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

FORM 10-Q

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

For the quarterly period ended June 30, 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 Ave, Suite 200 Garden City, New York	11530
(Address of principal executive office)	(Zip Code)

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

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

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

Indicate by check mark whether the registrant (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 during the preceding 12 months (or shorter period that the registration 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 the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding August 12, 2022
Common Stock, $0.0005 par value	16,006,222

ProPhase Labs, Inc. and Subsidiaries
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

ProPhase Labs, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	June 30 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 23,959	$ 8,408
Restricted cash	-	250
Marketable debt securities, available for sale	3,539	8,779
Marketable equity securities, at fair value	-	76
Accounts receivable, net	36,670	37,708
Inventory, net	4,509	4,600
Prepaid expenses and other current assets	1,598	1,496
Total current assets	70,275	61,317
Property, plant and equipment, net	6,252	5,947
Prepaid expenses, net of current portion	167	460
Operating lease right-of-use asset, net	4,234	4,402
Intangible assets, net	9,434	10,852
Goodwill	5,709	5,709
Deferred tax asset	594	-
Other assets	1,282	608
TOTAL ASSETS	**$ 97,947**	**$ 89,295**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,445	$ 7,026
Accrued diagnostic services	760	1,890
Accrued advertising and other allowances	155	104
Operating lease liabilities	628	663
Deferred revenue	2,430	2,034
Income tax payable	6,787	1,312
Other current liabilities	1,517	2,495
Total current liabilities	16,722	15,524
Non-current liabilities:		
Deferred revenue, net of current portion	983	905
Note payable	-	44
Unsecured convertible promissory notes, net	7,998	9,996
Operating lease liabilities, net of current portion	4,086	4,198
Total non-current liabilities	13,067	15,143
Total liabilities	29,789	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, $0.0005 par value, 15,722,827 and 15,485,900 shares outstanding, respectively	16	16
Additional paid-in capital	106,162	104,552
Retained earnings	13,231	2,642
Treasury stock, at cost, 17,352,419 and 16,818,846 shares, respectively	(51,015)	(48,407)
Accumulated other comprehensive loss	(236)	(175)
Total stockholders' equity	68,158	58,628
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 97,947**	**$ 89,295**

See accompanying notes to condensed consolidated financial statements

ProPhase Labs, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share amounts)
(unaudited)

	For the three months ended		For the six months ended	
	June 30, 2022	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Revenues, net	$ 29,092	$ 9,142	$ 76,623	$ 24,413
Cost of revenues	10,372	4,676	29,226	11,020
Gross profit	18,720	4,466	47,397	13,393
Operating expenses:				
Diagnostic expenses	1,799	830	6,471	4,639
General and administration	6,306	4,993	14,130	8,775
Research and development	28	93	63	208
Total operating expenses	8,133	5,916	20,664	13,622
Income (loss) from operations	10,587	(1,450)	26,733	(229)
Interest income, net	25	214	98	301
Interest expense	(201)	(323)	(434)	(574)
Change in fair value of investment securities	-	164	(76)	164
Income (loss) from operations before income taxes	10,411	(1,395)	26,321	(338)
Income tax expense	(2,965)	-	(6,381)	-
Income (loss) from operations after income taxes	7,446	(1,395)	19,940	(338)
Net income (loss)	**$ 7,446**	**$ (1,395)**	**$ 19,940**	**$ (338)**
Other comprehensive loss:				
Unrealized loss on marketable debt securities	(98)	(67)	(61)	(78)
Total comprehensive income	$ 7,348	$ (1,462)	$ 19,879	$ (416)
Earnings (loss) per share:				
Basic	$ 0.48	$ (0.09)	$ 1.28	$ (0.02)
Diluted	$ 0.40	$ (0.09)	$ 1.07	$ (0.02)
Weighted average common shares outstanding:				
Basic	15,576	15,154	15,531	14,860
Diluted	19,272	15,154	18,964	14,860

See accompanying notes to condensed consolidated financial statements

ProPhase Labs, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	For the Three Months Ended June 30, 2022						
	Common Stock Shares Outstanding	Par Value	Additional Paid in Capital	Retained Earnings	Treasury Stock	Accumulated Other Comprehensive Loss	Total
Balance as of Apri 1, 2022	**15,485,900**	**$ 16**	**$ 105,634**	**$ 10,490**	**$ (49,557)**	**$ (138)**	**$ 66,445**
Cash dividends	-	-	-	(4,705)	-	-	(4,705)
Unrealized loss on marketable debt securities, net of realized loss of $7, net of taxes	-	-	-	-	-	(98)	(98)
Issuance of common stock upon stock options cashless exercise	236,927	-	-	-	-	-	-
Treasury shares repurchased to satisfy tax withholding obligations	-	-	-	-	(1,458)	-	(1,458)
Stock-based compensation	-	-	528	-	-	-	528
Net income	-	-	-	7,446	-	-	7,446
Balance as of June 30, 2022	**15,722,827**	**$ 16**	**$ 106,162**	**$ 13,231**	**$ (51,015)**	**$ (236)**	**$ 68,158**

	For the Three Months Ended June 30, 2021						
	Common Stock Shares Outstanding	Par Value	Additional Paid in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Loss	Total
Balance as of April 1, 2021	**15,154,253**	**$ 16**	**$ 102,735**	**$ (2,574)**	**$ (47,490)**	**$ (22)**	**$ 52,665**
Cash dividends	-	-	(4,546)	-	-	-	(4,546)
Unrealized loss on marketable debt securities, net of realized loss of $5, net of taxes	-	-	-	-	-	(67)	(67)
Stock-based compensation	-	-	1,076	-	-	-	1,076
Net loss	-	-	-	(1,395)	-	-	(1,395)
Balance as of June 30, 2021	**15,154,253**	**$ 16**	**$ 99,265**	**$ (3,969)**	**$ (47,490)**	**$ (89)**	**$ 47,733**

	For the Six Months Ended June 30, 2022						
	Common Stock Shares Outstanding	Par Value	Additional Paid in Capital	Retained Earnings	Treasury Stock	Accumulated Other Comprehensive Loss	Total
Balance as of January 1, 2022	**15,485,900**	**$ 16**	**$ 104,552**	**$ 2,642**	**$ (48,407)**	**$ (175)**	**$ 58,628**
Issuance of common shares for debt conversion	200,000	-	600	-	-	-	600
Cash dividends	-	-	-	(9,351)	-	-	(9,351)
Repurchases of common shares	(200,000)	-	-	-	(1,150)	-	(1,150)
Issuance of common stock upon stock options cashless exercise	236,927	-	-	-	-	-	-
Treasury shares repurchased to satisfy tax withholding obligations	-	-	-	-	(1,458)	-	(1,458)
Unrealized loss on marketable debt securities, net of realized loss of $186, net of taxes	-	-	-	-	-	(61)	(61)
Stock-based compensation	-	-	1,010	-	-	-	1,010
Net income	-	-	-	19,940	-	-	19,940
Balance as of June 30, 2022	**15,722,827**	**$ 16**	**$ 106,162**	**$ 13,231**	**$ (51,015)**	**$ (236)**	**$ 68,158**

	For the Six Months Ended June 30, 2021						
	Common Stock Shares Outstanding	Par Value	Additional Paid in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Loss	Total
Balance as of January 1, 2021	**11,604,253**	**$ 14**	**$ 61,674**	**$ (3,631)**	**$ (47,490)**	**$ (11)**	**$ 10,556**
Issuance of common stock and warrants for cash from public offering, net of $2,365 offering cost	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
Cash dividends	-	-	(4,546)	-	-	-	(4,546)
Unrealized loss on marketable debt securities, net of realized loss of $7, net of taxes	-	-	-	-	-	(78)	(78)
Stock-based compensation	-	-	1,504	-	-	-	1,504
Net loss	-	-	-	(338)	-	-	(338)
Balance as of June 30, 2021	**15,154,253**	**$ 16**	**$ 99,265**	**$ (3,969)**	**$ (47,490)**	**$ (89)**	**$ 47,733**

