

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

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 01-21617

ProPhase Labs, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation or organization)

621 N. Shady Retreat Road, Doylestown, Pennsylvania

(Address of principal executive offices)

23-2577138

(I.R.S. Employer
Identification No.)

18901

(Zip Code)

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

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

Title of each class

Common Stock, \$0.0005 par value per share

Name of each exchange on which registered

NASDAQ Capital Market

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☐
Emerging growth company

Accelerated filer ☐
[]

Non-accelerated filer ☐

Smaller reporting 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 Act). Yes [] No [X]

The aggregate market value of the registrant’s voting and non-voting common stock held by non-affiliates was \$27,560,318 as of June 30, 2018, based on the closing price of the common stock on The Nasdaq Capital Market.

Number of shares of each of the registrant’s classes of securities outstanding on March 26, 2019:

Common stock, \$0.0005 par value per share: 11,556,685

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement relating to its 2019 annual meeting of stockholders (the “2019 Proxy Statement”) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2019 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (“Annual Report”) contains “forward looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). 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. These forward looking statements relate to future events or our future financial 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 or achievements 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. Given the risks and uncertainties surrounding forward-looking statements, you should not place undue reliance on these statements. You are cautioned that such forward looking statements are not guarantees of future performance and that all forward-looking statements address matters that involve risks and uncertainties, and that there are many important risks, uncertainties and other factors that could cause our actual results, levels of activity, performance, achievements and prospects, as well as those of the markets we serve, to differ materially from the forward-looking statements contained in this Annual Report.

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

- The ability of our management to successfully implement our business plan and strategy;
- 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 ability to fund our operations including the cost and availability of capital and credit;
- Our ability to grow our manufacturing business and operate it profitably;
- Potential disruptions in our ability to manufacture our products and those of others or our access to raw materials;
- Our ability to successfully develop and commercialize our existing products and new products;
- The general financial and economic uncertainty, fluctuations in consumer confidence and the strength of the United States economy, and their impacts on our business including demand for our products;
- Our ability to protect our proprietary rights;
- Our continued ability to comply with regulations relating to our current products and those we manufacture for others, any new products we develop, including our ability to effectively respond to changes in laws and regulations or the interpretation thereof including changing market rules and evolving federal, state and regional laws and regulations;
- Seasonal fluctuations in demand for the products we manufacture at our manufacturing facility; and
- Our ability to attract, retain and motivate our key employees.

You should also consider carefully the statements under other sections of this Annual Report, including the Risk Factors included in Item 1A, which 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 of the date of this Annual Report. We undertake no obligation to publicly update or review any forward-looking statements, whether as a result of new information, future developments or otherwise except as otherwise required by law.

PART I

Item 1. Business

General

ProPhase Labs, Inc. (“ProPhase” or the “Company”) was initially organized in Nevada in July 1989. Effective June 18, 2015, we changed our state of incorporation from the State of Nevada to the State of Delaware. Our principal executive offices are located at 621 N. Shady Retreat Road, Doylestown, Pennsylvania 18901 and our telephone number is 215-345-0919.

We are a vertically integrated and diversified branding, marketing and technology company with deep experience with over-the-counter (“OTC”) consumer healthcare products and dietary supplements and other remedies. We are engaged 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.

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

We use a December 31 year-end for financial reporting purposes. References in this Annual Report to “Fiscal 2018” mean the Fiscal year ended December 31, 2018 and references to other “Fiscal” years mean the year, that ended on December 31 of the year indicated. The term “we”, “us” or the “Company” as used herein also refer, where appropriate, to the Company, together with its subsidiaries unless the context otherwise requires.

Revenues from continuing operations for Fiscal 2018 and 2017 were \$13.1 million and \$9.9 million, respectively. As of December 31, 2018, we had working capital of approximately \$14.0 million, including \$6.7 million of marketable securities available for sale. We believe our current working capital is an acceptable and adequate level of working capital to support our business for at least the next twelve months.

Net income (loss) for Fiscal 2018 and 2017 were (\$1.7) million and \$40.6 million, respectively.

Contract Manufacturing Services

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

As part of the sale of our Cold-EEZE[®] Business in March 2017 (see “Discontinued Operations” below), PMI entered into a manufacturing agreement with Mylan Consumer Healthcare Inc. (formerly known as Meda Consumer Healthcare Inc.) (“MCH”) and Mylan Inc. (together with MCH, “Mylan”) to supply various Cold-EEZE[®] lozenge products to Mylan following the sale for a period of five years with annual renewal options.

For each of Fiscal 2018 and 2017, our revenues from continuing operations have come principally from our contract manufacturing services. Three third-party contract manufacturing customers accounted for 45.7%, 31.1%, and 10.9%, respectively, of our Fiscal 2018 revenues from continuing operations. The loss of sales to any one or more of these large third-party contract manufacturing customers could have a material adverse effect on our business operations and financial condition, unless we are able to increase revenue from other sources.

TK Supplements[®] Product Line

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

In Fiscal 2017, we initiated shipments of Legendz XL[®] to a national chain drug retailer and several regional retailers. Currently, we are awaiting product acceptance from other national retailers to leverage our existing infrastructure and retail distribution platform during Fiscal 2019. In addition, we have produced, tested and refined a direct response television commercial and initiated television and digital media testing for Legendz XL[®] for marketing direct to consumers. We have also completed a broad series of clinical studies that support important product claims that have now been incorporated into our product packaging and marketing communications for Legendz XL[®].

Once we have established a larger retail presence with Legendz XL[®], we expect to initiate a TV campaign with short form TV spots as well as other forms of advertising designed to support our retail efforts and generate additional direct-to-consumer sales, a two-pronged strategy of retail and e-commerce consumer engagement. We are preparing to leverage the advertising and targeting technology of PDM to drive e-commerce sales for our e-commerce campaign related to Legendz XL[®] and Super Prostaflow+[™].

We plan to introduce Triple Edge XL[®] as part of our e-commerce initiative in Fiscal 2019.

As with any new product launch, we anticipate losses from our TK Supplements[®] product line as we optimize our market strategy and expand our channels of distribution. There can be no assurance that our strategic focus will result in any revenue growth.

Direct Marketing Services

In August 2017, we formed ProPhase Digital Media (“PDM”), Inc., a Delaware corporation and wholly-owned subsidiary. Our objective is for PDM to become an independent full-service direct marketing agency. PDM’s first initiative will be to market the TK Supplements[®] product line. If successful, this may lead to the marketing of other companies’ consumer products.

Discontinued Operations

Prior to March 29, 2017, our flagship OTC drug brand was Cold-EEZE[®] and our principal product was Cold-EEZE[®] cold remedy zinc gluconate lozenges. In addition to Cold-EEZE[®] cold remedy lozenges, we also marketed and distributed non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE[®] cold remedy QuickMelts[®], (ii) Cold-EEZE[®] Gummies and (iii) Cold-EEZE[®] cold remedy oral spray.

Effective March 29, 2017, we sold our intellectual property rights and other assets related to our Cold-EEZE[®] brand and product line, including all then current and pipeline over-the-counter allergy, cold, flu, multi-symptom relief and immune support treatments for adults and children to the extent each was, or was intended to be, branded “Cold-EEZE[®]”, including all formulations and derivatives thereof (collectively referred to as the “Cold-EEZE[®] Business”) to Mylan. As a consequence of the sale of the Cold-EEZE[®] Business, for the year ended December 31, 2017, we have classified as discontinued operations (i) all income and expenses attributable to the Cold-EEZE[®] Business, (ii) the gain from the sale of the Cold-EEZE[®] Business, and (iii) the income tax expense attributed to the sale of the Cold-EEZE[®] Business. Excluded from the sale of the Cold-EEZE[®] Business were our accounts receivable and inventory. We have also retained all liabilities associated with our Cold-EEZE[®] Business operations arising prior to March 29, 2017.

Seasonality of the Business

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

Patents, Trademarks and Royalty Agreements

We do not currently own any patents. We maintain various trademarks for our TK Supplements[®] products including Legendz XL[®], Triple Edge XL[®] and Super ProstaFlow+[™].

Government Regulation

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

U.S. Food and Drug Administration

Pharmaceutical Regulation

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

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

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

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

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

The FDA and the United States Pharmacopeia Convention (the “USP”) have embarked on an initiative to modernize the monograph requirements of OTC drugs. We are monitoring the situation and will make appropriate adjustments to remain in compliance. In addition, regulations may change from time to time, requiring formulation, packaging or labeling changes for certain products. We cannot predict whether new legislation regulating our activities will be enacted or what effect any legislation would have on our business.

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

Dietary Supplement Regulation

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

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

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

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

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

Consumer Product Safety Commission

Under the Poison Prevention Packaging Act (“PPPA”), the CPSC has authority to require that certain dietary supplements and certain pharmaceuticals have child-resistant packaging to help reduce the incidence of accidental poisonings. The CPSC has published regulations requiring iron-containing dietary supplements and various pharmaceuticals to have child resistant packaging, and has established rules for testing the effectiveness of child-resistant packaging and for ensuring senior adult effectiveness.

The Consumer Product Safety Improvement Act of 2008 (“CPSIA”) amended the Consumer Product Safety Act (“CPSA”) to require that the manufacturer of any product that is subject to any CPSC rule, ban, standard or regulation certify that based on a reasonable testing program the product complies with CPSC requirements. This certification applies to pharmaceuticals and dietary supplements that require child-resistant packaging under the PPPA. The CPSC lifted the stay of enforcement of the certification requirement and the regulation has been in effect since February 9, 2010.

Federal Trade Commission

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

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

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

Other Regulatory Oversight

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

Competition

We compete with other contract manufacturers of OTC healthcare products. These suppliers range widely in size. Management believes that our manufacturing capacity and abilities offer a significant advantage over many of our competitors in the full service contract development and manufacturing organization for the OTC healthcare market. We have over 20 years of manufacturing experience and industry know how in large scale batch production of OTC lozenge products. The markets for OTC healthcare products and dietary supplements are highly competitive. Many of the participants in these industries have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, and distribution experience than we do. We believe that our ability to compete in these industries will depend on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support.

Employees

At December 31, 2018, we employed 47 full-time employees and 3 part-time employees, the majority of who were employed at our manufacturing facility in a production function. The remaining employees were involved in an executive, sales, marketing or administrative capacity. None of our employees are covered by a collective bargaining agreement or are members of a union.

Where You Can Find Other Information

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

Item 1A. Risk Factors

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

We have a history of losses.

We have experienced net losses from continuing operations before income tax for our last two Fiscal years. As of December 31, 2018, we had working capital of approximately \$14.0 million, which we believe is an acceptable and adequate level of working capital to support our business for at least the next twelve months ending March 2020. Following 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 opportunities and may consider and pursue other alternatives and strategies, including, but not limited to, investments and acquisitions in other sectors and industries. There can be no assurance that our strategic focus will result in any revenue growth or that we will be successful in initiating or acquiring any new lines of business, or that any such new lines of business will achieve profitability.

We have contingent liabilities up to the amount paid by Mylan for our Cold-EEZE[®] Business, which could adversely affect our ability to pursue our business goals and objectives.

We made customary representations and warranties to Mylan in the asset purchase agreement to purchase the Cold-EEZE[®] Business. Pursuant to the terms of the asset purchase agreement, we agreed to indemnify Mylan for any losses caused by breaches of most of our representations, warranties or covenants that occur, in most cases, within 24 months after the closing date of the sale to Mylan.

On August 2, 2018, we received notice of an indemnification claim from Mylan in relation to certain product advertising claims brought against Mylan relating to certain Cold-EEZE[®] products. Pursuant to the terms of the asset purchase agreement with Mylan, we have elected to assume the defense of these claims on behalf of Mylan. We dispute these product advertising claims and intend to vigorously contest such claims. While management expects to collect the full remaining escrow balance within the next twelve months, net of an immaterial reserve representative of our best estimate of the cost to adjudicate this matter.

While we believe these claims are without merit, in the event that these claims are successful, we may be required to pay Mylan such amounts out of the escrow fund, which may reduce the amount we ultimately collect from escrow or could even require us to return a portion of the net proceeds received from the sale of the Cold-EEZE[®] Business if the escrow funds are insufficient to cover the losses.

If we do not have sufficient cash to fund our remaining operations, we may need to seek to raise equity or debt financing or sell additional assets, which may not be possible under satisfactory terms, if at all.

Our business is subject to significant competitive pressures.

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

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

There can be no assurance that we will be able to compete successfully in the future. If we are unable to compete effectively, our earnings may be significantly negatively impacted.

The loss of sales to any one or more of our large third-party contract manufacturing customers could have a material adverse effect on our business operations and financial condition.

For each of Fiscal 2018 and 2017, our revenues from continuing operations came principally from our contract manufacturing services. Three third-party contract manufacturing customers, including Mylan, accounted for 45.8%, 31.1%, and 10.9%, respectively, of Fiscal 2018 revenues from continuing operations. The loss of sales to any one or more of these third-party contract manufacturing customers could have a material adverse effect on our business operations and financial condition, unless we are able to increase revenue from other sources.

The customers for whom we contract manufacture may significantly influence our business, financial condition and results of operations.

Our contract manufacturing business is dependent on demand for the products we manufacture for our customers and we have no control or influence over the market demand for those products. Demand for our customers' products may be adversely affected by, among other things, regulatory issues, the loss of patent or other intellectual property rights protection, the emergence of competing products, competition from other contract manufacturers, negative public or consumer perception of those products or our industry and changes in the marketing strategies for such products. If production volumes of products that we manufacture for third-parties and related revenues are not maintained or if there is any change in the terms or termination of our manufacturing agreement with Mylan or any of our other significant customers, it may have a material adverse impact on our business, financial condition and results of operations.

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

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

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

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

Our product development and commercialization efforts may be unsuccessful.

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

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

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

We may require additional capital to support our product development and commercialization programs.

