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

FORM 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016

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	23-2577138
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
621 N. Shady Retreat Road, Doylestown, Pennsylvania	18901
(Address of principal executive offices)	(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	Name of each exchange on which registered
Common Stock, $0.0005 par value per share	NASDAQ Capital Market
Common Share Purchase Rights	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 [X]

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 [X]

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes [X] 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. [X]

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

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [X]

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 $14,429,673 as of June 30, 2016, 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 February 22, 2017

Common stock, $0.0005 par value per share:	17,080,776
Common share purchase rights:	-0-

DOCUMENTS INCORPORATED BY REFERENCE

Information set forth in Part III of this report is incorporated by reference to the registrant's proxy statement for the 2017 annual meeting of stockholders.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K ("Report") contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward looking statements relate to future events or our future financial performance and involve 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. Forward-looking statements typically are identified by use of terms such as "anticipate", "believe", "plan", "expect", "intend", "may", "will", "should", "estimate", "predict", "potential", "continue" and similar words although some forward-looking statements are expressed differently. This Report may contain forward-looking statements attributed to third parties relating to their estimates regarding the growth of our markets. You are cautioned that such forward looking statements are not guarantees of future performance and that all forward-looking statements address matters that involve risk and uncertainties, and 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 Report.

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

- Our ability to consummate the proposed sale of our Cold-EEZE ® Division (defined below) to Meda Consumer Healthcare Inc. ("MCH"), an affiliate of Mylan Inc. (together with MCH, "Mylan"), as described in this Report;
- The ability of our management to successfully implement our business plan and strategy;
- Our ability to continue to fund our operations including the cost and availability of capital and credit;
- 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 grow our manufacturing business and operate it profitably;
- Our ability to successfully develop and commercialize our existing products and new products without leveraging the Cold-EEZE ® brand name if the proposed sale of our Cold-EEZE ® Division is consummated;
- Changes in our retail and distribution customers strategic business plans including, but not limited to, (i) expansions, mergers, and/or consolidations, (ii) retail shelf space allocations for products within each outlet and in particular the homeopathic and health care category in which we compete, (iii) changes in their private label assortment and (iv) product selections, distribution allocation, merchandising programs and retail pricing of our products as well as competitive 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 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;
- Potential disruptions in our ability to manufacture our products or our access to raw materials;
- Seasonal fluctuations in demand for our products;
- Our ability to attract, retain and motivate our key employees;
- Our ability to pay our debts and meet our liquidity needs; and
- Other risks identified in this Report.

You should also consider carefully the statements under other sections of this 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 the date of this 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.

Where You Can Find Other Information

ProPhase Labs, Inc. ("we", "us" or the "Company") files 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 Report. You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington D.C. 20549-1004. You may request copies of these documents, upon payment of a duplication fee, by writing the SEC at its principal office at 100 F Street, NE Room 1580, Washington, D.C. 20549-1004. 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 1. Business

General Development of Business

We are a manufacturer, marketer and distributor of a diversified range of homeopathic and health care products that are offered to the general public. We are also engaged in the research and development of potential over-the-counter ("OTC") drug, natural base health products along with supplements, personal care and cosmeceutical products.

Our primary business has been the manufacture, distribution, marketing and sale of OTC homeopathic and health care products, particularly cold remedy products, to consumers through national chain, regional, specialty and local retail stores. We also perform contract manufacturing services of cough drops and other OTC healthcare products for third parties. Our flagship brand is Cold-EEZE ® and our principal product is Cold-EEZE ® cold remedy zinc gluconate lozenges, proven in clinical studies to reduce the duration and severity of symptoms of the common cold. In addition to Cold-EEZE ® cold remedy lozenges, we market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE ® cold remedy QuickMelts ® , (ii) Cold-EEZE ® Gummies (see below) and (iii) Cold-EEZE ® cold remedy Oral Spray. Each of our Cold-EEZE ® QuickMelts ® products are based on our proprietary zinc gluconate formulation in combination with certain (i) immune system support, (ii) energy, (iii) sleep and relaxation, and/or (iv) cold and flu symptom relieving active ingredients.

In Fiscal 2014 we introduced and began shipments in June 2014 of our new Cold-EEZE ® Plus Natural Multi-Symptom QuickMelts ® . In Fiscal 2015, we introduced three new Cold-EEZE ® product line extensions: (i) a Cold-EEZE ® Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE ® Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE ® Natural Allergy Relief caplets for indoor and outdoor allergies. Shipments for these three new Cold-EEZE ® product line extensions began in the third quarter of Fiscal 2015. In Fiscal 2016, we expanded our Cold-EEZE ® product line further to include (i) Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu and (ii) Cold-EEZE ® Nighttime Multi-Symptom Relief for Cold and Flu QuickMelts ® . Shipments began for these two new products in the third quarter of Fiscal 2016.

Cold-EEZE ® is an established product in the health care and cough-cold market. For Fiscal 2016, 2015 and 2014, our revenues have come principally from (i) our OTC health care and cold remedy products and (ii) were related to markets in the United States.

As further described below under "Strategic Initiatives", on January 6, 2017, we entered into an asset purchase agreement with Mylan, pursuant to which we agreed to sell substantially all of our assets and other rights related to the Cold-EEZE ® brand and product line, which is comprised principally of our intellectual property rights and other assets relating to Cold-EEZE ® (collectively referred to as the "Cold-EEZE ® Division") to Mylan, subject to the approval of our stockholders and other customary closing conditions.

In addition to our Cold-EEZE ® product line, we market and distribute OTC lozenge and dietary supplement products under the ORXx brand name. The ORXx brand includes the products sold under the following names: ORXx Complete ™ and ORXx Defense ™ .

We are also pursuing a series of new product development and pre-commercialization initiatives in the dietary supplement category. Initial dietary supplement product development activities were completed in the fourth quarter of Fiscal 2015 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 ® , a daily energy booster plus testosterone support, and (iii) Super ProstaFlow Plus ™ for prostate and urinary health.

In addition to the Company's products, our wholly owned subsidiary, Pharmaloz Manufacturing, Inc. ("PMI"), produces our Cold-EEZE ® cold remedy lozenges and other products in addition to performing operational tasks such as warehousing, customer order processing and shipping.

We use a December 31 year-end for financial reporting purposes. References herein to the fiscal year ended December 31, 2016 shall be the term "Fiscal 2016" and references to other "Fiscal" years shall mean the year, which ended on December 31 of the year indicated.

We were 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. Our principal executive offices are located at 621 N. Shady Retreat Road, Doylestown, Pennsylvania 18901 and our telephone number is 215-345-0919. The terms, "we", "us" and the "Company" refer to the Company together with its consolidated subsidiaries unless the context otherwise requires.

Seasonality of the Business

Our net sales are derived principally from our OTC health care and cold remedy products. Currently, our sales have historically been subject to fluctuations and influenced by the timing, length and severity of each cold season. Generally, a cold season is defined as the period of September to March when the incidence of the common cold and flu rises as a consequence of the change in weather and other factors. We generally have experienced higher levels of net sales in the first, third and fourth quarter along with a corresponding increase in marketing and advertising expenditures designed to promote our products during the cold season. Revenues and related marketing costs are generally at their lowest levels in the second quarter when consumer demand generally declines. We track health and wellness trends and develop retail promotional strategies to align our production scheduling, inventory management and marketing programs to optimize consumer purchases.

Strategic Initiatives

In August 2016, management initiated a process to explore and evaluate a wide range of strategic initiatives and alternatives to further enhance stockholder value. These include the possible sale of core assets of the Company as well as a range of potential acquisitions. We engaged Bourne Partners, a boutique investment bank focused on the consumer health and pharmaceutical industries, to assist in our strategic review. This process was approved by the Board of Directors.

On January 9, 2017, we announced that we had signed an asset purchase agreement, pursuant to which we have agreed to sell our Cold-EEZE ® Division to Mylan for $50 million before taking into account taxes, transaction costs and related deal expenses, restructuring costs and post-closing escrow requirements. We will retain ownership of our manufacturing facility and manufacturing business in Lebanon, Pennsylvania, and our headquarters in Doylestown, Pennsylvania, and our assets related to our ORXx and TK Supplements ® brands, product lines and operations. As part of the transaction, PMI will enter into a manufacturing and supply agreement with Mylan pursuant to which Mylan will purchase the current inventory of the Cold-EEZE ® Division and PMI will manufacture certain of the Cold-EEZE ® products for Mylan.

The closing of the proposed sale, which is currently expected to occur in late March or April of 2017, is subject to the approval of the stockholders of the Company and other customary closing conditions. In connection with the execution of the asset purchase agreement, our executive officers and directors executed voting agreements. The voting agreements provide, among other things, for our executive officers and directors to vote all of the shares owned by them in favor of the proposed sale. The shares subject to the voting agreements represent approximately 24.1% of the outstanding common stock of the Company.

Since the proposed sale has not been approved by our stockholders and is subject to other conditions to be completed by Mylan and the Company prior to closing, the Cold-EEZE ® Division does not meet the criterion for classification of an asset held for sale or as discontinued operations. As there can be no assurance that this proposed sale or any strategic initiative will be consummated, we intend to operate our business as discussed throughout this Report.

Description of Our Business Operations

Cold-EEZE ® has historically been our most popular OTC health care and cold remedy product. Cold-EEZE ® cold remedy lozenges, QuickMelts ® ,Oral Spray and Gummies product benefits are derived from our proprietary zinc gluconate formulation. Our Cold-EEZE ® cold remedy lozenges effectiveness has been substantiated in two double-blind clinical studies proving that Cold-EEZE ® cold remedy lozenges reduce the duration of the common cold by 42%. We acquired worldwide manufacturing and distribution rights to our lozenge formulation in 1992 and commenced national marketing in 1996. In addition to our lozenge product, the Cold-EEZE ® Cold Remedy proprietary zinc gluconate formulation is available in three additional cold remedy delivery forms, (i) a fast dissolving QuickMelt, (ii) an Oral Spray and (iii) a Gummies product. We also offer our product line extensions (i) Cold-EEZE ® Daytime and Nighttime Multi-Symptom Relief in liquid for each of adults and children and (ii) Cold-EEZE ® Natural Allergy Relief caplets for indoor and outdoor allergies.

Our business operations have been concentrated on the development, manufacturing, marketing and distribution of our proprietary Cold-EEZE ® cold remedy lozenge products and on the development of various product extensions. Our product line of OTC homeopathic and health care products are reviewed regularly to identify new consumer opportunities and/or trends in flavor, convenience, packaging and delivery systems or forms to help improve market share for our products.