See accompanying notes to condensed consolidated financial statements

Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	For the six months ended	
	June 30, 2022	**June 30, 2021**
Cash flows from operating activities		
Net income (loss)	$ 19,940	$ (338)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Realized loss on marketable debt securities	186	7
Depreciation and amortization	2,516	1,118
Amortization of debt discount	2	3
Amortization on operating lease right-of-use assets	168	167
Loss on sale of assets	74	-
Stock-based compensation expense	1,010	1,504
Change in fair value of investment securities	76	(164)
Accounts receivable allowances	1,988	-
Inventory valuation reserve	25	-
Non-cash interest income on secured promissory note receivable	-	(315)
Changes in operating assets and liabilities:		
Accounts receivable	(941)	(3,466)
Inventory	66	(12,130)
Prepaid expenses and other current assets	104	2,434
Deferred tax asset	(594)	
Other assets	(674)	(8)
Accounts payable	(2,583)	3,343
Accrued diagnostic services	(1,130)	-
Accrued advertising and other allowances	51	-
Deferred revenue	474	-
Operating lease liabilities	(147)	205
Income tax payable	5,475	-
Other current liabilities	(978)	4,190
Net cash provided by (used in) operating activities	25,108	(3,450)
Cash flows from investing activities		
Issuance of secured promissory note receivable	-	(1,000)
Purchase of marketable securities	(607)	(16,841)
Proceeds from sale of marketable debt securities	5,600	300
Proceeds from dispositions of property and other assets, net	372	-
Capital expenditures	(1,769)	(4,237)
Net cash provided by (used in) investing activities	3,596	(21,778)
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 note payable	(1,444)	-
Repurchases of common shares	(1,150)	-
Payment of dividends	(9,351)	(4,546)
Repurchase of common stock for payment of statutory taxes due on cashless exercise of stock option	(1,458)	-
Net cash (used in) provided by financing activities	(13,403)	36,089
Increase in cash, cash equivalents and restricted cash	15,301	10,861
Cash, cash equivalents and restricted cash, at the beginning of the period	8,658	6,816
Cash, cash equivalents and restricted cash, at the end of the period	**$ 23,959**	**$ 17,677**
Supplemental disclosures:		
Cash paid for income taxes	$ 1,500	$ -
Interest payment on the promissory notes	$ 441	$ 500
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of common shares for debt conversion	$ 600	$ -
Net unrealized loss, investments in marketable debt securities	$ (61)	$ (78)

See accompanying notes to condensed consolidated financial statements

ProPhase Labs, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1 - Organization and Business

ProPhase Labs, Inc. ("ProPhase", "we", "us", "our" or the "Company") is a diversified company that offers a range of services including diagnostic testing, genomics testing and contract manufacturing. We provide traditional CLIA molecular laboratory services, including SARS-CoV-2 ("COVID-19") testing and seek to leverage our Clinical Laboratory Improvement Amendments ("CLIA") accredited laboratory services to provide whole genome sequencing and research direct to consumers, while building a genomics database to be used for further research. In addition, we have deep experience with over-the-counter ("OTC") consumer healthcare products and dietary supplements. We currently conduct our operations through two operating segments: diagnostic services and consumer products. Until late fiscal year 2020, we were engaged primarily in the research, development, manufacture, distribution, marketing and sale of OTC consumer healthcare products and dietary supplements in the United States. However, commencing in December 2020, we also began offering COVID-19 and other Respiratory Pathogen Panel (RPP) molecular tests through our diagnostic services business, and in August 2021 we began offering personal genomics products and services.

Our wholly owned subsidiary, ProPhase Diagnostics, Inc. ("ProPhase Diagnostics"), which was formed on October 9, 2020, offers a broad array of clinical diagnostic and testing services at its CLIA certified laboratories including state-of-the-art polymerase chain reaction ("PCR") testing for COVID-19. Critical to COVID-19 testing, we provide fast turnaround times for results. We also offer rapid antigen and antibody/immunity testing for COVID-19. On October 23, 2020, we acquired Confucius Plaza Medical Laboratory Corp. ("CPM"), which included a non-operating but certified 4,000 square foot CLIA accredited laboratory located in Old Bridge, New Jersey. 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.

On August 10, 2021, we acquired Nebula Genomics, Inc. ("Nebula"), a privately owned personal genomics company, through our new wholly owned subsidiary, ProPhase Precision Medicine, Inc. ("ProPhase Precision") (see Note 3, Business Acquisitions). ProPhase Precision focuses on genomics testing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic testing can 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.

Our wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO"), which was formed on June 28, 2022, for the licensing, development and commercialization of novel drugs and compounds beginning with Equivir and Equivir G. PBIO announced a second licensing agreement for two small molecule PIM kinase inhibitors, Linebacker LB-1 and LB-2, in July 2022, with plans to pursue development and commercialization of LB-1 as a cancer co-therapy.

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.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial statements and the rules of the Securities and Exchange Commission ("SEC") applicable to interim financial statements, and therefore do not include all disclosures that might normally be required for financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying unaudited condensed consolidated financial statements have been prepared by management without audit and should be read in conjunction with our audited consolidated financial statements, including the notes thereto, appearing in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. In the opinion of management, all adjustments necessary for a fair presentation of the consolidated financial position, consolidated results of operations and other comprehensive loss and consolidated cash flows, for the periods indicated, have been made. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of operating results that may be achieved over the course of the full year.

Segments

In accordance with FASB ASC 280, "Segment Reporting" ("ASC 280"), the Company discloses financial and descriptive information about its reportable operating segments.

ASC 280 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 and personal genomics products and services) (see Note 15 Segment Information).

Business and Liquidity Risks and Uncertainties

We launched our diagnostic service business in December 2020 and expanded in January 2021 with the opening of our Garden City, New York CLIA accredited laboratory. Our diagnostic service business is and will continue to be influenced 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, 2021 and the first six months of fiscal year 2022 as a result of the launch of our diagnostic services business, we will continue to be 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. Approximately 49% and 79% of our diagnostic services revenue for the six months ended June 30, 2022 and 2021, respectively was generated from this program for the uninsured. 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. 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 as of the financial statement issuance date. We continue to perform limited testing for uninsured persons and are incurring the accompanying costs. However, as a result of the suspension of the HRSA uninsured program, we did not recognize any revenue related to COVID-19 testing that we performed for uninsured individuals from March 23, 2022 through June 30, 2022. If funding for the HRSA program is reinstituted in the future, we will submit eligible claims for reimbursement to HRSA and record the associated revenues.

In addition, our diagnostic service business is subject to extensive federal, state, and local laws and regulations, all of which are subject to change, as well as laws and regulations governing the submission of claims for payment for our services, such as those relating to: coverage of our services under Medicare, Medicaid and other federal health care programs; the amounts that we may bill for our services; and the party to which we must submit claims. Also, reimbursement policies and requirements for some payers and procedures are ambiguous, which could lead to billing errors and related disputes. There can be no assurance that our efforts to offer and perform COVID-19 or other diagnostic testing will be successful in the future or that the revenue and operating profits from such business will increase or maintain their current level.

We acquired and commenced our personal genomics business in August 2021. This business is and will continue to be influenced by demand for our genetic testing products and services, our marketing and service capabilities, and our ability to comply with applicable regulatory requirements.

Our consumer sales are and will continue to be influenced 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 the OTC healthcare and cold remedy products that we manufacture, 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.

