized in our financial statements or tax returns. In estimating future tax consequences, we generally consider all expected future events other than enactments of changes in the tax law or rates. Until sufficient taxable income to offset the temporary timing differences attributable to operations and the tax deductions attributable to option, warrant and stock activities are assured, a valuation allowance equaling the total net current and non-current deferred tax asset is being provided.

Inventories

Inventory is valued at the lower of cost, determined on a first-in, first-out basis ("FIFO"), or net realizable value. We regularly review inventory quantities on hand and record a provision for excess and obsolete inventory based primarily on current and anticipated customer demand, production and laboratory requirements.

Recently Adopted Accounting Standards

The Company adopted, recently issued, ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470- 20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, to reduce complexity in applying GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in ASC 260, Earnings Per Share, to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities, excluding smaller reporting companies, for fiscal years beginning after December 15, 2021. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

The Company adopted, recently issued, ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Standards, Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments". ASU 2016-13 adds a current expected credit loss ("CECL") impairment model to U.S. GAAP that is based on expected losses rather than incurred losses. Modified retrospective adoption is required with any cumulative-effect adjustment recorded to retained earnings as of the beginning of the period of adoption. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, excluding smaller reporting entities, which will be effective for fiscal years beginning after December 15, 2022. We will adopt ASU 2016-13 beginning January 1, 2023 and do not expect the application of the CECL impairment model to have a significant impact on our allowance for uncollectible amounts for accounts receivable.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the AICPA and the SEC did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Like virtually all commercial enterprises, we may be exposed to the risk ("market risk") that the cash flows to be received or paid relating to certain financial instruments could change as a result of changes in interest rate, exchange rates, commodity prices, equity prices and other market changes.

Our operations are not subject to risks of material foreign currency fluctuations, nor do we use derivative financial instruments in our investment practices. We place our marketable investments in instruments that meet high credit quality standards. We do not expect material losses with respect to our investment portfolio or excessive exposure to market risks associated with interest rates. The impact on our results of one percentage point change in short-term interest rates would not have a material impact on our future earnings, fair value, or cash flows related to investments in cash equivalents or interest-earning marketable securities.

Current economic conditions may cause a decline in business and consumer spending which could adversely affect our business and financial performance including the collection of accounts receivables, realization of inventory and recoverability of assets. In addition, our business and financial performance may be adversely affected by current and future economic conditions, including a reduction in the availability of credit, financial market volatility and recession.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Members of ProPhase Labs, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ProPhase Labs, Inc. and Subsidiaries (the Company) as of December 31, 2022, and the related consolidated statements of operations and comprehensive income, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Diagnostic Service Revenue, Accounts Receivable, and Allowances

As described in Note 2 to the consolidated financial statements, the Company's diagnostic service revenue is derived from third party insurers and government agencies. Management estimates the amount of consideration it expects to receive for providing diagnostic services based on historical billing and collection information. Management takes into consideration expected reimbursements from insurance providers (including uncollectible billings) and government agency programs, including those for uninsured patients. Revenue and accounts receivable are billed based on standard test rates. Revenue and accounts receivable are recognized based on finalized tests and historical reimbursement rate based on the type of service performed and billing code requirements. Given the nature of these estimates, performing audit procedures to evaluate appropriate revenue recognition and allowances associated with diagnostic services with billing discrepancies required a high degree of auditor judgment and an increased extent of effort.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. The procedures included the following:

a. Gaining an understanding of the internal controls relating to the diagnostic services' billing and collection process.
b. Testing the completeness and accuracy of the Company's billing system, which included, among other things, performing transaction testing on a sample of diagnostic tests performed, which included review of patient information including insurance carrier as reimbursement rate is based on payer, review of finalization of test results, and an analysis of the reimbursements rate to date for each payer.
c. Performed a cash reconciliation to ensure the revenue and accounts receivable recognized was reasonable, based on deposits received through December 31, 2022.
d. Reviewed management's estimated allowances as compared to historical collection rates, specific allowances for uncollectible items based on longevity of the outstanding balance and specific reserve by type and payer for probability of payment through December 31, 2022.

/s/ Morison Cogen LLP
PCAOB ID 536
We have served as the Company's auditor since 2022.

Blue Bell, Pennsylvania
March 29, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of ProPhase Labs, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ProPhase Labs, Inc. and subsidiaries (the "Company" or "ProPhase") as of December 31, 2021 and the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity, and cash flows for the year ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 2, *Business and Liquidity Risks & Uncertainties,* on March 15, 2022, the Health Resources & Services Administration ("HRSA"), which constituted $42.0 million and 57.6% of the Company's fiscal 2021 diagnostic service revenue, announced that the uninsured program would stop accepting claims for COVID-19 testing and treatment as of March 22, 2022 due to lack of sufficient funding. If additional funding is not provided, the Company's ability to collect payments form HRSA and generate revenue subsequent to March 22, 2022 from HRSA covered patients would be adversely affected and have a material adverse impact on the Company's results of operations and financial condition. Our opinion is not modified with respect to this matter.

/s/ Friedman LLP
PCAOB ID 711
We served as the Company's auditor from 2020 through June 27, 2022.

East Hanover, New Jersey
March 31, 2022

PROPHASE LABS, INC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
in thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 9,109	$ 8,408
Restricted cash	—	250
Marketable debt securities, available for sale	8,328	8,779
Marketable equity securities, at fair value	—	76
Accounts receivable, net	37,054	37,708
Inventory, net	3,976	4,600
Prepaid expenses and other current assets	2,366	1,496
Total current assets	60,833	61,317
Property, plant and equipment, net	7,288	5,947
Prepaid expenses, net of current portion	121	460
Right-of-use asset, net	4,059	4,402
Intangible assets, net	8,475	10,852
Goodwill	5,709	5,709
Other assets	1,163	608
TOTAL ASSETS	**$ 87,648**	$ 89,295
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 5,905	$ 7,026
Accrued diagnostic services	1,009	1,890
Accrued advertising and other allowances	99	104
Lease liabilities	301	663
Deferred revenue	2,499	2,034
Income tax payable	4,190	1,312
Other current liabilities	2,072	2,495
Total current liabilities	16,075	15,524
Non-current liabilities:		
Deferred revenue, net of current portion	1,059	905
Deferred tax liability, net	224	—
Note payable	—	44
Unsecured convertible promissory notes, net	2,400	9,996
Lease liabilities, net of current portion	4,259	4,198
Total non-current liabilities	7,942	15,143
Total liabilities	24,017	30,667
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity		
Preferred stock authorized 1,000,000, $0.0005 par value, no shares issued and outstanding	—	—
Common stock authorized 50,000,000, $0.0005 par value, 16,210,776 and 15,485,900 shares outstanding, respectively	16	16
Additional paid-in capital	109,138	104,552
Retained earnings (accumulated deficit)	11,753	2,642
Treasury stock, at cost, 18,126,970 and 16,818,846 shares, respectively	(58,033)	(48,407)
Accumulated other comprehensive loss	757	(175)
Total stockholders' equity	63,631	58,628
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 87,648**	$ 89,295

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE INCOME
(in thousands, except per share amounts)

	For the years ended	
	December 31, 2022	**December 31, 2021**
Revenues, net	$ 122,647	$ 79,042
Cost of revenues	51,993	37,054
Gross profit	70,654	41,988
Operating expenses:		
Diagnostic expenses	12,022	9,174
General and administration	34,385	22,493
Research and development	652	520
Total operating expenses	47,059	32,187
Income (loss) from operations	23,595	9,801
Interest income, net	153	642
Interest expense	(764)	(1,148)
Change in fair value of investment securities	(76)	(240)
Impairment of secured promissory note receivable	—	(3,750)
Income from operations before income taxes	22,908	5,305
Income tax benefit (expense)	(4,445)	968
Income from operations after income taxes	**$ 18,463**	**$ 6,273**
Other comprehensive income (loss):		
Unrealized income (loss) on marketable debt securities	932	(164)
Total comprehensive income	$ 19,395	$ 6,109
Earnings per share:		
Basic	$ 1.17	$ 0.41
Diluted	$ 1.02	$ 0.40
Weighted average common shares outstanding:		
Basic	15,845	15,172
Diluted	18,651	18,393

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock Shares Outstanding	Par Value	Additional Paid in Capital	Accumulated (Deficit) Earnings	Comprehensive Loss	Treasury Stock	Total
Balance as of January 1, 2021	**11,604,253**	**$ 14**	**$ 61,674**	**$ (3,631)**	**$ (11)**	**$ (47,490)**	**$10,556**
Unrealized loss on marketable debt securities, net of realized losses of $3, net of taxes	3,000,000	2	35,133	—	—	—	35,135
Issuance of common stock and warrants for cash from private offering	550,000	—	5,500	—	—	—	5,500
Issuance of common shares related to business acquisition	483,685	—	3,608	—	—	—	3,608
Cash dividends	—	—	(4,546)	—	—	—	(4,546)
Repurchases of common shares	(166,824)	—	—	—	—	(917)	(917)
Unrealized loss on marketable debt securities, net of taxes	—	—	—	—	(164)	—	(164)
Cashless warrants exercise	5,986	—	—	—	—	—	—
Stock-based compensation	8,800	—	3,183	—	—	—	3,183
Net income	—	—	—	6,273	—	—	6,273
Balance as of December 31, 2021	**15,485,900**	**16**	**104,552**	**2,642**	**(175)**	**(48,407)**	**58,628**
Issuance of common stock for debt conversion	200,000	—	600	—	—	—	600
Issuance of common stock upon stock options cashless exercise	828,021	—	—	—	—	—	—
Repurchase of common shares	(303,145)	—	—	—	—	(2,152)	(2,152)
Cash dividends	—	—	—	(9,352)	—	—	(9,352)
Treasury shares repurchased to satisfy tax withholding obligations	—	—	—	—	—	(7,474)	(7,474)
Unrealized gain on marketable debt securities, net of taxes	—	—	—	—	932	—	932
Stock-based compensation	—	—	3,986	—	—	—	3,986
Net income	—	—	—	18,463	—	—	18,463
Balance as of December 31, 2022	**16,210,776**	**$ 16**	**$ 109,138**	**$ 11,753**	**$ 757**	**$ (58,033)**	**$63,631**

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended	
	December 31, 2022	**December 31, 2021**
Cash flows from operating activities		
Net income	$ 18,463	$ 6,273
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Realized loss on marketable debt securities	354	165
Depreciation and amortization	4,718	3,234
Amortization of debt discount	4	5
Amortization on right-of-use assets	343	329
Loss on sales of assets	(127)	—
Impairment of secured promissory note receivable	—	3,750
Stock-based compensation expense	3,986	3,183
Change in fair value of investment securities	(174)	240
Non-cash interest income on secured promissory note receivable	—	(316)
Accounts receivable allowances	(761)	3,866
Inventory valuation reserve	(78)	267
Bad debt expense, direct write-offs	6,163	
Changes in operating assets and liabilities:		
Accounts receivable	(4,498)	(38,197)
Inventory	702	(1,746)
Prepaid and other assets	(617)	1,445
Other assets	(555)	(368)
Accounts payable and accrued expenses	(1,121)	2,450
Accrued diagnostic services	(881)	1,890
Accrued advertising and other allowances	(5)	
Deferred revenue	619	2,608
Deferred tax liability, net	(138)	
Lease liabilities	(301)	130
Income taxes payable	2,878	
Other liabilities	(423)	(2,827)
Net cash provided by (used in) operating activities	28,551	(13,619)
Cash flows from investing activities		
Business acquisitions, net of cash acquired	—	(9,066)
Issuance of secured promissory note receivable	—	(1,000)
Purchase of marketable securities	(6,777)	(21,527)
Proceeds from maturities of marketable securities	7,120	
Proceeds from sale of marketable debt securities	1,047	15,858
Proceeds from promissory note	—	300
Proceeds form dispositions of property and other assets, net	452	—
Capital expenditures	(3,919)	(4,231)
Net cash (used in) provided by investing activities	(2,077)	(19,666)
Cash flows from financing activities		
Proceeds from issuance of common stock from public offering, net	—	35,135
Proceeds from issuance of common stock and warrants from private offering	—	5,500
Repayment of common stock for payment of statutory taxes on cashless exercise of stock options	(7,474)	—
Repayment of note payable	(7,044)	(45)
Repurchases of common shares	(2,152)	(917)
Payment of dividends	(9,353)	(4,546)
Net cash (used in) provided by financing activities	(26,023)	35,127
Increase in cash, cash equivalents and restricted cash	451	1,842
Cash, cash equivalents and restricted cash, at the beginning of the year	8,658	6,816
Cash, cash equivalents and restricted cash, at the end of the year	**$ 9,109**	**$ 8,658**
Supplemental disclosures:		
Cash paid for income taxes	$ 1,696	$ —
Interest payment on the promissory notes	$ 763	$ 1,000
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of common shares related to business acquisition	$ —	$ 3,608
Issuance of common shares for debt conversion	$ 600	$ —
Net unrealized loss, investments in marketable debt securities	$ 1,294	$ (164)
Recognize additional goodwill related to deferred tax liability	$ —	$ 362

See accompanying notes to consolidated financial statement

Note 1 – Organization and Business

ProPhase Labs, Inc. ("ProPhase", "we", "us", "our" or the "Company") is a growth oriented and diversified company focused on diagnostic and genomic products and services, the development and commercialization of novel drugs, dietary supplements, and compounds, and contract manufacturing.

Until late fiscal year 2020, the Company was engaged primarily in the research, development, manufacture, distribution, marketing and sale of over-the-counter ("OTC") consumer healthcare products and dietary supplements in the United States.