Although we have continued to expand our Cold-EEZE ® product offerings, some retailers are limiting and/or reallocating shelf and promotional space away from the cough-cold category to other product categories. With cough-cold shelf and promotional space at a premium, opportunities in the future to introduce new Cold-EEZE ® products and to compete in the competitive cough-cold category, where many other OTC product suppliers are larger and have significantly greater financial, technical and marketing resources than we do, may be limited. For this reason, among others, we have determined that it is in our best interest to sell our Cold-EEZE ® Division to Mylan and to instead focus on and grow our PMI manufacturing business, ORXx and TK Supplements ® product lines and to pursue other opportunities.

Initial dietary supplement product development activities were completed in the fourth quarter of Fiscal 2015 under the brand name of TK Supplements ® . The inaugural TK Supplements ® product line is comprised of three men's health products: (i) Legendz XL ® for sexual health, (ii) Triple Edge XL ® , a daily energy booster plus testosterone support, and (iii) Super ProstaFlow *Plus* ™ for prostate and urinary health.

During Fiscal 2016, we produced, tested and refined a direct response television commercial and initiated television and digital media testing for Legendz XL ® . Additionally, we completed a broad series of clinical studies which support important product claims which have now been incorporated into our product packaging and marketing communication. Our next goal is to introduce Legendz XL ® in retail stores leveraging our existing infrastructure and retail distribution platform. We have received initial product acceptance into a national chain drug retailer and several regional retailers to begin shipments of Legendz XL ® to such retailers during the second or third quarter of Fiscal 2017.

Once we have established a retail presence, we expect to initiate a TV campaign with short form TV spots as well as other forms of advertising designed to support our retail launch and generate additional direct-to-consumer sales, a two pronged strategy of retail and e-commerce consumer engagement. As with any new product launch, we anticipate losses from the TK Supplements ® initiatives as we optimize our market strategy.

While management anticipates the growth potential in this category may be better, the risks associated with introducing new products that do not leverage the Cold-EEZE ® brand name may be higher. Therefore, no assurance can be made that our new product efforts will be successful and/or profitable.

Additionally, we are active in exploring new product technologies, applications, product line extensions and other new product opportunities and will also consider and pursue other alternatives and strategies, including, but not limited to, investments and acquisitions in other sectors and industries.

Manufacturing Facility

Our wholly owned subsidiary, PMI, produces our Cold-EEZE ® cold remedy lozenges and other lozenge products in addition to performing operational tasks such as warehousing, customer order processing and shipping. Our PMI facility is located in Lebanon, Pennsylvania. Additionally, our PMI facility is a United States Food and Drug Administration ("FDA") registered facility that engages in contract manufacturing and distribution activities. PMI also produces and sells therapeutic lozenges to unaffiliated third party retail, wholesale and distribution outlets.

If the proposed sale of our Cold-EEZE ® Division to Mylan is approved by our stockholders, PMI will enter into a manufacturing and supply agreement with Mylan, pursuant to which Mylan will purchase the current inventory of the Cold-EEZE ® Division and PMI will manufacture certain of the Cold-EEZE ® products for Mylan.

Products

OTC Health Care and Cold-Remedy Products

In May 1992, we entered into an exclusive agreement for worldwide representation, manufacturing and marketing of a zinc gluconate formulation. This zinc gluconate formulation is the foundation of our brand; Cold-EEZE ® health care and cold remedy products which are distributed principally in the United States. Cold-EEZE ® cold remedy products are an OTC consumer product used to reduce the duration of the common cold. We have substantiated the effectiveness of Cold-EEZE ® cold remedy lozenges through a variety of studies. A randomized double-blind placebo-controlled study, conducted at Dartmouth College of Health Science, Hanover, New Hampshire, concluded that the lozenge formulation treatment, initiated within 48 hours of symptom onset, resulted in a significant reduction in the total duration of the common cold.

On May 22, 1992, "Zinc and the Common Cold, a Controlled Clinical Study," was published in England in the *Journal of International Medical Research* , Volume 20, Number 3, Pages 234-246. According to this publication, (a) flavorings used in other zinc lozenge products (citrate, tartrate, separate, orotate, picolinate, mannitol or sorbitol) render the zinc inactive and unavailable to the patient's nasal passages, mouth and throat where cold symptoms have to be treated, (b) our zinc gluconate patented formulation delivers approximately 93% of the active zinc to the mucosal surfaces and (c) a patient treated with our zinc gluconate formulation has the same sequence of symptoms as in the absence of treatment but treated with our zinc gluconate formulation goes through the phases at an accelerated rate and with reduced symptom severity.

On July 15, 1996, results of a randomized double-blind placebo-controlled study on the common cold, which commenced at the Cleveland Clinic Foundation on October 3, 1994, were published. The study "Zinc Gluconate Lozenges for Treating the Common Cold" was completed and published in *The Annals of Internal Medicine* – Volume 125 Number 2. Using a 13.3 mg lozenge (almost half the strength of the lozenge used in the Dartmouth study), the result still showed a 42% reduction in the duration of common cold symptoms.

In addition to our Cold-EEZE ® cold remedy lozenges, we also market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE ® cold remedy QuickMelts ® are fast dissolving tablets that are taken orally, (ii) Cold-EEZE ® cold remedy Oral Spray a liquid form of our zinc gluconate formulation that is sprayed in the mouth and (iii) Cold-EEZE ® Gummies Multi-Symptom Relief Cold and Flu. The Cold-EEZE ® cold remedy QuickMelts ® product line is comprised of (i) Cold-EEZE ® Daytime/Nighttime QuickMelts ® (launched in Fiscal 2012), (ii) Cold-EEZE ® Plus Immune Support + Energy QuickMelts ® (launched in Fiscal 2013) and (iii) Cold-EEZE ® Plus Multi-Symptom QuickMelts ® (launched in Fiscal 2014). Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu was launched in Fiscal 2016.

We also (i) manufacture, market and distribute cough drops and a Vitamin C supplement, (ii) perform contract manufacturing services of cough drop, dietary supplements, and other OTC cough-cold-flu products for third parties and (iii) market and distribute TK Supplements ® products.

Our business is subject to federal and state health and safety laws and regulations. Our OTC health care and cold remedies are subject to regulations by various federal, state and local agencies, including the FDA. Additionally, Cold-EEZE ® homeopathic cold remedy lozenges, QuickMelts ® , Oral Spray, Gummies and Allergy caplets are subject to the Homeopathic Pharmacopoeia of the United States. See "Regulatory Matters" below for more information.

Patents, Trademarks, Royalty and Commission Agreements

Patents and Trademarks

We do not currently own patents for our OTC health care and cold-remedy products. We maintain various trademarks for each of our products including Cold-EEZE ® , QuickMelts ® , Organix Rx Complete ® and Organix Rx Defense ® , ORXx Complete ® and ORXx Defense ® , TK Supplements ® , Legendz XL ® , Triple Edge XL ® and Super ProstaFlow *Plus* ™ .

We currently own various domestic and international patents covering certain product development initiatives principally developed under our Pharma subsidiary operations. To date, we have not realized any meaningful levels of revenues from such patents and we suspended in Fiscal 2009 any further commercialization efforts for various products under such patents.

TK Supplements ®

On June 30, 2015, we executed a Direct Response Production Agreement ("DRPA") with Pacific Custom Video Productions Inc. ("PCV") to produce a series of direct response television commercials for certain TK Supplements ® products at a cost of $300,000 which was charged to operations in Fiscal 2016 due to changes in our future consumer engagement strategy which is expected to include both e-commerce (direct-to-consumer) and traditional retail store distribution. In addition, we agreed to pay to PCV a three percent performance incentive in the form of a royalty (aka commission) of net sales collected, as defined in the agreement, of certain TK Supplements ® products marketed and promoted with PCV. For Fiscal 2015 and Fiscal 2016, we charged to operations zero and $2,000 for performance incentive fees pursuant to terms of the DRPA. The DRPA was terminated effective February 2017.

Product Distribution and Customers

Our products are distributed through national chain, regional, specialty and local retail stores throughout the United States. We also provide contract manufacturing services to third parties. Revenues for Fiscal 2016, 2015 and 2014 were $21.0 million, $20.6 million and $22.1 million, respectively. Two retail customers and one third party contract manufacturing customer accounted for 13.6%, 12.1% and 10.5%, respectively, of our Fiscal 2016 revenues. Two retail customers accounted for approximately 15.8% and 11.3%, respectively, of our Fiscal 2015 revenues. Three retail customers accounted for approximately 18.9%, 16.9% and 11.3%, respectively, of our Fiscal 2014 revenues. The loss of sales to any one or more of these large retail or 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.

In addition, we have entered into multiple broker, distributor and representative agreements with third parties which provide for commission compensation based on sales performance.

Research and Development

We have historically invested significantly in research and development activities. Our research and development costs for Fiscal 2016, 2015 and 2014 were $575,000, $1.1 million and $1.3 million, respectively. Our research and development initiatives have been principally focused on product line development and/or line extensions for OTC health care and cold remedy products under the Cold-EEZE ® and TK Supplements ® brands.

Currently, we fund our research and development costs with cash generated from operations. In addition to funding from operations, we may seek to raise capital through the issuance of securities or from other financing sources to support our research and development activities including new product technologies, applications, licensing, commercialization and other development opportunities, as well as acquisitions of new formulations, ingredients, applications and other products. Any such funding through the issuance of our equity securities would result in the dilution of current stockholder ownership. Should research or commercialization activity progress on certain formulations, resulting expenditures may require substantial financial support and may necessitate the consideration of alternative approaches such as licensing, joint venture or partnership arrangements that meet our long term goals and objectives. Ultimately, should internal working capital be insufficient and external funding methods or other business arrangements become unattainable, it could result in the deferral or loss of future growth and development opportunities.

Regulatory Matters

We are subject to federal and state laws and regulations adopted for the health and safety of users of pharmaceutical and health care products. Our OTC homeopathic and health care products are subject to regulation by various federal, state, and local agencies, including the FDA. In addition, our Cold-EEZE ® cold remedy products are subject to the standards established by the Homeopathic Pharmacopoeia of the United States. These regulatory authorities have broad powers, and we may be subject to regulatory and legislative changes that can affect the economics of the industry by requiring changes in operating practices or by influencing the demand for and the costs of manufacturing or distributing our products. Our Cold-EEZE ® cold remedy products are considered a homeopathic drug and are exempt from pre-approval requirements and other, but not all, FDA requirements.