For the six months ended June 30, 2022, $25.1 million was provided by operating activities. The Company had cash, cash equivalents and marketable securities of $27.5 million as of June 30, 2022. 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 unaudited condensed 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 management's business plan and cash flow projections, particularly if the Company is unable to grow its diagnostic testing business beyond COVID-19 testing services.

The Company's future capital needs and the adequacy of its available funds will depend on the Company's ability to achieve sustained profitability from its diagnostic services, the Company's ability to successfully diversify its diagnostic services revenue streams and the Company's ability to market and grow its personal genomics business. 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 condensed consolidated 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 condensed consolidated 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 of diagnostic test reimbursement rates, the provision for uncollectible receivables and billing errors, allowances, slow moving and/or dated inventory and associated provisions, the potential impairment of long-lived assets, stock based compensation valuations, 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 condensed consolidated 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, 2021 includes approximately $250,000 held in escrow related to a potential purchase of an additional lab facility. The potential purchase was not consummated, and we are pursuing the return of the escrow, which is in dispute. As of June 30, 2022, we recognized an expense for this balance as the recovery of the funds was no longer considered probable.

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.

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

	As of June 30, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government obligations	$ 1,051	$ -	$ (67)	$ 984
Corporate obligations	2,549	123	(117)	2,555
	$ 3,600	$ 123	$ (184)	$ 3,539

	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

Marketable Equity Securities

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

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 at the time of issuance and a fair value of $76,000 at December 31, 2021. The investment was classified as a Level 1 financial instrument. We recorded a $76,000 decrease in fair value of investment securities within the condensed consolidated statement of operations and comprehensive income (loss) for the six months ended June 30, 2022.

Accounts Receivable, net

Accounts receivable consists primarily of amounts due from government agencies and healthcare insurers for our diagnostic services. 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 for which we have a right to receive payment. Unbilled accounts receivable is classified as accounts receivable on the condensed 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 receivables based on the following payer types: healthcare insurers and government payers. The Company principally estimates the allowances by pool based on historical collection experience, current economic conditions, government and healthcare insurer payment trends, and the period of time that the receivables have been outstanding. Should a payer's reimbursement policy change or their credit quality deteriorate, the Company removes the payer from their respective pools and establishes allowances based on the individual risk characteristics of such payer.

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):

	June 30, 2022	December 31, 2021
Trade accounts receivable	$ 35,793	$ 18,520
Unbilled accounts receivable	6,766	23,089
	42,559	41,609
Less allowances	(5,889)	(3,901)
Total accounts receivable	$ 36,670	$ 37,708

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 June 30, 2022 and December 31, 2021, the components of inventory are as follows (in thousands):

	June 30, 2022	December 31, 2021
Diagnostic services testing material	$ 2,122	$ 2,989
Raw materials	1,721	1,514
Work in process	676	260
Finished goods	421	272
Inventory	$ 4,940	$ 5,035
Inventory valuation reserve	(431)	(435)
Inventory, net	$ 4,509	$ 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 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 June 30, 2022, our cash and cash equivalents and restricted cash balance was $24.0 million. Of the total bank balance, $0.9 million was covered by federal depository insurance and $23.1 million was uninsured at June 30, 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 depends on information provided to the payors and meeting their requirements for reimbursement.

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 condensed consolidated 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 condensed consolidated balance sheet leases with terms of 12 months or less. We typically only include an initial lease term in our 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 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.

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.

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 statements of operation and comprehensive income (loss). The components of marketable securities are as follows (in thousands):

	As of June 30, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. government obligations	$ -	$ 984	$ -	$ 984
Corporate obligations	-	2,555	-	2,555
	$ -	$ 3,539	$ -	$ 3,539

	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 six months ended June 30, 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.

Transaction Price

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.

Recognize Revenue When the Company Satisfies a Performance Obligation

Recognition for contract manufacturing and retail customers is 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.

For diagnostic services, recognition occurs 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 our 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 $0.3 million and $0.4 million for the three and six months ended June 30, 2022, respectively.

Contract Balances

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 research and development ("R&D") work. As of June 30, 2022 and December 31, 2021, we have deferred revenue of $3.4 million and $2.9 million, respectively. Our new personal genomics business comprised $3.2 million and $2.7 million of the deferred revenue as of June 30, 2022 and December 31, 2021, respectively. The deferred revenue balance within the personal genomics business is comprised of kits to be sequenced and subscription services, which have an average life between 12 and 36 months. The remainder of deferred revenue relates to research and development ("R&D") stability and release testing programs recognized as contract manufacturing revenue.

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

Recognition Period	June 30, 2022	December 31, 2021
0-12 Months	$ 2,430	$ 2,034
13-24 Months	699	530
Over 24 Months	284	375
Total	$ 3,413	$ 2,939

Disaggregation of Revenue

We disaggregate revenue from contracts with customers into four categories: diagnostic services, contract manufacturing, retail and others, 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 the three and six months ended June 30, 2022 and 2021 (in thousands):

	For the three months ended		For the six months ended	
Revenue by Customer Type	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Diagnostic services	$ 26,158	$ 7,536	$ 71,071	$ 20,274
Contract manufacturing	1,759	1,041	2,913	2,949
Retail and others	465	565	1,011	1,190
Genomic products and services	710	-	1,628	-
Total revenue, net	$ 29,092	$ 9,142	$ 76,623	$ 24,413

Customer Consideration

The Company makes payments to certain diagnostic services customers for distinct services that approximate the 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 condensed consolidated statements of operations and comprehensive income (loss).

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 for the three months ended June 30, 2022 and 2021 were $63,000 and $111,000, respectively. Advertising and incentive promotion expenses incurred for the six months ended June 30, 2022 and 2021 were $124,000 and $279,000, 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 condensed consolidated 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 six months ended June 30, 2022 and 2021 were $63,000 and $208,000, respectively. R&D costs are principally related to personnel expenses and new product development initiatives and costs associated with our OTC health care products, dietary supplements and validation costs in association with the diagnostic services business.

Income Taxes

The Company recognizes 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. Future realization of deferred income tax assets requires sufficient taxable income within the carryback, 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 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

The Financial Accounting Standards Board ("FASB") recently issued Accounting Standards Update ("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. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. This was adopted on January 1, 2022. The adoption of ASU 2020-06 did not have a material impact on the Company's condensed consolidated financial statements or disclosures.

In May 2021, the FASB 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. This was adopted on January 1, 2022. The adoption of ASU 2021-04 did not have a material impact on the Company's condensed consolidated financial statements or disclosures.

Recently Issued Accounting Standards, Not Yet Adopted

In September 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326). The ASU sets forth a "current expected credit loss" (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. In February 2020, the FASB issued ASU 2020-02, Financial Instruments - Credit Losses (Topic 326), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. We are currently assessing the impact of the adoption of this ASU on our condensed consolidated financial statements.

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 "Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". The FASB is issuing this Update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. We are currently assessing the impact of the adoption of this ASU on our condensed consolidated financial statements.

Note 3 - Business Acquisition

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, each of the stockholders of Nebula (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 from the Seller Parties, for an aggregate purchase price of approximately $14.3 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, 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") is being 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 entered into with the Escrow Agent, as security for the indemnification obligations of the Seller Parties. At the Escrow Termination Date, the remaining amount, if any, of the Escrow Amount, less any amount reasonably necessary to pay any claim with respect to which a notice of claim has been timely and properly given, will be delivered to the Seller Parties, as applicable.

In connection with the Nebula Acquisition, ProPhase Precision entered into an employment agreement with Kamal Obbad, the Chief Executive Officer of Nebula, on the Effective Date, pursuant to which Mr. Obbad serves as Senior Vice President, Director of Sales and Marketing of ProPhase Precision. 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 common stock on the Effective Date (see Note 7, Stockholders' Equity).