We may require additional capital to support our product development and commercialization programs. The amount of capital that may be needed to support our product development initiatives will depend on many factors which may include, but are not limited to (i) the cost involved in applying for and obtaining FDA, international regulatory or other technical approvals, if required (ii) whether we elect to establish partnering or other strategic arrangements for the development, sales, manufacturing and marketing of such products, and (iii) the revenue we generate from our manufacturing services and the expenses incurred in marketing our manufacturing capabilities.

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

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

Disruptions, uncertainty or volatility in the credit markets could adversely impact the availability and cost of credit to us in the future. Accordingly, we may be forced to delay raising capital or pay unattractive interest rates, which could increase our interest expense, decrease our profitability and significantly reduce our financial flexibility. Longer-term disruptions in the capital and credit markets as a result of uncertainty, changing or increased regulation, reduced alternatives or failures of significant financial institutions could adversely affect our access to liquidity needed for our business. Any disruption could require us to take measures to conserve cash until the markets stabilize or until alternative credit arrangements or other funding for our business needs can be arranged. Such measures could include deferring capital expenditures or other discretionary uses of cash. Overall, our results of operations, financial condition and cash flows could be materially adversely affected by disruptions in the credit markets.

General economic and other conditions that impact consumer spending could adversely affect the Company.

Adverse economic conditions, declines in the stock market and the instability of the credit markets, could cause a reduction in consumer spending. While there has been a trend toward lower unemployment in recent periods, which has contributed to a better economic climate, there is uncertainty about the continued strength of the economy. If the economy weakens, consumers may reduce consumer spending.

Increases in the price or shortages of supply of key raw materials could materially and adversely affect our business, financial condition and results of operations.

Our TK Supplements[®] products and the products we manufacture for third parties are composed of certain key raw materials. If the prices of these raw materials were to increase significantly, it could result in a significant increase to us in the prices charged to us for our own branded products and third-party products. Raw material prices may increase in the future and we may not be able to pass on those increases to customers who purchase our products or to the customers whose products we manufacture. A significant increase in the price of raw materials that cannot be passed on to customers could have a material adverse impact on our business, financial condition and results of operations.

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

In addition, if we are no longer able to obtain products from one or more of our suppliers on terms reasonable to us or at all, our ability to perform under contracts with third parties for whom we manufacture products and our customer relationships could be materially and adversely affected.

Our business is subject to extensive governmental regulation.

We are subject to laws and regulations that cover:

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

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

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

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

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

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

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

The storage, processing, and use of data, some of which contain personal information, are subject to complex and evolving privacy and data protection laws and regulations that could adversely affect our business and financial condition.

Some data we store, process, and use, contains personal information, which subjects us to a variety of privacy, rights of publicity, data protection, content, protection of minors, and consumer protection laws and regulations in the United States. These laws and regulations are constantly evolving, can be particularly restrictive and may impose significant fines or penalties. The application and interpretation of these laws and regulations are often uncertain and could result in investigations, claims, changes to our business practices, and/or increased cost of operations, any of which could have a material adverse effect on our results of operations and financial condition.

While several proposals and discussions are before the United States federal government, a number of states have enacted laws or are considering the enactment of laws governing the release of credit card or other personal information received from consumers. For example, in June 2018, California enacted legislation, the California Consumer Privacy Act (the “CCPA”), that will, among other things, require covered companies to provide new disclosures to California consumers, and afford such consumers new abilities to opt-out of certain sales of personal information, when it goes into effect on January 1, 2020. There is debate surrounding the CCPA and amendments to the CCPA are possible before it becomes effective.

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

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

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

Although many of the ingredients in our current dietary supplement products are vitamins, minerals, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. While we believe that all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer

who has certain medical conditions. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects could be harmed significantly.

We may be subject to product liability claims.

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

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

Our success is dependent on key personnel.

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

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

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the “Section 382”), a corporation that undergoes an “ownership change” is subject to limitations on its ability to use its pre-change net operating loss carryforwards (the “NOLs”), to offset future taxable income. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations.

Based on our Section 382 analysis, we do not believe our current net operating loss carryforwards are subject to these limitations as of December 31, 2018. Should we identify any limitations upon the completion of our final 2018 income tax return, the impact could be material to our consolidated financial statements.

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

Future sales of substantial amounts of shares of our Common Stock in the public market, or the perception that such sales are likely to occur, could affect prevailing trading prices of our Common Stock.

If a significant number of our outstanding stock options are exercised, and the holders of these options attempt to sell a substantial amount of their holdings all at once, the market price of our Common Stock would likely decline. Moreover, the perceived risk of this potential dilution could cause stockholders to attempt to sell their shares and investors to “short” our stock, a practice in which an investor sells shares that he or she does not own at prevailing market prices, hoping to purchase shares later at a lower price to cover the sale. As each of these events would cause the number of shares of Common Stock being offered for sale to increase, our Common Stock’s market price would likely further decline. All of these events could combine to make it very difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

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

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

Our Chief Executive Officer owns a substantial amount of our Common Stock .

As of March 26, 2019, our Chief Executive Officer beneficially owned approximately 27.0% of our Common Stock. As such, our Chief Executive Officer may exert significant influence over the outcome of all matters submitted to stockholders for approval, including the election of directors. Consequently, he exercises substantial influence over major decisions including major corporate actions such as mergers and other business combinations transactions which could result in or prevent a change of control of the Company. Circumstances may occur in which the interests of our Chief Executive Officer could be in conflict with the interests of other stockholders. Accordingly, a stockholder's ability to influence us through voting their shares may be limited.

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

Our Certificate of Incorporation and By-laws contain certain provisions which may deter, discourage, or make it difficult for another person or entity to gain control of the Company through a tender offer, merger, proxy contest or similar transaction or series of transactions. These provisions may deter a future tender offer or other takeover attempt which could include a premium over the market price of our Common Stock at the time. Such provisions could depress the trading price of our Common Stock.

We have agreed to indemnify our Officers and Directors from liability.

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

A number of companies are seeking to make acquisitions in our industry, which may make our acquisition strategy more difficult or expensive to pursue.

The emergence and growth of OTC consumer healthcare products, dietary supplements and related products has brought increased media attention, and a number of companies and investors have begun making acquisitions of businesses or announced their intention to do so. We compete with many of these companies, and certain of them have greater financial resources than we do for pursuing and consummating acquisitions and developing and integrating acquired businesses. Any acquisitions we undertake may result in unanticipated costs, delays or other operational or financial problems related to integrating the acquired company and business with our Company, which may result in the diversion of our capital and our management's attention from other business issues and opportunities. We may not be able to successfully integrate operations that we acquire, including their personnel, technology, financial systems, distribution and general business operations and procedures. We cannot provide assurance that any acquisition we make will be successful and our operating results may be adversely impacted by the integration of a new business and its financial results.

We may be unsuccessful in identifying suitable acquisition candidates which may negatively impact our competitive position and our growth strategy.

We may be unable to identify suitable targets for future acquisition or acquire businesses at favorable prices, which would negatively impact our growth strategy. In addition, in the course of negotiating potential acquisitions, we may enter into term sheets, letters of intent, purchase options or other similar agreements that provide the counterparties with advances and termination or break-up fees in the event that we do not ultimately consummate any such acquisition. In the aggregate, the payment of any such termination or break-up fees may negatively impact our financial condition. We may not be able to execute our growth strategy through organic expansion, and if we are unable to identify and successfully acquire new businesses or products complementary to ours, we may not be able to expand or achieve profitability.

We have identified a material weakness in our internal control over financial reporting which, if not timely remediated, may adversely affect the accuracy and reliability of our financial statements, and our reputation, business and the price of our common stock, as well as lead to a loss of investor confidence in us.

In completing our Federal and State tax preparation review procedures during the second quarter of 2018, the Company identified errors in the treatment of the Net Operating Loss (NOL) limitations and our treatment of the amount of tax benefit allocated to continuing operations. We did not perform an effective risk assessment related to our internal controls over the accounting for income taxes. As a result, we identified a deficiency in the design of our internal control over financial reporting related to our accounting for income taxes, which affected the recording of income tax accounts by us in our interim and annual consolidated financial statements during 2017, including audit adjustments to the income tax accounts.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As part of our plan to remediate the deficiency in internal controls, management has taken steps to improve its income tax controls, including the replacement of its outside tax consultants. We may identify additional material weaknesses in our internal control over financial reporting in the future. If we are unable to remediate the material weakness previously identified or we identify other material weaknesses in our internal control over financial reporting in the future, our ability to analyze, record and report financial information accurately, to prepare our financial statements within the time periods specified by the rules and forms of the SEC and to otherwise comply with our reporting obligations under the federal securities laws and our long-term debt and credit agreements will likely be adversely affected. Our failure to remediate the material weakness previously identified or any material weakness in our internal control over financial reporting we may identify in the future could adversely affect the accuracy and reliability of our financial statements, and our reputation, business and the price of our Common Stock or any other securities we may issue, as well as lead to a loss of investor confidence in us.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are located in Doylestown, Pennsylvania. We purchased this property in 1998. Our headquarters are approximately 13,000 square feet and is comprised of office space and a storage area. Our principal manufacturing facility is located in Lebanon, Pennsylvania. The facility was purchased in October 2004. The facility has a total area of approximately 57,500 square feet and is comprised of manufacturing, warehousing and office space. We believe that our existing facilities are adequate at this time and do not anticipate the need for additional facilities in the foreseeable future.

Item 3. Legal Proceedings

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of business. We are not presently a party to any material litigation. It is our policy to vigorously defend litigation and/or enter into settlements of claims where management deems appropriate.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our Common Stock is currently traded on The Nasdaq Capital Market under the trading symbol “PRPH.”

As of March 20, 2019, there were approximately 194 holders of record of our Common Stock, including brokerage firms, clearing houses, and/or depository firms holding the Company’s securities for their respective clients. The exact number of beneficial owners of our securities is not known but exceeds 400.

Securities Authorized Under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

Not applicable because we are a smaller reporting company.

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

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

General

We are a vertically integrated and diversified branding, marketing and technology company with deep experience with OTC consumer healthcare products and dietary supplements. We are engaged 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.

In August 2017, we formed ProPhase Digital Media Inc. ("PDM"), a Delaware corporation and wholly-owned subsidiary. Our objective is for PDM to become an independent full-service direct marketing agency. PDM's first initiative will be to market the TK Supplements[®] product line. If successful, this may lead to the marketing of other companies' consumer products.

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

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 has 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.

A valuation allowance for all of our net deferred tax assets has been provided as we are unable to determine, at this time, that the generation of future taxable income against which the net operating losses ("NOL") carryforwards could be used is more likely than not. As a result of ongoing losses from continuing operations the Company has concluded that it is more likely than not that it will not realize all of its deferred tax assets relating to federal and state filing jurisdictions. As of December 31, 2018, there is a valuation allowance of \$4.2 million. As of December 31, 2018, the Company has state NOL carryforwards of \$1.1 million, which begin to expire in 2023 and federal NOL carryforwards of \$3.0 million. The amount of the federal NOL generated prior to the 2017 legislation commonly referred to as the Tax Cuts and Jobs Act ("TCJA") of \$2.6 million may be carried forward for 20 years and begins to expire in 2032. The remaining amount of \$442,000 federal NOL generated in year 2018 may be carried forward indefinitely.

We file a consolidated federal income tax returns and separate company state returns as well as combined state returns where applicable. There are currently no pending income tax examinations.

Results of Operations from Continuing Operations

Fiscal 2018 compared with Fiscal 2017

Net sales for Fiscal 2018 increased \$3.2 million to \$13.1 million as compared to \$9.9 million for Fiscal 2017. The increase in net sales from Fiscal 2017 to Fiscal 2018 is principally due to an increase in product volume and pricing changes.

Cost of sales for Fiscal 2018 were \$8.3 million as compared to \$7.9 million for Fiscal 2017. The increase in gross profit to \$4.8 million for Fiscal 2018 as compared to \$1.9 million for Fiscal 2017 is principally due to increased shipments during Fiscal 2018 as compared to Fiscal 2017. For Fiscal 2018 and Fiscal 2017, we realized a gross margin of 36.4% and 19.7%, respectively. The increase of 16.7% in gross margin from Fiscal 2017 to Fiscal 2018 is principally due to higher margins on certain products and lower manufacturing costs.

Sales and marketing expense for Fiscal 2018 increased \$408,000 to \$1.1 million as compared to \$699,000 for Fiscal 2017. The increase in sales and marketing expense for Fiscal 2018 as compared to Fiscal 2017 was a consequence of the increase in marketing expenses associated with our TK Supplement[®] product line.

Administrative expense increased \$102,000 for Fiscal 2018 to \$4.9 million as compared to \$4.8 million in Fiscal 2017. The increase in administrative expense for Fiscal 2018 as compared to Fiscal 2017 was principally due to an increase in professional and legal fees.

Research and development costs for Fiscal 2018 and 2017 were \$398,000 and \$431,000, respectively. The decrease of \$33,000 in research and development costs for Fiscal 2018 as compared to Fiscal 2017 was principally due to a decrease in the amount and timing of research and development expenditures.

Interest income and other expense for Fiscal 2018 was \$358,000 and \$191,000, respectively, as compared to \$231,000 and \$54,000, respectively, for Fiscal 2017. The increase in interest income in Fiscal 2018 as compared to Fiscal 2017 is principally due to interest earned on our investment account. The increase in other expense is principally due to the realized losses on our investment account. The other income for Fiscal 2018 was zero compared to \$150,000 for Fiscal 2017. The decrease in other income is principally due to the transition service fees received from Mylan in 2017 earned in pursuant to the terms of the transition service agreement with Mylan.