Many homeopathic drug and dietary supplement products, including Cold-EEZE ® cold remedy and TK Supplements ® products, are manufactured and distributed under FDA enforcement policies that provide requirements for marketing a homeopathic OTC drug or dietary supplement products without FDA approval. We believe we meet those requirements, which include registration of our manufacturing facility, listing of our product in the FDA's product database, and packaging, labeling, and manufacturing homeopathic drugs and dietary supplements in compliance with current good manufacturing practice ("cGMP") regulations. In addition, the FDA is currently not enforcing the requirement for a laboratory determination of identity and strength of each active ingredient prior to release for distribution, although this exemption is pending FDA review and we cannot assure that the exemption will be permanently implemented. We also cannot assure that the FDA will agree with our determination of compliance. If the FDA disagrees, the FDA could, upon inspection, issue a notice of violations, referred to as a form FDA-483, or issue a Warning Letter, or both. If we fail to take timely corrective actions to the satisfaction of FDA, the agency can initiate legal actions, such as seizure and injunction, which could include a recall order or the entry of a consent decree, or both. In addition, we could be subject to monetary penalties and even criminal prosecution for egregious conduct. We believe that we are in compliance with all such laws, regulations, and standards currently in effect including the Food, Drug, and Cosmetics Act, as amended, from time to time, and the standards established under the Homeopathic Pharmacopoeia of the United States.

Pre-clinical development, clinical trials, product manufacturing, labeling, marketing, distribution and licensing and/or acquisition of potential new products are also generally subject to federal and state regulation in the United States and other countries. Obtaining FDA and any other required regulatory approval for certain OTC products, or seeking the issuance of a final monograph from the FDA for certain OTC products, can require substantial resources and take several years. The length of this process depends on the type, complexity and novelty of the product and the nature of the disease or other indications to be treated. If we cannot obtain regulatory approval of, or final OTC monograph for, a new product(s) in a timely manner or if patents are not granted or are subsequently challenged, it could have a material adverse effect on our business and financial condition.

Competition

We compete with other suppliers of OTC homeopathic and health care products. These suppliers range widely in size. Management believes that our Cold-EEZE ® cold remedy lozenge products, which have been clinically proven in two double-blind studies to reduce the severity of common cold symptoms, offer a significant advantage over many of our competitors in the OTC cold remedy market. However, we have limited capital resources which limit our ability to further innovate and expand our Cold-EEZE ® product offerings to compete in the competitive cough and cold category, where many other OTC product suppliers are larger and have significantly greater financial, technical or marketing resources than we do. Accordingly, we believe that it is in our best interests to sell our Cold-EEZE ® Division to Mylan and to instead focus on and grow our PMI manufacturing business, ORXx and TK Supplements ® product lines and to pursue other opportunities. We believe that our ability to compete depends 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, 2016, we employed 52 full-time employees and 1 part-time employee, 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.

Suppliers; Raw Materials

We have derived our sales to date principally from our Cold-EEZE ® cold remedy zinc gluconate products which are available in various forms – lozenges, oral spray, QuickMelts ® and Gummies – and various flavors for purchase by consumers at retail stores. We also produce private label lozenge products for sale to certain retail customers. We manufacture our lozenge products at our Lebanon, Pennsylvania facility. The constituent raw materials and packaging used in the manufacture and presentation of these items have been procured from various sources with additional suppliers having been identified in the event that alternatives are required. While the absence of a current raw materials or packaging source may cause short term interruption, we expect that identified alternative sources would fill our needs in a short time and any transition period would be mitigated by adequate levels of finished product available for sale.

Item 1A. Risk Factors

Any of the following risks could materially affect our business, financial condition, or results of operations. These risks could also cause our actual results to differ materially from those indicated in the forward-looking statements contained herein and elsewhere. The risks described below are not the only risks facing us. Additional risks not currently known to us or those we currently deem to be immaterial may also materially and adversely affect our business, financial condition or results of operations.

If the proposed sale to Mylan of our Cold-EEZE® Division is completed, our remaining business and assets will be limited

If the proposed sale of our Cold-EEZE ® Division to Mylan is completed, we will be selling substantially all of our intellectual property assets. Our remaining assets will consist primarily of the net proceeds from the transaction, our PMI manufacturing business, our Company headquarters and our ORXx and TK Supplements ® brands, product lines and operations. We may invest in other intellectual property in the future or seek to merge, be acquired by or combine with another company that has products or technologies, but we have no current specific plans to do so at this time. This increases our business risk because we will be less diversified than before the sale of Cold-EEZE ® Division to Mylan and because our remaining business will be very limited.

While the sale of our Cold-EEZE ® Division is pending, it creates uncertainty about our future which could have a material adverse effect on our business, financial condition and results of operations

While the proposed sale of our Cold-EEZE ® Division to Mylan is pending, it creates uncertainty about our future. As a result of this uncertainty, our current or potential business partners may decide to delay, defer or cancel entering into new business arrangements with us pending completion or termination of the proposed sale. In addition, while the proposed sale is pending, we are subject to a number of risks, including:

- the diversion of management and employee attention from our day-to-day business;
- the potential disruption to business partners and other service providers;
- the loss of employees who may depart due to their concern about losing their jobs following the sale of our Cold-EEZE ® Division; and
- we may be unable to respond effectively to competitive pressures, industry developments and future opportunities.

The occurrence of any of these events individually or in combination could have a material adverse effect on our business, financial condition and results of operations. Additionally, we have incurred substantial transaction costs and diversion of management resources in connection with the proposed sale of our Cold-EEZE ® Division to Mylan, and we will continue to do so until the closing.

If the proposed sale to Mylan is not completed, we may need to raise additional capital

If the proposed sale of our Cold-EEZE ® Division to Mylan is not completed, we may be required to raise additional capital or take on additional debt to fund current operations. In addition, the Company is obligated to pay off certain secured promissory notes in 2017 and may need to find additional capital to do so.

The amount of net proceeds that we will receive from the proposed sale of our Cold-EEZE ® Division to Mylan, if consummated, is subject to uncertainties

Pursuant to the terms of the asset purchase agreement with Mylan, the amount that we receive from Mylan for our Cold-EEZE ® Division is subject to reduction after the closing if Mylan successfully asserts claims to indemnification pursuant to the indemnification provisions of the asset purchase agreement. Further, we may have unforeseen liabilities and expenses that must be satisfied from the after tax net proceeds of the sale to Mylan, leaving less to fund our remaining operations. 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.

The Asset Purchase Agreement with Mylan will expose us to contingent liabilities up to an amount equal to the purchase price for our Cold-EEZE ® Division, which could adversely affect our ability to pursue our remaining business operations or our ability to pursue other alternatives following the closing

We have made customary representations and warranties to Mylan in the asset purchase agreement for our Cold-EEZE ® Division. Pursuant to the asset purchase agreement, we agreed to indemnify Mylan for any losses from 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. A breach by us of certain fundamental representations would expose us to indemnification payments up to the purchase price. The payment of any such indemnification obligations could adversely impact our cash resources following the completion of the proposed sale to Mylan and our ability to pursue other alternatives after the closing, including transactions with third parties, distribution of funds to stockholders or dissolution or liquidation of our company.

We may be required to pay a termination fee to Mylan if the transaction is not completed and we engage in another transaction

The asset purchase agreement with Mylan requires us to pay Mylan a termination fee if the asset purchase agreement is terminated prior to closing under certain cases. If Mylan terminates the asset purchase agreement as a result of a triggering event, which includes approval by us of an offer from a third party that our board of directors concludes is superior to the proposed transaction with Mylan, then we must pay Mylan a termination fee equal to $1.5 million. If we are required to pay Mylan a termination fee, we might not have sufficient funds to pay the termination fee, and our business could be seriously harmed.

We may not receive any competing transaction proposals, including as a result of the termination fee payable to Mylan

The asset purchase agreement with Mylan requires us to pay Mylan a termination fee equal to $1.5 million if the asset purchase agreement is terminated prior to completion, including in the event of an approval by us of an offer from a third party that our board of directors concludes is superior to the proposed transaction with Mylan. The amount of this termination fee may have the effect of causing other potential third-party buyers to not submit a proposal to buy either the Company and its subsidiaries or our assets at a higher price or to enter into a more favorable alternative transaction.

If the sale to Mylan is not completed, we may explore other potential transactions but there may not be any other offers from potential acquirers

If the sale to Mylan is not completed, we may explore other strategic alternatives, including a sale of our assets to, or a business combination with, another party. There can be no assurance that any potential transaction will provide consideration equal to or greater than the price proposed to be paid by Mylan in the transaction, or that we will be able to complete any alternative transaction.

The failure to complete the proposed sale of our Cold-EEZE® Division will likely result in a decrease in the market value of our common stock and will create substantial doubt as to our ability to continue as an ongoing business

The proposed sale of our Cold-EEZE ® Division to Mylan is subject to a number of contingencies, including approval by our stockholders and other customary closing conditions. If our stockholders fail to approve the proposal to sell our Cold-EEZE ® Division to Mylan or if the proposed sale is not completed for any other reason, the market price of our common stock would likely decline, and there would be substantial doubt as to our ability to continue as a going concern.

Our business is subject to significant competitive pressures

The OTC healthcare product, pharmaceutical, dietary supplement and consumer product industries are highly competitive. Many of our competitors have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, distribution and experience than we do. Our competitors may have certain advantages, including the ability to allocate greater resources for new product development, marketing and other purposes.

We believe that our ability to compete depends 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, and new and existing product innovation and commercialization. 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.

Our new product efforts may be unsuccessful

Our flagship Cold-EEZE ® cold remedy brand is an established brand within the cough-cold category. However, some retailers are reallocating shelf space away from the cough-cold category to other product categories. With cough-cold shelf space at a premium, opportunities in the future to introduce new Cold-EEZE ® branded products in the cough-cold category may be limited. For this reason, among others, we have determined that it is in our best interests to sell our Cold-EEZE ® Division to Mylan and to instead focus on and grow our PMI manufacturing business, ORXx and TK Supplements ® product lines and to pursue other opportunities. While management anticipates the growth potential in the dietary supplement product category may be better, the risks associated with introducing new products that do not leverage the Cold-EEZE ® brand name may be significant. Therefore, no assurance can be made that our new product efforts will be successful.

New product development; our long range business plan may not be successful

We face significant technological risks inherent in developing new products. We may be subject to delays and/or ultimately unable to successfully implement our business plan and strategy to develop and commercialize one or more non-prescription remedies and/or dietary supplements. The commercialization and ultimate product market acceptance is subject to, among other influences, consumer purchasing trends, demand for our product, 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 become commercially viable. Even if we 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.