Based on the valuation, the total consideration of $12.7 million, which is net of $1.6 million in cash acquired, 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	171
Inventory	133
Prepaid expenses 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.

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 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	

Note 4 - Goodwill and Acquired Intangible Assets

Goodwill

There were no changes in goodwill for the six months ended June 30, 2022.

Intangible Assets, Net

Intangible assets as of June 30, 2022 and December 31, 2021 consisted of the following (in thousands):

	June 30, 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	(2,863)	(1,445)	
Total intangible assets, net	$ 9,434	$ 10,852	

Amortization expense for acquired intangible assets was $709,000 and $109,000 during the three months ended June 30, 2022 and 2021, respectively. Amortization expense for acquired intangible assets was $1.4 million and $207,000 during the six months ended June 30, 2022 and 2021, respectively. The estimated future amortization expense of acquired intangible assets as of June 30, 2022 is as follows (in thousands):

Remaining periods in the year ended December 31, 2022	$ 960
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
Thereafter	3,555
	$ 9,434

Note 5 - Property, Plant and Equipment

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

	June 30, 2022	December 31, 2021	Estimated Useful Life
Land	$ 352	$ 352	
Building improvements	1,729	1,729	10-39 years
Machinery	4,705	4,740	3-7 years
Lab equipment	4,440	4,330	3-7 years
Computer equipment	2,130	1,211	3-5 years
Furniture and fixtures	468	468	5 years
	13,824	12,830	
Less: accumulated depreciation	(7,572)	(6,883)	
Total property, plant and equipment, net	$ 6,252	$ 5,947	

Depreciation expense incurred for the three months ended June 30, 2022 and 2021 was $607,000 and $474,000, respectively. Depreciation expense incurred for the six months ended June 30, 2022 and 2021 was $1,098,000 and $900,000, 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 as of June 30, 2022 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 outstanding September 2020 Note at any time after the 13-month anniversary of the initial issuance date 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, on and after the 13-month anniversary of the initial issuance date 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 September 2020 Note has been guaranteed by our wholly owned subsidiary, PMI.

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 contain 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 September 2020 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 the Lender.

For the three months ended June 30, 2022 and 2021, we incurred $200,000 and $251,000, respectively, in interest expense related to the September 2020 Notes. For the six months ended June 30, 2022 and 2021, we incurred $433,000 and $574,000, respectively, in interest expense related to 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 our certificate of incorporation may be issued from time to time in one or more series. As of June 30, 2022 and December 31, 2021, no shares of preferred stock have been issued.

Common Stock Dividends

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.

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.

Common Stock

Stock Repurchase Program

On September 8, 2021, the board of directors (the "Board") approved a stock repurchase program under which the Company was authorized to repurchase up to $6.0 million of its outstanding shares of common stock from time to time, over a six-month period.

During the six months ended June 30, 2022, the Company did not make any common shares repurchase under the stock repurchase program. The stock repurchase program expired on March 30, 2022.

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 of the Company (the "2022 Annual Meeting"). The 2022 Directors' Plan amended and restated the Company's 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 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 June 30, 2022, there were 425,126 stock options outstanding and there were 300,000 shares of common stock available to be issued under the Amended 2022 Directors' Plan.

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 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).

As of June 30, 2022, there were 4,920,000 stock options outstanding and 1,295,785 stock options available to be issued under the 2022 Plan. We will recognize an aggregate of approximately $1,470,000 of remaining share-based compensation expense related to outstanding stock options over a weighted average period of 3.9 years.

The 2018 Stock Incentive Plan

On April 12, 2018, our 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 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 have been granted in the form of stock options to Ted Karkus (the "CEO Option"), our Chief Executive Officer. To date, no stock options have been exercised under the 2018 Stock Plan. No share based compensation expense will be recognized in forward periods related to the 2018 Stock Plan.

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, 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 Award

As part of Nebula Acquisition, the Company issued a non-qualified stock option to Kamal Obbad, the Chief Executive Officer of Nebula, as an inducement to his employment with the Company (the "2021 Inducement Award"). The 2021 Inducement 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 2021 Inducement Award was granted to Mr. Obbad on the closing date of the Nebula Acquisition. The 2021 Inducement 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 2021 Inducement Award expires on the seventh anniversary of the grant date. Any portion of the 2021 Inducement Award that does not vest and become exercisable will be forfeited for no consideration. The grant date fair value of the 2021 Inducement Award was approximately $1,128,000.

Also during the year ended December 31, 2021, we issued 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.

On May 9, 2022, the Company issued a non-qualified stock option to Bill White, the Chief Financial Officer of the Company, as an inducement to his employment with the Company, effective May 23, 2022 (the "2022 Inducement Award"). The 2022 Inducement Award entitles Mr. White to purchase up to 400,000 shares of the Company's common stock (the "CFO Option") at an exercise price of $6.74 per share, the closing price of the Company's common stock on May 9, 2022. The CFO Option requires 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 Option 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 CFO Option vests over a four-year period, with 12.5% vesting every six months following the date his employment began, and contingent upon his continued service through each vesting date. The CFO Option expires on the seventh anniversary of the grant date. Any portion of the Inducement Award that does not vest and become exercisable will be forfeited for no consideration. The grant date fair value of the Inducement Award was approximately $1,604,000.

All inducement awards have been granted outside of the Company's equity compensation plans.

The following table summarizes stock options activity during the six months ended June 30, 2022 for the 2022 Plan, the 2022 Directors' Plan, the 2018 Stock Plan and the Inducement Awards (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, 2022	5,110	$ 3.27	3.4	$ 20,820
Granted	400	6.44	7.0	-
Cashless exercised	(570)	2.66	-	-
Forfeited	(20)	2.87	-	-
Outstanding as of June 30, 2022	4,920	$ 3.30	3.3	$ 46,159
Options vested and exercisable	3,662	$ 2.31	2.3	$ 37,972

The following table summarizes weighted average assumptions used in determining the fair value of the options at the date of grant during the six months ended June 30, 2022 and 2021:

	For the six months ended June 30,	
	2022	**2021**
Exercise price	$ 6.74	$ 9.13
Expected term (years)	4.8	3.5
Expected stock price volatility	77%	83%
Risk-free rate of interest	3.0%	0.6%
Expected dividend yield (per share)	0%	0%

During the six months ended June 30, 2022 certain holders of stock options elected to exercise their stock options pursuant to a cashless exercise provision resulting in the net issuance of 236,927 shares of common stock and the return of 333,573 shares to the Company. The Company also made a cash payment of approximately $1.5 million to repurchase 172,110 shares of treasury stock to satisfy tax withholding obligations related to these cashless exercise of stock options.

As of June 30, 2022, there were 4,920,000 stock options outstanding and 1,595,785 stock options available to be issued. We will recognize an aggregate of approximately $3,821,000 of remaining share-based compensation expense related to outstanding stock options over a weighted average period of 3.9 years.

Stock Warrants

The following table summarizes warrant activity during the six months ended June 30, 2022 (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, 2022	**855**	**$ 8.23**	**1.9**
Warrants granted	-	-	-
Outstanding as of June 30, 2022	855	$ 8.23	1.4
Warrants vested and exercisable	855	$ 8.23	1.4

We recognized $0 and $88,000 of share-based compensation expense during the three months ended June 30, 2022 and 2021, respectively. We recognized $0 and $193,000 of share-based compensation expense during the six months ended June 30, 2022 and 2021, respectively.

Note 8 - Defined Contribution Plans

We maintain the ProPhase Labs, Inc. 401(k) Savings and Retirement Plan, a defined contribution plan for our employees. Our contributions to the plan are based on the amount of the employee plan contributions and compensation. Our contributions to the plan in the three months ended June 30, 2022 and 2021 were $47,000 and $23,000, respectively. Our contributions to the plan in the six months ended June 30, 2022 and 2021 were $99,000 and $35,000, respectively.