As a result of the effects of the above, the loss from continuing operations for Fiscal 2018 was \$1.6 million, or (\$0.14) per share, as compared to a loss from continuing operations of \$2.2 million, or (\$0.14) per share, for Fiscal 2017. Loss from discontinued operations for Fiscal 2018 was \$170,000, or (\$0.01) per share, as compared to income from discontinued operations of \$42.8 million, or \$2.75 per share, for Fiscal 2017. Net loss for Fiscal 2018 was \$1.7 million, or (\$0.15) per share, as compared to a net income of \$40.6 million, or \$2.61 per share for Fiscal 2017.

Liquidity and Capital Resources

Our aggregate cash and cash equivalents and marketable securities as of December 31, 2018 were \$8.2 million as compared to \$21.9 million at December 31, 2017. Our working capital was \$14.0 million and \$26.6 million as of December 31, 2018 and 2017, respectively. The decrease of \$13.7 million in our cash and cash equivalents and marketable securities balance for the 12 months ended December 31, 2018 was principally due to the net effect of (i) proceeds from the exercise of stock options of \$338,000, offset by (ii) our payment of \$11.7 million in June 2018 in connection with a special \$1.00 cash dividend to stockholders and (iii) the cash used in operating activities of \$2.1 million.

As a consequence of the seasonality of our business, we realize variations in operating results and demand for working capital from quarter to quarter.

Amended and Restated Employment Agreement with Ted Karkus

On February 16, 2018, our board of directors approved the Amended and Restated 2015 Executive Employment Agreement with Ted Karkus, our Chief Executive Officer (the “Amended Employment Agreement”), which became effective February 23, 2018, and was approved by stockholders at a special meeting of stockholders held April 12, 2018. Pursuant to the terms of the Amended Employment Agreement, Mr. Karkus voluntarily agreed to reduce his base salary from the rate set forth in his prior agreement (*i.e.*, not less than \$675,000 per annum) to a base salary of \$125,000 per annum (the “Term Base Salary”) through February 22, 2021. Unless otherwise determined by the mutual agreement of the Company and Mr. Karkus, on February 22, 2021 and thereafter, Mr. Karkus’s salary will increase from the Term Base Salary to not less than \$675,000 per annum.

In consideration of Mr. Karkus’s voluntary reduction in salary, our board of directors awarded Mr. Karkus a stock option to purchase 2,300,000 shares of our Common Stock at an exercise price of \$3.00 per share on February 23, 2018 (the “CEO Option”). The CEO Option will vest and be exercisable in 35 equal monthly installments of 63,888 shares and one monthly installment of 63,290 shares, subject to his continued employment, and subject to accelerated vesting in the event Mr. Karkus’s employment is terminated for any reason other than by us for Cause or by Mr. Karkus without Good Reason (as such terms are defined in the Amended Employment Agreement). The CEO Option is exercisable for a five year term commencing on the date of grant. The CEO Option was granted pursuant to the 2018 Stock Plan, which was also adopted and approved by our board of directors on February 16, 2018. The 2018 Plan, like the Amended Employment Agreement, received stockholder approval at a special meeting of stockholders held on April 12, 2018 at which time the options were considered granted for accounting purposes. The 2018 Plan authorizes the issuance of up to 2,300,000 shares pursuant to stock options granted under the 2018 Plan, all of which were issued to Mr. Karkus as part of the CEO Option.

As discussed further in Note 10, on May 7, 2018, the Compensation Committee of the board of directors, as required by the terms of the 2018 Stock Plan in order to maintain parity, adjusted the terms of the CEO Option, such that the exercise price of the CEO Option was reduced from \$3.00 per share to \$2.00 per share, effective as of June 5, 2018, the date the special \$1.00 cash dividend was paid in order to maintain parity, and from \$2.00 to \$1.75 per share, effective as of January 24, 2019, the date of the special \$0.25 cash dividend was paid in order to maintain parity.

Asset purchase agreement with Mylan

We have indemnification obligations to Mylan under the asset purchase agreement with Mylan (the “asset purchase agreement”) that may require us to make future payments to Mylan and other related persons for any damages incurred by Mylan or such related persons as a result of any breaches of our representations, warranties, covenants or agreements contained in the asset purchase agreement, or arising from the Retained Liabilities (as such term is defined in the asset purchase agreement) or certain third-party claims specified in the asset purchase agreement. Generally, our representations and warranties survive for a period of 24 months from the closing date, which was March 29, 2017, other than certain fundamental representations which survive until the expiration of the applicable statute of limitations. There is a limited indemnification cap with respect to a majority of the Company’s indemnification obligations under the asset purchase agreement with the exception of claims for actual fraud, the breach of any fundamental representations and certain other items, which have a larger indemnification cap (e.g., the purchase price).

Pursuant to the terms of the asset purchase agreement, we, Mylan, and an escrow agent entered into an Escrow Agreement at closing, pursuant to which Mylan deposited \$5 million of the aggregate purchase price for the Cold-EEZE[®] Business into an escrow account established with the Escrow Agent in order to satisfy, in whole or in part, certain of our indemnity obligations under the asset purchase agreement. If, on the 18th month anniversary of the closing date, there are funds remaining in the escrow account, then the escrow account will be reduced by the difference, if a positive number, of (i) \$2.5 million minus (ii) the aggregate amount of all escrow claims asserted by Mylan prior to this date that have either been paid out of the escrow account or are pending as of such date, and, within two business days of such date, the Escrow Agent will disburse such difference, if a positive number, to us. Within two business days of the second anniversary of the closing date, the Escrow Agent will release any funds remaining in the escrow account to us minus any amounts being reserved for escrow claims asserted by Mylan prior to such date. Upon the resolution of any pending escrow claims, the Escrow Agent will, within two business days of receipt of joint instructions or a final order from a court (as described in the Escrow Agreement) disburse such reserved amount to the parties entitled to such funds.

On May 31, 2018, we received notice of an indemnification claim for \$800,000 in losses. We have resolved this claim pursuant to a settlement agreement with Mylan, which became effective October 16, 2018, pursuant to which \$160,000 of the funds held in escrow were released to Mylan. This expense is reflected in discontinued operations for the year ended December 31, 2018.

On August 2, 2018, we received notice of an indemnification claim from Mylan in relation to certain product advertising claims brought against Mylan related to certain Cold-EEZE[®] products. Pursuant to the terms of the asset purchase agreement, we have elected to assume the defense of these claims on behalf of Mylan. We dispute these product advertising claims and intend to vigorously contest such claims. While we believe these claims are without merit, in the event that these or any other indemnity claims are successful, we may be required to pay Mylan such amounts out of escrow fund, pursuant to the indemnification provisions of the asset purchase agreement, which may reduce the amount we ultimately collect from escrow or could even require us to return a portion of the net proceeds received from the sale of the Cold-EEZE[®] Business if the escrow funds are insufficient to cover the losses. Management expects to collect the full remaining escrow balance within the next twelve months, net of an immaterial reserve representative of our best estimate of the cost to adjudicate this matter.

General

Management is not aware of any other trends, events or uncertainties that have or are reasonably likely to have a material negative impact upon our (i) short-term or long-term liquidity, or (ii) net sales or income from continuing operations. Any challenge to our trademark rights could have a material adverse effect on our future; however, we are not aware of any condition that would make such an event probable. Our business is subject to seasonal variations thereby impacting our liquidity and working capital during the course of our fiscal year.

To the extent that we do not generate sufficient cash from operations, our cash balances will decline. We may also use our cash to explore and/or acquire new product technologies, applications, product line extensions, new contract manufacturing applications and other new business opportunities. In the event that our available cash is insufficient to support such initiatives, we may need to incur indebtedness or issue Common Stock to finance plans for growth. Volatility in the credit markets and the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms that we believe to be reasonable, if at all.

Off-Balance Sheet Arrangements

It is not our usual business practice to enter into off-balance sheet arrangements such as guarantees on loans and financial commitments and retained interests in assets transferred to an unconsolidated entity for securitization purposes. We have no off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Impact of Inflation

We are subject to normal inflationary trends and anticipate that any increased costs would be passed on to our customers. Inflation has not had a material effect on our business.

Critical Accounting Policies and Estimates

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

Use of Estimates

The preparation of financial statements and the accompanying notes thereto, in conformity with generally accepted accounting principles in the United States of America (“GAAP”) , requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the respective reporting periods. Examples include the provision for bad debt, sales returns and allowances, inventory obsolescence, useful lives of property and equipment, impairment of property and equipment, income tax valuations and assumptions related to accrued advertising. When providing for the appropriate sales returns, allowances, cash discounts and cooperative incentive promotion costs, we apply a uniform and consistent method for making certain assumptions for estimating these provisions. These estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

Revenue Recognition

We generate sales principally through two types of customers, contract manufacturing customers and retail customers. Sales from product shipments to contract manufacturing and retailer customers are recognized at the time ownership is transferred to the customer. In 2018, approximately \$12.7 million of our approximately \$13.1 million of sales were from contract manufacturing customers.

Revenue Recognition – Sales Allowances

When providing for the appropriate sales returns, allowances, cash discounts and cooperative incentive promotion costs (“Sales Allowances”), we apply a uniform and consistent method for making certain assumptions for estimating these provisions. These estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

Our return policy accommodates returns for (i) discontinued products, (ii) store closings and (iii) products that have reached or exceeded designated expiration date. The following is a summary of the change in the return provision for the years ended December 31, 2018 (in thousands):

	Amount
Return provision at December 31, 2017	\$ 480
Net change in the return provision Fiscal 2018	(284)
Return provision at December 31, 2018	\$ 196

For Fiscal 2018, the return provision decreased by \$284,000. The decrease in the return provision was principally due to net returns associated with Fiscal 2017.

A one percent deviation for these sales allowance provisions for Fiscal 2018 and 2017 would affect net sales by approximately \$60,000 and \$169,000, respectively.

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 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.

The Company recognizes 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.

Effect of Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers” on revenue recognition. See the Revenue Recognition section within the Summary of Significant Accounting Policies in Note 2 for further details on the impact on our consolidated financial statements upon adoption and practical expedients elected. The implementation of the new revenue recognition standard did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18 “Statement of Cash Flows: Restricted Cash” which requires a statement of cash flows to explain the change during a period in the total cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Under the new standard, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown in the statement of cash flows. ASU 2016-18 was effective for us as of January 1, 2018. We have not generally had restricted cash or restricted cash equivalents, and there is no restricted cash on the balance sheet as of December 31, 2018 and 2017. The adoption of this update did not have a material impact on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments.” The new standard attempts to reduce diversity in practice in how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU No. 2016-15 provides guidance on eight specific cash flow issues, none of which currently apply to us. The new guidance was effective for us in the first quarter of 2018. The adoption of ASU 2016-15 did not have a material impact on our financial statements.

In October 2016, the FASB issued ASU No. 2016-16, “Income Taxes: Intra-Entity Transfers of Assets Other than Inventory.” The new standard requires entities to recognize the income tax consequences of an asset other than inventory when the asset transfer occurs. The new guidance was effective for us in the first quarter of 2018. The adoption of ASU 2016-15 did not have a material impact on our financial statements.

Recently Issued Accounting Standards, Not Yet Adopted

In June 2018, the FASB issued ASU 2018-07 intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The current accounting requirements for nonemployee and employee share-based payment transactions are significantly different. This ASU expands the scope of Topic 718, Compensation-Stock Compensation (which currently includes only share-based payments to employees) to include share-based payments to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, Equity-Equity-Based Payments to Nonemployees. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2018, with early adoption permitted. We are currently evaluating the impact of this new standard on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. We adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. We do not have material amounts of rental or lease expense. We do not expect the new accounting guidance to have a material impact on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments—Credit Losses.” The standard modifies the impairment model for most financial assets, including trade accounts receivables and loans, and will require the use of an “expected loss” model for instruments measured at amortized cost. Under this model, entities will be required to estimate the lifetime expected credit loss on such instruments and record an allowance to offset the amortized cost basis of the financial asset, resulting in a net presentation of the amount expected to be collected on the financial asset. The effective date of the standard is for fiscal years beginning after December 15, 2019 with early adoption permitted. We are currently evaluating the impact of adoption of this update on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820), – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement,” which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. We do not expect the adoption of this guidance to have a material impact on our condensed consolidated financial statements.

In August 2018, the SEC adopted SEC Final Rule Release No. 33-10532, Disclosure Update and Simplification, which amended certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements regarding stockholders’ equity for interim financial statements. Under the amendments, a description of the changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The description must include a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule became effective on November 5, 2018. We are evaluating the impact of this guidance on our consolidated financial statements. We anticipate our first presentation of changes in stockholders’ equity will be included in our Form 10-Q for the quarter ended March 31, 2019.

Item 7A. 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, realization of inventory and recoverability of assets. In addition, our business and financial performance may be adversely affected by current and future economic conditions, including a reduction in the availability of credit, financial market volatility and recession.

Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ProPhase Labs, Inc. and Subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations and other comprehensive income (loss), stockholders’ equity, and cash flows for each of the years then ended and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ EisnerAmper LLP

We have served as the Company’s auditor since 2010.