We have aligned our operations to focus principally in the research, development, manufacture, marketing and sale of OTC health care and cold remedy consumer products, natural based health products and more recently, dietary supplement products. In addition, we may seek to acquire from third parties or enter into other arrangements with respect to new formulations, ingredients, applications and other products developed by third parties who may be seeking our commercialization, marketing and distribution expertise.

There can be no assurance that we will be able to effectuate our business plan successfully or that our revenue will grow. In addition, we may not be successful in acquiring or otherwise entering into any new lines of business, including dietary supplement products, and, if we are successful in doing so, there can be no assurance that such new business will achieve profitability.

We will need to obtain additional capital to support long term product development and commercialization programs

Our ability to achieve and sustain operating profitability depends in large part on our ability to commence, execute and complete new and existing product innovation and commercialization and, if required, clinical programs to obtain regulatory approvals in the United States and elsewhere. We can give no assurance that we will be able to achieve such product innovation and commercialization, to obtain any required approvals or to achieve significant levels of sales.

The amount of capital that may be needed to complete 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, (ii) whether we elect to establish partnering arrangements for the development, sales, manufacturing and marketing of such products, (iii) the level of future sales of OTC health care, cold remedy or dietary supplement products, and expense levels for marketing efforts, (iv) whether we can establish and maintain strategic arrangements for the development, sales, manufacturing and marketing of our products, and (v) whether any or all of the options for our common stock, $0.0005 par value, ("Common Stock") issued to employees of the Company are exercised and the timing and amount of these exercises.

Should research or commercialization activity progress on certain formulations, resulting expenditures may require substantial financial support. Following the proposed sale of our Cold-EEZE ® Division to Mylan, if approved by our stockholders, income from our OTC homeopathic and health care products sales and PMI manufacturing business may not generate all the funds we anticipate will be needed to support future product acquisition or development. Accordingly, in addition to funding from operations, we may in the short and long term seek to raise capital through the issuance of securities or to secure other financing sources to support our research, new product technologies, applications, licensing, commercialization and other development opportunities. If we obtain such funding through the issuance of equity securities, it would result in the dilution of current stockholders' ownership in the Company. Any debt financing, if available, may include financial and other covenants that could restrict use of proceeds of 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. There can be no assurances that we will have access to the capital required to fund these aspects of our business on favorable terms or at all.

We may not be able to access our Equity Line of Credit under commercially reasonable terms

On July 30, 2015 we executed an equity line of credit agreement (such arrangement, the "2015 Equity Line") with Dutchess Opportunity Fund II LP ("Dutchess") whereby, Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,200,000 shares of the Company's Common Stock, over a period of 36 months expiring August 2018. At December 31, 2016, we have 2,450,000 shares of our Common Stock available for sale to Dutchess, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

To the extent that we do not generate sufficient cash from operations, we may need to access our 2015 Equity Line to finance our growth. Our 2015 Equity Line is limited and may not be sufficient to meet our capital requirements. If we need to seek other sources of capital, uncertainty in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through our 2015 Equity Line on terms that we believe to be reasonable, or at all.

Any draw downs under our 2015 Equity Line with Dutchess may result in dilution to our stockholders

If we sell shares to Dutchess under the 2015 Equity Line, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our Common Stock. If we draw down amounts under the 2015 Equity Line, we will issue shares to Dutchess at a discount of 5% from the average price of our Common Stock. If we draw down amounts under the 2015 Equity Line when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

We may be unable to generate sufficient cash flows from operations to meet our debt service payments

On December 11, 2015, we executed two Subscription Agreements (the "Subscription Agreements") with the investors named therein (the "Investors") providing for the purchase of 12% Secured Promissory Notes – Series A ("Notes") in the aggregate principal amount of up to $3.0 million and warrants to purchase shares of our Common Stock (the "Warrants"). The Warrants grant the Investors the right to purchase 17,000 shares of our Common Stock for every $500,000 of principal amount of Notes purchased by the Investors.

Notes in the amount of $1,500,000 and 51,000 Warrants, at an exercise price of $1.35 per share, were issued by the Company and its wholly-owned subsidiaries PMI and Quigley Pharma Inc. (collectively, the "Obligors") and funded on December 11, 2015. The Notes are secured by all of our tangible and intangible assets. The Notes bear interest at the rate of 12% per annum, payable semi-annually and the principal is due and payable on June 15, 2017. The Notes may be pre-paid at any time prior to maturity without penalty.

As of December 31, 2016, we had total secured Notes outstanding of $1.5 million, excluding $10,000 in unamortized interest for loan origination costs and the fair value of the Warrants. We may incur additional debt to refinance the Notes and to finance future research and development, and product launch and related marketing activities.

Our ability to generate sufficient cash flows from operations to make scheduled debt service payments depends on a range of economic, competitive and business factors, many of which are outside of our control. Our business may generate insufficient cash flows from operations to meet our debt service and other obligations, and currently anticipated cost savings, capital investment plans, working capital reductions and operating improvements and/or the potential sale of our Cold-EEZE ® Division to Mylan, which is subject to stockholder approval and other customary closing conditions, may not be realized on schedule, or at all. To the extent our cash flow from operations is insufficient to fund our debt service obligations, aside from our current liquidity, we would be dependent on outside capital to meet the funding of our debt service obligations and to fund capital expenditures and other obligations.

If we are unable to meet our expenses and debt service obligations, we may need to refinance all or a portion of our indebtedness on or before maturity, sell assets or issue additional equity securities. We may be unable to refinance any of our indebtedness, sell assets or issue equity securities on commercially reasonable terms, or at all, which could cause us to default on our obligations and result in the acceleration of our debt obligations. Our inability to generate sufficient cash flows to satisfy our outstanding debt obligations, or to refinance our obligations on commercially reasonable terms, would have a material adverse effect on our business, financial condition and results of operations.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations and cash flows

In recent years, there has been substantial volatility in financial markets due at least in part to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to financing is uncertain. Moreover, customer spending habits may be adversely affected by the changes to the economic environment and current prevailing high under employment rates in the United States. These conditions could have an adverse effect on our industry and business, including our access to funding sources, demand for our products and our customers' ability to continue to purchase our products, which could have a material adverse effect on our financial condition, results of operations and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue equity or to incur indebtedness to finance our growth. Turmoil and volatility in the credit markets and the potential impact on 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, or at all.

Commodity price increases will increase our operating costs and may negatively affect financial results

Commodity prices impact our business directly through the cost of raw materials used to make our products (such as corn syrup, sucrose and other commodities and ingredients) and the amount we pay to purchase packaging for our products (such as paper, board and plastic). Commodities such as these are susceptible to price volatility caused by conditions outside of our control, including fluctuations in commodities markets, currency fluctuations, availability of supply, weather, consumer demand and changes in governmental agricultural programs. Increases in the price of our commodities and other raw materials would negatively impact our gross margins and/or our sales volume if we were unable to offset such increases through increases in our selling price, changes in product mix or cost reduction/productivity enhancement efforts.

The sales of our primary product fluctuates by season and from Cold Season to Cold Season

Our sales are derived principally from our OTC homeopathic and health care products. Our sales have historically been subject to fluctuations and influenced by the timing, length and severity of each cold season. The first, third and fourth quarters have generally represented the largest sales volume for our OTC homeopathic and health care products. 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.

There can be no assurance that we will be able to manage our working capital needs and inventory to meet the fluctuating demand for these products. Failure to accurately predict and respond to consumer demand may result in the production of excess inventory which may be expensive to store or which we may be required to dispose if such excess inventory remains unsold. Conversely, if products achieve greater success than anticipated for any given quarter, this may result in insufficient inventory to meet customer demand. If we do not manage our working capital needs and inventory, our business and financial condition may be materially adversely affected.

Our performance may fluctuate when our customers are affected simultaneously by the same economic, regulatory or health and wellness factors

Our revenues are significantly concentrated in our OTC health care and cold remedy products. Our customers are subject to fluctuations of business based upon consumer purchasing trends, demand for cold remedy products and overall economic and market conditions. Consequently, many customers will likely be influenced at the same time by similar economic conditions, regulatory factors or health and wellness trends, which can affect the level of demand for our products. It is reasonable to expect that, if one customer reduces or delays its purchasing in response to a general economic, regulatory or health and wellness factor, other customer may also decide to reduce or delay their purchasing at approximately the same time. Accordingly, our sales are subject to fluctuations as a result of such factors.

We have a concentration of sales to and accounts receivable from several large customers

Although we have a broad range of customers that includes many national chain, regional, specialty and local retail stores, our five largest customers accounted for a significant percentage of our sales, approximately 53% and 48% of total revenues for Fiscal 2016 and 2015, respectively. In addition, retail customers comprising the five largest accounts receivable balances represented 57% and 60% of total accounts receivable balances at December 31, 2016 and 2015, respectively. We extend credit to retail customers based upon an evaluation of their financial condition and credit history, and collateral is not generally required. If one or more of these large retail customers cannot pay, the write-off of their accounts receivable could have a material adverse effect on our operations and financial condition. The loss of sales to any one or more of these large retail customers would also have a material adverse effect on our financial condition, results of operations and cash flows.

Retail customer's strategic business plans may negatively influence the distribution of our products to consumer

Changes in our retail and distribution customers strategic business plans including, but not limited to, (i) expansions, mergers, and/or consolidations, (ii) retail shelf space allocations for products within each outlet and in particular the OTC homeopathic and health care category in which we compete, (iii) changes in their private label assortment and (iv) product selections, distribution allocation, merchandising programs, commercial terms and retail pricing of our products as well as competitive products could affect the consumer sales of our products and result in a material adverse effect to our business and financial condition.

Our products and potential new products are or may be subject to extensive governmental regulation

Our business is regulated by various agencies of the states and localities where our products are sold. Governmental regulations in foreign countries where we plan to commence or expand sales may prevent or delay entry into a market or prevent or delay the introduction, or require the reformulation of certain of our products. In addition, no prediction can be made as to whether new domestic or foreign legislation regulating our activities will be enacted. Any new legislation could have a material adverse effect on our business, financial condition and operations. Non-compliance with any applicable requirements may subject us or the manufacturers of our products to agency action, including warning letters, fines, product recalls, seizures and injunctions.

The manufacturing, processing, formulation, packaging, labeling and advertising of our health care and cold remedy products are subject to regulation by several federal agencies, including (i) the FDA, (ii) the Federal Trade Commission ("FTC"), (iii) the Consumer Product Safety Commission, (iv) the United States Department of Agriculture, (v) the United States Postal Service, (vi) the United States Environmental Protection Agency and (vii) the United States Occupational Safety and Health Administration.