In October 2020, the Company completed the acquisition of all of the issued and outstanding shares of capital stock of Confucius Plaza Medical Laboratory Corp. ("CPM"), which owned a 4,000 square foot CLIA accredited laboratory located in Old Bridge, New Jersey for approximately $2.5 million, and began offering COVID-19 diagnostic tests through our wholly-owned subsidiary, ProPhase Diagnostics, Inc. ("ProPhase Diagnostics") in December 2020. Also in December 2020, we expanded our diagnostic service business with the build-out of a second, larger CLIA accredited laboratory in Garden City, New York. Operations at this second facility commenced in January 2021. We currently offer a broad array of COVID-19 related clinical diagnostic and testing services including polymerase chain reaction ("PCR") testing for COVID-19 and Influenza A and B through ProPhase Diagnostics, as well as rapid antigen and antibody/immunity testing for COVID-19.

In August 2021, we acquired Nebula Genomics, Inc. ("Nebula Genomics"), a privately owned personal genomics company, through our wholly-owned subsidiary, ProPhase Precision Medicine Inc. ("ProPhase Precision"). Nebula Genomics focuses on genomics sequencing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic sequencing can be used to help 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's wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO"), was formed in June 2022, for the licensing, development and commercialization of novel drugs, dietary supplements 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 also own the exclusive rights to the BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets.

In connection with the activities of PBIO, 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. The development of these novel drugs and compounds is highly dependent on how each performs during the testing and development stage, the demand for these product and services once entered into the marketplace, our marketing and service capabilities and our ability to comply with applicable regulatory requirements.

The Company's wholly-owned subsidiary, Pharmaloz Manufacturing, Inc. ("PMI"), is a full-service contract manufacturer and private label developer of a broad range of non-GMO, organic and natural-based cough drops and lozenges and OTC drug and dietary supplement products.

The Company also develops and markets dietary supplements under the TK Supplements® brand. The TK Supplements® product line includes Legendz XL®, a male sexual enhancement and Triple Edge XL®, an energy and stamina booster.

The Company continues to actively pursue acquisition opportunities for other companies, technologies and products within and outside the consumer products industry.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. Certain prior period amounts have been reclassified to conform to the current period presentation. These reclassifications had no effect on the reported results of operations.

Segments

In accordance with the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") 280, "Segment Reporting" ("ASC 280"), the Company discloses financial and descriptive information about its reportable operating segments. Operating segments are components of an enterprise about which separate financial information is available and regularly evaluated by the chief operating decision maker in deciding how to allocate resources and in assessing performance.

The Company follows ASC 280, which establishes standards for reporting information about operating segments in annual and interim financial statements, and requires that companies report financial and descriptive information about their reportable segments based on a management approach. ASC 280 also establishes standards for related disclosures about products and services, geographic areas and major customers.

Operating segments are defined as components of an enterprise that engage in business activities for which separate financial information is available and is evaluated by the Chief Operating Decision Maker ("CODM"), which for the Company is its Chief Executive Officer, in deciding how to allocate resources and assess performance. We maintain two operating segments: diagnostic services (which includes our COVID-19 and other diagnostic testing services) and consumer products (which includes our contract manufacturing, retail customers, biopharma and personal genomics products and services). See Note 15 Segment Information.

Business and Liquidity Risks and Uncertainties

Our diagnostic service business is and will continue to be impacted by the level of demand for COVID-19 and other diagnostic testing, how long this demand persists, the prices we are able to receive for performing our testing services, our ability to collect payment or reimbursement for our testing services, as well as the availability of COVID-19 testing from other laboratories and the period of time for which we are able to serve as an authorized laboratory offering COVID-19 testing under various Emergency Use Authorizations.

While our revenues increased significantly for the year ended December 31, 2022 as a result of the diagnostic services business line, we have made and will continue to make substantial investments to secure the necessary equipment, supplies and personnel to provide these testing services. Our customer base for our COVID-19 tests is principally comprised of governmental bodies, municipalities, and large corporations who pay us directly or through third-party payers. While our revenues increased significantly since the launch of our diagnostic services business, we have been dependent on both government agency and insurance company reimbursement as well as the prevalence of COVID-19 associated strains.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), was enacted, providing for reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding. On March 22, 2022, the Health Resources & Services Administration (HRSA) program stopped accepting claims for COVID-19 testing and treatment due to lack of sufficient funds. As a result of the suspension of the HRSA uninsured program, we have not recognized any revenue related to COVID-19 testing that we performed for uninsured individuals from March 22, 2022 through December 31, 2022.

Our personal genomics business is and will continue to be influenced by demand for our genetic sequencing products and services, our marketing and service capabilities, and our ability to comply with applicable regulatory requirements.

Our contracting manufacturing business is and will continue to be impacted by demand for our services, which is largely a function of the timing, length and severity of each cold season. Generally, a cold season is defined as the period from September to March when the incidence of the common cold rises as a result of the change in weather and other factors. We generally experience in the first, third and fourth quarter higher levels of net revenues from our contract manufacturing business. Revenues are generally at their lowest levels in the second quarter when customer demand generally declines.

Our consumer sales are and will continue to be impacted by (i) the timing of acceptance of our TK Supplements® consumer products in the marketplace, and (ii) fluctuations in the timing of purchase and the ultimate level of demand for these products.

For the year ended December 31, 2022, $28.6 million was provided by operating activities. The Company had cash, cash equivalents and marketable securities of $17.4 million as of December 31, 2022. Based on management's current business plans, the Company estimates that it will have enough cash and liquidity to finance its operating requirements for at least one year from the date of filing these financial statements. However, due to the nature of the diagnostic business and the Company's focus thus far on COVID-19, there are inherent uncertainties associated with managements' business plan and cash flow projections if the Company is unable to grow its diagnostic testing business beyond COVID-19 testing services and to grow its other businesses.

As such, the Company's future capital needs and the adequacy of its available funds will depend on many factors. These include, but not necessarily limited to, the actual cost and time necessary to achieve sustained profitability from diagnostic services, the ability to successfully diversify the diagnostic services revenue streams and the ability to market and grow the personal genomics, biopharma, manufacturing and supplement businesses. The Company may be required to raise additional funds through equity or debt securities offerings or strategic collaboration and/or licensing agreements in order to fund operations until it is able to generate enough revenues. Such financing may not be available on acceptable terms, or at all, and the Company's failure to raise capital when needed could have a material adverse effect on its strategic objectives, results of operations and financial condition.

Use of Estimates

The preparation of financial statements and the accompanying notes thereto, in conformity with generally accepted accounting principles in the United States of America ("GAAP"), requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the respective reporting periods. Examples include revenue recognition and the impact of the variable consideration around diagnostic test reimbursement rates, the provision for uncollectible receivables and billing errors, sales returns and allowances, rates, slow moving, dated inventory and associated provisions, the estimated useful lives and potential impairment of long-lived assets, stock based compensation valuation, income tax asset valuations and assumptions related to accrued advertising.

Our estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents include cash on hand and monies invested in money market funds. The carrying amount approximates the fair market value due to the short-term maturity of these securities.

Restricted Cash

Restricted cash as of December 31, 2022 and 2021 includes approximately $250,000 held in escrow related to a potential purchase of an additional lab facility. The Company fully reserved for this amount in Fiscal 2022.

Marketable Debt Securities

We have classified our investments in marketable debt securities as available-for-sale and as a current asset. Our investments in marketable debt securities are carried at fair value, with unrealized gains and as a separate component of stockholders' equity. Realized gains and losses from our marketable debt securities are recorded as interest income (expense). These investments in marketable debt securities carry maturity dates between one and three years from date of purchase and interest rates of 1.40% to 4.90% during fiscal 2022.

The following is a summary of the components of our marketable debt securities and the underlying fair value input level tier hierarchy (see fair value of financial instruments) (in thousands):

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government obligations	$ 1484	$ 6	$ (12)	$ 1478
Corporate obligations	5,702	1,228	(80)	6,850
	$ 7,186	$ 1,234	$ (92)	$ 8,328

	As of December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government obligations	$ 650	$ 17	$ —	$ 667
Corporate obligations	8,304	—	(192)	8,112
	$ 8,954	$ 17	$ (192)	$ 8,779

We believe that the unrealized gains or losses generally are the result of a change in the risk premiums required by market participants rather than an adverse change in cash flows or a fundamental weakness in the credit quality of the issuer or underlying assets.

Marketable Equity Securities

Marketable equity securities are recorded at fair value in the consolidated balance sheets. The change in fair value of marketable equity securities is recognized within other non-operating income, net in the consolidated statements of income.

On June 25, 2021, we were issued 1,260,619 common shares (the "Investment Shares") as an interest payment under our note receivable (see Note 13, Consulting Agreement and Secured Promissory Note Receivable) with a fair value of $315,000 and a fair value of $76,000 and $0 at December 31, 2021 and 2022, respectively. The investment was classified as a Level 1 financial instrument. We recorded a $76,000 decrease in fair value of investment securities within the statement of operations for the year ended December 31, 2022.

Accounts Receivable, net

Accounts receivable consists primarily of amounts due from government agencies and healthcare insurers. Unbilled accounts receivable relates to the delivery of our diagnostic testing services for which the related billings will occur in a future period, after a patient's insurance information has been validated, and represent amounts we have an unconditional right to receive payment. Unbilled accounts receivable is classified as accounts receivable on the consolidated balance sheet. We carry our accounts receivable at the amount of consideration for which we expect to be entitled less allowances. When estimating the allowances for our diagnostics business, the Company pools its trade receivables based on the following payer types: healthcare insurers and government payers. The Company principally estimates the allowance for credit losses by pool based on historical collection experience, current economic conditions, expectations of future economic conditions, other credits and the period of time that the receivables have been outstanding. To the extent that any individual payers are identified that have deteriorated in credit quality, the Company removes the payers from their respective pools and establishes allowances based on the individual risk characteristics of such payers. On a periodic basis, we evaluate our receivables and establish an allowance, based on a history of past write-offs, government and healthcare insurer payment trends, collections, current credit conditions or generally accepted future trends.

Accounts are written off as uncollectible at the time we determine that collections are unlikely. Accounts receivable, net is comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Trade accounts receivable	$ 37,568	$ 18,520
Unbilled accounts receivable	2,626	23,089
	40,194	41,609
Less allowances	(3,140)	(3,901)
Total accounts receivable	$ 37,054	$ 37,708

For Fiscal 2022, we recorded $5.9 million to bad debt expense in operating expenses representing a write-off of trade receivables we have determined to be uncollectible. Additionally, we wrote off $2.9 million of trade receivables and related allowances at December 31, 2022, that were fully reserved for in 2021 and did not impact the result of operations for the year ended December 31, 2022. The Company also increased its allowance for doubtful accounts in Fiscal 2022 by $5.5 million. The results of these adjustments and our current year allowances, resulted in an allowance of $3.1 million at December 31, 2022. For Fiscal 2021, we recorded $3.9 million to the allowance with a corresponding charge to net revenues with no write-off to bad debt expense in 2021.

Inventory, net

Inventory is valued at the lower of cost, determined on a first-in, first-out basis ("FIFO"), or net realizable value. Inventory items are analyzed to determine cost and the net realizable value and appropriate valuation adjustments are established.

At December 31, 2022 and 2021, the components of inventory are as follows (in thousands):

	December 31, 2022	December 31, 2021
Diagnostic services testing material	$ 1,739	$ 2,989
Raw materials	1,639	1,514
Work in process	754	260
Finished goods	356	272
Inventory	$ 4,488	$ 5,035
Inventory valuation reserve	(512)	(435)
Inventory, net	$ 3,976	$ 4,600

Property, Plant and Equipment

Property, plant and equipment are recorded at cost. We use the straight-line method in computing depreciation for financial reporting purposes. Depreciation expense is computed in accordance with the following ranges of estimated asset lives: building and improvements - ten to thirty-nine years; machinery and equipment including lab equipment - three to seven years; computer equipment and software - three to five years; and furniture and fixtures - five years.

Concentration of Financial Risks

Financial instruments that potentially subject us to significant concentrations of credit risk consist principally of cash investments, marketable debt securities, and trade accounts receivable. Our marketable securities are fixed income investments, which are highly liquid and can be readily purchased or sold through established markets.

We maintain cash and cash equivalents with certain major financial institutions. As of December 31, 2022, our cash and cash equivalents and restricted cash balance was $9.1 million. Of the total bank balance, $1.0 million was covered by federal depository insurance and $8.4 million was uninsured at December 31, 2022.

Accounts receivable subject us to credit risk concentrations from time-to-time. We extend credit to our consumer healthcare product customers based upon an evaluation of the customer's financial condition and credit history and generally do not require collateral. Our diagnostic services receivable credit risk is based on payer reimbursement experience, which includes government agencies and healthcare insurers, the period the receivables have been outstanding and the historical collection rates. The collectability of the diagnostic services receivables is also directly linked to the quality of our billing processes, which depend on information provided and billing services of third parties. These credit concentrations impact our overall exposure to credit risk, which could be further affected by changes in economic, regulatory or other conditions that may impact the timing and collectability of trade receivables and diagnostic test receivables. Additionally, the reimbursement receivables from the diagnostic service business are subject to billing errors and related disputes.

We also assess the financial condition of the debtor under our note receivable (see Note 13, Consulting Agreement and Secured Promissory Note Receivable and Consulting Agreement), balances due to us. As of December 31, 2022 and the financial statements reporting date, the Company did not expect full realization upon maturity.

In addition, see Note 14 - Significant Customers Concentrations.

Leases

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. We have elected not to recognize on the balance sheet leases with terms of 12 months or less. We typically only include an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in our assessment unless there is reasonable certainty that we will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in our leases is typically not readily determinable. As a result, we utilize our incremental borrowing rate, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term and in a similar economic environment (see Note 12, Leases).