EISNERAMPER LLP

Iselin, New Jersey

March 26, 2019

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

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,554	\$ 3,173
Marketable securities, available for sale	6,687	18,765
Escrow receivable, current portion	4,830	2,500
Accounts receivable, net	2,968	1,945
Inventory	1,903	1,531
Prepaid expenses and other current assets	296	481
Assets held for sale, discontinued operations	-	22
Total current assets	<u>18,238</u>	<u>28,417</u>
Property, plant and equipment, net of accumulated depreciation of \$5,854 and \$5,471, respectively	2,499	2,742
Escrow receivable	-	2,500
TOTAL ASSETS	<u>\$ 20,737</u>	<u>\$ 33,659</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 437	\$ 562
Accrued advertising and other allowances	101	200
Dividend payable	2,929	-
Other current liabilities	766	1,050
Total current liabilities	<u>4,233</u>	<u>1,812</u>
COMMITMENTS AND CONTINGENCIES	-	-
Stockholders' equity		
Preferred stock authorized 1,000,000, \$.0005 par value, no shares issued	-	-
Common stock authorized 50,000,000, \$.0005 par value, issued 28,201,541 and 27,696,593 shares, respectively	14	14
Additional paid-in capital	59,471	58,034
Retained earnings	4,533	20,902
Treasury stock, at cost, 16,652,022 and 16,566,701 shares	(47,490)	(47,025)
Accumulated comprehensive loss	(24)	(78)
Total stockholders' equity	<u>16,504</u>	<u>31,847</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 20,737</u>	<u>\$ 33,659</u>

See accompanying notes to consolidated financial statements

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

	For the Years Ended	
	December 31, 2018	December 31, 2017
Net sales	\$ 13,126	\$ 9,867
Cost of sales	8,345	7,919
Gross profit	4,781	1,948
Operating expenses:		
Sales and marketing	1,107	699
Administration	4,910	4,808
Research and development	398	431
Total operating expenses	6,415	5,938
Loss from operations	(1,634)	(3,990)
Interest income, net	167	177
Other income	-	150
Total interest and other income	167	327
Loss from continuing operations before income taxes	(1,467)	(3,663)
Income tax benefit (provision) from continuing operations	(103)	1,421
Loss from continuing operations	(1,570)	(2,242)
Discontinued operations:		
Income from discontinued operations	-	530
Gain (loss) on sale of discontinued operations, net of taxes	(170)	42,301
Income (loss) from discontinued operations	(170)	42,831
Net income (loss)	\$ (1,740)	\$ 40,589
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	54	(78)
Total comprehensive income (loss)	\$ (1,686)	\$ 40,511
Basic earnings (loss) per share:		
Loss from continuing operations	\$ (0.14)	\$ (0.14)
Income (loss) from discontinued operations	(0.01)	2.75
Net income (loss)	<u>\$ (0.15)</u>	<u>\$ 2.61</u>
Diluted earnings (loss) per share:		
Loss from continuing operations	\$ (0.14)	\$ (0.14)
Income (loss) from discontinued operations	(0.01)	2.73
Net income (loss)	<u>\$ (0.15)</u>	<u>\$ 2.59</u>
Weighted average common shares outstanding:		
Basic	11,396	15,565
Diluted	11,396	15,696

See accompanying notes to consolidated financial statements

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

	Common Stock Shares Outstanding, Net of Shares of Treasury Stock	Par Value	Additional Paid in Capital	Retained Earnings	Accumulated Comprehensive Loss	Treasury Stock	Total
Balance as of January 1, 2017	17,080,776	\$ 13	\$ 56,378	\$ (19,687)	\$ -	\$ (30,742)	\$ 5,962
Proceeds for warrants exercised	51,000	-	69	-	-	-	69
Proceeds for options exercised	1,332,000	1	1,509	-	-	-	1,510
Unrealized loss on marketable securities	-	-	-	-	(78)	-	(78)
Stock based compensation	-	-	78	-	-	-	78
Treasury stock acquired	(7,333,884)	-	-	-	-	(16,283)	(16,283)
Net income	-	-	-	40,589	-	-	40,589
Balance as of December 31, 2017	11,129,892	14	58,034	20,902	(78)	(47,025)	31,847
Proceeds for options exercised	240,000	-	338	-	-	-	338
Cashless options exercise	164,679	-	465	-	-	(465)	-
Cash dividends	-	-	-	(14,629)	-	-	(14,629)
Unrealized gain on marketable securities	-	-	-	-	54	-	54
Stock based compensation	14,948	-	634	-	-	-	634
Net loss	-	-	-	(1,740)	-	-	(1,740)
Balance as of December 31, 2018	11,549,519	\$ 14	\$ 59,471	\$ 4,533	\$ (24)	\$ (47,490)	\$ 16,504

See accompanying notes to consolidated financial statements

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

	For the Years Ended	
	December 31, 2018	December 31, 2017
Cash flows from operating activities		
Net (loss) income	\$ (1,740)	\$ 40,589
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Realized gain on marketable securities	130	-
Loss (gain) on sale of discontinued operations, net of tax	170	(42,301)
Change in valuation allowance, income tax	-	(1,421)
Depreciation and amortization	383	337
Loss on fixed asset disposal	-	291
Amortization of loan origination and warrant expenses	-	10
Stock-based compensation expense	634	78
Changes in operating assets and liabilities:		
Accounts receivable	(1,023)	3,825
Inventory	(372)	1,205
Prepaid and other assets	185	199
Accounts payable and accrued expenses	(125)	(1,594)
Accrued advertising and other allowances	(99)	(2,605)
Due to Mylan, Inc. and affiliates	(59)	59
Other current liabilities	(225)	(1,488)
Assets held for sale	22	(22)
Net cash used in operating activities	(2,119)	(2,838)
Cash flows from investing activities		
Net proceeds from the sale of assets	-	40,825
Purchase of marketable securities	(13,350)	(31,693)
Proceeds from maturities of marketable securities	14,280	12,850
Proceeds from sale of marketable securities	11,071	-
Capital expenditures	(140)	(208)
Net cash provided by investing activities	11,862	21,774
Cash flows from financing activities		
Payments to retire notes	-	(1,500)
Payments to acquire treasury stock	-	(16,283)
Payment of dividends	(11,700)	-
Proceeds from exercise of warrants	-	69
Proceeds from exercise of stock options	337	1,510
Net cash used in financing activities	(11,362)	(16,204)
(Decrease) increase in cash and cash equivalents	(1,619)	2,732
Cash and cash equivalents, at the beginning of the year	3,173	441
Cash and cash equivalents, at the end of the year	\$ 1,554	\$ 3,173
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ -	\$ 54
Income taxes paid	\$ 738	\$ 1,350
Supplemental disclosure of non-cash investing and financing activities:		
Net unrealized gain (loss), investments in marketable securities	\$ 54	\$ (78)
Declaration of dividend payable	\$ 2,929	\$ -
Cashless options exercise	\$ 465	\$ -
Escrow receivable	\$ -	\$ 5,000

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Organization and Business

ProPhase Labs, Inc. (“we”, “us” or the “Company”) was initially organized as a corporation in Nevada in July 1989. Effective June 18, 2015, we changed our state of incorporation from the State of Nevada to the State of Delaware. We are a vertically integrated and diversified branding, marketing and technology company engaged in the research, development, manufacture, distribution, marketing and sale of over-the-counter (“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.

ProPhase Digital Media, Inc. (“PDM”), a wholly-owned subsidiary of ProPhase Labs, Inc., is an independent full-service direct marketing agency. PDM’s first initiative will be to market the TK Supplements[®] product line. If successful, this may lead to the marketing of other companies’ consumer products.

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

We use a December 31 year-end for financial reporting purposes. References herein to “Fiscal 2018” shall mean the fiscal year ended December 31, 2018 and references to other “fiscal” years shall mean the year, which ended on December 31 of the year indicated. The term “we”, “us” or the “Company” as used herein also refer, where appropriate, to the Company, together with its subsidiaries and consolidated variable interest entities unless the context otherwise requires.

Discontinued Operations

Prior to March 29, 2017, our flagship OTC drug brand was Cold-EEZE[®] and our principal product was Cold-EEZE[®] cold remedy zinc gluconate lozenges. In addition to Cold-EEZE[®] cold remedy lozenges, we also marketed and distributed non-lozenge forms of the proprietary zinc gluconate formulation, (i) Cold-EEZE[®] cold remedy QuickMelts[®], (ii) Cold-EEZE[®] Gummies and (iii) Cold-EEZE[®] cold remedy oral spray.

Effective March 29, 2017, we sold our intellectual property rights and other assets related to our Cold-EEZE[®] brand and product line, including all then current and pipeline over-the-counter allergy, cold, flu, multi-symptom relief and immune support treatments for adults and children to the extent each was, or was intended to be, branded “Cold-EEZE[®]”, including all formulations and derivatives thereof (collectively referred to as the “Cold-EEZE[®] Business”) to Mylan Consumer Healthcare Inc. (formerly known as Meda Consumer Healthcare Inc.) (“MCH”) and Mylan Inc. (together with MCH, “Mylan”). As a result of the sale of the Cold-EEZE[®] Business, for Fiscal 2017, we have classified as discontinued operations (i) all income and expenses attributable to the Cold-EEZE[®] Business, (ii) the gain from the sale of the Cold-EEZE[®] Business, and (iii) the income tax expense attributed to the sale of the Cold-EEZE[®] Business. Excluded from the sale of the Cold-EEZE[®] Business were our accounts receivable and inventory. We have also retained all liabilities associated with our Cold-EEZE[®] Business operations arising prior to March 29, 2017.

Continuing Operations

We continue to own and operate our manufacturing facility and manufacturing business in Lebanon, Pennsylvania, and our headquarters in Doylestown, Pennsylvania. As part of the sale of the Cold-EEZE[®] Business, we entered into a manufacturing agreement with Mylan and our wholly-owned subsidiary, Pharmed Manufacturing, Inc. (“PMI”), to supply various Cold-EEZE[®] lozenge products to Mylan. In addition to the production services we provide to Mylan under the manufacturing agreement, we also produce OTC healthcare and dietary supplement products for other third-party customers in addition to performing operational tasks such as warehousing and shipping.

We are also engaged in development and distribution of a product line of OTC dietary supplements under the brand name of TK Supplements[®]. The TK Supplements[®] product line comprises three men’s health products: (i) Legendz XL[®] for sexual health, (ii) Triple Edge XL[®], an energy booster plus testosterone support, and (iii) Super ProstaFlow Plus[™] for prostate and urinary health. In addition to developing direct-to-consumer (“Direct Response”) marketing strategies for Legendz XL[®], we are currently in distribution in a national chain drug retailer and several regional retailers.

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 – Summary of Significant Accounting Policies

For Fiscal 2018 and 2017, our revenues from continuing operations have come principally from our OTC healthcare contract manufacturing business and sales to retail customers of dietary supplement product.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated.

Discontinued Operations Carve Out and ProPhase Allocations

For Fiscal 2018 and 2017, results from operations for the Cold-EEZE[®] Business are classified as discontinued operations. The carve out of the discontinued operations (i) were prepared in accordance with the SEC's carve out rules under Staff Accounting Bulletin ("SAB") Topic 1B1 and (ii) are derived from identifying and carving out the specific assets, liabilities, net sales, cost of sales, operating expenses and interest expense associated with the Cold-EEZE[®] Business's operations. Administrative and overhead expenses, including personnel expenses and bonuses, and research and development overhead expenses incurred by us (for which the discontinued operation benefits from such resources) are allocated to discontinued operations based upon the percentage of the Cold-EEZE[®] Business's net sales to our consolidated net sales. For Fiscal 2018 and 2017, we allocated (i) \$0 and \$348,000, respectively, of administrative expenses, \$0 and \$1.7 million, respectively of sales and marketing expenses and (iii) \$0 and \$52,000, respectively, of research and development expenses, to discontinued operations in the accompanying statements of operations.

Product Innovation, Seasonality of the Business and Liquidity

Our net sales are derived principally from our contract manufacturing of OTC healthcare and dietary supplement products sold in the United States. In addition, we are engaged in market activities for the TK Supplements[®] product line of dietary supplements.

Our sales are influenced by and subject to (i) the scope and timing of TK Supplement[®] product market testing and the ultimate market launch, 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 for others, which are 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 consequence of the change in weather and other factors. We generally experience in the first, third and fourth quarter higher levels of net sales from our contract manufacturing of OTC healthcare and cold remedy products. Revenues are generally at their lowest levels in the second quarter when customer demand generally declines.

As a consequence of the scope and timing of our TK Supplements[®] product market testing and the ultimate market launch and the seasonality of our business, we realize variations in operating results and demand for working capital from quarter to quarter. As of December 31, 2018, we had working capital of approximately \$14.0 million, including \$6.7 million marketable securities available for sale. We believe our current working capital at December 31, 2018 is at an acceptable and adequate level to support our business for at least the next twelve months.

Use of Estimates

The preparation of financial statements and the accompanying notes thereto, in conformity with generally accepted accounting principles in the United States of America ("GAAP"), requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the respective reporting periods. Examples include the provision for bad debt, sales returns and allowances, inventory obsolescence, useful lives of property and equipment, impairment of property and equipment, income tax valuations and assumptions related to accrued advertising. When providing for the appropriate sales returns, allowances, cash discounts and cooperative incentive promotion costs ("Sales Allowances"), we apply a uniform and consistent method for making certain assumptions for estimating these provisions. These estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Cash and Cash Equivalents

We consider all highly liquid investments with an initial 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 investments.

Marketable Securities

We have classified our investments in marketable securities as available-for-sale and as a current asset. Our investments in marketable securities are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Realized gains and losses from our marketable securities are recorded as other interest income (expense). We initiated short term investments in marketable securities, which carry maturity dates between one and three years from date of purchase with interest rates of 2.39% - 3.67%, during Fiscal 2018. For Fiscal 2018 and 2017, we reported an unrealized gain of \$54,000 and unrealized loss of \$78,000, respectively. We had an accumulated unrealized loss of \$24,000 and \$78,000 as of December 31, 2018 and 2017, respectively. Unrealized gains and losses are classified as other comprehensive income (loss) and cost is determined on a specific identification basis. The following is a summary of the components of our marketable securities and the underlying fair value input level tier hierarchy (see long-lived assets below) (in thousands):

As of December 31, 2018			
	Amortized Cost	Unrealized Losses	Market Value
U.S treasuries	\$ 2,401	\$ (3)	\$ 2,398
Corporate bonds	4,310	(21)	4,289
	<u>\$ 6,711</u>	<u>\$ (24)</u>	<u>\$ 6,687</u>

As of December 31, 2017			
	Amortized Cost	Unrealized Losses	Market Value
U.S treasuries	\$ 1,744	\$ -	\$ 1,744
Corporate bonds	17,099	(78)	17,021
	<u>\$ 18,843</u>	<u>\$ (78)</u>	<u>\$ 18,765</u>

We have determined that the unrealized losses are deemed to be temporary as of December 31, 2018. We believe that the unrealized losses generally are the result of increases in the risk premiums required by market participants rather than an adverse change in cash flows or a fundamental weakness in the credit quality of the issuer or underlying assets. We have the ability and intent to hold these investments until a recovery of fair value, which may be maturity. We do not consider the investment in corporate bonds to be other-than-temporarily impaired at December 31, 2018.