In addition to OTC and prescription drug products, the FDA regulates the safety, manufacturing, labeling and distribution of dietary supplements, including vitamins, minerals and herbs, food additives, food supplements, over-the-counter and prescription drugs and cosmetics. The FTC also has overlapping jurisdiction with the FDA to regulate the promotion and advertising of vitamins, over-the-counter drugs, cosmetics and foods. In addition, our cold remedy products are homeopathic remedies which are subject to standards established by the Homeopathic Pharmacopoeia of the United States ("HPUS"). HPUS sets the standards for source, composition and preparation of homeopathic remedies which are officially recognized under the Federal Food, Drug and Cosmetics Act, as amended.

Preclinical development, clinical trials, product manufacturing, labeling, distribution and marketing of potential new products are also subject to federal and state regulation in the United States and other countries. Clinical trials and product marketing and manufacturing are subject to the rigorous review and approval processes of the FDA and foreign regulatory authorities. To obtain approval of a new drug product, a company must demonstrate through adequate and well-controlled clinical trials that the drug product is safe and effective for its intended use. Obtaining FDA and other required regulatory approvals is lengthy and expensive. Typically, obtaining regulatory approval for pharmaceutical products requires substantial resources and takes several years. The length of this process depends on the type, complexity and novelty of the product and the nature of the disease or other indication to be treated. Preclinical studies must comply with FDA regulations. Clinical trials must also comply with FDA regulations to ensure safety of the human subjects in the trial and may require large numbers of test subjects, complex protocols and possibly lengthy follow-up periods. Consequently, satisfaction of government regulations may take several years: may cause delays in introducing potential new products for considerable periods of time and may require imposing costly procedures upon our activities. If regulatory approval of new products is not obtained in a timely manner or not at all, we could be materially adversely affected. Even if regulatory approval of new products is obtained, such approval may impose limitations on the indicated uses for which the products may be marketed which could also materially adversely affect our business, financial condition and future operations.

We have a history of losses and limited working capital

We have experienced net losses for each of the four of the past five fiscal years. 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. As of December 31, 2016, we had working capital of approximately $2.8 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 31, 2018. Our ability to fund working capital and debt service needs will depend on our ability to generate cash in the future.

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 "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or 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 of the Code. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

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, Mr. Robert V. Cuddihy, Jr., Chief Operating Officer and Chief Financial 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 be 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.

We are dependent on our manufacturing facility and suppliers for certain of our cold remedy products

Our manufacturing, warehousing and distribution center is located in Lebanon, Pennsylvania. In the event of a disruption of this facility, we would need to outsource to third parties, at least temporarily, our manufacturing, warehousing and distribution requirements. While such secondary sources have been identified for our products, if we are unable to find other sources or there were a delay in the ramp-up for the production and distribution operations for some of our products, it could have a material adverse effect on our operations.

Our inability to find alternative sources for some of our manufacturing and raw materials may have a material adverse effect on our operations and financial condition. In addition, the terms on which manufacturers and suppliers will make products and raw materials available to us could have a material effect on our success.

In addition, if the proposed sale of our Cold-EEZE ® Division to Mylan is consummated, we intend to focus on and grow our PMI manufacturing business. Our ability to grow our manufacturing business and operate it profitably will be subject to 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. If we are unsuccessful in our efforts to grow our PMI manufacturing business, we may be unable to generate sufficient cash flows to sustain our operations.

The manufacturing of OTC healthcare products and dietary supplements is subject to applicable current good manufacturing practice ("cGMP") regulations and FDA inspections. We believe we are in substantial compliance with material provisions of the applicable cGMP regulations. Contract manufacturers are also subject to these same requirements and we require such compliance in our contractual relationships with such manufacturers. However, we cannot assure that the FDA will agree with our determination of compliance. If the FDA disagrees, it could, upon inspection of our facility, issue a notice of violations, referred to as a form FDA-483, or issue a Warning Letter, or both. If the FDA concludes that there is an imminent public health threat or if we fail to take timely corrective actions to the satisfaction of the FDA, the agency can initiate legal actions, such as seizure and injunction, which could include a recall order or the entry of a consent decree, or both. In addition, we could be subject to monetary penalties and even criminal prosecution for egregious conduct. The FDA could initiate similar legal actions against the contract manufacturer if it concludes its facility is not in compliance, which would affect the availability of our products. While secondary sources have been identified for our products, our inability to find other sources or a delay in the ramp-up for the production and distribution operations for some of its products may have a material adverse effect on our operations.

We are uncertain as to whether we can protect our proprietary rights

The strength of our patent position and proprietary formulations and compounds may be important to our long-term success. We currently own numerous U.S. and foreign patents in connection with potential products; however there can be no assurance that these patents and proprietary formulations and compounds will effectively protect our products from duplication by others. In addition, we may not be able to afford the expense of any litigation which may be necessary to enforce our rights under any of the patents. Furthermore, there can be no assurance that third parties will not obtain access to or independently develop our technologies, know-how, ideas, concepts and documentation, which could have a material adverse effect on our financial condition.

Although we believe that current and future products do not and will not infringe upon the patents or violate the proprietary rights of others, if any of our current or future products do infringe upon the patents or proprietary rights of others, we may have to modify the products or obtain an additional license for the manufacture and/or sale of such products. We could also be prohibited from selling the infringing products. If we were found to infringe on the proprietary rights of others, it is uncertain whether we would be able to take corrective actions in a timely manner, upon acceptable terms and conditions, or at all, and the failure to do so could have a material adverse effect upon our business, financial condition and operations.

Our existing products and potential new products expose us to potential product liability claims

Our business results in exposure to an inherent risk of potential product liability claims, including claims for serious bodily injury or death caused by the sales of our existing products and the products which are being developed. These claims could lead to substantial damage awards. While we currently maintain product liability insurance, a successful claim brought against us in excess of, or outside of, existing insurance coverage could have a material adverse effect on our results of operations and financial condition. Claims against us, regardless of their merit or eventual outcome, may also have a material adverse effect on the consumer demand for our products.

We are involved in litigation matters

We are, from time-to-time, subject to various legal proceedings and claims, either asserted or unasserted. Any such claims, whether with or without merit, can be time-consuming and expensive to defend and can divert management's attention and resources. Furthermore, there is no assurance that the outcome of all current or future litigation will not have a material adverse effect on us.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Capital Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to all of these requirements. Moreover, the reporting requirements, rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, may make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers.

In addition, the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley") and the related rules of the Securities and Exchange Commission require that we maintain effective internal control over financial reporting and disclosure controls and procedures. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall.

Our compliance with Section 404 of Sarbanes-Oxley requires that we incur substantial expense and expend significant management time on compliance related issues. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock would likely decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our stock price is volatile

The market price of our Common Stock has experienced significant volatility. From January 1, 2016 to February 22, 2017, the closing price of our stock has ranged from $1.16 to $2.16 per share. There are several factors which could affect the price of our Common Stock, including announcements of technological innovations for new commercial products by us or our competitors, developments concerning propriety rights, new or revised governmental regulation or general conditions in the market for our products. Sales of a substantial number of shares by existing stockholders could also have an adverse effect on the market price of our Common Stock.

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. As of February 22, 2017, we had 17,080,776 shares of Common Stock outstanding.

As of February 22, 2017, there were outstanding options, which were fully vested, to purchase an aggregate of 1,699,000 shares of our Common Stock at an average exercise price of $1.20 per share. If these options are exercised, and the holders of these options were to attempt to sell a substantial amount of their holdings 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 officers and directors own a substantial amount of our Common Stock

As of February 22, 2017, our executive officers and directors beneficially owned approximately 30% of our Common Stock. These individuals have significant influence over the outcome of all matters submitted to stockholders for approval, including the election of directors. Consequently, they exercise substantial influence over all 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 officers and directors 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 or the market price of our Common Stock may be adversely affected.

We do not intend to pay cash dividends in the foreseeable future

We have not paid cash dividends on our Common Stock since our inception. Our intention is to retain earnings, if any, for use in the business and we do not anticipate paying any cash dividends to stockholders in the foreseeable future.

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 and Mr. Cuddihy. 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. These indemnity provisions may reduce the likelihood of derivative litigation against directors and officers and discourage or deter stockholders from suing directors or officers for breaches of their duties to the Company, even though such an action, if successful, might otherwise benefit the Company or its stockholders. In addition, to the extent that we expend funds to indemnify directors and officers, funds will be unavailable for operational purposes.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters is located in Doylestown, Pennsylvania. We purchased this property in 1998. Our headquarters is 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, 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

On October 17, 2014, we initiated a demand for arbitration with the American Arbitration Association, case number 01-14-0001-7373. This demand for arbitration pertains to our Phusion joint venture and the matter is against PSI Parent and PSI (collectively known as the "Phosphagenics Entities").

In November 2016, the arbitration case was resolved and is now concluded. The arbitrator rejected all of the counterclaims asserted by Phosphagenics that ProPhase pay damages to Phosphagenics. The arbitrator also awarded to ProPhase recovery of approximately $350,000 (net of the payment of certain wind down expenses) that had been invested in the Phusion joint venture entity; terminated the intellectual property license that had been granted to Phusion from Phosphagenics; and directed the wind down and termination of Phusion Laboratories LLC, the joint venture entity. The steps to wind down and terminate Phusion Laboratories LLC, the joint venture entity, were initiated in December 2016 and it is expected to be completed in the first half of Fiscal 2017.

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.

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." The price set forth in the following table represents the high and low closing bid prices for our Common Stock for each quarter of Fiscal 2016 and 2015, as reported on The NASDAQ Capital Market.

Common Stock

	2016		2015	
Quarter Ended	High	Low	High	Low
March 31,	$ 1.51	$ 1.16	$ 1.67	$ 1.30
June 30,	$ 1.47	$ 1.22	$ 1.42	$ 1.23
September 30,	$ 2.06	$ 1.29	$ 1.71	$ 1.33
December 31,	$ 2.16	$ 1.92	$ 1.62	$ 1.20

Holders

As of February 22, 2017, there were approximately 214 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.

Dividends

We have not declared, nor paid any cash dividends on our Common Stock since our Company's inception. At this time, we intend to retain our earnings to finance future growth and maintain liquidity. Future cash dividends, if any, will be at the discretion of our Board of Directors and will depend upon, among other things, our future operations and earnings, capital requirements, general financial condition, contractual and financing restrictions and such other factors as our Board of Directors may deem relevant.