The components of a lease should be allocated between lease components (*e.g.*, land, building, etc.) and non-lease components (*e.g.*, common area maintenance, consumables, etc.). The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Goodwill and Intangible Assets

Goodwill represents the excess of the fair value of the consideration transferred over the fair value of the underlying identifiable assets and liabilities acquired in a business combination. Goodwill and intangible assets deemed to have an indefinite life are not amortized, but instead are assessed for impairment annually. Additionally, if an event or change in circumstances occurs that would more likely than not reduce the fair value of the reporting unit below its carrying value, we would evaluate goodwill and other intangibles at that time.

In testing for goodwill impairment, we have the option to first assess qualitative factors to determine whether the existence of events or circumstances lead to a determination that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If, after assessing the totality of events and circumstances, we conclude that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is not required. If we conclude otherwise, we are required to perform the two-step impairment test. The goodwill impairment test is performed at the reporting unit level by comparing the estimated fair value of a reporting unit with its respective carrying value. If the estimated fair value exceeds the carrying value, goodwill at the reporting unit level is not impaired. If the estimated fair value is less than the carrying value, an impairment charge will be recorded to reduce the reporting unit to fair value. Management completed a qualitative assessment of Goodwill and it was not deemed impaired at December 31, 2022.

Intangible assets deemed to have finite lives are amortized on a straight-line basis over their estimated useful lives, where the useful life is the period over which the asset is expected to contribute directly, or indirectly, to our future cash flows.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and finite-lived intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when the asset's carrying value exceeds the total undiscounted cash flows expected from its use and eventual disposition. The amount of the impairment loss is determined as the excess of the carrying value of the asset over its fair value. For the fiscal years ended December 31, 2022 and 2021, the Company did not have an impairment of the long-lived assets.

Fair Value of Financial Instruments

We measure assets and liabilities at fair value based on expected exit price as defined by the authoritative guidance on fair value measurements, which represents the amount that would be received on the sale date of an asset or paid to transfer a liability, as the case may be, in an orderly transaction between market participants. As such, fair value may be based on assumptions that market participants would use in pricing an asset or liability. The authoritative guidance on fair value measurements establishes a consistent framework for measuring fair value on either a recurring or nonrecurring basis whereby inputs, used in valuation techniques, are assigned a hierarchical level.

The following are the hierarchical levels of inputs to measure fair value:

- Level 1: Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

- Level 2: Inputs reflect quoted prices for identical assets or liabilities in markets that are not active; quoted prices for similar assets or liabilities in active markets; inputs other than quoted prices that are observable for the assets or liabilities; or inputs that are derived principally from or corroborated by observable market data by correlation or other means.

- Level 3: Unobservable inputs reflecting the Company's assumptions incorporated in valuation techniques used to determine fair value. These assumptions are required to be consistent with market participant assumptions that are reasonably available.

The carrying amounts of our financial assets and liabilities, such as cash, accounts receivable, accounts payable, and unsecured note payable, approximate their fair values because of the short-term nature of these instruments.

We account for our marketable securities at fair value, with the net unrealized gains or losses of marketable debt securities reported as a component of accumulated other comprehensive income or loss and marketable equity securities change in fair value reported on the condensed consolidated statement of operations. The components of marketable securities are as follows (in thousands):

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
U.S. government obligations	$ —	$ 1,478	$ —	$ 1,478
Corporate obligations	5,497	1,354	—	6,851
	$ 5,497	$ 2,832	$ —	$ 8,329

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
U.S. government obligations	$ —	$ 667	$ —	$ 667
Corporate obligations	—	8,112	—	8,112
Marketable equity securities	76	—	—	76
	$ 76	$ 8,779	$ —	$ 8,855

There were no transfers of marketable debt securities between Levels 1, 2 or 3 for the years ended December 31, 2022 and 2021.

Revenue Recognition

We recognize revenue that represents the transfer of promised goods or services to customers at an amount that reflects the consideration that is expected to be received in exchange for those goods or services. We recognize revenue when performance obligations with our customers have been satisfied. At contract inception, we evaluate the contract to determine if revenue should be recognized using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

Contract with Customers and Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. Sales from product shipments to contract manufacturing and retailer customers are recognized at the time ownership is transferred to the customer. Revenue from diagnostic services is recognized when the results are made available to the customer. Revenue from our personal genomics business is recognized when the genetic testing results are provided to the customer. For subscription services associated with our genomic testing, we recognize revenue ratably over the term of the subscription.

The Company's performance obligation for contract manufacturing and retail customers is to provide the goods ordered by the customer. The Company has one performance obligation for its diagnostic services, which is to provide the results of the laboratory test to the customer. Our personal genomics business has separate performance obligations to provide initial testing and genome results and subscriptions services to our customers.

Transaction Price

For our diagnostic services business, a revenue transaction is initiated when we receive a requisition order to perform a diagnostic test. The information provided on the requisition form is used to determine the party that will be billed for the testing performed and the expected reimbursement. We provide diagnostic services to a range of customers. In many cases, the customer that orders our services is not responsible for paying for these services. Depending on the billing arrangement and applicable law, the payer may be the patient or a third party, such as a health plan, Medicare or Medicaid program and other government reimbursement programs. We bill the providers at standard price and take into consideration negotiated discounts and anticipated reimbursement remittance adjustments based on the payer portfolio, when revenue is recorded. We use the most expected value method to estimate the transaction price for reimbursements that vary from the listed contract price.

For our personal genomics business, a revenue transaction is initiated by a DNA test kit sale direct to the consumer sales via our website or through online retailers. The kit sales and subscriptions are billed at a standard price and take into consideration any discounts when revenue is recorded. We also contract with third party B2B partners and universities and sell DNA test kits directly to them.

For contract manufacturing and retail customers, the transaction price is fixed based upon either (i) the terms of a combined master agreement and each related purchase order, or (ii) if there is no master agreement, the price per individual purchase order received from each customer. The customers are invoiced at an agreed upon contractual price for each unit ordered and delivered by the Company.

Revenue from retail customers is reduced for trade promotions, estimated sales returns and other allowances in the same period as the related sales are recorded. No such allowance is applicable to our contract manufacturing customers. We estimate potential future product returns and other allowances related to current period revenue. We analyze historical returns, current trends, and changes in customer and consumer demand when evaluating the adequacy of the sales returns and other allowances.

We do not accept returns from our contract manufacturing customers. Our return policy for retail customers accommodates returns for (i) discontinued products, (ii) store closings and (iii) products that have reached or exceeded their designated expiration date. We do not impose a period of time during which product may be returned. All requests for product returns must be submitted to us for pre-approval. We will not accept return requests pertaining to customer inventory "Overstocking" or "Resets". We will accept return requests only for products in their intended package configuration. We reserve the right to terminate shipment of product to customers who have made unauthorized deductions contrary to our return policy or pursue other methods of reimbursement. We compensate the customer for authorized returns by means of a credit applied to amounts owed.

For our diagnostic services business, a revenue transaction is initiated when we receive a requisition order to perform a diagnostic test. The information provided on the requisition form is used to determine the party that will be billed for the testing performed and the expected reimbursement. We provide diagnostic services to a range of customers. In many cases, the customer that orders our services is not responsible for paying for these services. Depending on the billing arrangement and applicable law, the payer may be the patient or a third party, such as a health plan, Medicare or Medicaid program and other government reimbursement programs. We bill the providers at standard price and take into consideration negotiated discounts and anticipated reimbursement remittance adjustments based on the payer portfolio, when revenue is recorded. We use the most expected value method to estimate the transaction price for reimbursements that vary from the listed contract price.

For our personal genomics business, a revenue transaction is initiated by a DNA test kit sale direct to the consumer sales via our website or through online retailers. The kit sales and subscriptions are billed at a standard price and take into consideration any discounts when revenue is recorded. We also contract with third party B2B partners and universities and sell DNA test kits directly to them.

Recognize Revenue When the Company Satisfies a Performance Obligation

For diagnostic services, the Company satisfies its performance obligation at the point in time that the results are made available to the customer, which is when the customer benefits from the information contained in the results and obtains control.

For genomic services, we satisfy our product performance obligation at a point in time when the genetic testing results are provided to the customer. For subscriptions services associated with its genomic testing, we satisfy our performance obligation ratably over the subscription period. If the customer does not return the test kit, services cannot be completed by us, potentially resulting in unexercised rights ("breakage") revenue, including lifetime subscription services. We estimate breakage for the portion of test kits not expected to be returned using an analysis of historical data and consider other factors that could influence customer test kit return behavior. When breakage revenue is recognized on a kit, we recognize breakage on any associated subscription services ratably over the term of the subscription. The Company recognized breakage revenue from aggregate unreturned test kits and subscriptions of $1.0 million for the year ended December 31, 2022.

Performance obligations related to contract manufacturing and retail customers are satisfied at a point in time when the goods are shipped to the customer as (i) we have transferred control of the assets to the customers upon shipping, and (ii) the customer obtains title and assumes the risks and rewards of ownership after the goods are shipped.

Contract Balances

As of December 31, 2022 and December 31, 2021, we have deferred revenue of $3.6 million and $2.9 million, respectively. Our new personal genomics business comprised $3.5 million of the deferred revenue as of December 31, 2022. The remainder of deferred revenue relates to research and development ("R&D") stability and release testing programs recognized as contract manufacturing revenue. Deferred revenues primarily consist of amounts that have been billed to or received from customers in advance of revenue recognition and prepayments received from customers in advance of services performed for the R&D work. We recognize deferred revenues as revenues when the services are performed and the corresponding revenue recognition criteria are met. Customer prepayments are generally applied against invoices issued to customers when services are performed and billed.

The following table disaggregates our deferred revenue by recognition period (in thousands):

	As of December 31, 2022	As of December 31, 2021
Recognition Period		
0-12 Months	$ 2,499	$ 2,034
13-24 Months	683	530
Over 24 Months	376	375
Total	$ 3,558	$ 2,939

Disaggregation of Revenue

We disaggregate revenue from contracts with customers into four categories: contract manufacturing, retail and others, diagnostic services and genomic products and services. We determined that disaggregating revenue into these categories achieves the disclosure objective to depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors.

The following table disaggregates the Company's revenue by revenue source for Fiscal 2022 and 2021 (in thousands):

	For the years ended	
Revenue by Customer Type	December 31, 2022	December 31, 2021
Diagnostic services	$ 108,329	$ 68,559
Contract manufacturing	8,740	5,786
Retail and others	1,281	2,454
Genomic products and services	4,297	2,243
Total revenue, net	$ 122,647	$ 79,042

Customer Consideration

The Company makes payments to certain diagnostic services customers for distinct services that approximate fair value for those services. Such services include specimen collection, the collection and delivery of insurance and patient information necessary for billing and collection, and logistics services. Consideration associated with specimen collection services is classified in cost of revenues and the remaining costs are classified as diagnostic expenses within operating expenses in the accompanying statement of operations.

Sales Tax Exclusion from the Transaction Price

We exclude from the measurement of the transaction price all taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction and collected by the Company from the customer.

Shipping and Handling Activities

We account for shipping and handling activities that we perform as activities to fulfill the promise to transfer the good.

Advertising and Incentive Promotions

Advertising and incentive promotion costs are expensed within the period in which they are utilized. Advertising and incentive promotion expense is comprised of (i) media advertising, presented as part of general and administrative expense, (ii) cooperative incentive promotions and coupon program expenses, which are accounted for as part of net revenue, and (iii) free product, which is accounted for as part of cost of revenues. Advertising and incentive promotion expenses incurred from continuing operations for Fiscal 2022 and 2021 were $0.4 million and $0.4 million, respectively.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with FASB ASC 718, "Compensation – Stock Compensation." Under the fair value recognition provision of the ASC, stock-based compensation cost is estimated at the grant date based on the fair value of the award. The Company estimates the fair value of stock options and warrants granted using the Black-Scholes-Merton option pricing model and stock grants at their closing reported market value. We recognize all stock-based payments to employees and directors, including grants of stock options, as compensation expense in the financial statements based on their grant date fair values. The grant date fair values of stock options are determined through the use of the Black-Scholes option pricing model. The compensation cost is recognized as an expense over the requisite service period of the award, which usually coincides with the vesting period. We account for forfeitures as they occur.

Stock and stock options to purchase our common stock have been granted to employees pursuant to the terms of certain agreements and stock option plans (see Note 7, Stockholders' Equity). Stock options are exercisable during a period determined by us, but in no event later than seven years from the date granted.

Research and Development

R&D costs are charged to operations in the period incurred, R&D costs incurred for the years ended December 31, 2022 and 2021 were $0.7 million and $0.5 million, respectively. R&D costs are principally related to personnel expenses and new product development initiatives and costs associated with the OTC health care products, dietary supplements and validation costs associated with the diagnostic services business.

Income Taxes

The Company accounts for income taxes in accordance with accounting guidance now codified as FASB ASC 740, "Income Taxes," which requires that the Company recognize deferred tax liabilities and assets based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse.

The provision for, or benefit from, income taxes includes deferred taxes resulting from the temporary differences in income for financial and tax purposes using the liability method. Such temporary differences result primarily from the differences in the carrying value of assets and liabilities. Future realization of deferred income tax assets requires sufficient taxable income within the carry-back, carryforward period available under tax law. We evaluate, on a quarterly basis whether, based on all available evidence, it is probable that the deferred income tax assets are realizable. Valuation allowances are established when it is more likely than not that the tax benefit of the deferred tax asset will not be realized. The evaluation, as prescribed by ASC 740- 10, "Income Taxes," includes the consideration of all available evidence, both positive and negative, regarding historical operating results including recent years with reported losses, the estimated timing of future reversals of existing taxable temporary differences, estimated future taxable income exclusive of reversing temporary differences and carryforwards, and potential tax planning strategies which may be employed to prevent an operating loss or tax credit carryforward from expiring unused.