Inventory

Inventory is valued at the lower of cost, determined on a first-in, first-out basis (FIFO), or net realizable value. Inventory items are analyzed to determine cost and the net realizable value and appropriate valuation adjustments are established. At December 31, 2018, after the 2018 write-off of certain inventory previously reserved, the financial statements include adjustments to reduce inventory for excess, obsolete or short-dated shelf-life inventory of \$377,000, inclusive of adjustments of \$270,000 for product samples of TK Supplements[®] products. At December 31, 2017, the financial statements include adjustments to reduce inventory for excess, obsolete or short-dated shelf-life inventory of \$1.1 million, inclusive of an adjustment of \$541,000 for product samples of TK Supplements[®] products. The components of inventory are as follows (in thousands):

	December 31, 2018	December 31, 2017
Raw materials	\$ 1,374	\$ 1,269
Work in process	371	245
Finished goods	158	17
	<u>\$ 1,903</u>	<u>\$ 1,531</u>

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 – three to seven years; computer equipment and software – three to five years; and furniture and fixtures – five years.

Concentration of Risks

Future revenues, costs, margins and profits will continue to be influenced by our ability to maintain our manufacturing availability and capacity together with our marketing and distribution capabilities and the regulatory requirements associated with the development of OTC consumer healthcare products, dietary supplements and other remedies in order to compete on a national level and/or international level.

Our business is subject to federal and state laws and regulations adopted for the health and safety of users of our products. The manufacturing and distribution of OTC healthcare and dietary supplement products are subject to regulations by various federal, state and local agencies, including the Food and Drug Administration (“FDA”) and, as applicable, the Homeopathic Pharmacopoeia of the United States.

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

We maintain cash and cash equivalents with certain major financial institutions. As of December 31, 2018, our cash and cash equivalents balance was \$1.6 million and our bank balance was \$1.6 million. Of the total bank balance, \$250,000 was covered by federal depository insurance and \$1.4 million was uninsured at December 31, 2018.

Trade accounts receivable potentially subject us to credit concentrations from time-to-time as a consequence of the timing, payment pattern and ultimate purchase volumes or shipping schedules with our customers. We extend credit to our customers based upon an evaluation of the customer’s financial condition and credit history and generally we do not require collateral. Our customers include consumer products companies and large national chain, regional, specialty and local retail stores. These credit concentrations may impact our overall exposure to credit risk, either positively or negatively, in that our customers may be similarly affected by changes in economic, regulatory or other conditions that may impact the timing and collectability of amounts due to us. As a consequence of an evaluation of our customer’s financial condition, payment patterns, balance due to us and other factors, we did not offset our account receivable with an allowance for bad debt at December 31, 2018 and 2017.

Long-lived Assets

We review the carrying value of our long-lived assets with definite lives whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When indicators of impairment exist, we determine whether the estimated undiscounted sum of the future cash flows of such assets is less than their carrying amounts. If less, an impairment loss is recognized in the amount, if any, by which the carrying amount of such assets exceeds their respective fair values. 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; industry competition; and general economic and business conditions, among other factors.

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Fair value is based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a three-tier fair value hierarchy prioritizes the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Fair Value of Financial Instruments

Cash and cash equivalents, marketable securities, accounts receivable, assets held for sale, accounts payable, and accrued expenses are reflected in the consolidated financial statements at carrying value which approximates fair value. We account for our marketable securities at fair value pursuant to Accounting Standards Codification, or ASC, 820-10, with the net unrealized gains or losses reported as a component of accumulated other comprehensive income or loss.

As of December 31, 2018				
	Level 1	Level 2	Level 3	Total
Marketable securities				
U.S. government obligations	\$ -	\$ 2,398	\$ -	\$ 2,398
Corporate obligations	-	4,289	-	4,289
	<u>\$ -</u>	<u>\$ 6,687</u>	<u>\$ -</u>	<u>\$ 6,687</u>
As of December 31, 2017				
	Level 1	Level 2	Level 3	Total
Marketable securities				
U.S. government obligations	\$ -	\$ 1,744	\$ -	\$ 1,744
Corporate obligations	-	17,021	-	17,021
	<u>\$ -</u>	<u>\$ 18,765</u>	<u>\$ -</u>	<u>\$ 18,765</u>

There were no transfers of marketable securities between Levels 1, 2 or 3 for the Fiscal 2018 and 2017.

Revenue Recognition

We account for revenue in accordance with ASC 606, which requires revenue recognized to represent the transfer of promised goods or services to customers at an amount that reflects the consideration which 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 determine if a contract is within the scope of ASC Topic 606 and then evaluate the contract 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.

We adopted ASC 606 as of January 1, 2018 using the modified retrospective method. For the year ended December 31, 2018, there were no changes to our opening balances upon the adoption of ASC 606 and the amounts which would have been reported under the standards in effect prior to adoption.

Performance Obligations

We generate sales principally through two types of customers, contract manufacturing and retail customers. Sales from product shipments to contract manufacturing and retailer customers are recognized at the time ownership is transferred to the customer. Net sales from OTC healthcare contract manufacturing and retail dietary supplement product customers were \$12.6 million and \$0.5 million, respectively, for Fiscal 2018 and \$9.7 million and \$0.2 million, respectively, for Fiscal 2017. Revenue from retailer customers is reduced for trade promotions, estimated sales returns, cash discounts and other allowances in the same period as the related sales are recorded. No such allowance is applicable to our contract manufacturing customers. We make estimates of 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.

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 in accordance with ASC 606. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The combined duties and responsibilities within each contract will be considered one single performance obligation under ASC 606 as these items would not be separately identifiable from each other promise in the contract and we provide a significant service of integrating the duties with other promises in the contracts.

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Transaction Price

The transaction price is fixed based upon either (i) a combined Master Agreement and each related purchase order, or (ii) if there is no Master Agreement, the price per the individual purchase order received from each customer. The customers are invoiced at an agreed upon contractual price for each unit ordered and delivered by us.

Consistent with Company practice prior to the adoption of ASC 606, we do not collect sales tax or other similar taxes from customers. As such, there is no effect on the measurement of the transaction price.

Recognize Revenue When the Company Satisfies a Performance Obligation

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

We do not accept returns in the contract manufacturing revenue stream. Our return policy for retailer 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 within which product may be returned. All requests for product returns must be submitted to us for pre-approval. The main components of our returns policy are: (i) we will accept returns that are due to damaged product that is un-saleable and such return request activity falls within an acceptable range, (ii) we will accept returns for products that have reached or exceeded designated expiration dates and (iii) we will accept returns in the event that we discontinue a product provided that the customer will have the right to return only such items that it purchased directly from us. We will not accept return requests pertaining to customer inventory “Overstocking” or “Resets”. We will accept return requests for only products in its 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 or to be owed and in the case of discontinued product only, also by way of an exchange. We do not have any significant product exchange history.

Under ASC 606, we continue to recognize revenue from contract manufacturing and retail customers at a point in time as we have an enforceable right to payment for goods as products are shipped to customers.

As of December 31, 2018 and 2017, we included a provision for sales allowances from continuing operations of \$1,000 and \$2,000, respectively, which are reported as a reduction to account receivables. Additionally, accrued advertising and other allowances from discontinued operations as of December 31, 2018 included (i) 181,000 for estimated returns which is reported as a reduction to account receivables and (ii) \$88,000 for cooperative incentive promotion costs, which is reported as accrued advertising and other allowances under current liabilities. As of December 31, 2017, accrued advertising and other allowances from discontinued operations included (i) \$480,000 for estimated future sales returns which is reported as a reduction to account receivables and (ii) \$200,000 for cooperative incentive promotion costs which is reported as accrued advertising and other allowances under current liabilities.

As of December 31, 2018, we have deferred revenue of \$206,000 in relation to Research and Development (“R&D”) stability and release testing programs. No revenue was deferred as of December 31, 2017. 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 for implementation, maintenance and other services, as well as initial subscription fees. We recognize deferred revenues as revenues when the services are performed and the corresponding revenue recognition criteria are met. Customer prepayments are generally applied against invoices issued to customers when services are performed and billed.

The following table disaggregates the Company’s deferred revenue by recognition period (in thousands):

Recognition Period	Deferred Revenue
0-12 Months	\$ 184
13-24 Months	22
Total	<u>\$ 206</u>

Disaggregation of Revenue

We disaggregate revenue from contracts with customers into two categories: contract manufacturing and retail customers. 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.

PROPHASE LABS, INC. AND SUBSIDIARIES
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The following table disaggregates the Company's revenue by revenue source for Fiscal 2018 and 2017 (in thousands):

Revenue by Customer Type	For the Years Ended	
	December 31, 2018	December 31, 2017
Contract manufacturing	\$ 12,633	\$ 9,666
Retail and others	493	201
Total revenue	\$ 13,126	\$ 9,867

Practical Expedients Elected

We have elected the following practical expedients in applying ASC 606 across all revenue stream:

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 sales and marketing expense, (ii) cooperative incentive promotions and coupon program expenses, which are accounted for as part of net sales, and (iii) free product, which is accounted for as part of cost of sales. Advertising and incentive promotion expenses (i) incurred from continuing operations for Fiscal 2018 and 2017 were \$264,000 and \$45,000, respectively, and (ii) attributed to and classified as discontinued operations for Fiscal 2018 and 2017 were \$0 and \$2.8 million, respectively.

Share-Based Compensation

We recognize all share-based payments to employees and directors, including grants of stock options, as compensation expense in the financial statements based on their fair values. 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.

Stock and stock options for the purchase of our common stock, \$0.0005 par value ("Common Stock"), have been granted to both employees and non-employees pursuant to the terms of certain agreements and stock option plans (see Note 6). Stock options are exercisable during a period determined by us, but in no event later than ten years from the date granted.

Research and Development

R&D costs are charged to operations in the period incurred R&D costs incurred for Fiscal 2018 and 2017 (i) from continuing operations were \$398,000 and \$431,000, respectively, and (ii) attributed to and classified as discontinued operations were \$0 and \$52,000, 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 other remedies.

Income Taxes

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 deferred tax asset is being provided.

PROPHASE LABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

We utilize a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than fifty percent likely of being realized upon ultimate settlement. Any interest or penalties related to income taxes will be recorded as interest or administrative expense, respectively.

As a result of our losses from continuing operations, we have recorded a full valuation allowance against a net deferred tax asset. Additionally, we have not recorded a liability for unrecognized tax benefit.

Recently Adopted Accounting Standards, Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers” on revenue recognition. See the Revenue Recognition section within the Summary of Significant Accounting Policies in Note 2 for further details on the impact to our consolidated financial statements upon adoption and practical expedients elected. The implementation of the new revenue recognition standard did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18 “Statement of Cash Flows: Restricted Cash” which requires a statement of cash flows to explain the change during a period in the total cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Under the new standard, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown in the statement of cash flows. ASU 2016-18 was effective for us as of January 1, 2018. We have not generally had restricted cash or restricted cash equivalents, and there is no restricted cash on the balance sheet as of December 31, 2018 and 2017. The adoption of this update did not have a material impact on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments.” The new standard attempts to reduce diversity in practice in how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU No. 2016-15 provides guidance on eight specific cash flow issues, none of which currently apply to us. The new guidance was effective for us in the first quarter of 2018. The adoption of ASU 2016-15 did not have a material impact on our financial statements.

In October 2016, the FASB issued ASU No. 2016-16, “Income Taxes: Intra-Entity Transfers of Assets Other than Inventory.” The new standard requires entities to recognize the income tax consequences of an asset other than inventory when the asset transfer occurs. The new guidance was effective for us in the first quarter of 2018. The adoption of ASU 2016-15 did not have a material impact on our financial statements.

Recently Issued Accounting Standards

In June 2018, the FASB issued ASU 2018-07 intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. Currently, the accounting requirements for nonemployee and employee share-based payment transactions are significantly different. This ASU expands the scope of Topic 718, Compensation-Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, Equity-Equity-Based Payments to Nonemployees. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2018, with early adoption permitted. We are currently evaluating the impact of this new standard on our consolidated financial statements.

PROPHASE LABS, INC. AND SUBSIDIARIES
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In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. We do not expect the new accounting guidance to have a material impact on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments—Credit Losses.” The standard modifies the impairment model for most financial assets, including trade accounts receivables and loans, and will require the use of an “expected loss” model for instruments measured at amortized cost. Under this model, entities will be required to estimate the lifetime expected credit loss on such instruments and record an allowance to offset the amortized cost basis of the financial asset, resulting in a net presentation of the amount expected to be collected on the financial asset. The effective date of the standard is for fiscal years beginning after December 15, 2019 with early adoption permitted. We are currently evaluating the impact of adoption of this update on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820), – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement,” which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In August 2018, the SEC adopted SEC Final Rule Release No. 33-10532, Disclosure Update and Simplification, which amended certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements regarding stockholders’ equity for interim financial statements. Under the amendments, a description of the changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The description must include a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. Our first presentation of changes in stockholders’ equity will be included in our Form 10-Q for the quarter ended March 31, 2019.

Note 3 – Discontinued Operations, Sale of the Cold-EEZE[®] Business

Effective March 29, 2017, we completed the sale of the Cold-EEZE[®] Business to Mylan. As a consequence of the sale of the Cold-EEZE[®] Business, for Fiscal 2017, we have classified as discontinued operations (i) the gain from the sale of the Cold-EEZE[®] Business, (ii) all gains and losses attributable to the Cold-EEZE[®] Business operations and (iii) the income tax expense attributed to the sale of the Cold-EEZE[®] Business (see Note 9). Excluded from the sale of the Cold-EEZE[®] Business were our accounts receivable and inventory, and we also retained all liabilities associated with our Cold-EEZE[®] Business operations arising prior to March 29, 2017.