Note 9 - Income Taxes

We recognize 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. We are 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 June 30, 2022 the Company has net deferred tax liabilities for federal and combined states jurisdictions compared to net deferred tax assets with a full valuation allowance as of December 31, 2021. The decrease in deferred tax assets with a corresponding decrease in valuation allowance against those assets as of June 30, 2022 is primarily due to utilization of net operating losses. The Company has net deferred tax assets in other states jurisdictions where we maintain a full valuation allowance. Judgment is required to estimate forecasted future taxable income, which may be impacted by future business developments, actual results, tax initiatives, legislative, and other economic factors. The Company will continue to monitor income levels and potential changes to its operating and tax model, and other legislative or global developments in its determination.

The Company's effective tax rate for the six months ended June 30, 2022 is 24.24% and it is primarily driven by federal tax at 21%, state taxes at 8.02%, and a decrease in the valuation allowance for federal and combined states jurisdictions. The total tax expense for the six months ended June 30, 2022 is $3.4 million and it mostly relates to current federal and combined state taxes.

Note 10 - Other Current Liabilities

The following table sets forth the components of other current liabilities at June 30, 2022 and December 31, 2021, respectively (in thousands):

	June 30 2022	December 31, 2021
Accrued commissions	$ 849	$ 1,283
Accrued payroll	81	514
Accrued expenses	226	300
Accrued returns	309	338
Accrued benefits and vacation	52	60
Total other current liabilities	$ 1,517	$ 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 Consumer Healthcare Inc. (formerly known as Meda Consumer Healthcare Inc.) ("MCH") and Mylan Inc. (together with MCH, "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 four 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.

Future Obligations

We have estimated future minimum obligations for an executive's employment agreement over the next five years as of June 30, 2022, as follows (in thousands):

	Employment Contracts
Remaining periods in 2022	$ 738
2023	1,375
2024	1,375
2025	1,375
2026	1,375
Total	$ 6,238

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, we 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 has agreed to lease 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 "Second Floor Commencement Date") when the facility was made available to us by the landlord. The initial term of the NY Second Floor Lease is 10 years and seven months (the "Second Floor Initial Term"), unless sooner terminated as provided in the NY Second Floor Lease. We may extend the term of the NY Second Floor Lease for one additional option period of five years. We have the option to terminate the NY Second Floor Lease on the sixth anniversary of the Second Floor Commencement Date, provided that we give 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, we 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 Second Floor Initial Term. In addition to the monthly base rent, we are responsible for its proportionate share of real estate tax escalations in accordance with the terms of the NY Second Floor Lease.

We also have 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 Second Floor Lease. We also have a right of first offer to purchase the Building during the term of the NY Second Floor Lease.

On June 10, 2022, we 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 has agreed to lease 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 June 30, 2022, we had operating lease liabilities for the New York and New Jersey leases of approximately $4.7 million and right of use assets of approximately $4.2 million, which were included in the condensed consolidated balance sheet.

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

	For the Three months ended		For the six months ended	
	June 30, 2022	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Operating leases				
Operating lease cost	$ 204	$ 204	$ 408	$ 408
Operating lease expense	204	204	408	408
Total rent expense	$ 204	$ 204	$ 408	$ 408

	For the six months ended	
	June 30, 2022	**June 30, 2021**
Operating cash flows used in operating leases	$ (387)	$ (36)
Weighted-average remaining lease term – operating leases (in years)	9.0	9.9
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):

Remaining periods in the year ended December 31, 2022	$	387
Year Ended December 31, 2023		738
Year Ended December 31, 2024		747
Year Ended December 31, 2025		768
Year Ended December 31, 2026		783
Thereafter		3,876
Total		7,299
Less present value discount		(2,585)
Operating lease liabilities	$	4,714

Note 13 - Consulting Agreement and Secured Promissory Note Receivable

Promissory Note and Security Agreement

On September 25, 2020 (the "Restatement Effective Date"), we entered into the Secured Note with a company consulting for us ("the Consultant"), pursuant to which we 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 we 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 we 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, will be due and payable, if not sooner paid, on September 30, 2022.

The Secured 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 Secured Note may be accelerated.

Amendment and Termination Agreement

On January 14, 2021, we 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 former consulting agreement with the Consultant (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 any additional consulting fees. As a result, the initial principal amount due under the Secured Note was increased from $2.75 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"). We 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 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. The Company did not receive any payments from the Consultant for either contractual 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 $3.75 million during the year ended December 31, 2021.

Note 14 - Significant Customer Concentrations

Revenue for the three months ended June 30, 2022 and 2021 was $29.1 million and $9.1 million, respectively. One diagnostic services client accounted for 67.2% of our revenue for the three months ended June 30, 2022. Two diagnostic services clients accounted for 24.9% and 16.8% of our revenue for the three months ended June 30, 2021. No contract manufacturing customer's accounted for a significant portion of our revenue for the three month ended June 30, 2022 or 2021. The loss of sales to any of these large customers could have a material adverse effect on our business operations and financial condition.

Revenue for the six months ended June 30, 2022 and 2021 was $76.6 million and $24.4 million, respectively. Three diagnostic services clients accounted for 48.9%, 15.7%, and 10.0% of our revenue for the six months ended June 30, 2022. Two diagnostic services clients accounted for 38.5% and 24.0% of our revenue for the six months ended June 30, 2021. No contract manufacturing customer's accounted for a significant portion of our revenue for the six month ended June 30, 2022 or 2021. The loss of sales to any of these large customers could have a material adverse effect on our business operations and financial condition.

Two diagnostic services payers comprised 51.1% and 19.3% of our total reimbursement receivable balances from government agencies and healthcare issuers at June 30, 2022. Four diagnostic services payers comprised 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, 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.

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 three and six months ended June 30, 2022 and 2021 (amounts in thousands):

	For the three months ended		For the six months ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Net revenues				
Diagnostic services	$ 26,158	$ 7,537	$ 71,071	$ 20,274
Consumer products	2,934	1,605	5,552	4,139
Consolidated net revenue	29,092	9,142	76,623	24,413
Cost of revenue				
Diagnostic services	8,403	3,479	25,105	7,824
Consumer products	1,969	1,197	4,121	3,196
Consolidated cost of revenue	10,372	4,676	29,226	11,020
Depreciation and amortization expense				
Diagnostic services	594	392	1,170	737
Consumer products	601	3	1,201	6
Total Depreciation and amortization expense	1,195	395	2,371	743
Operating and other expenses	7,114	5,466	18,705	12,988
Income (loss) from operations, before income taxes				
Diagnostic services	12,872	1,164	32,898	4,004
Consumer products	(313)	540	(2,176)	505
Unallocated corporate	(2,148)	(3,099)	(4,401)	(4,847)
Total income from operations, before income taxes	10,411	(1,395)	26,321	(338)
Income tax expense	(2,965)	-	(6,381)	-
Total income (loss) from operations, after income taxes	7,446	(1,395)	19,940	(338)
Net income (loss)	$ 7,446	$ (1,395)	$ 19,940	$ (338)

The following table is a summary of segment information as of June 30, 2022 and December 31, 2021 (amounts in thousands):

	June 30, 2022	December 31, 2021
ASSETS		
Diagnostic services	$ 49,493	$ 51,150
Consumer products	23,027	24,139
Unallocated corporate	25,427	14,006
Total assets	$ 97,947	$ 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 three months ended		For the six months ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Net income - basic	$ 7,446	$ (1,395)	$ 19,940	$ (338)
Interest on unsecured convertible promissory note	200	-	432	-
Net income - diluted	$ 7,646	$ (1,395)	$ 20,372	$ (338)
Weighted average shares outstanding - basic	15,576	15,154	15,531	14,860
Diluted shares- Stock Options	2,635	-	2,389	-
Diluted shares- Stock Warrants	261	-	244	-
Unsecured convertible promissory note	800	-	800	-
Weighted average shares outstanding - diluted	19,272	15,154	18,964	14,860

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 three months ended		For the six months ended	
Anti-dilutive securities	**June 30, 2022**	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Common stock purchase warrants	455	4,378	455	4,378
Stock Options	275	905	275	905
Unsecured convertible promissory note	-	1,000	-	1,000
Anti-dilutive securities	730	5,283	730	5,283

Note 17 - Related Parties

Jason Karkus, Executive Vice President and Co-Chief Operations Officer of ProPhase Diagnostics, is the son of Ted Karkus, the Company's Chairman and Chief Executive Officer. For the six months ended June 30, 2022 and 2021, Mr. Karkus received compensation of $110,000 and $84,000, respectively.