The Company accounts for income taxes under ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which simplifies various aspects related to accounting for income taxes. This standard became effective for the Company January 1, 2021. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application.

The Company accounts for uncertainties in income taxes under the provisions of FASB ASC 740-10-05 (the "Subtopic"). The Subtopic clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The Subtopic prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Subtopic provides guidance on the de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

Recently Issued Accounting Standards, Adopted

In October 2021, the FASB issued ASU No. 2021-08, Business Combinations (Topic 805)-*Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*. The amendments in ASU No. 2021-08 address diversity and inconsistency related to the recognition and measurement of contract assets and contract liabilities acquired in a business combination. The amendments in ASU No. 2021-08 require that an acquirer recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, Revenue from Contracts with Customers. Upon adoption, an acquirer should account for the related revenue contracts of the acquiree as if it has originated the contracts.

For public business entities, the amendments in ASU No. 2021-08 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The amendments in ASU No. 2021-08 should be applied prospectively to business combinations occurring on or after the effective date of the amendments. Early adoption of the amendments is permitted. An entity that early adopts should apply the amendments (1) retrospectively to all business combinations for which the acquisition date occurs on or after the beginning of the fiscal year that includes the interim period of early application and (2) prospectively to all business combinations that occur on or after the date of initial application. The Company has early adopted ASU No. 2021-08 effective January 1, 2021.

The adoption of ASU No. 2021-08 resulted in adjustments to the fair values assigned to goodwill and deferred revenue assumed as of the acquisition dates of acquisitions occurring during the year ended December 31, 2021, and an increase in revenue for the year ended December 31, 2021, due to recognition of revenue earned during the period for deferred revenue contracts acquired in business combinations. The following tables present the material impacts of adopting ASU No. 2021-08 on the Company's consolidated balance sheets as of December 31, 2021 (in thousands):

	As of December, 31 2021		
	Excluding impacts of adoption of ASU 2021-08	**Adjustment**	**Presentation with adoption of ASU 2021-08**
Assets			
Goodwill	$ 4,458	$ 1,251	$ 5,709
Liabilities			
Deferred Revenue	$ 2,655	$ 284	$ 2,939
Stockholders' equity			
Retained earnings	$ 1,675	$ 967	$ 2,642

The following tables present the material impacts of adoption of ASU No. 2021-08 on the Company's consolidated statements of operations for the year ended December 31, 2021 (in thousands):

	As of December, 31 2021		
	Excluding impacts of adoption of ASU 2021-08	**Adjustment**	**Presentation with adoption of ASU 2021-08**
Revenue	$ 78,075	$ 967	$ 79,042
Net income	$ 5,306	$ 967	$ 6,273
Comprehensive income	$ 5,142	$ 967	$ 6,109

The change in revenues from the ASU adoption did not cause a change in the DTA/DTL or tax expense accounts due to the full valuation allowance for federal tax purposes (any state impact was deemed immaterial). The only tax impact was due to the purchase accounting entry between goodwill and deferred revenue which resulted in a tax entry to goodwill and deferred taxes.

The Company adopted, recently issued, ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470- 20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, to reduce complexity in applying GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in ASC 260, Earnings Per Share, to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities, excluding smaller reporting companies, for fiscal years beginning after December 15, 2021. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

The Company adopted, recently issued, ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Standards, Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments". ASU 2016-13 adds a current expected credit loss ("CECL") impairment model to U.S. GAAP that is based on expected losses rather than incurred losses. Modified retrospective adoption is required with any cumulative-effect adjustment recorded to retained earnings as of the beginning of the period of adoption. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, excluding smaller reporting entities, which will be effective for fiscal years beginning after December 15, 2022. The Company will adopt ASU 2016-13 beginning January 1, 2023 and does not expect the application of the CECL impairment model to have a significant impact on its allowance for uncollectible amounts for accounts receivable.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the AICPA and the SEC did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

Note 3 – Business Acquisitions

Nebula Acquisition

On August 10, 2021 (the "Effective Date"), the Company and its wholly owned subsidiary, ProPhase Precision, entered into and closed a Stock Purchase Agreement (the "Nebula Stock Purchase Agreement") with Nebula Genomics, each of the stockholders of Nebula Genomics (the "Seller Parties"), and Kamal Obbad, as Seller Party Representative. Pursuant to the terms of the Nebula Stock Purchase Agreement, ProPhase Precision acquired all of the issued and outstanding shares of common stock of Nebula Genomics from the Seller Parties, for an aggregate purchase price of approximately $14.6 million, subject to post-closing adjustments (the "Nebula Acquisition"). A portion of the purchase price equal to $3.6 million was paid in shares of the Company's common stock to certain Seller Parties and noteholders of Nebula Genomics, based on their election to receive shares of the Company's common stock in lieu of cash, which shares were valued at a price per share of $7.46, which is equal to the average closing price of the Company's common stock on Nasdaq for the five trading days preceding the signing of the Nebula Stock Purchase Agreement. A portion of the purchase price equal to $1,080,000 (the "Escrow Amount") was held in escrow by Citibank, N.A. (the "Escrow Agent") until February 23, 2023 ("Escrow Termination Date"), pursuant to the terms and conditions of an escrow agreement ("Escrow Agreement") entered into with the Escrow Agent, as security for the indemnification obligations of the Seller Parties.

In connection with the Nebula Acquisition, ProPhase Precision entered into an employment agreement with Kamal Obbad, the Chief Executive Officer of Nebula Genomics, on the Effective Date, pursuant to which Mr. Obbad serves as Senior Vice President, Director of Sales and Marketing of ProPhase Precision Medicine, Inc. As a condition to the employment agreement, Mr. Obbad was awarded a stock option to purchase 250,000 shares of Company common stock at an exercise price equal to $7.67 per share, the closing price of the Company's common stock on the Effective Date. The award was issued as a material inducement to Mr. Obbad's acceptance of employment with ProPhase Precision in accordance with Nasdaq Listing Rule 5635(c)(4) and was approved by the Company's Compensation Committee (see Note 7, Stockholders' Equity).

Based on the preliminary valuation, the total consideration of $12.7 million, which is net of $1.6 million in cash acquired and $0.3 million anticipated to be paid back to the Company from the Escrow Amount, has been allocated to assets acquired and liabilities assumed based on their respective fair values as follows (in thousands):

Account	Amount
Short term investments	$ 1,800
Accounts receivable	222
Inventory	82
Prepaid and other current assets	379
Definite-lived intangible assets	10,990
Total assets acquired	**13,473**
Accounts payable	(805)
Accrued expenses and other current liabilities	(43)
Deferred revenue	(2,391)
Note payable	(81)
Deferred tax liability	(1,925)
Total liabilities assumed	**(5,245)**
Net identifiable assets acquired	**8,228**
Goodwill	4,446
Total consideration, net of cash acquired (1)	**$ 12,674**

(1) Net of $1.6 million cash acquired and $0.3 million anticipated amounts due back to the Company from the escrow account.

On March 8, 2023, pursuant to the terms of the Escrow Agreement, the Company received a $0.5 million payment as a return of a portion of the purchase price. The remainder of the escrow of $0.6 million was disbursed to the Sellers of Nebula Genomics.

The Company recorded measurement period adjustments during Fiscal 2021 to (a) increase deferred revenue and increase goodwill related to the adoption of ASU 2021-08, (b) increase inventory and increase accounts payable for additional accounts payable invoices that arose subsequent to the third quarter of 2021, (c) increase inventory and decrease goodwill for adjustments to the inventory valuation as of the acquisition date, (d) increase deferred tax liability and increase goodwill, and (e) decrease accounts receivable and increase goodwill to for adjustments to the accounts receivable valuation as of the acquisition date.

Goodwill represents the excess of the purchase price over the net identifiable tangible and intangible assets acquired. The Company believes the goodwill related to the acquisition was a result of the expected synergies to be realized from combining operations and is not deductible for income tax purposes. The preliminary purchase price allocation is adjusted, as necessary, up to one year after the acquisition closing date if management obtains more information regarding asset valuations and liabilities assumed.

The intangible assets preliminarily identified in conjunction with the Nebula Acquisition are as follows (in thousands):

	Gross Carrying Value	Estimated Useful Life (in years)
Trade names	$ 5,550	15
Proprietary intellectual property	4,260	5
Customer relationships	1,180	1
Total	$ 10,990	

The Company recognized $1.9 million and $0.9 million amortization expense on the above identified intangible assets during the year ended December 31, 2022 and 2021, respectively.

Pro Forma Results

The following table summarizes, on a pro forma basis, the combined results of the Company as though the Nebula Acquisition had occurred as of January 1, 2021. These pro forma results are not necessarily indicative of the actual consolidated results had the acquisition occurred as of that date or of the future consolidated operating results for any period. Pro forma results are (in thousands):

	For the year ended December 31, 2021
Revenue, net	$ 81,164
Net income (loss)	$ 6,135

Note 4 – Goodwill and Acquired Intangible Assets

Goodwill

Changes in goodwill for Fiscal 2022 are as follows (in thousands):

	Amount
Goodwill, beginning of Fiscal 2021	$ 901
Acquisition of Nebula	4,446
Adjustment for deferred tax liability	362
Goodwill, end of Fiscal 2021	5,709
Goodwill, end of Fiscal 2022	$ 5,709

Intangible Assets, Net

Intangible assets as of December 31, 2022 and 2021 consisted of the following (in thousands):

	December 31, 2022	**December 31, 2021**	**Estimated Useful Life (in years)**
Trade names	$ 5,550	$ 5,550	15
Proprietary intellectual property	4,260	4,260	5
Customer relationships	1,180	1,180	1
CLIA license	1,307	1,307	3
	12,297	12,297	
Less: accumulated amortization	(3,822)	(1,445)	
Total intangible assets, net	$ 8,475	$ 10,852	

Amortization expense for acquired intangible assets was $2.4 million and $1.4 million during the years ended December 31, 2022 and 2021, respectively. The estimated future amortization expense of acquired intangible assets as of December 31, 2022 is as follows (in thousands):

Year ended December 31, 2023	$ 1,585
Year ended December 31, 2024	1,222
Year ended December 31, 2025	1,222
Year ended December 31, 2026	890
Year ended December 31, 2027	370
Thereafter	3,186
	$ 8,475

Note 5 – Property, Plant and Equipment

The components of property, plant and equipment are as follows (in thousands):

	December 31, 2022	December 31, 2021	Estimated Useful Life
Land	$ 352	$ 352	
Building improvements	1,729	1,729	10-39 years
Machinery	5,048	4,740	3-7 years
Lab equipment	5,788	4,330	3-7 years
Computer equipment and software	2,350	1,211	3-5 years
Furniture and fixtures	461	468	5 years
	15,728	12,830	
Less: accumulated depreciation	(8,440)	(6,883)	
Total property, plant and equipment, net	$ 7,288	$ 5,947	

Depreciation expense for Fiscal 2022 and 2021 were $2.3 million and $1.9 million, respectively.

Note 6 -Unsecured Convertible Promissory Notes Payable

On September 15, 2020, we issued two unsecured, partially convertible, promissory notes (the "September 2020 Notes") for an aggregate principal amount of $10 million to two investors (collectively, the "Lenders").

On February 28, 2022, we entered into a letter agreement (the "Letter Agreement") with one of the Lenders providing for the payoff of its September 2020 Note in the principal amount of $2,000,000.

Pursuant to the terms of the Letter Agreement, (i) the Lender converted $600,000 of the principal amount due to him under his September 2020 Note into 200,000 shares of Company common stock (the "Conversion Shares") at a price of $3.00 per share as provided for under the terms of the September 2020 Note (the "Conversion"), (ii) the Company paid to the Lender $1,440,548 in cash, representing $1,400,000 of the remaining principal under the September 2020 Note following the Conversion plus $40,548 in accrued and outstanding interest under the September 2020 Note, and (iii) the Company repurchased the Conversion Shares at a price of $5.75 per share for an aggregate amount of $1,150,000 (for a total aggregate payment to the Lender of $2,590,548).

The September 2020 Note that remains outstanding is due and payable on September 15, 2023 and accrues interest at a rate of 10% per year from the closing date, payable on a quarterly basis, until the September 2020 Note is repaid in full. We have the right to prepay the September 2020 Note at any time after providing written notice to the Lender and may prepay the September 2020 Note prior to such time with the consent of the Lender. The Lender has the right, at any time, and from time to time, to convert up to an aggregate of $3.0 million of the September 2020 Note into common stock of the Company at a conversion price of $3.00 per share. Repayment of the outstanding September 2020 Note has been guaranteed by our wholly owned subsidiary, PMI. In November 2022, the Company paid back $5.6 million in principal on the remaining September 2020 Note.

The September 2020 Note contains customary events of default. If a default occurs and is not cured within the applicable cure period or is not waived, any outstanding obligations under the September 2020 Note may be accelerated. The September 2020 Note also contains certain restrictive covenants which, among other things, restrict the Company's ability to create, incur, assume or permit to exist, directly or indirectly, any lien (other than certain permitted liens described in the September 2020 Note) securing any indebtedness of the Company, and prohibits the Company from distributing or reinvesting the proceeds from any divestment of assets (other than in the ordinary course) without the prior approval of the Lender.

For the year ended December 31, 2022 and 2021, we incurred $0.8 million and $1.0 million, respectively, in interest expense under the September 2020 Notes.