Warrants and Options

In addition to our outstanding Common Stock, there were reserved for issuance 1,750,000 shares of our Common Stock underlying outstanding unexercised and vested options and Warrants as of December 31, 2016 at the price-per-share stated and expiration date indicated, as follows:

Description	Number of Options	Exercise Price	Expiration Date
Option Plan	935,000	$ 1.00	December 14, 2017
Option Plan	75,000	$ 1.08	May 28, 2018
Option Plan	20,000	$ 0.87	November 5, 2018
Warrants	51,000	$ 1.35	December 10, 2018
Option Plan	100,000	$ 1.17	December 18, 2018
Option Plan	403,000	$ 1.65	December 18, 2019
Option Plan	15,000	$ 1.36	December 20, 2019
Option Plan	15,000	$ 1.48	April 9, 2020
Option Plan	136,000	$ 1.39	December 19, 2021
Total	1,750,000		

Securities Authorized Under Equity Compensation Plans

The following table sets forth certain information regarding stock option and warrant grants made to employees, directors and consultants:

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)	Weighted Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A) (C)
Equity Plans Approved by Security Holders [1,2]	1,699,000	$ 1.20	881,467

(1) On May 5, 2010, our stockholders approved the 2010 Equity Compensation Plan which was subsequently amended, restated and approved by stockholders on April 24, 2011, and further amended and approved by stockholders on May 6, 2013, and further amended and approved by stockholders on May 24, 2016 (the "2010 Plan"). The 2010 Plan, as amended, provides that the total number of shares of Common Stock that may be issued under the 2010 Plan is equal to 3.2 million shares. Consultants and advisors who perform services for us are also eligible to participate in the 2010 Plan. At December 31, 2016, we have outstanding 1,699,000 stock options, subject to vesting, under the 2010 Plan. For Fiscal 2016, we charged to operations $1,000 for compensation expense for the fair value of the vested portion of the stock options (see Note 6 to Notes to Consolidated Financial Statements). At December 31, 2016, there are 733,659 shares of Common Stock that may be issued in the future pursuant to the 2010 Plan.

(2) On May 5, 2010, our stockholders approved the 2010 Directors' Equity Compensation Plan which was subsequently amended and approved by our stockholders on May 6, 2013. The 2010 Directors' Equity Compensation Plan provides that the total number of shares of Common Stock that may be issued under the 2010 Directors' Equity Compensation Plan is equal to 425,000. For Fiscal 2016 there were no shares of our Common Stock granted under the 2010 Directors' Equity Compensation Plan. At December 31, 2016, there are 147,808 shares of Common Stock that may be issued pursuant to the 2010 Directors Equity Compensation Plan.

Item 6. Selected Financial Data

The following table sets forth the selected financial data appearing in or derived from our consolidated financial statements for and at the end of the years ended December 31, 2016, 2015, 2014, 2013 and 2012. The selected financial data should be read in conjunction with the consolidated financial statements appearing elsewhere herein, and with Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations (in thousands, except per share amounts):

	Year Ended December 31,				
	2016	**2015**	**2014**	**2013**	**2012**
Statement of Income Data:					
Net sales	$ 21,014	$ 20,604	$ 22,070	$ 25,032	$ 22,406
Gross profit	$ 10,066	$ 12,178	$ 14,179	$ 16,671	$ 14,252
Income (loss) from operations before taxes	$ (2,868)	$ (3,600)	$ (7,834)	$ 405	$ (1,091)
Net income (loss)	$ (2,868)	$ (3,600)	$ (7,834)	$ 405	$ (1,091)
Basic income (loss) per share	$ (0.17)	$ (0.22)	$ (0.47)	$ 0.03	$ (0.07)
Diluted income (loss) per share	$ (0.17)	$ (0.22)	$ (0.47)	$ 0.03	$ (0.07)
Weighted average shares outstanding:					
Basic	17,081	16,398	16,773	15,839	14,843
Diluted	17,081	16,398	16,773	16,276	14,843

	As of December 31,				
	2016	**2015**	**2014**	**2013**	**2012**
Balance Sheet Data:					
Working capital	$ 2,787	$ 7,345	$ 8,217	$ 6,655	$ 5,809
Total assets	$ 9,627	$ 14,829	$ 16,057	$ 17,420	$ 16,661
Long term debt and other obligations	$ -	$ 1,466	$ 100	$ 200	$ 300
Stockholders' equity	$ 5,962	$ 8,829	$ 10,716	$ 12,596	$ 11,451

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

Our Business. We are a manufacturer, marketer and distributor of a diversified range of homeopathic and health care products that are offered to the general public. We are also engaged in the research and development of potential over-the-counter ("OTC") drug, natural base health products along with supplements personal care and cosmeceutical products.

Our primary business has been the manufacture, distribution, marketing and sale of OTC homeopathic and health care products, particularly cold remedy products, to consumers through national chain, regional, specialty and local retail stores. Our flagship brand is Cold-EEZE ® and our principal product is Cold-EEZE ® cold remedy zinc gluconate lozenges, proven in clinical studies to reduce the duration and severity of symptoms of the common cold. In addition to Cold-EEZE ® cold remedy lozenges, we market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE ® cold remedy QuickMelts ® , (ii) Cold-EEZE ® Gummies (see below) and (iii) Cold-EEZE ® cold remedy Oral Spray. Each of our Cold-EEZE ® QuickMelts ® products are based on our proprietary zinc gluconate formulation in combination with certain (i) immune system support, (ii) energy, (iii) sleep and relaxation, and/or (iv) cold and flu symptom relieving active ingredients.

In Fiscal 2014 we introduced and began shipments in June 2014 of our new Cold-EEZE ® Plus Natural Multi-Symptom QuickMelts ® . In Fiscal 2015, we introduced three new Cold-EEZE ® product line extensions: (i) a Cold-EEZE ® Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE ® Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE ® Natural Allergy Relief caplets for indoor and outdoor allergies. Shipments for these three new Cold-EEZE ® product line extensions began in the third quarter of Fiscal 2015. In Fiscal 2016, we expanded our Cold-EEZE ® product line further to include (i) Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu and (ii) Cold-EEZE ® Nighttime Multi-Symptom Relief for Cold and Flu QuickMelts ® . Shipments began for these two new products in the third quarter of Fiscal 2016.

As further described in the "Business" section of this Report under "Strategic Initiatives", on January 6, 2017, we entered into an asset purchase agreement with Mylan, pursuant to which we agreed to sell our Cold-EEZE ® Division to Mylan, subject to the approval of our stockholders and other customary closing conditions.

In addition to our Cold-EEZE ® product line, we market and distribute OTC lozenge and dietary supplement products under the ORXx brand name. The ORXx brand includes the products sold under the following names: ORXx Complete ™ and ORXx Defense ™ .

We are also pursuing a series of new product development and pre-commercialization initiatives in the dietary supplement category. Initial dietary supplement product development activities were completed in the fourth quarter of Fiscal 2015 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 ® , a daily energy booster plus testosterone support, and (iii) Super ProstaFlow Plus ™ for prostate and urinary health.

In addition to the Company's products, our wholly owned subsidiary, PMI, produces our Cold-EEZE ® cold remedy lozenges and other products in addition to performing operational tasks such as warehousing, customer order processing and shipping.

Product Development

Our flagship Cold-EEZE ® brand has generally performed well within the cough-cold category over the past several years. Although we have continued to expand our Cold-EEZE ® product offerings, some retailers are limiting and/or reallocating shelf and promotional space away from the cough-cold category to other product categories. With cough-cold shelf and promotional space at a premium, opportunities in the future to introduce new Cold-EEZE ® products and to compete in the competitive cough-cold category, where many other OTC product suppliers are larger and have significantly greater financial, technical and marketing resources than we do, may be limited. For this reason, among others, we have determined that it is in our best interests to sell our Cold-EEZE ® Division to Mylan and to instead focus on and grow our PMI manufacturing business, ORXx and TK Supplements ® product lines and to pursue other opportunities.

Initial dietary supplement product development activities were completed in the fourth quarter of Fiscal 2015 under the brand name of TK Supplements ® . The inaugural TK Supplements ® product line is comprised of three men's health products: (i) Legendz XL ® for sexual health, (ii) Triple Edge XL ® , a daily energy booster plus testosterone support, and (iii) Super ProstaFlow *Plus* ™ for prostate and urinary health.

During Fiscal 2016, we produced, tested and refined a direct response television commercial and initiated television and digital media testing for Legendz XL ® . Additionally, we completed a broad series of clinical studies which support important product claims which have now been incorporated into our product packaging and marketing communication. Our next goal is to introduce Legendz XL ® in retail stores leveraging our existing infrastructure and retail distribution platform. We have received initial product acceptance into a national chain drug retailer and several regional retailers to begin shipments of Legendz XL ® to such retailers during the second or third quarter of Fiscal 2017.

Once we have established a retail presence, we expect to initiate a TV campaign with short form TV spots as well as other forms of advertising designed to support our retail launch and generate additional direct-to-consumer sales, a two pronged strategy of retail and e-commerce consumer engagement. As with any new product launch, we anticipate losses from the TK Supplements ® initiatives as we optimize our market strategy.

While management anticipates the growth potential in this category may be better, the risks associated with introducing new products that do not leverage the Cold-EEZE ® brand name may be higher. Therefore, no assurance can be made that our new product efforts will be successful and/or profitable.

Additionally, we are active in exploring new product technologies, applications, product line extensions and other new product opportunities and will also consider and pursue other alternatives and strategies, including, but not limited to, investments and acquisitions in other sectors and industries.

Income Taxes

As of December 31, 2016, we have net operating loss carry-forwards of approximately $47.1 million for federal purposes that will expire beginning in Fiscal 2020 through 2036. Additionally, there are net operating loss carry-forwards of $22.1 million for state purposes that will expire beginning in Fiscal 2020 through 2036. 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. As a consequence of the accumulated losses of the Company, we believe that this allowance is required due to the uncertainty of realizing these tax benefits in the future.