Note 18 - Subsequent Event

License Agreement

On 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 "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 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, 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.

Under the terms of the License Agreement, the development of the Licensed Compound and the first 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 Licensed Product (the "Development Plan"). The Development Plan may be amended by the mutual written agreement of the parties to the 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 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 ProPhase BioPharma for any reason or for convenience in its sole discretion: (i) on a Licensed Product-by-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 Lessor. Lessor may terminate the License Agreement solely for a material breach of the License Agreement by ProPhase BioPharma, which is not cured within 60 days' of written notice to ProPhase BioPharma of such breach.

Stock Repurchase Plan

On July 26, 2022, the Company announced that its Board of Directors has authorized a stock repurchase program of up to $6 million in the Company's common stock, which will become effective three business days after the date the Company issues its quarterly earnings release for the six months ended June 30, 2022 (the "Commencement Date").

Following the Commencement Date, and for a period of six months thereafter, repurchases may be made through open market transactions (based on prevailing market prices), privately negotiated transactions, block trades, or any combination thereof, in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934, as amended. 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 of the Company will re-evaluate the program from time to time, and may authorize adjustments to its terms. The Company expects to utilize its existing funds to fund repurchases under the repurchase program.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our interim unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q ("Quarterly Report") and the audited financial statements and notes thereto as of and for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 31, 2022 (the "2021 Annual Report"). As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," or "ProPhase" refer to ProPhase Labs, Inc. and its subsidiaries, unless the context otherwise requires.

Forward-Looking Statements

This Quarterly 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"). These forward-looking statements relate to future events or our future financial performance. 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. This Quarterly Report may also contain forward-looking statements attributable to third parties relating to their estimates regarding the growth of our markets.

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.

Such risks and uncertainties include, but are not limited to:

- Our ability to generate revenue and sufficient profits from Respiratory Pathogen Panel ("RPP") Molecular tests if and when demand for COVID-19 testing decreases or becomes no longer necessary;
- Our ability to collect payment for the tests we deliver;
- Our ability to manage our growth successfully;
- Our ability to compete effectively, including our ability to maintain and increase our markets and/or market share in the markets in which we do business;
- Our dependence on our largest diagnostic services customers;
- Our ability to successfully offer, perform and generate revenues from our personal genomics businesses;
- Our ability to secure additional capital, when needed to support our diagnostic services business, personal genomics business, manufacturing business and product development, clinical research and development, and commercialization programs;
- Potential disruptions to our supply chain or increases to the price of or adulteration of key raw materials or supplies;
- Potential disruptions in our ability to manufacture our products and those of others;
- Seasonal fluctuations in demand for the products and services we provide;
- [Risks related to the initiation, cost, timing, progress and results of current and future research and development programs, preclinical studies and clinical trials and our ability to obtain and maintain regulatory approvals;]
- Our ability to successfully develop and commercialize our existing products and any new products;
- Our ability to attract, retain and motivate our key employees;

- Our ability to protect our proprietary rights;
- Our ability to comply with regulatory requirements applicable to our businesses;
- The complexity of billing for, and collecting revenue for, testing services;
- Our dependence on third parties to provide services critical to our lab diagnostic services business;
- [Our reliance upon third parties, including contract research organizations, collaborative partners, and independent investigators to analyze, collect, monitor, and manage data for our ongoing nonclinical and clinical programs;]
- General economic conditions, including as a result of the ongoing COVID-19 pandemic and the war in Ukraine; and
- Our ability to remediate the material weakness in our internal controls over financial reporting and prevent other material weaknesses.

Given the risks and uncertainties surrounding forward-looking statements, you should not place undue reliance on these statements. You should also consider carefully the statements we make under other sections of this Quarterly Report and in our 2021 Annual Report, as well as in other documents we file from time to time with the SEC that address additional 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 the date of this Quarterly 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 required by law.

General

We are a diversified company that offers a range of services including diagnostic testing, genomics testing and contract manufacturing. We provide traditional CLIA molecular laboratory services, including SARS-CoV-2 ("COVID-19") testing and seek to leverage our Clinical Laboratory Improvement Amendments ("CLIA") accredited laboratory services to provide whole genome sequencing and research direct to consumers, while building a genomics data base to be used for further research. In addition, we have deep experience with over-the-counter ("OTC") consumer healthcare products and dietary supplements. We conduct our operations through two operating segments: diagnostic services and consumer products. Until late fiscal year 2020, we were engaged primarily in the research, development, manufacture, distribution, marketing and sale of OTC consumer healthcare products and dietary supplements in the United States. This includes the development and marketing of dietary supplements under the TK Supplements® brand. However, commencing in December 2020, we also began offering COVID- 19 and other RPP Molecular tests through our diagnostic service business, and in August 2021 we began offering personal genomics products and services.

Our wholly owned subsidiary, ProPhase Diagnostics, Inc. ("ProPhase Diagnostics"), which was formed on October 9, 2020, offers a broad array of clinical diagnostic and testing services at its CLIA certified laboratories including state-of-the-art polymerase chain reaction ("PCR") testing for COVID-19. Critical to COVID-19 testing, we provide fast turnaround times for results. We also offer best-in-class rapid antigen and antibody/immunity testing for COVID-19. On October 23, 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. 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.

On August 10, 2021, we acquired Nebula Genomics, Inc. ("Nebula"), a privately owned personal genomics company, through our new wholly owned subsidiary, ProPhase Precision Medicine Inc. ("ProPhase Precision"). We offer whole genome sequencing and related services through this new subsidiary. ProPhase Precision Medicine, Inc. focuses on genomics testing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic testing can 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.

Our wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO"), which was formed on June 28, 2022, for the licensing, development and commercialization of novel drugs and compounds beginning with Equivir and Equivir G. PBIO announced a second licensing agreement for two small molecule PIM kinase inhibitors, Linebacker LB-1 and LB-2, in July 2022, with plans to pursue development and commercialization of LB-1 as a cancer co-therapy.

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 diagnostic service business is and will continue to be influenced 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 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.

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

Our consumer sales are and will continue to be influenced 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 the OTC healthcare and cold remedy products that we manufacture, 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.

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

While our revenues have increased significantly as a result of our diagnostic services business, we will continue to be dependent on both government agency and insurance company reimbursement as well as the prevalence of COVID-19 associated strains. There can be no assurance that our efforts to offer and perform COVID-19 or other diagnostic testing will continue to be successful and the revenue and operating profits from such business will increase from or maintain their current level.

Results of Operations

Three Months Ended June 30, 2022 as Compared to the Three Months Ended June 30, 2021

For the three months ended June 30, 2022, net revenue was $29.1 million as compared to $9.1 million for the three months ended June 30, 2021. The increase in net revenue was the result of a $18.6 million increase in net revenue from diagnostic services and $1.3 million increase in consumer products. The increase in net revenue for 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 56,000 tests in the second quarter of 2021 to 144,000 tests in the second quarter of 2022, of which 57.6% and 0.0% were reimbursed by the HRSA uninsured program, respectively. The average variable consideration received was $152.08 per adjudicated test in the second quarter of 2022 versus $115.51 per adjudicated test in the second quarter of 2021.