Note 7 – Stockholders' Equity

Our authorized capital stock consists of 50 million shares of common stock, $0.0005 par value, and one million shares of preferred stock, $0.0005 par value.

Preferred Stock

The preferred stock authorized under the Company's certificate of incorporation may be issued from time to time in one or more series. As of December 31, 2022, no shares of preferred stock have been issued. The Company's board of directors have the full authority permitted by law to establish, without further stockholder approval, one or more series of preferred stock and the number of shares constituting each such series and to fix by resolution voting powers, preferences and relative, participating, optional and other special rights of each series of preferred stock, and the qualifications, limitations or restrictions thereof, if any. Subject to the limitation on the total number of shares of preferred stock that the Company has authority to issue under its certificate of incorporation, the board of directors is also authorized to increase or decrease the number of shares of any series, subsequent to the issue of that series, but not below the number of shares of such series then-outstanding. In case the number of shares of any series is so decreased, the shares constituting such decrease will resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The Company may, subject to any required stockholder approval, amend from time to time its certificate of incorporation to increase the number of authorized shares of preferred stock or common stock or to make other changes or additions to our capital structure or the terms of our capital stock.

Common Stock Dividends

On May 9, 2022, the board of directors of the Company declared a special cash dividend of $0.30 per share on the Company's common stock, paid on June 4, 2022, in the amount of $4.7 million to holders of record of the Company's common stock as of May 25, 2022.

On February 14, 2022, the board of directors of the Company declared a special cash dividend of $0.30 per share on the Company's common stock, paid on March 10, 2022, in the amount of $4.6 million to holders of record of the Company's common stock on March 1, 2022.

During the year ended December 31, 2021, the Board declared a special cash dividend of $0.30 per share on the Company's common stock to holders of record on May 25, 2021, resulting in the payment of $4.5 million to stockholders on June 3, 2021.

Common Stock

Registered Direct Offering

On January 5, 2021, the Company entered into a securities purchase agreement with certain accredited investors and qualified institutional buyers, pursuant to which the Company issued and sold to the purchasers an aggregate of (i) 550,000 shares of the Company's common stock, and (ii) warrants to purchase up to 275,000 shares of the Company's common stock in a registered direct offering.

The shares and warrants were sold at a purchase price of $10.00 per share for net proceeds to the Company of $5.5 million. Each Warrant has an exercise price equal to $11.00 per share of common stock, will be exercisable at any time and from time to time, subject to certain conditions described in the Warrant, after the date of issuance, and will expire on the date that is three years from the date of issuance. The Shares and the Warrants are immediately separable and were issued separately.

Public Offering

On January 18, 2021, the Company entered into an underwriting agreement for the public offering of three million shares of common stock, at a price to the public of $12.50 per share. On January 21, 2021, the Company completed the offering for net proceeds of $35.1 million, after deducting the underwriting discounts and commissions and estimated offering expenses. As part of the offering, the Company also issued to the underwriters warrants to purchase up to an aggregate of 180,000 shares of common stock (6% of the shares of common stock sold in the offering) at an exercise price of $15.625 per share (equal to 125% of the public offering price per share).

At-the-market Offering

On December 28, 2021, the Company entered into a Sales Agreement (the "Sales Agreement") with ThinkEquity LLC (the "Sales Agent"), pursuant to which the Company may offer and sell, from time to time through the Sales Agent, shares (the "ATM Shares") of the Company's common stock, having an aggregate offering price of up to $100,000,000, subject to the terms and conditions of the Sales Agreement. The Company is not obligated to make any sales of the ATM Shares under the Sales Agreement.

The offering pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all of the ATM Shares subject to the Sales Agreement and (ii) termination of the Sales Agreement as permitted therein. The Company may terminate the Sales Agreement in its sole discretion at any time by giving three business days' prior notice to the Sales Agent. The Sales Agent may terminate the Sales Agreement under the circumstances specified in the Sales Agreement and in its sole discretion at any time by giving three business days' prior notice to the Company.

The Company will pay the Sales Agent a fixed commission rate of 2.0% of the aggregate gross proceeds from the sale of the ATM Shares pursuant to the Sales Agreement and has agreed to provide the Sales Agent with customary indemnification and contribution rights. The Company also agreed to reimburse the actual out-of-pocket accountable expenses of the Sales Agent up to $60,000 (of which a $25,000 advance was paid on December 7, 2021), which amount will include the fees and expenses of legal counsel to the Sales Agent up to $50,000, and to pay the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, in an amount not to exceed $3,000.

Additionally, the Company will pay to H.C. Wainwright & Co. ("Wainwright"), a fee equal to 1.0% of the gross proceeds of the sales price of all the ATM Shares sold under the Sales Agreement, pursuant to a separate financial services agreement with Wainwright. Wainwright is not a sales agent under the Sales Agreement.

For the years ended December 31, 2022 and 2021, the Company did not have any sales under the At-the-market Offering program.

Nebula Acquisition

As part of Nebula Acquisition (see Note 3, Business Acquisitions), a portion of the purchase price was paid in shares to certain Seller Parties and noteholders of Nebula G, based on their election to receive shares of the Company's common stock in lieu of cash, which shares have been valued at a price per share of $7.46, which is equal to the average closing price of the Company's common stock on Nasdaq for the five trading days preceding the signing of the Nebula Stock Purchase Agreement.

The Company issued 483,685 shares of its common stock in in lieu of $3.6 million cash payment to Seller Parties and noteholders of Nebula.

Stock Repurchase Program

On July 26, 2022 and September 8, 2021, the Company announced that its board of directors (the "Board") had approved new stock repurchase programs. Under each of the stock repurchase programs, the Company was authorized to repurchase up to $6.0 million million of its outstanding shares of common stock from time to time, over a six-month period.

The Company repurchased 303,145 and 166,824 shares during the years ended December 31, 2022 and 2021, respectively, pursuant to the stock repurchase programs for an aggregate amount of $2,152,000 and $944,000 respectively, including commissions.

The 2010 Directors' Equity Compensation Plan

On May 20, 2021, the stockholders of the Company approved the Amended and Restated 2010 Directors' Equity Compensation Plan (the "Amended 2010 Directors' Plan") at the 2021 annual meeting of stockholders of the Company (the "2021 Annual Meeting"). The Amended 2010 Directors' Plan authorizes the issuance of up to 775,000 shares of common stock.

During the year ended December 31, 2021, stock options to purchase an aggregate of 225,126 shares of the Company's common stock were granted to the Company's directors in lieu of director fees under the Amended 2010 Directors' Plan with a strike price of $5.28 per share.

The 2022 Directors' Equity Compensation Plan

On May 19, 2022, the stockholders of the Company approved the 2022 Directors' Equity Compensation Plan (the "2022 Directors' Plan") at the 2022 annual meeting of stockholders (the "2022 Annual Meeting"). The 2022 Director's Plan amended and restated the Amended and Restated 2010 Directors' Equity Compensation Plan and provides for an increase in the number of shares reserved for issuance under the plan by 300,000 shares and provides for the adjustment of the per share exercise price of stock options granted under the 2022 Directors' Plan in the event of any change in the outstanding shares of common stock of the Company as a result of, among other things, any distribution or special dividend to stockholders of shares, cash or other property (other than regular cash dividends). At December 31, 2022, there were 120,000 stock options outstanding and there were 180,000 shares of common stock available to be issued under the 2022 Directors' Plan.

During the year ended December 31, 2022, stock options to purchase an aggregate of 120,000 shares of the Company's common stock were granted to our directors in lieu of director fees under the 2022 Plan with a strike price of $5.28 per share.

The 2010 Equity Compensation Plan

On May 20, 2021, the stockholders of the Company approved the Amended and Restated 2010 Equity Compensation Plan (the "Amended 2010 Plan") at the 2021 Annual Meeting. The Amended 2010 Plan authorizes the issuance of up to 4,900,000 shares of common stock.

During Fiscal 2021, 1,249,874 stock options were granted to our employees and non-employees under the 2010 Plan at an exercise price between $5.28 - $11.03, the closing price of the Company's common stock on the date of grant, with 25% of the stock options vested on the grant date, and 75% vesting over a 3-year period in equal annually installments.

The 2022 Equity Compensation Plan

On May 19, 2022, the stockholders of the Company approved the 2022 Equity Compensation Plan (the "2022 Plan") at the 2022 Annual Meeting. The 2022 Plan amended and restated the Company's Amended and Restated 2010 Equity Compensation Plan and provides for an increase in the number of shares reserved for issuance under the plan by 1,000,000 shares for a total of 5,900,000 and provides for the adjustment of the per share exercise price of stock options granted under the 2022 Plan in the event of any change in the outstanding shares of common stock of the Company as a result of, among other things, any distribution or special dividend to stockholders of shares, cash or other property (other than regular cash dividends).

During Fiscal 2022, 325,000 stock options were granted to the Company's employees and non-employees under the 2022 Plan at exercise prices between $8.96 and $12.01, equal to the closing price of the Company's common stock on the date of grant, with 25% of each such stock option vested on the grant date, and 75% vesting over a 3-year period in equal annually installments.

The 2018 Stock Incentive Plan

On April 12, 2018, the Company's stockholders approved the 2018 Stock Incentive Plan (the "2018 Stock Plan"). The 2018 Stock Plan provides for the grant of incentive stock options to eligible employees of the Company, and for the grant of non-statutory stock options to eligible employees, directors and consultants. The purpose of the 2018 Stock Plan is to advance the interests of the Company and its stockholders by providing an incentive to attract, retain, and reward persons performing services for the Company and by motivating such persons to contribute to the growth and profitability of the Company. The 2018 Stock Plan provides that the total number of shares that may be issued pursuant to the 2018

Stock Plan is 2,300,000 shares. At April 12, 2018, all 2,300,000 shares had been granted in the form of stock options to Ted Karkus (the "CEO Option"), the Company's Chief Executive Officer, and, through December 31, 2022, 1,650,000 options under the 2018 Stock Plan had been exercised.

The 2018 Stock Plan requires certain proportionate adjustments to be made to the stock options granted under the 2018 Stock Plan upon the occurrence of certain events, including a special distribution (whether in the form of cash, shares, other securities, or other property) in order to maintain parity. Accordingly, the Compensation Committee of the board of directors, as required by the terms of the 2018 Stock Plan, adjusted the terms of the CEO Option, such that the exercise price of the CEO Option was reduced from $3.00 per share to $2.00 per share, effective as of September 5, 2018, the date the special $1.00 special cash dividend was paid to stockholders. The exercise price of the CEO Option was further reduced from 2.00 $2.00 to $1.75 per share, effective as of January 24, 2019, the date the $0.25 special cash dividend was paid to stockholders. The exercise price of the CEO Option was further reduced from $1.75 to $1.50 per share, effective as of December 12, 2019, the date another $0.25 special cash dividend was paid to stockholders. The exercise price of the CEO Option was further reduced from $1.50 to $1.20 per share, effective as of June 3, 2021, the date another $0.30 special cash dividend was paid to Company's stockholders. Accordingly, the Compensation Committee of the board of directors, as required by the terms of the 2018 Stock Plan, has adjusted the exercise price of the CEO Option in connection with each special cash dividend paid by the Company proportionately to the amount of the dividend paid. The current exercise price of the CEO Option is $0.60 per share after the latest special cash dividend paid on June 3, 2022.

Inducement Option Awards

As part of Nebula Acquisition, the Company issued a non-qualified stock option to Kamal Obbad, the Chief Executive Officer of Nebula Genomics, as an inducement to his employment with the Company (the "Obbad Award"). The Obbad Award entitles Mr. Obbad to purchase up to 250,000 shares of the Company's common stock at an exercise price of $7.67 per share, the closing price of the Company's common stock on the closing date of the Nebula Acquisition. The Obbad Award was granted to Mr. Obbad on the closing date of the Nebula Acquisition. The Obbad Award vested 25% on the grant date and will vest 25% per year for the next three years subject to Mr. Obbad's continued employment with the Company. The Obbad Award expires on the seventh anniversary of the grant date. Any portion of the Obbad Award that does not vest and become exercisable will be forfeited for no consideration. The grant date fair value of the Obbad Award was approximately $1,128,000.

On May 9, 2022, the Company issued a non-qualified stock option to the prospective Chief Financial Officer of the Company (the "CFO"), as an inducement to his employment with the Company, effective May 23, 2022 (the "CFO Award"). The CFO Award entitled the CFO to purchase up to 400,000 shares of the Company's common stock at an exercise price of $6.74 per share, the closing price of the Company's common stock on May 9, 2022. The CFO Award provided for certain proportionate adjustments to be made in the event of any change in the outstanding shares of common stock of the Company as a result of, among other things, any distribution or special dividend to stockholders of shares, cash or other property (other than regular cash dividends) in order to maintain parity. The exercise price of the CFO Award was reduced from $6.74 to $6.44 per share, effective as of June 3, 2022, the date $0.30 special cash dividend was paid to Company's stockholders. The grant date fair value of the CFO Award was approximately $1,604,000. In connection with CFO's separation from service on October 4, 2022, these options were forfeited on October 4, 2022. The Company reversed $149,000 of stock based compensation expense previously recognized for the unvested options at the time of forfeiture.

During the year ended December 31, 2022, the Company issued an inducement award to a prospective employee to purchase up to 250,000 shares of the Company's common stock at an exercise price of $13.00, the closing price of the common stock on the date of grant. The award vested 50% on the date of grant and the remaining portion will vest 25% per year for the next two years. The award expires on the seventh anniversary of the grant date.

For the year ended December 31, 2021, the Company granted an inducement award to a prospective employee to purchase up to 100,000 shares of the Company's common stock at an exercise price of $5.76, the closing price of the common stock on the date of grant. The award vests in four equal installments from the date of grant. The award expires on the seventh anniversary of the grant date.