Results of Operations

Fiscal 2016 compared with Fiscal 2015

Net sales for Fiscal 2016 increased $410,000, or 1.9%, to $21.0 million as compared to $20.6 million for Fiscal 2015. The increase in net sales from Fiscal 2015 to Fiscal 2016 is due principally to the net effects of an increase of $1.7 million in our contract manufacturing operations from non-related third party entities to produce lozenge-based products offset by a decrease in net sales of OTC health care and cold remedy products (principally in the period from January through March 2016 as compared to January through March 2015) due to the timing of customer purchases, product mix shipped from period to period and lower consumer demand as a consequence of several factors including the decreased incidence and severity of upper respiratory illnesses, principally from January through March 2016 as compared to the prior year January through March 2015. According to IMS Health (a healthcare industry information provider), key industry statistics reveal that the incidence of upper respiratory illness across the country declined approximately 11% for the period from January through March 2016 as compared to the prior year period from January through March 2015. The category of cough and cold product sales, including our Cold-EEZE ® sales, are highly correlated to the incidence of upper respiratory illness.

Cost of sales for Fiscal 2016 were $10.9 million as compared to $8.4 million for Fiscal 2015. For Fiscal 2016 and Fiscal 2015, we realized a gross margin of 47.9% and 59.1%, respectively. The decrease of 11.2% in gross margin from the prior period is principally due to (i) initial distribution expenses and sales allowances attributed principally to the launch of the new Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu in Fiscal 2016, (ii) a reduction in the absorption of fixed production costs, (iii) fluctuations in our product mix shipped from period to period, (iv) inventory adjustments of $989,000 for Cold-EEZE ® Division and TK Supplements ® products, (v) an increase in certain commodity costs to convert in July 2016 to non-GMO ingredients for our lozenge products and (vi) an increase in contract manufacturing net sales which carry lower gross margins. Gross margins are generally influenced by fluctuations in quarter-to-quarter production volume, fixed production costs and related overhead absorption, raw ingredient costs, inventory mark to market write-downs retail cooperative incentive promotion and the timing of shipments to customers which are factors of the seasonality of our sales activities and products.

Sales and marketing expense for Fiscal 2016 decreased $613,000 to $7.1 million as compared to $7.7 million for Fiscal 2015. The decrease in sales and marketing expense for Fiscal 2016 as compared to Fiscal 2015 was principally due to a decrease in (i) our marketing expenditures as we managed the scope and timing of our media and product promotion advertising campaigns from period to period and (ii) a decrease in personnel and other sales costs.

General and administrative ("G&A") expenses decreased $1.9 million for Fiscal 2016 to $5.1 million as compared to $7.0 million in Fiscal 2015. The decrease in G&A expense for Fiscal 2016 as compared to Fiscal 2015 was principally due to a decrease in professional and legal fees related to certain, now resolved, litigation matters.

Research and development costs for Fiscal 2016 and 2015 were $575,000 and $1.1 million, respectively. The decrease of $502,000 in research and development costs for Fiscal 2016 as compared to Fiscal 2015 was principally due a decrease in the scope, timing, cost and amount of research and development activity from period to period. We continue to engage in other research and development activities that we determine are appropriate and we may increase our research and development activities in future periods.

Interest income and interest expense for Fiscal 2016 was $1,000 and $213,000, respectively, as compared to $2,000 and $18,000, respectively, for Fiscal 2015. The decline in interest income in Fiscal 2016 as compared to Fiscal 2015 is due principally to lower invested cash balances from period to period. The increase in interest expense for Fiscal 2016 as compared to Fiscal 2015 was due principally to the interest expense incurred pursuant to the issuance of the Notes in December 2015.

As noted above, we have net operating loss carry-forwards for both federal and certain states. As a consequence of these loss carry-forwards, we did not incur income tax expense for Fiscal 2016 or Fiscal 2015.

As a consequence of the effects of the above, the net loss for Fiscal 2016, was $2.9 million, or ($0.17) per share, as compared to a net loss of $3.6 million, or ($0.22) per share, for Fiscal 2015.

Fiscal 2015 compared with Fiscal 2014

Net sales for Fiscal 2015 decreased $1.5 million, or 6.6%, to $20.6 million as compared to $22.1 million for Fiscal 2014. The decrease in net sales from Fiscal 2014 to Fiscal 2015 is due principally to the net effects of (i) the timing of customer purchases, product mix shipped from period to period and lower consumer demand as a consequence of several factors including the decreased incidence and severity of upper respiratory illnesses, from period to period, offset by (ii) an increase of $1.0 million in our contract manufacturing operations from non-related third party entities to produce lozenge-based products. According to IMS Health (a healthcare industry information provider), key industry statistics reveal that the incidence of upper respiratory illness across the country was down 12.6% for the period from September through December 2015 as compared to the prior year period from September through December 2014. The category of cough and cold product sales, including our Cold-EEZE ® sales, are highly correlated to the incidence of upper respiratory illness.

Cost of sales for Fiscal 2015 were $8.4 million as compared to $7.9 million for Fiscal 2014. For Fiscal 2015 and Fiscal 2014, we realized a gross margin of 59.1% and 64.2%, respectively. The decrease of 5.1% in gross margin from the prior period was principally due to (i) a reduction in the absorption of fixed production costs, (ii) fluctuations in our product mix shipped from period to period and (iii) an increase in contract manufacturing net sales which carry lower gross margins. Gross margins are generally influenced by fluctuations in quarter-to-quarter production volume, fixed production costs and related overhead absorption, raw ingredient costs, inventory mark to market write-downs retail cooperative incentive promotion and the timing of shipments to customers which are factors of the seasonality of our sales activities and products.

Sales and marketing expense for Fiscal 2015 decreased $1.3 to $7.7 million as compared to $9.0 million for Fiscal 2014. The decrease in sales and marketing expense for Fiscal 2015 as compared to Fiscal 2014 was principally due to a decrease in advertising expenditures as we managed the scope and timing of our media and product promotion advertising campaigns from period to period.

G&A expenses decreased $1.1 million for Fiscal 2015 to $7.0 million as compared to $8.1 million in Fiscal 2014. The decrease in G&A expense for Fiscal 2015 as compared to Fiscal 2014 was principally due to a decrease in professional and legal fees related to certain, now resolved, litigation matters, and in corporate personnel expenses.

Research and development costs for Fiscal 2015 and 2014 were $1.1 million and $1.3 million, respectively. The decrease of $244,000 in research and development costs for Fiscal 2015 as compared to Fiscal 2014 was principally due a decrease in the scope, timing, cost and amount of research and development activity from period to period. Additionally, we continue to engage in other research and development activities that we determine are appropriate and we may increase our research and development activities in future periods.

Interest income and expense for Fiscal 2015 was $2,000 and $18,000, respectively, as compared to $4,000 and $10,000, respectively for Fiscal 2014. The decline in interest income in Fiscal 2015 as compared to Fiscal 2014 was due principally to lower invested cash balances from period to period. The increase in interest expense for Fiscal 2015 as compared to Fiscal 2014 was due principally to the interest expense incurred pursuant to the issuance of the Notes in December 2015.

As noted above, we have net operating loss carry-forwards for both federal and certain states. As a consequence of these loss carry-forwards, we did not incur income tax expense for Fiscal 2015 or Fiscal 2014.

As a consequence of the effects of the above, the net loss for Fiscal 2015, was $3.6 million, or ($0.22) per share, as compared to a net loss of $7.8 million, or ($0.47) per share, for Fiscal 2014.

Liquidity and Capital Resources

Our aggregate cash and cash equivalents as of December 31, 2016 were $441,000 as compared to $1.7 million at December 31, 2015. Our working capital was $2.8 million and $7.3 million as of December 31, 2016 and December 31, 2015, respectively. As discussed below, we have Secured Promissory Notes due and payable June 15, 2017. We believe that our current working capital and available 2015 Equity Line of Credit is at an acceptable and adequate level to support our business for at least the next twelve months ending March 31, 2018. Changes in our working capital for Fiscal 2016 is principally due to the net effect of (i) the classification of the $1.5 million Notes as a current liability due to its June 15, 2017 maturity date, (ii) cash used in operations of $472,000 comprised principally of (a) a net loss of $2.9 million and (b) an increase in accounts receivable of $1.8 million, offset by (c) a decrease in inventory and prepaid expenses of $1.6 million and $1.2 million, respectively, (c) an increase in accounts payable of $1.2 million, (iii) capital expenditures of $651,000 and (iv) the final installment payment of $100,000 pursuant to the terms of the Godfrey Settlement Agreement.

Secured Promissory Notes

On December 11, 2015, we executed two Subscription Agreements (the "Subscription Agreements") with the investors named therein (the "Investors") providing for the purchase of 12% Secured Promissory Notes – Series A ("Notes") in the aggregate principal amount of up to $3.0 million and warrants to purchase shares of our Common Stock (the "Warrants"). The Warrants grant the Investors the right to purchase 17,000 shares of common stock for every $500,000 of principal amount of Notes purchased by the Investors.

Notes in the amount of $1,500,000 and 51,000 Warrants, at an exercise price of $1.35 per share, which is equal to the closing price of our Common Stock on the date of investment, were issued by the Company and its wholly-owned subsidiaries PMI and Quigley Pharma Inc. (collectively, the "Obligors") and funded on December 11, 2015.

The Notes are secured by all of our tangible and intangible assets. The Notes bear interest at the rate of 12% per annum, payable semi-annually and the principal is due and payable on June 15, 2017. The Notes may be pre-paid at any time prior to maturity without penalty. The effective interest, inclusive of the Warrants and loan origination costs, is 14.3% per annum. The net proceeds from the Notes will be used for general working capital.

In connection with the issuance of the Notes, we entered into a security agreement with John E. Ligums, Jr., an Investor and a stockholder in the Company, as collateral agent for the Investors (the "Security Agreement") to secure the timely payment and performance in full of the Obligors' obligations under the Notes. Under the Security Agreement, the Obligors 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 the Obligors' personal property, inventory, equipment, general intangibles, cash and cash equivalents, and proceeds.

2014 Equity Line of Credit

On May 28, 2014, we entered into an equity line of credit agreement (such arrangement, the "2014 Equity Line") with Dutchess whereby Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,000,000 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. On May 29, 2014, we filed a registration statement with the SEC to register for sale up to 3,000,000 shares of our Common Stock and the registration statement was declared effective by the SEC on June 4, 2014.

During the period June 4, 2014 through September 30, 2014, we sold an aggregate of 2,561,520 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of $3.7 million. In June 2015, we sold an aggregate of 438,480 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of $524,000. The sales of the shares under the 2014 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Section 4(a)(2) (or Regulation D promulgated thereunder). At June 30, 2015, there were no shares of our Common Stock available for sale under the terms of the 2014 Equity Line. As a consequence of the utilization of the 2014 Equity Line, on July 23, 2015 we filed a post-effective amendment to the underlying registration statement for the 2014 Equity Line to terminate the registration statement.