Cost of revenues for the three months ended June 30, 2022 were $10.4 million, comprised of $8.4 million for diagnostic services and $2.0 million for consumer products. Cost of revenues for the three months ended June 30, 2021 were $4.7 million, comprised of $3.5 million for diagnostic services and $1.2 million for consumer products.

We realized a gross profit of $18.7 million for the three months ended June 30, 2022 as compared to $4.5 million for the three months ended June 30, 2021. The increase of $14.2 million was comprised of an increase of $13.7 million from diagnostic services and an increase of $0.5 million in consumer products. For the three months ended June 30, 2022 and 2021 we realized an overall gross margin of 64.3% and 48.9%, respectively. Gross margin for diagnostic services was 67.9% and 53.8% in the 2022 and 2021 comparable periods, respectively. The increase in gross margin was principally due to (i) increased efficiencies in our lab processing, (ii) a decreased sample collection costs and (iii) a decrease in cost of test materials. Gross margin for consumer products was 32.9% and 25.4% in the 2022 and 2021 comparable periods, respectively. Gross margin for consumer products have 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 services costs for the three months ended June 30, 2022 were $1.8 million compared to $830,000 for the three months ended June 30, 2021. The increase of $1.0 million was 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 for the three months ended June 30, 2022 were $6.3 million as compared to $5.0 million for the three months ended June 30, 2021. The increase of $1.3 million in general and administration expenses was principally related to an increase in personnel expenses and professional fees associated with our diagnostic services business.

Research and development costs for the three months ended June 30, 2022 were $28,000 as compared to $93,000 for the three months ended June 30, 2021. The decrease in research and development costs for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was principally due to a decrease in personnel expenses associated with our diagnostics services business.

Interest and other income for the three months ended June 30, 2022 and 2021 was $25,000 and $214,000, respectively. The decrease in interest income for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was principally due to the lower account balance of our investment account that bears interest.

Interest expense for the three months ended June 30, 2022 was $201,000 compared to $323,000 for the three months ended June 30, 2021. The decrease in interest expense for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 was principally due to the repayment during the three months ended June 30, 2022 of one of the two September 2020 unsecured convertible notes payable that accrued interest at a rate of 10% per year.

As a result of the effects described above, net income/(loss) from operations for the three months ended June 30, 2022 was $7.4 million, or $0.48 per share, as compared to ($1.4 million), or ($0.09) per share, for the three months ended June 30, 2021. Diluted earnings per share for the three months ended June 30, 2022 and 2021 were $0.40 and ($0.09), respectively.

Six Months Ended June 30, 2022 as Compared to the Six Months Ended June 30, 2021

For the six months ended June 30, 2022, net revenue was $76.6 million as compared to $24.4 million for the six months ended June 30, 2021. The increase in net revenue was the result of a $50.8 million increase in net revenue from diagnostic services and an immaterial increase in consumer products. The increase in net revenue for 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 169,000 tests in the first half of 2021 to 521,000 tests in the first half of 2022, of which 79.1% and 48.0% were reimbursed by the HRSA uninsured program, respectively. The average variable consideration received was $142.70 per adjudicated test in the first half of 2022 versus $108.48 per adjudicated test in the first half of 2021.

Cost of revenues for the six months ended June 30, 2022 were $29.2 million, comprised of $25.1 million for diagnostic services and $4.1 million for consumer products. Cost of revenues for the six months ended June 30, 2021 were $11.0 million, comprised of $7.8 million for diagnostic services and $3.2 million for consumer products.

We realized a gross profit of $47.4 million for the six months ended June 30, 2022 as compared to $13.4 million for the six months ended June 30, 2021. The increase of $34.0 million was comprised of an increase of $33.5 million from diagnostic services and an increase of $0.5 million in consumer products. For the six months ended June 30, 2022 and 2021 we realized an overall gross margin of 61.9% and 54.9%, respectively. Gross margin for diagnostic services was 64.7% and 61.4% in the 2022 and 2021 comparable periods, respectively. The increase in gross margin was principally due (i) increased efficiencies in our lab processing, (ii) a decreased sample collection costs and (iii) a decrease in cost of test materials. Gross margin for consumer products was 25.8% and 22.8% in the 2022 and 2021 comparable periods, respectively. Gross margin for consumer products have 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 services costs for the six months ended June 30, 2022 were $6.5 million compared to $4.6 million for the six months ended June 30, 2021. The increase of $1.9 million was 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 for the six months ended June 30, 2022 were $14.1 million as compared to $8.8 million for the six months ended June 30, 2021. The increase of $5.3 million in general and administration expenses was principally related to an increase in personnel expenses and professional fees associated with our diagnostic services business.

Research and development costs for the six months ended June 30, 2022 were $63,000 as compared to $208,000 for the six months ended June 30, 2021. The decrease in research and development costs for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 was principally due to a decrease in personnel expenses associated with our diagnostics services business.

Interest and other income for the six months ended June 30, 2022 and 2021 was $98,000 and $301,000, respectively. The decrease in interest income for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 was principally due to the lower account balance of our investment account that bears interest.

Interest expense for the six months ended June 30, 2022 was $434,000 compared to $574,000 for the six months ended June 30, 2021. The decrease in interest expense for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 was principally due to the repayment during the six months ended June 30, 2022 of one of the two September 2020 unsecured convertible notes payable that accrued interest at a rate of 10% per year.

As a result of the effects described above, net income/(loss) from operations for the six months ended June 30, 2022 was $19.9 million, or $1.28 per share, as compared to ($338,000), or ($0.02) per share, for the six months ended June 30, 2021. Diluted earnings per share for the six months ended June 30, 2022 and 2021 were $1.07 and ($0.02), respectively.

Non-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 measure 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 three months ended		For the six months ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
GAAP net income [1]	$ 7,446	$ (1,395)	$ 19,940	$ (338)
Interest, net	176	109	336	273
Income tax expense	2,965	-	6,381	-
Depreciation and amortization	1,267	503	2,517	960
EBITDA	11,854	(783)	29,174	895
Share-based compensation expense	528	1,076	1,010	1,504
Non-cash rent expense [2]	11	186	21	372
Bad debt expense [3]	-	-	250	-
Adjusted EBITDA	$ 12,393	$ 479	$ 30,455	$ 2,771

(1) We believe that net income (loss) 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) 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.

(3) Full allowance reserved related to restricted cash.

Liquidity and Capital Resources

Our aggregate cash, cash equivalents and restricted cash as of June 30, 2022 were $24.0 million as compared to $8.7 million at December 31, 2021. Our working capital was $53.6 million and $45.8 million as of June 30, 2022 and December 31, 2021, respectively. The increase of $15.3 million in our cash, cash equivalents and restricted cash for the six months ended June 30, 2022 was principally due to our proceeds from the sale of marketable debt securities of $5.6 million, proceeds from dispositions of property and other assets of $0.4 million, and $25.1 million cash provided by operating activities, offset by (i) purchases of marketable securities of $0.6 million, (ii) cash dividend payments of $9.4 million, (iii) repayment of note payable of $1.4 million, (iv) repurchase of common shares for $1.2 million, and (v) capital expenditures of $1.8 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 unaudited condensed 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.

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, 2021 and six months ended June 30, 2022, primarily as a result of revenue from our diagnostic services business, which offers COVID-19 testing. 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.