All inducement awards have been granted outside of the Company's equity compensation plans pursuant to Nasdaq Listing Rule 5635(c)(4).

Summary of all option grants

For the year ended December 31, 2022, the Company granted in the aggregate 1,095,000 stock options at an exercise price of $6.44-$12.92, the closing price of the Company's common stock on the date of grant, to certain employees. The stock options vest in four equal annual installments beginning on the date of grant. The options were valued at $6.6 million at fair value, using the Black-Scholes option pricing model to calculate the grant-date fair value of the options. The fair value of stock options for employees are expensed over the vesting term in accordance with the terms of the related stock option agreements and non-employees are expensed over the terms of the service period..

For the year ended December 31, 2021, the Company granted 1,249,874 stock options at an exercise price of $5.28- $11.03, the closing price of the Company's common stock on the date of grant, to certain employees. The stock options will vest in four equal annual installments beginning on the date of grant. The options were valued at $6.1 million at fair value, using the Black-Scholes option pricing model to calculate the grant-date fair value of the options. The fair value of stock options for employees are expensed over the vesting term in accordance with the terms of the related stock option agreements and non-employees are expensed over the terms of the service period.

The following table summarizes stock options activity during Fiscal 2022 and 2021 (in thousands, except per share data).

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Outstanding as of January 1, 2021	3,795	2.21	3.4	$ 26,441
Granted	1,825	7.29	6.2	—
Forfeited	(505)	8.50	0	—
Expired	(5)	1.39	0	—
Outstanding as of December 31, 2021	5,110	$ 3.27	3.4	$ 20,820
Granted	1,095	9.92	7	—
Exercised	(1,833)	1.29	0	—
Forfeited	(420)	1.56	0	—
Outstanding as of December 31, 2022	3,952	$ 5.35	4	$ 20,379
Options vested and exercisable	2,961	$ 4.06	3.2	$ 17,257

The following table summarizes weighted average assumptions used in determining the fair value of the stock options at the date of grant during Fiscal 2022 and 2021:

	For the years ended December 31,	
	2022	2021
Exercise price	$ 10.03	$ 7.29
Expected term (years)	4.5	4
Expected stock price volatility	79%	79%
Risk-free rate of interest	2.5%	0.8%
Expected dividend yield (per share)	0%	0%

The expected stock price volatility is based on the Company's historical common stock trading prices and the expected term is based on the period that the Company's stock-based awards are expected to be outstanding based on the simplified method.

The fair value of the stock options at the time of the grant in Fiscal 2022 and 2021 was $6.9 million and $6.1 million, respectively. For Fiscal 2022 and 2021, we charged to operations approximately $4.0 million and $3.2 million. As of December 31, 2022, there were 3,952,000 stock options outstanding and 2,961,000 stock options vested and exercisable.

The Company will recognize an aggregate of approximately $4.5 million of remaining share-based compensation expense related to outstanding stock options over a weighted average period of 3 years.

For the year ended December 31, 2022, we issued 828,021 shares of common stock through a cashless exercise of 1,833,000 options. In connection with the cashless exercise, the company repurchased 1,103,000 common stock at a cost of $7.5 million to satisfy tax withholding.

Common Stock Warrants

For the year ended December 31, 2021, the Company issued warrants to purchase 275,000 shares of common stock in a registered direct offering and warrants to purchase 180,000 shares of common stock to the underwriters in an underwritten public offering.

For the year ended December 31, 2021, the Company issued 5,986 shares of common stock through a cashless exercise of 50,000 common stock warrants.

During the year ended December 31, 2022, there were no stock warrants issued.

The following table summarizes warrant activities during Fiscal 2022 and 2021 (in thousands, except per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2021	450	$ 3.22	2.7
Warrants granted	455	12.83	3
Cashless exercise	(50)	5.00	0
Outstanding as of December 31, 2021	855	$ 8.23	1.9
Warrants granted	—	—	0
Outstanding as of December 31, 2022	855	$ 8.23	1.9
Warrants vested and exercisable	855	$ 8.23	1.9

The following table summarizes weighted average assumptions used in determining the fair value of the warrants at the date of grant during Fiscal 2022 and Fiscal 2021:

	For the years ended December 31,	
	2022	2021
Exercise price	$ —	$ 12.83
Expected term (years)	0	3.0
Expected stock price volatility	0%	81%
Risk-free rate of interest	0.0%	0.2%
Expected dividend yield (per share)	0%	0%

As of December 31, 2022, there were 855,000 warrants outstanding, and the full share-based compensation expense was recognized in prior years. The Company recognized $253,000 of share-based compensation expense for the year ended December 31, 2021.

Note 8 – Defined Contribution Plans

The Company maintains the ProPhase Labs, Inc. 401(k) Savings and Retirement Plan, a defined contribution plan for its employees. The Company's contributions to the plan are based on the amount of the employee plan contributions and compensation. The Company's contributions to the plan for the years ended December 31, 2022 and 2021 were $0.2 million and $0.1 million, respectively.

Note 9 – Income Taxes

The components of the provision (benefit) for income taxes, in the consolidated statements of operations are as follows (in thousands):

	For the years ended	
	December 31, 2022	December 31, 2021
Continuing Operations		
Current		
Federal	$ 1,040	$ —
State	3,543	1,318
	$ 4,583	$ 1,318
Deferred		
Federal	72	(1,511)
State	(210)	(775)
	$ (138)	$ (2,286)
Income taxes from continuing operations	$ 4,445	$ (968)

A reconciliation of the statutory federal income tax expense (benefit) to the effective tax is as follows (in thousands):

	2022	2021
Statutory Rate – federal	$ 4,811	$ 1,232
State taxes, net of federal benefit	2,789	366
Research & development tax credit	(1,200)	—
Permanent differences and other	(601)	227
Income taxes from continuing operations before valuation allowance	$ 5,799	$ 1,825
Change in valuation allowance	(1,354)	(2,793)
Income tax expense (benefit)	$ 4,445	$ (968)
Total	$ 4,445	$ (968)

The tax effects of the primary "temporary differences" between values recorded for assets and liabilities for financial reporting purposes and values utilized for measurement in accordance with tax laws giving rise to our deferred tax assets are as follows (in thousands):

	For the years ended	
	December 31, 2022	December 31, 2021
Net operating loss and capital loss carryforward	$ 1,324	$ 3,584
Right of use asset	(1,466)	1,348
Other	2,684	2,531
Capital lease obligations	1,466	(1,348)
Depreciation	(705)	(948)
Amortization	(2,703)	(2,989)
Valuation allowance	(824)	(2,178)
Total	$ (224)	$ —

The Company accounts for income taxes under ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which simplifies various aspects related to accounting for income taxes. This standard became effective for the Company January 1, 2021. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application.

The Company recognizes tax assets and liabilities for the future tax consequences related to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and for net operating loss carryforwards. Management evaluated the deferred tax assets for recoverability using a consistent approach that considers the relative impact of negative and positive evidence, including historical profitability and projections of future reversals of temporary differences and future taxable income. The Company is required to establish a valuation allowance for deferred tax assets if management determines, based on available evidence at the time the determination is made, that it is not more likely than not that some portion or all of the deferred tax assets will be realized.

As of December 31, 2022 the Company has net deferred tax liabilities for federal and combined state jurisdictions after releasing the valuation allowance in those jurisdictions. The Company continues to maintain a valuation allowance against some of the separate company state NOL carryforwards. As of December 31, 2022 there is a valuation allowance of $0.8 million compared to $2.2 million as of December 31, 2021. As of December 31, 2022, the Company has state NOL carryforwards of $0.8 million, which begin to expire in 2024 and federal NOL carryforwards of $0.5 million which can be carried forward indefinitely. The federal NOL is attributable to 2021 Nebula acquisition, and it is Section 382 limited with an annual limitation of $0.6 million.

The Company files a consolidated federal income tax return and separate company state returns as well as combined state returns where applicable.

Note 10 - Other Current Liabilities

The following table sets forth the components of other current liabilities at December 31, 2022 and 2021, respectively (in thousands):

	December 31, 2022	December 31, 2021
Accrued diagnostic services commissions	$ 1,093	$ 1,283
Accrued payroll	202	514
Accrued expenses	714	300
Accrued returns	13	338
Accrued benefits and vacation	50	60
Total other current liabilities	$ 2,072	$ 2,495

Note 11 – Commitments and Contingencies

Manufacturing Agreement

The Company and its wholly owned subsidiary, PMI, entered into a manufacturing agreement (the "Manufacturing Agreement") with Mylan in connection with the asset purchase agreement we entered into with Mylan in 2017. Pursuant to the terms of the Manufacturing Agreement, Mylan (or an affiliate or designee) purchased the inventory of the Company's Cold-EEZE® brand and product line, and PMI agreed to manufacture certain products for Mylan, as described in the Manufacturing Agreement, at prices that reflect current market conditions for such products and include an agreed upon mark-up on our costs. On May 1, 2021, the Manufacturing Agreement was assigned by Mylan to Nurya Brands, Inc. ("Nurya") in connection with Nurya's acquisitions of certain assets from Mylan, including the Cold-EEZE® brand and product line. Unless terminated sooner by the parties, the Manufacturing Agreement will remain in effect until March 29, 2023. Thereafter, the Manufacturing Agreement may be renewed by Nurya for up to five successive one-year periods by providing notice of its intent to renew not less than 90 days prior to the expiration of the then-current term. In November 2022, Meda provided a notice to extend the original agreement for another year through March 2024.

License Agreement

In July 19, 2022, the Company through its wholly-owned subsidiary ProPhase BioPharma entered into a License Agreement (the "License Agreement") with Global BioLife, Inc. (the "Licensor"), with an effective date of July 18, 2022 (the "Linebacker Effective Date"), pursuant to which it acquired from Licensor a worldwide exclusive right and license under certain patents identified in the License Agreement (the "Licensed Patents") and know-how (collectively, the "Licensed IP") to exploit any compound covered by the Licensed Patents (the "Licensed Compound"), including Linebacker LB1 and LB2, and any product comprising or containing a Licensed Compound ("Licensed Products") in the treatment of cancer, inflammatory diseases or symptoms, memory-related syndromes, diseases or symptoms including dementia and Alzheimer's Disease (the "Field"). Under the terms of the License Agreement, the Licensor reserves the right, solely for itself and for GRDG Sciences, LLC ("GRDG") to use the Licensed Compound and Licensed IP solely for research purposes inside the Field and for any purpose outside the Field.

Subject to certain conditions set forth in the License Agreement, the Company may grant sublicenses (including the right to grant further sublicenses) to its rights under the License Agreement to any of its affiliates or any third party with the prior written consent of Licensor, which consent may not be unreasonably withheld. Either party to the License Agreement may assign its rights under the License Agreement (i) in connection with the sale or transfer of all or substantially all of its assets to a third party, (b) in the event of a merger or consolidation with a third party or (iii) to an affiliate; in each case contingent upon the assignee assuming in writing all of the obligations of its assignor under the License Agreement.

Under the terms of License Agreement, the Company is required to pay to Licensor a one-time upfront license fee of $50,000 within 10 days of the Linebacker Effective Date and must pay an additional $900,000 following the achievement of a first Phase 3 study which may be required by FDA for the first Licensed Product and an additional $1 million upon the receipt of regulatory approval of a New Drug Application (NDA) for the first Licensed Product.

During the term of the License Agreement, the Company is also required to pay to Licensor 3% royalties on Net Revenue (as defined in the License Agreement) of each Licensed Product, but no less than the minimum royalty of $250,000 of Net Revenue per year minus any royalty payments for any required third party licenses.

In connection with the License Agreement, the Company has incurred approximately $0.5 million in general and administrative expenses that are included in the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the year ended December 31, 2022. No clinical studies have begun under this agreement.

Litigation

In the normal course of our business, we may be named as a defendant in legal proceedings. It is our policy to vigorously defend litigation or to enter into a reasonable settlement where management deems it appropriate.

Note 12 – Leases

On October 23, 2020, the Company completed the acquisition of CPM, which included the acquisition of a 4,000 square foot CLIA accredited laboratory located in Old Bridge, New Jersey, which was owned by CPM (which is now known as ProPhase Diagnostics NJ, Inc.). The lease is for a term of 24 months with a monthly base lease payment of $5,950.

New York Second Floor Lease

On December 8, 2020, the Company entered into a Lease Agreement (the "NY Second Floor Lease") with BRG Office L.L.C. and Unit 2 Associates L.L.C. (the "Landlord"), pursuant to which the Company leases certain premises located on the second floor (the "Second Floor Leased Premises") of 711 Stewart Avenue, Garden City, New York (the "Building"). The Second Floor Leased Premises serve as the Company's second location and corporate headquarters, offering a wide range of laboratory testing services for diagnosis, screening and evaluation of diseases, including COVID-19 and Respiratory Pathogen Panel Molecular tests.

The NY Second Floor Lease was effective as of December 8, 2020, and commenced in January 2021 (the "Commencement Date") when the facility was made available to us by the landlord. The initial term of the NY Lease is 10 years and 7 months (the "Initial Term"), unless sooner terminated as provided in the NY Lease. The Company may extend the term of the NY Lease for one additional option period of five years. The Company has the option to terminate the NY Lease on the sixth anniversary of the Commencement Date, provided that it gives the landlord written notice not less than nine months and not more than 12 months in advance and that we pay the landlord a termination fee.