Pursuant to the asset purchase agreement, we also agreed to a one-time sale to Mylan of certain non-lozenge-based Cold-EEZE[®] inventory. At December 31, 2017, we have classified as assets held for sale approximately \$22,000 of such inventory, which approximates our cost.

Pursuant to the asset purchase agreement, we entered into a transition service arrangement with Mylan, for which we earned \$150,000 in transition service fees through December 31, 2017. Pursuant to this arrangement, we (i) received, processed, fulfilled, and shipped customer orders, and billed such customers for these shipments on behalf of Mylan from March 30, 2017 to June 30, 2017, (ii) processed certain sales allowances, returns and other customer promotional deductions, and (iii) paid certain Cold-EEZE[®] Business expenses which are to be reimbursed by Mylan. For Fiscal 2017, the \$150,000 transition service fees earned were recorded as a component of other income (expense).

PROPHASE LABS, INC. AND SUBSIDIARIES
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The net proceeds received from the sale of the Cold-EEZE[®] Business were as follows (in thousands):

	Amount
Gross consideration from the sale of the Cold-EEZE [®] Business	\$ 50,000
Closing and transaction costs	(4,175)
Net proceeds from sale of the Cold-EEZE [®] Business	45,825
Book value of assets sold	(13)
Gain on sale of the Cold-EEZE [®] Business before income taxes	45,812
Income tax expense	(3,511)
Gain on sale of the Cold-EEZE [®] Business after income taxes	\$ 42,301
Net proceeds:	
Cash paid at closing, net of closing and transaction costs	\$ 43,145
Proceeds due on sale of assets, cash held in escrow	5,000
	\$ 48,145

For Fiscal 2017, we incurred \$4.2 million in closing and transaction costs associated with the sale of the Cold-EEZE[®] Business which were comprised of (i) transaction fees and related closing costs of \$1.9 million and (ii) performance bonuses, contract termination compensation and severance payments to certain employees associated with the sale of the Cold-EEZE[®] Business of \$2.3 million. The compensation committee of our board of directors approved these compensation arrangements. These compensation and termination payments were paid by us in April 2017.

The following table sets forth the operating results of our discontinued operations for Fiscal 2018 and 2017, respectively, (in thousands):

	For the Years ended	
	December 31, 2018	December 31, 2017
Net sales	\$ -	\$ 4,687
Cost of sales	-	2,037
Sales and marketing	-	1,720
Administration	-	348
Research and development	-	52
Income from discontinued operations	\$ -	\$ 530

For Fiscal 2018, we incurred costs of \$170,000 which was charged against the gain on sale of discontinued assets, net of taxes.

Note 4 – Property, Plant and Equipment

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

	December 31, 2018	December 31, 2017	Estimated Useful Life
Land	\$ 504	\$ 504	
Leasehold improvements	3,059	3,059	10-39 years
Machinery	4,126	4,099	3-7 years
Computer equipment	457	355	3-5 years
Furniture and fixtures	207	197	5 years
	8,353	8,213	
Less: accumulated depreciation	(5,854)	(5,471)	
Total property, plant and equipment, net	\$ 2,499	\$ 2,742	

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Depreciation expense incurred for Fiscal 2018 and 2017 (i) from continuing operations were \$383,000 and \$315,000, respectively, and (ii) attributed to and classified as discontinued operations of \$0 and \$22,000, respectively.

Note 5 – Secured Promissory Notes and Other Obligations

Secured Promissory Notes

On March 29, 2017, in connection with the sale of the Cold-EEZE[®] Business, we paid in full the remaining principal and accrued interest due under certain 12% Secured Promissory Notes – Series A that were issued in December 2015 (the “Notes”), in the total amount of \$1.5 million. Of the \$1.5 million paid to the Investors of the Notes (the “Investors”), \$69,000 was netted against the aggregate exercise price of the warrants held by these Investors, which were simultaneously exercised by the Investors.

In connection with the issuance of the Notes, the Company entered into a security agreement with John E. Ligums, Jr., as collateral agent for the Investors (the “Security Agreement”), to secure the timely payment and performance in full of the Company’s obligations under the Notes. Under the Security Agreement, we granted to the collateral agent, for the benefit of the Investors a lien upon and security interest in the property and assets listed as collateral in the Security Agreement, including without limitation, all of our personal property, inventory, equipment, general intangibles, cash and cash equivalents, and proceeds. In connection with the payoff of the Notes, the Security Agreement was terminated.

Note 6 – Transactions Affecting Stockholders’ Equity

Our authorized capital stock consists of 50 million shares of Common Stock and one million shares of preferred stock, \$0.0005 par value (“Preferred Stock”) per share.

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 December 31, 2018, no shares of Preferred Stock have been issued. Our board of directors have the full authority permitted by law to establish, without further stockholder approval, one or more series of Preferred Stock and the number of shares constituting each such series and to fix by resolution voting powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any. Subject to the limitation on the total number of shares of Preferred Stock that we have authority to issue under our certificate of incorporation, the board of directors is also authorized to increase or decrease the number of shares of any series, subsequent to the issue of that series, but not below the number of shares of such series then-outstanding. In case the number of shares of any series is so decreased, the shares constituting such decrease will resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. We may, subject to any required stockholder approval amend from time to time our certificate of incorporation to increase the number of authorized shares of Preferred Stock or Common Stock or to make other changes or additions to our capital structure or the terms of our capital stock.

Stockholder Rights Plan

On September 8, 1998, our Board of Directors declared a dividend distribution of Common Stock Purchase Rights (each individually, a “Right” and collectively, the “Rights”) payable to the stockholders of record on September 25, 1998, thereby creating a Stockholder Rights Plan (the “Rights Agreement”). The Rights Agreement was subsequently amended effective each of (i) May 23, 2008, (ii) August 18, 2009, (iii) June 2014 and (iv) January 6, 2017. The Rights Agreement, as amended and restated, provides that each Right entitles the stockholder of record to purchase from the Company that number of common shares of Common Stock having a combined market value equal to two times the Rights exercise price of \$45. The Rights are not exercisable until the distribution date, which will be the earlier of a public announcement that a person or group of affiliated or associated persons has acquired 15% or more of the outstanding common shares of Common Stock, or the announcement of an intention by a similarly constituted party to make a tender or exchange offer resulting in the ownership of 15% or more of the outstanding common shares of Common Stock (such person, the “acquirer”). The Rights Agreement, as amended and restated, allows for an exemption for Ted Karkus, our Chairman and Chief Executive Officer, to acquire up to 20% of our Common Stock without our Board of Directors declaring a dividend distribution.

The dividend has the effect of giving the stockholder a 50% discount on the share’s current market value for exercising such right. In the event of a cashless exercise of the Right, and the acquirer has acquired less than 50% beneficial ownership of the Company, a stockholder may exchange one Right for one common share of the Company. The Rights Agreement, as amended and restated, includes a provision pursuant to which our Board of Directors may exempt from the provisions of the Rights Agreement an offer for all outstanding shares of our Common Stock that the directors determine to be fair and not inadequate and to otherwise be in the best interests of the Company and its stockholders, after receiving advice from one or more investment banking firms. The expiration date of the Rights Agreement, as amended, is June 18, 2024.

PROPHASE LABS, INC. AND SUBSIDIARIES
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On February 16, 2018, our board of directors, approved the termination of the Rights Agreement effective February 20, 2018. As a consequence of the termination of the Rights Agreement, all of the Rights distributed to our stockholders expired on February 20, 2018.

2015 Equity Line of Credit

On July 30, 2015, we entered into an equity line of credit agreement (the “2015 Equity Line”) with Dutchess Opportunity Fund II, LP (“Dutchess”). Pursuant to the 2015 Equity Line, Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,200,000 shares of our Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the investment agreement. The 2015 Equity Line of Credit expired in July 2018.

Common Stock Dividend

On May 7, 2018, the Board declared a special cash dividend of \$1.00 per share on the Company’s common stock, \$11.7 million payable on June 5, 2018 to holders of record of the Company’s common stock on May 21, 2018.

On December 24, 2018, the Board declared a special cash dividend of \$0.25 per share on the Company’s common stock, \$2.9 million payable on January 24, 2019 to holders of record of the Company’s common stock on January 10, 2019.

The Company recorded \$2.9 million dividend payable as of December 31, 2018.

The 2010 Directors’ Equity Compensation Plan

On May 5, 2010, our stockholders approved the 2010 Directors’ Equity Compensation Plan which, was has been subsequently amended and restated by our stockholders (the “2010 Directors’ Plan”). A primary purpose of the 2010 Directors’ Plan is to provide us with the ability to pay all or a portion of the fees of directors in restricted stock instead of cash. The 2010 Directors’ Plan provides that the total number of shares of Common Stock that may be issued under the 2010 Directors’ Plan is equal to 675,000 shares.

During Fiscal 2018 and 2017, 14,948 shares and zero shares, respectively, were granted to our directors under the 2010 Directors’ Plan. We recorded \$45,000 of director fees during Fiscal 2018 in connection with these grants.

At December 31, 2018, there were 382,860 shares of Common Stock that may be issued pursuant to the terms of the 2010 Directors’ Plan.

The 2010 Equity Compensation Plan

On May 5, 2010, our stockholders approved the 2010 Equity Compensation Plan, which has been subsequently amended and restated by our stockholders (the “2010 Plan”). The 2010 Plan provides that the total number of shares of Common Stock that may be issued under the 2010 Plan is 3.9 million shares.

During Fiscal 2018, we granted 30,000 options, exercisable at \$2.35 per share and subject to vesting over a three-year term, to a consultant pursuant to the terms of the 2010 Plan and we granted 160,000 options to employees, exercisable at \$3.18 per share and subject to vesting over four years. During Fiscal 2017, we granted, 600,000 options to employees, exercisable at \$2.00 per share and subject to vesting over a four-year term. We use the Black-Scholes option pricing model to determine the fair value of the stock options at the date of grant. Options to non-employees are valued at initial issuance, then revalued at each reporting date until the date the options vest and at which point the final fair value is determined. Based upon our limited historical experience, we determined the expected term of the stock option grants to be 4.5 – 4.75 years, calculated using the “simplified” method in accordance with the SEC Staff Accounting Bulletin 110. We use the “simplified” method since our historical data does not provide a reasonable basis upon which to estimate expected term. Presented below is a summary of the terms of the grant of options.

PROPHASE LABS, INC. AND SUBSIDIARIES
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During Fiscal 2018 and 2017, there were 490,000 and 1,332,000 options exercised, respectively, and we derived \$337,500 and \$1.5 million from the exercise of options in 2018 and 2017, respectively. We had 250,000 shares that were exercised in Fiscal 2018 pursuant to a cashless exercise. At December 31, 2018, there were 679,500 stock options outstanding under the 2010 Plan.

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 nonstatutory stock options to eligible employees, directors and consultants. The purpose of the 2018 Stock Plan is to advance the interests of the Company and its stockholders by providing an incentive to attract, retain, and reward persons performing services for the Company and by motivating such persons to contribute to the growth and profitability of the Company. The 2018 Stock Plan provides that the total number of shares that may be issued pursuant to the 2018 Stock Plan is 2.3 million shares. At September 30, 2018, all 2.3 million shares have been granted in the form of stock options to Ted Karkus (the “CEO Option”), our Chief Executive Officer and no stock options have been exercised under the 2018 Stock Plan. We use the Black-Scholes option pricing model to determine the fair value of the stock options and Warrants at the date of grant. Based upon our limited historical experience, we determined the expected term of the stock option grants to be 4.5 years, calculated using the “simplified” method in accordance with the SEC Staff Accounting Bulletin 110. We use the “simplified” method since our historical data does not provide a reasonable basis upon which to estimate expected term.

The 2018 Plan requires certain proportionate adjustments to be made to stock options granted under the 2018 Plan upon the occurrence of certain events, including a special distribution (whether in the form of cash, shares, other securities, or other property). Accordingly, the Compensation Committee of the board of directors, as required by the terms of the 2018 Stock Plan, adjusted the terms of the CEO Option, such that the exercise price of the CEO Option was reduced from \$3.00 per share to \$2.00 per share, effective as of June 5, 2018, the date the special \$1.00 cash dividend was paid to stockholders. Pursuant to the terms of the CEO Option, the exercise price of the CEO Option was reduced from \$2.00 to \$1.75 per share, effective as of January 24, 2019, the date the special cash dividend was paid in order to maintain parity.

The following table summarizes stock options activities during Fiscal 2018 and 2017 for both 2010 Plan and 2018 Stock Plan (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, 2017	669	\$ 1.52	3.2	\$ 324
Granted	625	2.01	6.3	-
Exercised	(315)	1.55	-	-
Outstanding as of December 31, 2017	980	1.82	4.8	52
Granted	2,490	2.08	4.3	-
Exercised	(490)	1.64	-	-
Outstanding as of December 31, 2018	2,980	\$ 1.82	4.8	\$ 3,235
Options vested and exercisable	673	\$ 2.00	4.1	\$ 777

The following table summarizes weighted average assumptions used in determining the fair value of the stock options at the date of grant during Fiscal 2018 and 2017:

	For the Years Ended	
	December 31, 2018	December 31, 2017
Exercise price	\$ 2.52	\$ 2.01
Expected term in years	4.5	4.6
Expected volatility (annual)	40%	42%
Risk-free interest rate	2%	2%
Expected dividend yield (per share)	0%	0%

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The fair value of the stock options at the time of the grant in Fiscal 2018 and 2017 was \$1.8 million and \$476,000, respectively. For Fiscal 2018 and 2017, we charged to operations \$590,000 and \$78,000, respectively, for share-based compensation expense for the aggregate fair value of the vested stock options earned.