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 48% and 79% of our diagnostic services revenue for the six months ended June 30, 2022 and 2021, respectively, was generated from this program for the uninsured. 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. However, as a result of the suspension of the HRSA uninsured program, we did not recognize $16.7 million in revenues related to COVID-19 testing that we performed for uninsured individuals from March 23, 2022 through June 30, 2022. If funding for the HRSA program is reinstituted, we will submit eligible claims for reimbursement to HRSA and record the associated revenues.

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).

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.

As of June 30, 2022, we have not sold any shares under the Sales Agreement.

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 Condensed 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 condensed consolidated 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 condensed consolidated 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 condensed consolidated 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, contract manufacturing, genomic products and services, 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 Financial Accounting Standards Board ("FASB") recently issued Accounting Standards Update ("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. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The adoption of ASU 2020-06 did not have a material impact on our condensed consolidated financial statements or disclosures.

In May 2021, the FASB 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 ASU 2021-04 did not have a material impact on our condensed consolidated financial statements or disclosures.

Recently Issued Accounting Standards, Not Yet Adopted

In September 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326). The ASU sets forth a "current expected credit loss" (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. In February 2020, the FASB issued ASU 2020-02, Financial Instruments - Credit Losses (Topic 326), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for us for interim and annual periods in fiscal years beginning after December 15, 2022. We are currently assessing the impact of the adoption of this ASU on our condensed consolidated financial statements.

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 "Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". The FASB is issuing this Update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. We are currently assessing the impact of the adoption of this ASU on our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Like virtually all commercial enterprises, we can 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, notes receivable, 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.

Except for the broad effects of COVID-19 including its negative impact on the global economy and major financial markets, there have been no material changes to our market risk exposures since December 31, 2021.

Item 4. 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 June 30, 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 due to the material weakness described below, our disclosure controls and procedures were not effective at the reasonable assurance level as of June 30, 2022.

Material Weakness

In connection with our 2021 Annual Report, our management conducted an evaluation of the effectiveness of our 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 that 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 not effective as of December 31, 2021, as a material weakness exists. 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 relates 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 is committed to remediating the material weakness. We have employed a new process of implementing changes to our internal control over financial reporting to remediate the control deficiencies that gave rise to the material weakness, including further improvements in our processes, the current billing system and analyses that support the estimates associated with the allowances. Further, we expect to perform a comprehensive review of our billing standard operating procedures, training and resources in our billing and accounting functions.

We will not consider the material weakness remediated until the remedial controls operate for a sufficient period of time and we have concluded, through testing, that these controls are effectively designed and operating effectively. We will continue to assess throughout 2022.

Changes in Internal Control Over Financial Reporting

Except as described above, no change in internal control over financial reporting occurred during the most recent quarter with respect to our operations, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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 1A. Risk Factors.

Factors that could cause our actual results to differ materially from those in this Quarterly Report are any of the risks described in our Annual Report on Form 10-K filed with the SEC on March 31, 2022. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations.

As of the date of this Quarterly Report on Form 10-Q, except as described below, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K filed with the SEC on March 31, 2022. However, we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

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. We experienced net losses from continuing operations before Fiscal 2020.

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 Respiratory Pathogen Panel (RPP) Molecular tests. 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 intend to integrate 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 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 lines of business will achieve profitability.

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 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 48% and 79% of our diagnostic services revenue for the six months ended June 30, 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. However, as a result of the suspension of the HRSA uninsured program, we did not recognize $16.7 million of revenues related to COVID-19 testing which was performed for uninsured individuals from March 23, 2022 through June 30, 2022. If funding for the HRSA program is reinstituted, we will submit eligible claims for reimbursement to HRSA and record the associated revenues.

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.

Risks Related to Our Biopharmaceutical 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 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 that support an acceptable risk-benefit profile of our product candidates for our intended patient populations 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 our Linebacker portfolio (LB-1 and LB-2) and Equivir 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:

- severity or stage of the type of cancer under investigation;

- 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;
- availability of eligible prospective patients who are otherwise 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;
- perceived risks and benefits of participating in a clinical trial;
- 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, or public health crises;
- proximity and availability of clinical trial sites for prospective patients; and
- interruptions, delays, or staffing shortages resulting from the COVID-19 pandemic, other pandemics, or public health crises.

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:

- the 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, or public health crises.

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 for indications or patient populations that are not as broad as we intended or designed;
- 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 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 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. ProPhase BioPharma, Inc. (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. A NDA must include extensive preclinical and clinical data and supporting information to establish a 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 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 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 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 product candidates we may develop, the commercial prospects for those 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 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 our Linebacker portfolio (LB-1 and LB-2) as potential cancer treatments 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 cancers 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 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.

We face significant competition from other biotechnology and pharmaceutical companies, which may result in other companies developing or commercializing products before, or more successfully than, we do, thus rendering our product candidates non-competitive or reducing the size of our market. Our operating results will suffer if we fail to compete effectively.

The biopharmaceutical 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.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities may include completing preclinical studies and clinical trials of our product candidates; obtaining marketing and reimbursement approval for these product candidates; manufacturing, marketing, and selling those products that are approved; and satisfying any post-marketing requirements. We may never succeed in any or all these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the price of our common stock and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the price of our common stock also could cause stockholders to lose all or part of their investments.

Risks Related to Our Intellectual Property

If we or our licensors are unable to obtain and maintain effective patent or 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.

We rely upon a combination of patents, license rights and/or confidentiality agreements to protect the intellectual property related to our products and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries, as well as license rights, with respect to our proprietary technology, products and product candidates.

We have sought to protect our proprietary position by filing, where possible, patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development and manufacturing processes before it is too late to obtain patent protection.

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 own, or 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 we were the first to file any patent application related to our products or product candidates, or whether we were the first to make the inventions claimed in our owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our 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, our 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.

We have filed several patent applications covering various aspects of our products and product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or 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 we 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 patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents.

We 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 owned and 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.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

None

Item 6. Exhibits

Exhibit No.	Description
10.1	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).
10.2	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).
10.3	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 Company's Current Report on Form 8-K (File No. 000-21617) filed on June 13, 2022).
10.4	Guaranty dated June 10, 2022 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K (File No. 000-21617) filed on June 13, 2022).
10.5	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 Company's Current Report on Form 8-K (File No. 000-21617) filed on June 13, 2022).
10.6	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 10.3 of the Company's Current Report on Form 8-K (File No. 000-21617) filed on July 21, 2022).
31.1	Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101. INS#	Inline XBRL Instance Document
101.SCH#	Inline XBRL Taxonomy Extension Schema Document
101.CAL#	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF#	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB#	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements 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 and Chief Executive Officer (Principal Executive Officer)

Date: August 12, 2022

By: */s/ Bill White*
Bill White
Chief Financial Officer

Date: August 12, 2022

EXHIBIT 31.1

OFFICER'S CERTIFICATION PURSUANT TO
RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Ted Karkus, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ProPhase Labs, Inc.;

2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a- 15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2022

By: */s/ Ted Karkus*
Ted Karkus
Chairman of the Board and Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

OFFICER'S CERTIFICATION PURSUANT TO
RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Bill White, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ProPhase Labs, Inc.;

2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a- 15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2022

By: */s/ Bill White*
Bill White
Chief Financial Officer (Principal Financial Officer)

EXHIBIT 32.1

PROPHASE LABS, INC.
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934
AND 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Ted Karkus, Chief Executive Officer of ProPhase Labs, Inc., a Delaware corporation (the "Registrant"), in connection with the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), do hereby represent, warrant and certify, in compliance with Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Ted Karkus
Ted Karkus
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)
August 12, 2022

EXHIBIT 32.2

PROPHASE LABS, INC.
CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934
AND 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Bill White, Chief Financial Officer of ProPhase Labs, Inc., a Delaware corporation (the "Registrant"), in connection with the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), do hereby represent, warrant and certify, in compliance with Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Bill White
Bill White
Chief Financial Officer (Principal Financial Officer)
August 12, 2022