For the first year of the NY Second Floor Lease, the Company paid a base rent of $56,963 per month (subject to a seven-month abatement period), with a gradual rental rate increase of 2.75% for each 12-month period thereafter in lieu of paying its proportionate share of common area operating expenses, culminating in a monthly base rent of $74,716 during the final months of the Initial Term. In addition to the monthly base rent, the Company is responsible for its proportionate share of real estate tax escalations in accordance with the terms of the NY Lease.

The Company also has a right of first refusal to lease certain additional space located on the ground floor of the Building containing 4,500 square feet and 4,600 square feet, as more particularly described in the NY Lease. The Company also has a right of first offer to purchase the Building during the term of the NY Lease.

On June 10, 2022, the Company entered into a First Amendment to the NY Second Floor Lease (the "Second Floor Lease Amendment"). The Second Floor Lease Amendment amends the NY Second Floor Lease to provide that any uncured default by the Company or any of its affiliate under the NY First Floor Lease (defined below) will constitute a default by the Company under the NY Second Floor Lease.

New York First Floor Lease

On June 10, 2022, the Company entered into a second Lease Agreement (the "NY First Floor Lease") with Landlord, pursuant to which the Company leases approximately 4,516 sq. feet located on the first floor (the "NY First Floor Leased Premises") of the Building. As described above, the Company currently leases space on the second floor of the Building. The First Floor Leased Premises will be used to expand the Company's in-house lab capabilities to include traditional clinical testing across multiple specialty areas and Next Generation Sequencing (NGS) to perform Whole Genome Sequencing (WGS) and an array of genetic diagnostic test offerings for both clinical and research purposes.

The NY First Floor Lease became effective as of June 10, 2022 and will commence upon the date of the Landlord's substantial completion of certain improvements to the NY First Floor Leased Premises (the "First Floor Commencement Date"), as set forth in the NY First Floor Lease, targeted to be approximately five months from the execution of the NY First Floor Lease. The initial term of the NY First Floor Lease will expire on July 15, 2031, unless sooner terminated as provided in the NY First Floor Lease. The Company may extend the term of the NY First Floor Lease for one additional option period of five years pursuant to the terms described in the NY First Floor Lease. The Company has the option to terminate the NY First Floor Lease effective July 31, 2027 (the "Early Termination Date"), provided the Company gives the Landlord written notice not less than nine months and not more than 12 months prior to the Early Termination Date and pays the Landlord a termination fee as more particularly described in the Lease.

For the first year of the NY First Floor Lease, the Company will pay a base rent of $11,290 per month (subject to an eight month abatement period), with a gradual rental rate increase of approximately 2.75% for each 12 month period thereafter, culminating in a monthly base rent of $14,026 during the final months of the initial term of the NY First Floor Lease. In addition to the monthly base rent, the Company is responsible for its proportionate share of real estate tax escalations in accordance with the terms of the NY First Floor Lease. The Landlord will provide a construction allowance to the Company in an aggregate amount not to exceed $203,220, to reimburse the Company for the cost of certain improvements to be made by the Company to the First Floor Leased Premises.

At December 31, 2022, we had operating lease liabilities for the New York and New Jersey leases of approximately $4.6 million and right of use assets of approximately $4.1 million, which were included in the consolidated balance sheet.

The following summarizes quantitative information about our operating leases (in thousands):

	For the Years Ended	
	December 31, 2022	December 31, 2021
Operating leases		
Operating lease cost	$ 816	$ 816
Variable lease cost	$ —	$ —
Operating lease expense	816	816
Total rent expense	$ 816	$ 816

	For the Years Ended	
	December 31, 2022	December 31, 2021
Operating cash flows used in operating leases	$ (774)	$ (357)
Weighted-average remaining lease term – operating leases (in years)	8.5	9.4
Weighted-average discount rate – operating leases	10.00%	10.00%

Maturities of the Company's operating leases, excluding short-term leases, are as follows (in thousands):

Year Ended December 31, 2023	$ 739
Year Ended December 31, 2024	747
Year Ended December 31, 2025	768
Year Ended December 31, 2026	783
Year Ended December 31, 2027	804
Thereafter	3,071
Total	6,912
Less present value discount	(2,352)
Operating lease liabilities	$ 4,560

Note 13 – Consulting Agreement and Secured Promissory Note Receivable

Consulting Agreement

On September 25, 2020, the Company entered into a consulting agreement (the "Consulting Agreement") with an unaffiliated company acting as a consultant (the "Consultant"). The Consulting Agreement was to be effective through September 1, 2022; provided, however, that the Company could terminate this agreement at any time on five days' prior written notice.

The Consultant's duties were to include, among other things, (i) identifying and introducing us to new opportunities in the medical technology and testing fields, (ii) assisting and advising us in acquiring one or more CLIA certified labs suitable for COVID-19 and other testing ("Test Labs"); (iii) assisting us in equipping and staffing any Test Labs acquired by us; (iv) advising and assisting in the operation of such Test Labs; (v) validating and obtaining certification of such Test Labs; and (vi) assisting us in obtaining a flow of business, orders and revenues from multiple sources in the industry, including but not limited to at least one significant, nation-wide manufacturer and distributor of COVID-19 saliva sample collection test kits ("COVID-19 Test Kits").

All compensation earned by the Consultant would first be applied to the acceleration and prepayment of all sums due to us, including but not limited to sums due pursuant to the Amended and Restated Promissory Note ("Secured Note") described below.

Promissory Note and Security Agreement

On September 25, 2020 (the "Restatement Effective Date"), the Company entered into the Secured Note with the Consultant, pursuant to which it loaned $3.0 million to the Consultant (inclusive of $1.0 million in the aggregate previously loaned to the Consultant, as described below).

The Secured Note amended and restated in its entirety (i) that certain Promissory Note and Security Agreement, dated July 21, 2020 (the "Original July 21 Note"), pursuant to which the Company loaned $750,000 to the Consultant and (ii) that certain Promissory Note and Security Agreement, dated July 29, 2020 (the "Original July 29 Note", and, together with the Original July 21 Note, the "Original Notes"), pursuant to which the Company loaned $250,000 to the Consultant.

Commencing after September 1, 2021, in addition to payments of interest, the Consultant is also required to make payments on the principal amount of the loan equal to 1/36 of the then outstanding principal amount.

The entire remaining unpaid principal amount of the Secured Note, together with all accrued and unpaid interest thereon and all other amounts payable under the Secured Note, was due and payable on September 30, 2022. As discussed in Amendment and Termination Agreement below, the Company issued a Notice of Default to the Consultant on October 11, 2021.

Total interest income recorded in the years ended December 31, 2022 and 2021, was $— and $642,000, respectively.

Amendment and Termination Agreement

On January 14, 2021, the Company entered into an Amendment and Termination Agreement (the "Termination Agreement") with the Consultant pursuant to which the parties amended the Secured Note and terminated the Consulting Agreement. Pursuant to the terms of the Termination Agreement, the Company loaned an additional $1 million to the Consultant in consideration for the termination of the Consulting Agreement and termination of the Company's obligation to pay the Consultant additional consulting fees beyond the $250,000 already earned by the Consultant under the Consulting Agreement. As a result, the initial principal amount due under the Secured Note was increased from $2.75 million million to $3.75 million plus all accrued and unpaid interest arising under the Secured Note through and including January 14, 2021.

Under the terms of the Termination Agreement, the Consultant will continue to sell and process its viral test by RT-PCR (together with other viral and other types of tests). Until the Secured Note is paid in full, each COVID-19 Test Kit sold or processed from and after January 14, 2021, and for which payment of at least the specified amount as defined for the test, is received by the Consultant, the Consultant will pay us a specified amount (the "Test Fee"). The total payments will not exceed the aggregate amounts due under the Secured Note and will be applied first to interest and other amounts due under the Secured Note and then to the then-current outstanding principal. Test Fees will be due and payable on the 10th business day after the end of each month commencing in February 2021, and until the Secured Note is paid in full. The Company received the first payment in the amount of $95,000 with respect to the Test Fees from January 15 through February 2021. On June 25, 2021, we were issued 1,260,619 shares of common stock of the Consultant with a fair value of $315,000 as an interest payment under the Secured Note in lieu of Test Fees from March through June 2021.

Effective September 1, 2021, in addition to the payment of the Test Fees described above, the Consultant also is also required to make payments to us in an amount equal to the greater of (x) the Test Fee, or (y) 1/36th of the then outstanding principal amount together with interest thereon and interest accruing on the Secured Note, in accordance with the Secured Note. Accordingly, effective September 1, 2021, the minimum number of monthly payments due and payable to us is equal to the amount required to amortize fully the outstanding principal amount of the Secured Note, together with interest over a period of 36 months with level monthly payments. From September 1, 2021 through December 31, 2022, the Company did not receive any payments from the Consultant for either principal or interest.

On October 11, 2021, the Company provided the Consultant with a Notice of Default and demanded the Secured Note be paid in full immediately. On January 25, 2022, the Company filed a complaint with the United States District Court for the District of Delaware for judgment against the Consultant for money damages consisting of principal, interest, default interest and other fees and costs. As a result, the Company considered that it is not probable that it will collect all amounts due under the Secured Note and reduced the carrying value of the Secured Note to $0 as of December 31, 2021 with a corresponding charge-off of $— million and $3.7 million during the years ended December 31, 2022 and 2021, respectively, to bad debt expense, which is included in other income (loss) on the accompanying statements of operations.

Note 14 – Significant Customers Concentrations

Revenue for Fiscal 2022 and Fiscal 2021 was $122.6 million and $79.0 million , respectively. Two diagnostic services clients accounted for 65.0% and 15.0% , of our net revenue for the year ended December 31, 2022. Three diagnostic service clients accounted for 23.5%, 17.9% and 11.9% of our net revenue for the year ended December 31, 2021. For Fiscal 2022 and 2021, there were no third-party contract manufacturing customers accounted for 10% or more of our revenues, for each year , respectively. The loss of sales to any of these large customers could have a material adverse effect on our business operations and financial condition. Collections of diagnostic services revenues are driven by payers, which are government agencies (primarily HRSA), insurance providers, and client payers. In Fiscal 2022, requisitions from each payer group were 29% , 66% , and 5% , respectively. In Fiscal 2021, requisitions from each payer groups was 60%, 35% and 5%.

The Company is subject to account receivable credit concentrations from time-to-time as a result of the timing, payment pattern and ultimate purchase volumes or shipping schedules with our customers. These concentrations may impact its overall exposure to credit risk, either positively or negatively, in that our customers may be similarly affected by changes in economic, regulatory or other conditions that may impact the timing and collectability of amounts due to the Company. Two diagnostic services payers generated 68.8% and 16.0% of our total reimbursement receivable balances from government agencies and healthcare issuers at December 31, 2022. Four diagnostic services payers generated 43.0%, 11.6%, 10.7% and 10.7% of our total reimbursement receivable balances from government agencies and healthcare issuers at December 31, 2021.

Currently, the Company relies on a sole supplier to manufacture its saliva collection kits used by customers who purchase its personal genomics services. Change in the supplier or design of certain of the materials that the Company relies on, in particular the saliva collection kit, could result in a requirement for additional premarket review from the FDA before making such a change.

Note 15 – Segment Information

The Company has identified two operating segments, diagnostic services and consumer products, based on the manner in which the Company's CEO as CODM assesses performance and allocates resources across the organization. The operating segments are organized in a manner that depicts the difference in revenue generating synergies that include the separate processes, profit generation and growth of each segment. The diagnostic services segment provides COVID-19 diagnostic information services to a broad range of customers in the United States, including health plans, third party payers and government organizations. The consumer products segment is engaged in the research, development, manufacture, distribution, marketing and sale of OTC consumer healthcare products and dietary supplements in the United States and also provides personal genomics products and services. The unallocated corporate expenses mainly included professional fees associated with the public company.

The following table is a summary of segment information for Fiscal 2022 and Fiscal 2021 (in thousands):

	For the years ended	
	December 31, 2022	December 31, 2021
Net revenues		
Diagnostic services	$ 108,329	$ 68,559
Consumer products	14,318	10,483
Consolidated net revenue	122,647	79,042
Cost of revenue		
Diagnostic services	39,896	29,415
Consumer products	12,097	7,639
Consolidated cost of revenue	51,993	37,054
Depreciation and amortization expense		
Diagnostic services	2,336	1,976
Consumer products	2,206	7
Total Depreciation and amortization expense	4,542	1,983
Operating and other expenses	43,203	34,700
Income (loss) from operations, before income taxes		
Diagnostic services	56,389	18,197
Consumer products	(10,824)	(1,714)
Unallocated corporate	(22,657)	(11,178)
Total income from operations, before income taxes	22,908	5,305
Income tax benefit (expense)	(4,445)	968
Net Income	$ 18,463	$ 6,273

The following table is a summary of segment information for Fiscal 2022 and Fiscal 2021 (in thousands):

	December 31, 2022	December 31, 2021
ASSETS		
Diagnostic services	$ 50,832	$ 51,150
Consumer products	22,080	24,139
Unallocated corporate	14,736	14,006
Total assets	$ 87,648	$ 89,295

Note 16 – Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or otherwise result in the issuance of common stock that shared in the earnings of the entity. Diluted EPS also utilizes the treasury stock method which prescribes a theoretical buy back of shares from the theoretical proceeds of all options outstanding during the period, and the if-converted method for convertible debt.