Treasury Stock - Stock Purchase Agreements

On June 12, 2017 we entered into a stock purchase agreement with each of Mark S. Leventhal, a former director of the Company, and certain other persons and entities associated and/or affiliated with Mr. Leventhal (the “Leventhal Holders”), pursuant to which we purchased all 1,061,980 shares of our Common Stock then held by the Leventhal Holders, representing an approximate 6.2% aggregate ownership interest (based on 17.2 million shares of common stock outstanding as of June 12, 2017). Upon consummation of the transactions, the Leventhal Holders ceased to hold any direct or indirect ownership interest in the Company.

Pursuant to the terms of the stock purchase agreements, the total consideration paid by us to the Leventhal Holders for their shares was \$1,858,465, which amount was equal to the product of (i) \$1.75 multiplied by (ii) the number of shares purchased.

Treasury Stock – Tender Offers

In Fiscal 2017, we announced two discrete tender offers to purchase our Common Stock in each of August 2017 and November 2017.

On August 25, 2017, we announced a tender offer to purchase up to 4.0 million shares of our Common Stock at a price of \$2.30 per share (the “August 2017 Tender Offer”). The number of shares proposed to be purchased in the August 2017 Tender Offer represented approximately 24.7% of approximately 16.2 million shares our Common Stock issued and outstanding as of August 21, 2017. The last reported sale price of our Common Stock on August 15, 2017, the last full trading day before we announced the Tender Offer, was \$2.13 per share.

The August 2017 Tender Offer expired on September 25, 2017. Subject to the terms of the August 2017 Tender Offer, we accepted for purchase 4,323,335 shares of our Common Stock at a purchase price of \$2.30 per share, for an aggregate purchase price of approximately \$9.9 million. Based on the final tabulation, 5,910,327 shares of our Common Stock were properly tendered and not withdrawn. Prior to the August 2017 Tender Offer, an investor, BML Investment Partners, L.P. (“BLM”), owned 2,322,627 shares, or 13.6%, of our outstanding Common Stock. Pursuant to the terms of the Tender Offer, BML tendered and sold 1,695,305 shares of our Common Stock. In addition, Ted Karkus, our Chairman of the Board and Chief Executive Officer, Robert V. Cuddihy, Jr., our then Chief Operating Officer and Chief Financial Officer, and one of our directors tendered and sold 364,954, 358,621 and 4,379 shares of Common Stock, respectively.

On November 20, 2017, we announced a tender offer to purchase up to 1.7 million shares of our Common Stock at a price of \$2.30 per share (the “November 2017 Tender Offer”). The number of shares proposed to be purchased in the November 2017 Tender Offer represented approximately 13.7% of approximately 12.4 million shares our Common Stock issued and outstanding as of November 14, 2017. The last reported sale price of our Common Stock on November 9, 2017, the last full trading day before we announced the Tender Offer, was \$2.13 per share.

The November 2017 Tender Offer expired on December 18, 2017. Subject to the terms of the November 2017 Tender Offer, we accepted for purchase 1,948,569 shares of our Common Stock, at a purchase price of \$2.30 per share, for an aggregate purchase price of approximately \$4.5 million. Based on the final tabulation, 2,072,280 shares of our Common Stock were properly tendered and not withdrawn. Pursuant to the terms of the Tender Offer, Mr. Karkus sold 424,789 shares of Common Stock. Subsequent to the completion of the November 2017 Tender Offer, Mr. Karkus exercised 600,000 outstanding options. As a consequence of Mr. Karkus’s exercise of his options at an exercise price of \$1.00 per share, we derived net proceeds of \$600,000.

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Note 7 – 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 Fiscal 2018 and 2017 were \$90,000 and \$120,000, respectively. For Fiscal 2018 and 2017, we charged (i) to continuing operations \$90,000 and \$104,000, respectively and (ii) to discontinued operations \$0 and \$16,000, respectively, for our plan contribution.

Note 8 – Income Taxes

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

	2018	2017
Current		
Federal	\$ -	\$ (1,245)
State	103	(176)
	<u>103</u>	<u>(1,421)</u>
Deferred		
Federal	(86)	15,412
State	225	682
	<u>139</u>	<u>16,094</u>
Total	<u>\$ 242</u>	<u>\$ 14,673</u>
Income taxes from continuing operations before valuation allowance	\$ 242	\$ 14,673
Change in valuation allowance	(139)	(16,094)
Income tax provision (benefit)	<u>103</u>	<u>(1,421)</u>
Total	<u>\$ 103</u>	<u>\$ (1,421)</u>
Discontinued Operations		
Current		
Federal	\$ -	\$ 1,245
State	-	2,266
	<u>-</u>	<u>3,511</u>
Deferred		
Federal	(34)	-
State	-	-
	<u>(34)</u>	<u>-</u>
Total	<u>\$ (34)</u>	<u>\$ 3,511</u>
Income taxes from discontinued operations before valuation allowance	\$ (34)	\$ 3,511
Change in valuation allowance	34	-
Income tax expense	<u>-</u>	<u>3,511</u>
Total	<u>\$ -</u>	<u>\$ 3,511</u>
Total	<u>\$ 103</u>	<u>\$ 2,090</u>

PROPHASE LABS, INC. AND SUBSIDIARIES
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A reconciliation of the statutory federal income tax expense (benefit) to the effective tax is as follows (in thousands):

	2018	2017
Statutory rate - federal	\$ (341)	\$ 14,512
State taxes, net of federal benefit	306	2,061
Rate Change	-	1,804
Permanent differences and other	243	(193)
Income tax from continuing operation before valuation allowance	208	18,184
Change in valuation allowance	(105)	(16,094)
Income tax expense	103	2,090
Total	<u>\$ 103</u>	<u>\$ 2,090</u>

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

	Year Ended December 31,	
	2018	2017
Net operating loss and capital loss carryforward	\$ 4,081	\$ 3,595
Consulting-royalty costs	-	-
Trademark	-	21
Investment in Phusion	-	33
Depreciation	(109)	41
Other	216	604
Valuation allowance	(4,188)	(4,294)
Total	<u>\$ -</u>	<u>\$ -</u>

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.

PROPHASE LABS, INC. AND SUBSIDIARIES
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A valuation allowance for all of our net deferred tax assets has been provided as we are unable to determine, at this time, that the generation of future taxable income against which the net operating losses (“NOL”) carryforwards could be used is more likely than not. As a result of ongoing losses from continuing operations the Company has concluded that it is more likely than not that it will not realize all of its deferred tax assets relating to federal and state filing jurisdictions. As of December 31, 2018, there is a valuation allowance of \$4.2 million. As of December 31, 2017, the Company has state NOL carryforwards of \$1.1 million which begin to expire in 2023 and a federal NOL carryforwards of \$3.0 million. The amount of the federal NOL generated prior to the 2017 legislation commonly referred to as the Tax Cuts and Jobs Act (“TCJA”) of \$2.6 million can be carried forward for 20 years and begins to expire in 2032. The remaining amount of \$0.4 million federal NOL generated in year 2018 can be carried forward indefinitely.

We file a consolidated federal income tax return and separate company state returns as well as combined state returns where applicable.

Note 9 – Other Current Liabilities

The following table sets forth the components of other current liabilities at December 31, 2018 and 2017, respectively, (in thousands):

	December 31, 2018	December 31, 2017
Accrued Expenses	\$ 167	\$ 66
Accrued Benefits	24	15
Accrued Payroll	195	79
Accrued Vacation	66	88
Sales tax payable	3	3
Income taxes payable	106	740
Deferred revenue	206	-
Due to Mylan and affiliates	-	59
Total other current liabilities	<u>\$ 766</u>	<u>\$ 1,050</u>

Note 10 – Commitments and Contingencies

Escrow Receivable

We have indemnification obligations to Mylan under the asset purchase agreement that may require us to make future payments to Mylan and other related persons for any damages incurred by Mylan or such related persons as a result of any breaches of our representations, warranties, covenants or agreements contained in the asset purchase agreement, or arising from the Retained Liabilities (as such term is defined in the asset purchase agreement) or certain third party claims specified in the asset purchase agreement. Generally, our representations and warranties survive for a period of 24 months from the closing date, other than certain fundamental representations which survive until the expiration of the applicable statute of limitations. There is a limited indemnification cap with respect to a majority of the Company’s indemnification obligations under the asset purchase agreement with the exception of claims for actual fraud, the breach of any fundamental representations and certain other items, which have a larger indemnification cap (e.g., the purchase price).

Pursuant to the terms of the asset purchase agreement, we, Mylan, and an escrow agent entered into an Escrow Agreement at closing, pursuant to which Mylan deposited \$5 million of the aggregate purchase price for the Cold-EEZE[®] Business into an escrow account established with the Escrow Agent in order to satisfy, in whole or in part, certain of our indemnity obligations under the asset purchase agreement.

PROPHASE LABS, INC. AND SUBSIDIARIES
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The terms of the Escrow Agreement provide that if, as of September 29, 2018, there are funds remaining in the escrow account, then the escrow account will be reduced by the difference, if a positive number, of (i) \$2.5 million minus (ii) the aggregate amount of all escrow claims asserted by Mylan prior to this date that have either been paid out of the escrow account or are pending as of such date, and, within two business days of such date, the Escrow Agent will disburse such difference, if a positive number, to us. In addition, within two business days of March 29, 2019, the Escrow Agent will release any funds remaining in the escrow account to us minus any amounts being reserved for escrow claims asserted by Mylan prior to such date. Upon the resolution of any pending escrow claims, the Escrow Agent will, within two business days of receipt of joint instructions or a final order from a court (as described in the Escrow Agreement) disburse such reserved amount to the parties entitled to such funds. As described below, in August 2018, Mylan asserted an indemnification claim against us, for a yet to be determined amount. Accordingly, the first distribution was not released to us on September 29, 2018 and remains subject to resolution of this claim.

On August 2, 2018, we received notice of an indemnification claim from Mylan in relation to product advertising claims brought against Mylan on certain Cold-EEZE[®] products. While we believe this claim is without merit, in the event that this or any other indemnity claim is successful, we may be required to pay Mylan such amounts from the escrow fund, pursuant to the indemnification provisions of the asset purchase agreement which may reduce the amount we ultimately collect from escrow or could even require us to return a portion of the net proceeds received from the sale of the Cold-EEZE[®] Business if the escrow funds are insufficient to cover the losses. Management expects to collect the full remaining escrow balance within the next twelve months, net of an immaterial reserve representative of our best estimate of the cost to adjudicate this matter.

On May 31, 2018, we received notice of a claim for \$800,000 in losses against the escrow amount. We resolved this claim pursuant to a settlement agreement, effective October 16, 2018, pursuant to which \$160,000 of the funds held in escrow were released to Mylan. This expense is reflected in discontinued operations in the third quarter of 2018.

Manufacturing Agreement

In connection with the asset purchase agreement, the Company and its wholly-owned subsidiary, PMI, entered into a Manufacturing Agreement (the “Manufacturing Agreement”) with Mylan. 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 will 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. Unless terminated sooner by the parties, the Manufacturing Agreement will remain in effect until March 29, 2022. Thereafter, the Manufacturing Agreement may be renewed by Mylan for up to five successive one-year periods by providing notice of its intent to renew not less than 90 days prior to the expiration of the then-current term.

Employment Agreements

On April 17, 2017, we entered into an Employment Agreement Termination and Release Agreement (the “April 2017 Termination Agreement”) with Mr. Cuddihy our former Chief Financial Officer. The April 2017 Termination Agreement terminated Mr. Cuddihy’s prior employment agreement with us, and established new terms of Mr. Cuddihy’s employment with the Company. The April 2017 Termination Agreement was entered into in light of our recent successful sale of the Cold-EEZE[®] Business. The April 2017 Termination Agreement provided, among other things, that Mr. Cuddihy would remain employed by the Company on an at-will basis; he would relinquish his rights under the 2015 Employment Agreement, including his rights to separation payments, in consideration for the Company remitting to him a \$675,000 termination payment (the “Termination Payment”); and he would reduce his annual base salary to \$250,000 effective July 1, 2017.

On September 27, 2017, we entered into another Employment Agreement Termination and Release Agreement with Mr. Cuddihy (the “September 2017 Termination Agreement”). Pursuant to the terms of the September 2017 Termination Agreement, Mr. Cuddihy’s 2015 Employment Agreement terminated effective September 30, 2017 and we paid Mr. Cuddihy a one-time lump sum payment of \$55,000 on October 20, 2017. The September 2017 Termination Agreement contains a general release of claims in favor of us and other customary provisions.

On February 16, 2018, our board of directors approved the Amended and Restated 2015 Executive Employment Agreement with Ted Karkus, our Chief Executive Officer (the “Amended Employment Agreement”), which became effective February 23, 2018, and was approved by stockholders at a special meeting of stockholders held on April 12, 2018. Pursuant to the terms of the Amended Employment Agreement, Mr. Karkus voluntarily agreed to reduce his base salary from the rate set forth in his prior employment agreement (*i.e.*, not less than \$675,000 per annum) to a base salary of \$125,000 per annum (the “Term Base Salary”) through February 22, 2021. Unless otherwise determined by the mutual agreement of the Company and Mr. Karkus, on February 22, 2021 and thereafter, Mr. Karkus’s salary will increase from the Term Base Salary to not less than \$675,000 per annum.

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In consideration of Mr. Karkus's voluntary reduction in salary, our board of directors awarded Mr. Karkus a stock option to purchase 2,300,000 shares of our Common Stock at an exercise price of \$3.00 per share on February 23, 2018. The CEO Option will vest and be exercisable in 35 equal monthly installments of 63,888 options and one monthly installment of 63,290 options, subject to his continued employment, and subject to accelerated vesting in the event Mr. Karkus's employment is terminated for any reason other than by us for Cause or by Mr. Karkus without Good Reason (as such terms are defined in the Amended Employment Agreement). The CEO Option is be exercisable for a five year term commencing on the date of grant. The CEO Option was granted pursuant to the 2018 Stock Plan, which was also adopted and approved by our board of directors on February 16, 2018. The 2018 Plan, like the Amended Employment Agreement, received stockholder approval at a special meeting of stockholders held on April 12, 2018 at which time the CEO Option were considered granted for accounting purposes. The 2018 Plan authorizes the issuance of up to 2,300,000 shares pursuant to stock options granted under the 2018 Plan, all of which were issued to Mr. Karkus as part of the CEO Option.

As discussed further in Note 6, on May 7, 2018, the Compensation Committee of the board of directors, as required by the terms of the 2018 Stock Plan in order to maintain parity, adjusted the terms of the CEO Option, such that the exercise price of the CEO Option was reduced from \$3.00 per share to \$2.00 per share, effective as of June 5, 2018, the date of the special \$1.00 cash dividend was paid in order to maintain parity, and from \$2.00 to \$1.75 per share, effective as of January 24, 2019, the date of the special \$0.25 cash dividend was paid in order to maintain parity.

Future Obligations

We have estimated future minimum obligations over the next five years, including the remainder of Fiscal 2018, as follows (in thousands):

	Employment Contracts
2019	\$ 125
2020	125
2021	595
2022	675
2023	675
Total	<u>\$ 2,195</u>

Other Litigation

In the normal course of our business, we are named as a defendant in legal proceedings. It is our policy to vigorously defend litigation and/or enter into settlements of claims where management deems appropriate.

Note 11 – Earnings (Loss) Per Share

Basic earnings (loss) per share for continuing and discontinued operations are computed by dividing the respective net income or loss attributable to common stockholders by the weighted-average number of shares of our Common Stock outstanding for the period. Diluted earnings (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue Common Stock were exercised or converted into Common Stock or resulted in the issuance of Common Stock that shared in the earnings of the entity. Diluted earnings (loss) per share also utilize the treasury stock method which prescribes a theoretical buy-back of shares from the theoretical proceeds of all options and warrants outstanding during the period. Options and warrants outstanding to acquire shares of our Common Stock at December 31, 2018 and 2017 were 2,980,000 and 979,500, respectively.

For Fiscal 2018, dilutive earnings (loss) per share were the same as basic earnings per share due to the inclusion of Common Stock in the form of stock options and warrants ("Common Stock Equivalents"), when in a net loss position would have an anti-dilutive effect on loss per share. For Fiscal 2018, there were 923,006 that were excluded from the earnings (loss) per share computation as a consequence of their anti-dilutive effect. For Fiscal 2017 there were 954,500 Common Stock Equivalents that were in the money and there were 130,966 Common Stock Equivalents which were included in the fully diluted earnings per share computation.

Note 12 – Significant Customers

Revenue from continuing operations for Fiscal 2018 and 2017 was \$13.1 million and \$9.9 million, respectively. Three third-party contract manufacturing customers accounted for 45.7%, 31.1% and 10.9%, respectively, of our revenue from continuing operations for Fiscal 2018. Three third-party contract manufacturing customers accounted for 61.7%, 16.1% and 11.1%, respectively, of our revenues from continuing operations for Fiscal 2017. The loss of sales to any of these large third-party contract manufacturing customers could have a material adverse effect on our business operations and financial condition.

We are subject to account receivable credit concentrations from time-to-time as a consequence of the timing, payment pattern and ultimate purchase volumes or shipping schedules with our customers. These concentrations may impact our overall exposure to credit risk, either positively or negatively, in that our customers may be similarly affected by changes in economic, regulatory or other conditions that may impact the timing and collectability of amounts due to us. One customer represented 82% of our total trade receivable balances at December 31, 2018 and one customer represented 84% of our total trade receivable balances at December 31, 2017, respectively.

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

None

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that material information required to be disclosed by us in the reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that the information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. We performed an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the disclosure controls and procedures as of the end of the period covered by this report. Based on our review, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that due to the material weakness described below, the Company's disclosure controls and procedures were not effective at the reasonable assurance level as of the end of the period covered by this Report.

Management's Report on Internal Control Over Financial Reporting

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

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Our management conducted an evaluation of our effectiveness of the system of internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Because of the material weakness noted below, management concluded that the Company's internal controls over financial reporting were not effective as of December 31, 2018.

Following the filing of our original Form 10-K for Fiscal 2017 and during the financial statement close process for the quarter ended June 30, 2018 in connection with the preparation of our 2017 Federal and State income tax returns, management identified a material weakness that existed as of December 31, 2017, primarily related to our lack of adequate controls over the accounting for recording of income tax expense and the allocation of income tax expense/ benefit between continuing and discontinued operations.

Changes in Internal Control Over Financial Reporting

As part of our plan to remediate the deficiency in internal controls, management has taken steps to improve its income tax controls, including the formalizing our review procedures, implementing tax provision software and a change in our third-party tax consultants. We will continue to assess and enhance our internal control processes.

Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated by reference from the Company's Proxy Statement for the 2019 Annual Meeting of Stockholders (the "2019 Proxy Statement") which is to be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2018 and is hereby incorporated by reference.

As previously disclosed in a Current Report on Form 8-K filed with the Securities and Exchange Commission on December 27, 2018, Mark Burnett resigned from the Company's board of directors effective December 21, 2018. As a result of Mr. Burnett's resignation, the Company no longer has an audit committee financial expert serving on its audit committee. The Company is conducting a director search process and intends to replace Mr. Burnett with an independent director who qualifies as a financial expert for purposes of Regulation S-K Item 407(d)(5).

Item 11. Executive Compensation

The information required under this item is incorporated by reference to the 2019 Proxy Statement.

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

The information required under this item is incorporated by reference from the 2019 Proxy Statement.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated by reference from the 2019 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated by reference from the 2019 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) Financial Statements.

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

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Consolidated Balance Sheets	29
Consolidated Statements of Operations and Other Comprehensive Income (Loss)	30
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Consolidated Statements of Cash Flows	32
Notes to Consolidated Financial Statements	33

(a)(2) Financial Statement Schedules.

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

(a)(3) Exhibits

Exhibit	Description
2.1†+	Asset purchase agreement, dated January 6, 2017, by and between ProPhase Labs, Inc., Meda Consumer Healthcare Inc. and Mylan Inc., as Buyer Guarantor (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K (File No. 000-21617) filed on March 29, 2017).
2.2†+	Manufacturing Agreement, dated March 29, 2017, by and between Meda Consumer Healthcare Inc., Pharmaloz Manufacturing, Inc. and Prophase Labs, Inc. (incorporated by reference to Exhibit 2.2 of the Current Report on Form 8-K (File No. 000-21617) filed on March 29, 2017).
3.1	Certificate of Incorporation of the Company, (incorporated by reference to Exhibit 3.3 of the Current Report on Form 8-K (File No. 000-21617) filed on June 19, 2015).
3.2	Amended and Restated Bylaws of the Company (as of February 16, 2018) (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K (File No. 000-21617) filed on February 21, 2018).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Form 10-KSB/A (File No. 000-21617) filed on April 4, 1997).
4.2	Form of Voting Agreement, dated January 6, 2017, by and between Meda Consumer Healthcare Inc. and the undersigned stockholders of ProPhase Labs, Inc. (incorporated by reference to Exhibit 4.1 of the Current Report on Form 8-K (File No. 000-21617) filed on January 9, 2017).
10.1	Form of Indemnification Agreement between the Company and each of its Officers and Directors, dated August 19, 2009 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K (File No. 000-21617) filed on August 19, 2009).

- 10.2 [Amended and Restated 2010 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 24, 2018\).](#)
- 10.3 [Amended and Restated 2010 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 24, 2018\).](#)
- 10.4 [Form of Option Agreement pursuant to 2010 Equity Compensation Plan \(incorporated by reference to Exhibit 10.2 of the Quarterly Report on Form 10-Q \(File No. 000-21617\) filed on May 15, 2017\).](#)
- 10.5 [Form of Option Agreement pursuant to 2010 Directors' Equity Compensation Plan \(incorporated by reference to Exhibit 10.5 of the Current Report on Form 8-K \(File No. 000-21617\) filed on May 10, 2010\).](#)
- 10.6 [Form of Restricted Stock Award Agreement pursuant to 2010 Directors' Equity Compensation Plan \(incorporated by reference to Exhibit 10.6 of the Current Report on Form 8-K \(File No. 000-21617\) filed on May 10, 2010\).](#)
- 10.7 [Employment Agreement Termination and Release Agreement with Robert V. Cuddihy, Jr., dated April 17, 2017 \(incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K \(File No. 000-21617\) filed on April 19, 2017\).](#)
- 10.8 [Stock Purchase Agreement, dated June 12, 2017, by and between ProPhase Labs, Inc. and Mark S. Leventhal \(incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K \(File No. 000-21617\) filed on June 14, 2017\).](#)
- 10.9 [Stock Purchase Agreement, dated June 12, 2017, by and between ProPhase Labs, Inc. and Mark S. Leventhal and Donna R. Leventhal \(incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K \(File No. 000-21617\) filed on June 14, 2017\).](#)
- 10.10 [Stock Purchase Agreement, dated June 12, 2017, by and between ProPhase Labs, Inc. and The Mark S. and Donna R. Family Foundation, Inc. \(incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K \(File No. 000-21617\) filed on June 14, 2017\).](#)
- 10.11 [Stock Purchase Agreement, dated June 12, 2017, by and between ProPhase Labs, Inc. and The Bonnybrook Trust \(incorporated by reference to Exhibit 10.4 of the Current Report on Form 8-K \(File No. 000-21617\) filed on June 14, 2017\).](#)
- 10.12 [Employment Agreement Termination and Release Agreement, dated September 27, 2017, by and between ProPhase Labs, Inc. and Robert V. Cuddihy, Jr. \(incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K \(File No. 000-21617\) filed on October 2, 2017\).](#)
- 10.13 [Amended and Restated 2015 Executive Employment Agreement with Ted Karkus, effective February 23, 2018 \(incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K \(File No. 000-21617\) filed on February 21, 2018\).](#)
- 10.31 [Stock Option Agreement with Ted Karkus pursuant to 2018 Stock Incentive Plan \(incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K \(File No. 000-21617\) filed on February 21, 2018\).](#)
- 10.32 [2018 Stock Incentive Plan \(incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K \(File No. 000-21617\) filed on April 13, 2018\).](#)

- 21.1 [Subsidiaries of ProPhase Labs, Inc.](#)
- 23.1** [Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.](#)
- 31.1** [Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2** [Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1** [Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2** [Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

* Indicates a management contract or compensatory plan or arrangement

** Filed herewith

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

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

- 40** 101 INS — XBRL Instance Document
- 41** 101 SCH — XBRL Taxonomy Extension Schema Document
- 42** 101 CAL — XBRL Taxonomy Extension Calculation Linkbase Document
- 43** 101 DEF — XBRL Taxonomy Extension Definition Linkbase Document
- 44** 101 LAB — XBRL Taxonomy Extension Label Linkbase Document
- 45** 101 PRE — XBRL Taxonomy Extension Presentation Linkbase Document

Item 16. Form 10-K Summary

None.

SIGNATURES

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

PROPHASE LABS, INC.

By: /s/ Ted Karkus

Ted Karkus, Chairman of the Board,
Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ted Karkus and Monica Brady, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Ted Karkus</u> Ted Karkus	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 26, 2019
<u>/s/ Monica Brady</u> Monica Brady	Chief Financial Officer (Principal Financial Officer)	March 26, 2019
<u>/s/ Jason Barr</u> Jason Barr	Director	March 26, 2019
<u>/s/ Louis Gleckel</u> Louis Gleckel	Director	March 26, 2019

SUBSIDIARIES OF PROPHASE LABS, INC.

Subsidiaries	State or other Jurisdiction of Incorporation	Ownership Percentage
Pharmaloz Manufacturing Inc.	Delaware	100%
Phusion Labs Manufacturing, Inc.	Delaware	100%
ProPhase Digital Media, Inc.	Delaware	100%
Quigley Pharma Inc.	Delaware	100%
TK Supplements, Inc.	Delaware	100%

The above subsidiaries are included in the consolidated financial statements for the year ended December 31, 2018.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of ProPhase Labs, Inc. and Subsidiaries on Form S-8 (No. 333-73456, No. 333-61313, No. 333-10059, No. 333-14687, No. 333-26589, No. 333-132770, No. 333-169697, No. 333-189875, No. 333-217484, No. 333-224369 and No. 333-225496), Form SB-2 (No. 333-31241) and Forms S-3 (No. 333-86976, No. 333-104148, No. 333-119748, No. 333-185167, No. 333-196352, No. 333-206090 and No. 333-225875) of our report dated March 26, 2019, on our audit of the consolidated financial statements as of December 31, 2018 and 2017 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 26, 2019.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 26, 2019

**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 Annual Report on Form 10-K of ProPhase Labs, Inc.;
2. Based on my knowledge, this Annual 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 Annual Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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 131-15(f) and 15d015(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 Annual 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 Annual 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: March 26, 2019

By: /s/ Ted Karkus

Ted Karkus
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

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

I, Monica Brady, certify that:

1. I have reviewed this Annual Report on Form 10-K of ProPhase Labs, Inc.;
2. Based on my knowledge, this Annual 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 Annual Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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 131-15(f) and 15d015(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 Annual 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 Annual 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: March 26, 2019

By: /s/ Monica Brady
Monica Brady
Chief Financial Officer
(Principal Financial Officer)

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 Annual Report on Form 10-K for the period ended December 31, 2018, 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)

March 26, 2019

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, Monica Brady, Chief Financial Officer of ProPhase Labs, Inc., a Delaware corporation (the “Registrant”), in connection with the Registrant’s Annual Report on Form 10-K for the period ended December 31, 2018, 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/ Monica Brady

Monica Brady
Chief Financial Officer
(Principal Financial Officer)

March 26, 2019