The following is a reconciliation of the weighted average number of common shares outstanding used in calculating basic and diluted net loss per share (in thousands):

	For the years ended	
	December 31, 2022	December 31, 2021
Net income – basic	$ 18,464	$ 6,273
Interest on unsecured convertible promissory note	632	1,000
Net income – diluted	$ 19,096	$ 7,273
Weighted average shares outstanding – basic	15,845	15,172
Diluted shares- Stock Options	1,493	2,001
Diluted shares- Stock Warrants	1,073	220
Unsecured convertible promissory note	240	1,000
Weighted average shares outstanding – diluted	$ 18,651	$ 18,393

The following table represents the number of securities excluded from the income per share computation as a result of their anti-dilutive effect (in thousands):

	For the years ended	
Anti-dilutive securities	December 31, 2022	December 31, 2021
Common stock purchase warrants	455	455
Stock Options	770	828
Unsecured convertible promissory note	—	—
Anti-dilutive securities	1,225	1,283

Note 17 – Related Parties

The Company's Executive Vice President and Co-Chief Operations Officer of ProPhase Diagnostics, is a related party to the Company's Chairman and Chief Executive Officer. For the years ended December 31, 2022 and December 31, 2021, there were no payments made to the Executive Vice President outside compensation for the position held at the Company.

Note 18 – Subsequent Events

Stella Diagnostics - Asset Purchase Agreement

On December 15, 2022, the Company entered into an Asset Purchase Agreement (the "Stella Purchase Agreement"), by and among the Company and Stella Diagnostics Inc. ("Stella") and Stella DX, LLC ("Stella DX" and, together with Stella, the "Stella Sellers"), pursuant to which, on January 3, 2023, the Company purchased all of the assets, rights and interests of the Stella Sellers and their affiliates pertaining to the Stella Sellers' BE-Smart Esophageal Pre-Cancer diagnostic screening test and certain clinical assets, including all intellectual property rights (the "Stella Purchased Assets").

As consideration for the Stella Purchased Assets, the Company (i) paid to the Stella Sellers $3.5 million in cash, minus (a) the Secured Note Amount, if any, (b) the Liability Payoff Amount and (c) the Promissory Note Payoff Amounts (each as defined in the Stella Purchase Agreement), and (ii) issued to Stella DX 100,000 shares of common stock, par value $0.0005 per share, of the Company.

The Company is required to pay to the Stella Sellers for each of the seven calendar years (each, an "Annual Period") during the seven year period commencing on the first day of the calendar year following the date of the Commercialization Event (as defined in the Stella Purchase Agreement), a non-refundable, non-creditable royalty of 5% of the Adjusted Gross Margin (as defined in the Stella Purchase Agreement) for such Annual Period.

Management is reviewing the final closing transactions to complete the accounting. These amounts will be reported in the Company's Form 10-Q for the three months ended March 31, 2023.

Debt and Equity Transactions

On January 26, 2023, the Company issued an unsecured promissory note and guaranty for an aggregate principal amount of $7.6 million (the "Note") to JXVII Trust ("JXVII"). The Note is due and payable on January 27, 2026, the third anniversary of the date on which the Note was funded (the "Closing Date"), and accrues interest at a rate of 10% per year from the Closing Date, payable on a quarterly basis, until the Note is repaid in full. The Company has the right to prepay the Note at any time after the Closing Date and prior to the maturity date without premium or penalty upon providing seven days' written notice to JXVII. Repayment of the Note has been guaranteed by the Company's wholly-owned subsidiary, Pharmaloz Manufacturing, Inc.

In January 2023, the Company issued 603,881 shares of common stock through a cashless exercise of 1,348,250 options. In connection with the cashless exercise, the company repurchased 744,369 shares of common stock at a cost of $5,378 to satisfy tax withholding.

On March 13, 2023, the Company granted, in the aggregate, 205,000 stock options to seven employees under the 2022 Plan with an exercise price of $6.84, the closing price of the Company's common stock on the date of grant. The options vest 25% on the date of grant with the remaining 75% vesting over a 3-year period in equal annual installments. The estimated fair value of these options at the date of grant was $0.9 million, which will be expensed over the vesting term.

On March 15, 2023, the Company announced that its board of directors had approved a new stock repurchase program. Under the stock repurchase program, the Company is authorized to repurchase up to $6.0 million of its outstanding shares of common stock from time to time, over a six-month period. The number of shares to be repurchased and the timing of the repurchases, if any, will depend on a number of factors, including, but not limited to, price, trading volume and general market conditions, along with the Company's working capital requirements and general business conditions. The board of directors will re-evaluate the program from time to time and may authorize adjustments to its terms.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed with or submitted to the SEC under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial and accounting officer, to allow timely decisions regarding required disclosure.

We carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2022. This evaluation was carried out under the supervision and with the participation of our principal executive officer and principal financial and accounting officer. Based on that review, our management, including our principal executive officer and principal financial and accounting officer, concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Our management conducted an evaluation of our effectiveness of the system of internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based upon our review, our management, including our principal executive officer and principal financial and accounting officer, concluded that the Company's internal controls over financial reporting were effective as of December 31, 2022.

Remediation of Material Weakness

In connection with our 2021 Annual Report on Form 10-K, our management concluded that the Company's internal controls over financial reporting were not effective as of December 31, 2021, due to a material weakness. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements could occur but will not be prevented or detected on a timely basis.

The material weakness that was identified related to the lack of appropriate standard operating procedures and billing system controls associated with the diagnostic billing and revenue process, as well as the lack of contemporaneous assessments and associated documentation of the reimbursement receivables leading to additional allowance requirements.

Management committed to remediating the material weakness by making significant improvements to our billing processes, the billing system and the analyses that support the estimates associated with applicable allowances. We also performed a comprehensive review of our billing standard operating procedures, training and resources in our billing and accounting functions, and implemented certain changes.

We completed our remediation activities by testing the operating effectiveness of the enhanced controls and found them to be effective. Based on the implementation work and results of testing performed, we concluded that the previously identified material weakness has been remediated as of December 31, 2022.

Changes in Internal Control Over Financial Reporting

Except as described above in "Management's Report on Internal Control Over Financial Reporting", there was no change in our internal control over financial reporting identified in connection with evaluation required by paragraph (d) of Rules 13a-15 or 15d-15 under the Exchange Act that occurred during the fourth quarter of the fiscal year ended December 31, 2021 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated by reference from the sections of the Company's Proxy Statement for the 2023 Annual Meeting of Stockholders (the "2023 Proxy Statement") titled "Proposal 1 – Election of Board of Directors," "Executive Officers," "Governance Policies and Procedures – Code of Conduct," "Corporate Governance – Committees of the Board of Directors – Audit Committee." The 2023 Proxy Statement will be filed with the Securities and Exchange Commission ("SEC") not later than 120 days after the close of our fiscal year ended December 31, 2022 and is hereby incorporated by reference

Item 11. Executive Compensation

The information required under this item is incorporated by reference from the section of the 2023 Proxy Statement titled "Executive and Director Compensation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated by reference from the sections of the 2023 Proxy Statement titled "Equity Compensation Plan Information" and "Security Ownership."

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated by reference from the sections of the 2023 Proxy Statement titled "Corporate Governance – Certain Relationships and Related Transactions," and "Corporate Governance – Director Independence."

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated by reference from the section of the 2023 Proxy Statement titled "Audit and Non-Audit Fees."

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

The following consolidated financial statements of ProPhase Labs, Inc., together with the report thereon of Friedman LLP, independent registered public accounting firms, are included in this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the consolidated financial statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits

Exhibit	Description
2.1†+	Manufacturing Agreement, dated March 29, 2017, by and between Meda Consumer Healthcare Inc., Pharmaloz Manufacturing, Inc. and Prophase Labs, Inc. (incorporated by reference to Exhibit 2.2 of the Current Report on Form 8-K (File No. 000-21617) filed on March 29, 2017).
3.1	Certificate of Incorporation of the Company, (incorporated by reference to Exhibit 3.3 of the Current Report on Form 8-K (File No. 000-21617) filed on June 19, 2015).
3.2	Amended and Restated Bylaws of the Company (as of February 16, 2018) (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K (File No. 000-21617) filed on February 21, 2018).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Form 10-KSB/A (File No. 000-21617) filed on April 4, 1997).
4.2	Description of Common Stock (incorporated by reference to Exhibit 4.3 of the Annual Report on Form 10-K (File No. 000-21617) filed on March 26, 2020).
10.1	Form of Indemnification Agreement between the Company and each of its Officers and Directors, dated August 19, 2009 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on August 19, 2009).
10.2*	2022 Equity Compensation Plan (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (File No. 000-21617) filed on May 20, 2022).
10.3*	2022 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K (File No. 000-21617) filed on May 20, 2022).
10.4*	Form of Non-Qualified Stock Option Agreement pursuant to 2022 Equity Compensation Plan
10.5*	Form of Incentive Stock Option Agreement pursuant to 2022 Equity Compensation Plan
10.6*	Form of Option Agreement pursuant to 2022 Directors' Equity Compensation Plan
10.7*	Amended and Restated 2015 Executive Employment Agreement with Ted Karkus, effective February 23, 2018 (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K (File No. 000-21617) filed on April 16, 2018).
10.8*	2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on April 16, 2018).
10.9*	Stock Option Agreement with Ted Karkus pursuant to the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K (File No. 000-21617) filed on April 16, 2018).
10.10	Unsecured Convertible Promissory Note and Guaranty issued to JXVII Trust, dated September 15, 2020 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on September 18, 2020).
10.11	Amended and Restated Promissory Note and Security Agreement, dated September 25, 2020, by and between ProPhase Labs, Inc. and Predictive Labs, Inc. (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K (File No. 000-21617) filed on September 30, 2020).

10.12	Stock Purchase Agreement, dated October 22, 2020, by and among Confucius Plaza Medical Laboratory Corp., Pride Diagnostics LLC, the Members of Pride Diagnostics LLC and ProPhase Diagnostics, Inc. (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on October 26, 2020).
10.13	Form of Warrant (dated January 5, 2021) (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K (File No. 000-21617) filed on January 7, 2021).
10.14	Amendment and Termination Agreement, dated and effective as of January 14, 2021 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on January 15, 2021).
10.15	Lease agreement by and among ProPhase Diagnostics, Inc., BRG Office L.L.C. and Unit 2 Associates L.L.C. for the corporate headquarters and diagnostic lab facility located at 711 Stewart Avenue, Garden City, NY 11530 (incorporated by reference to Exhibit 10.18 of the Annual Report on Form 10-K (File No. 000-21617) filed on March 31, 2021).
10.16	Stock Purchase Agreement by and among Nebula Genomics, Inc., the Seller Parties Named therein, Kammal Obbad in the capacity as Seller Party Representative, ProPhase Labs, Inc and ProPhase Precision Medicine, Inc., dated August 10, 2021 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on August 16, 2021).
10.17	Sales Agreement, dated December 28, 2021, between ProPhase Labs, Inc. and ThinkEquity LLC (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on December 29, 2021).
10.18	Letter Agreement, dated February 28, 2022, by and between ProPhase Labs, Inc. and Justin J. Leonard (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on March 2, 2022).
10.19*	Employment Agreement, dated as of May 9, 2022, by and between ProPhase Labs, Inc. and Bill White (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on May 10, 2022)
10.20*	Inducement Option Award Agreement, dated May 9, 2022, by and between ProPhase Labs, Inc. and Bill White. (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K (File No. 000-21617) filed on May 10, 2022)
10.21*	Separation Agreement and Release, dated October 4, 2022, by and between ProPhase Labs, Inc. and Bill White (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on October 7, 2022)
10.22	Lease Agreement by and between ProPhase Diagnostics, Inc. and BRG Office L.L.C. and Unit 2 Associates L.L.C., as tenants in common, dated June 10, 2022 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on June 13, 2022)
10.23	Guaranty dated June 10, 2022 (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K (File No. 000-21617) filed on June 13, 2022)
10.24	First Amendment of Lease, dated June 10, 2022, by and between ProPhase Diagnostics, Inc. and BRG Office L.L.C. and Unit 2 Associates L.L.C., as tenants in common (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K (File No. 000-21617) filed on June 13, 2022)
10.25	License Agreement by and between ProPhase BioPharma, Inc. and Global BioLife, Inc., dated July 19, 2022 (effective as of July 18, 2022) (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on July 21, 2022)
10.26	Asset Purchase Agreement by and among Stella Diagnostics Inc., Stella DX, LLC and ProPhase Labs, Inc., dated December 15, 2022 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on December 20, 2022)
10.27	Unsecured Promissory Note and Guaranty issued to JXVII Trust, dated January 26, 2023 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on January 30, 2023)
10.28	Common Stock Purchase Warrant issued to JXVII Trust, dated January 27, 2023 (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K (File No. 000-21617) filed on January 30, 2023)
21.1	Subsidiaries of ProPhase Labs, Inc.
23.1	Consent of Morison Cogen LLP, Independent Registered Public Accounting Firm
23.2	Consent of Friedman LLP, Independent Registered Public Accounting Firm
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Finance Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Finance Officer and Principal Accounting Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Indicates a management contract or compensatory plan or arrangement

† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

+ Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Securities and Exchange Commission upon request.

40**	101 INS — Inline XBRL Instance Document
41**	101 SCH — Inline XBRL Taxonomy Extension Schema Document
42**	101 CAL — Inline XBRL Taxonomy Extension Calculation Linkbase Document
43**	101 DEF — Inline XBRL Taxonomy Extension Definition Linkbase Document
44**	101 LAB — Inline XBRL Taxonomy Extension Label Linkbase Document
45**	101 PRE — Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Item 16 Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PROPHASE LABS, INC.

By: */s/ Ted Karkus*
Ted Karkus, Chairman of the Board,
Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Ted Karkus Ted Karkus	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 29, 2023
/s/ Robert Morse Jr. Robert Morse Jr.	Principal Financial Officer	March 29, 2023
/s/ Jason Barr Jason Barr	Director	March 29, 2023
/s/ Louis Gleckel Louis Gleckel	Director	March 29, 2023
/s/ Warren Hirsch Warren Hirsch	Director	March 29, 2023