2015 Equity Line of Credit

On July 30, 2015, we entered into a new equity line of credit agreement (such arrangement, the "2015 Equity Line") with 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. On August 4, 2015, we filed a registration statement for the underlying shares of the 2015 Equity Line with the SEC and the registration statement was declared effective by the SEC on August 21, 2015.

We may, at our discretion, draw on the 2015 Equity Line from time to time, as and when we determine appropriate in accordance with the terms and conditions of the 2015 Equity Line. The maximum number of shares that we are entitled to put to Dutchess in any one draw down notice shall not exceed 500,000 shares with a purchase price calculated in accordance with the 2015 Equity Line. We may deliver a notice for a subsequent put from time to time, following the one day pricing period for the prior put.

The purchase price is set at ninety-five percent (95%) of the volume weighted average price (VWAP) of the Common Stock during the one trading day immediately following our put notice. We have the right to withdraw all or any portion of any put, except that portion of the put that has already been sold to a third party, including any portion of a put that is below the minimum acceptable price set forth on the put notice, before the closing. In the event Dutchess receives more than a five percent (5%) return on the net sales for a specific put, Dutchess must remit such excess proceeds to us; however, in the event Dutchess receives less than a five percent (5%) return on the net sales for a specific put, Dutchess has the right to deduct from the proceeds of the put amount on the applicable closing date so Dutchess's return will equal five percent (5%).

There are put restrictions applied on days between the draw down notice date and the closing date with respect to a particular put. In addition, Dutchess is not obligated to purchase shares if Dutchess' total number of shares beneficially held at that time would exceed 4.99% of the number of shares of Common Stock as determined in accordance with Rule 13d-1(j) of the Securities Exchange Act of 1934, as amended. In addition, we are not permitted to draw on the facility unless there is an effective registration statement to cover the resale of the shares.

During the period from August 21, 2015 through December 31, 2015 and Fiscal 2016, we sold an aggregate of 750,000 and zero shares, respectively, of our Common Stock to Dutchess under and pursuant to the 2015 Equity Line and we derived net proceeds of $1.0 million. The sales of the shares under the 2015 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Section 4(2) (or Regulation D promulgated thereunder). At December 31, 2016 we have 2,450,000 shares of our Common Stock available for sale to Dutchess, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

Our future contractual obligations and commitments at December 31, 2016 consist of the following (in thousands):

Year	Employment Contracts	Notes	Total
2017	$ 1,025	$ 1,500	$ 2,525
2018	512	-	512
2019	-		-
2020	-		-
2021	-		-
Total	$ 1,537	$ 1,500	$ 3,037

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 Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those 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 estimates and disclosures have been discussed with the Audit Committee of our Board of Directors. A discussion of our critical accounting policies, 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:

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 primary product, Cold-EEZE ® cold remedy lozenges, utilizes a proprietary zinc gluconate formulation which has been clinically proven to reduce the severity and duration of common cold symptoms. Factors considered in estimating the appropriate sales returns and allowances for this product include it being (i) a unique product with limited competitors, (ii) competitively priced, (iii) promoted, (iv) unaffected for remaining shelf-life as there is no product expiration date and (v) monitored for inventory levels at major customers and third-party consumption data. In addition to Cold-EEZE ® cold remedy lozenges, we market and distribute a variety of Cold-EEZE ® cold remedy QuickMelts ® , a Cold-EEZE ® cold remedy Oral Spray, Cold-EEZE ® Natural Allergy Relief caplets, Cold-EEZE ® Daytime and Nighttime Multi-Symptom Relief in a liquid form and Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu. We also manufacture, market and distribute an organic cough drop and a Vitamin C supplement. Each of the Cold-EEZE ® cold remedy Oral Spray and QuickMelts ® products, Cold-EEZE ® Natural Allergy Relief caplets, Cold-EEZE ® liquid forms, Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu and organic lozenge products carry shelf-life expiration dates for which we aggregate such new product market experience data and update our sales returns and allowances estimates accordingly. Sales allowances estimates are tracked at the specific customer and product line levels and are tested on an annual historical basis, and reviewed quarterly. Additionally, we monitor current developments by customer, market conditions and any other occurrences that could affect the expected provisions relative to net sales for the period presented.

Our return policy 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 fall 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 only accept return requests for product 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.

We classify product returns into principally three categories, (i) non-routine returns, (ii) obsolete product and (iii) product mix realignment by certain of our customers. “Non-routine” returns are defined as product returned to us as a consequence of unanticipated circumstances principally due to (i) retail store closings or (ii) unexpected poor retail sell through to consumers causing us to discontinue the product. “Obsolete” returns are defined as product returned to us as a consequence of product shelf-life “use by” expiration date. **“** Product mix realignment” returns are defined as product returned to us due to initiatives by the trade to discontinue purchasing certain of our products. Product mix realignment returns are generally nominal and are frequently related to discontinued or soon to be discontinued products.

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, 2016 and 2015 (in thousands):

	Amount
Return provision at December 31, 2014	$ 1,518
Net change in the return provision Fiscal 2015	(103)
Return provision at December 31, 2015	1,415
Net change in the return provision Fiscal 2016	(174)
Return provision at December 31, 2016	$ 1,241

For Fiscal 2016, 2015 and 2014, net sales of products with limited shelf-life and expiration dates were $5.4 million, $3.7 million and $5.1 million, respectively.

For Fiscal 2016, the return provision decreased by $174,000. The decrease in the return provision was principally due to (i) a charge of $869,000, including $806,000 for products with shelf-life expiration dates (obsolete returns), offset by (ii) net returns of $1.0 million associated principally with Fiscal 2016 and Fiscal 2015 received and processed during Fiscal 2016.

For Fiscal 2015, the return provision decreased by $103,000. The decrease in the return provision was principally due to (i) a charge of $886,000, including $514,000 for products with shelf-life expiration dates (obsolete returns), offset by (ii) net returns of $989,000 associated principally with Fiscal 2015 and Fiscal 2014 received and processed during Fiscal 2015.

A one percent deviation for these sales allowance provisions for the Fiscal 2016, 2015 and 2014 would affect net sales by approximately $266,000, $248,000 and $278,000, respectively. A one percent deviation for cooperative incentive promotions reserve provisions for Fiscal 2016, 2015 and 2014 could affect net sales by approximately $225,000, $224,000 and $263,000, respectively.

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. The new standard provides for a single five-step model to be applied to all revenue contracts with customers as well as requires additional financial statement disclosures that will enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows relating to customer contracts. Companies have an option to use either a retrospective approach or cumulative effect adjustment approach to implement the standard. As amended by ASU No. 2015-14 issued in August 2015, this ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. We do not intend to early adopt and are currently assessing the impact of this update, but preliminarily believe that its adoption will not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". The amendments in this update state that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued, when applicable). The amendments in this update are effective for the annual reporting period beginning after December 15, 2016 and for annual periods and interim periods thereafter. Early application is permitted. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11 "Simplifying the Measurement of Inventory" which requires an entity to measure inventory balances at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The adoption of this update did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02 "Leases". The new standard will require most leases to be recognized on the balance sheet which will increase reported assets and liabilities. Lessor accounting remains substantially similar to current guidance. The new standard is effective for annual and interim periods in fiscal years beginning after December 15, 2018, which for us is the first quarter of fiscal 2019 and mandates a modified retrospective transition method. We do not intend to early adopt and are currently assessing the impact of this update, but preliminarily believe that its adoption will not have a material impact on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting". The new standard simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU No. 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for financial statements that have not already been issued. We do not intend to early adopt but preliminarily believe the adoption of this update is not expected 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 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. The new guidance will be effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. Early adoption is permitted including adoption in an interim period. We do not intend to early adopt and we are currently assessing the impact of adoption of this update will have on our consolidated 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 should recognize the income tax consequences of an asset other than inventory when the asset transfer occurs. The new guidance will be effective for fiscal years beginning after December 15, 2017 and requires a modified retrospective adoption through a cumulative effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact of adoption of this update on our consolidated financial statements.

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. Our Notes bear interest at fixed rates, and therefore are not subject to market risk.

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of ProPhase Labs, Inc. and Subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2016. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ProPhase Labs, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Iselin, New Jersey
February 24, 2017

PROPHASE LABS, INC AND SUBSIDARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	December 31,	
	2016	2015
ASSETS		
Cash and cash equivalents (Note 2)	$ 441	$ 1,664
Accounts receivable, net (Note 2)	5,770	4,000
Inventory (Note 2)	2,736	4,331
Prepaid expenses and other current assets (Note 2)	680	1,884
Total current assets	9,627	11,879
Property, plant and equipment, net of accumulated depreciation of $5,134 and $4,708, respectively (Note 3)	3,175	2,950
Total assets	$ 12,802	$ 14,829
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Secured promissory notes, net (Note 5)	$ 1,490	$ -
Accounts payable	2,156	990
Accrued advertising and other allowances (Note 2)	2,805	2,508
Other current liabilities (Notes 4 and 5)	389	1,036
Total current liabilities	6,840	4,534
Secured promissory notes, net (Note 5)	-	1,466
Total long term liabilities	-	1,466
COMMITMENTS AND CONTINGENCIES (Note 9)	-	-
STOCKHOLDERS' EQUITY		
Preferred stock, authorized 1,000,000, $.0005 par value, no shares issued (Note 6)	-	-
Common stock, $.0005 par value; authorized 50,000,000; issued: 26,313,593 and 26,313,593 shares, respectively (Note 6)	13	13
Additional paid-in-capital	56,378	56,377
Accumulated deficit	(19,687)	(16,819)
Treasury stock, at cost, 9,232,817 shares (Note 6)	(30,742)	(30,742)
Total stockholders' equity	5,962	8,829
Total liabilities and stockholders' equity	$ 12,802	$ 14,829

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Net sales (Notes 2 and 12)	$ 21,014	$ 20,604	$ 22,070
Cost of sales (Note 2)	10,948	8,426	7,891
Gross profit	10,066	12,178	14,179
Operating expenses:			
Sales and marketing	7,084	7,698	8,965
Administrative	5,063	6,986	8,143
Research and development (Note 2)	575	1,078	1,322
Impairment charge (Note 10)	-	-	3,577
Total operating expense	12,722	15,762	22,007
Loss from operations	(2,656)	(3,584)	(7,828)
Interest income	1	2	4
Interest expense (Note 5)	(213)	(18)	(10)
Loss from operations before taxes	(2,868)	(3,600)	(7,834)
Income tax (Note 8)	-	-	-
Net loss	$ (2,868)	$ (3,600)	$ (7,834)
Basic and diluted loss per share:			
Net loss	$ (0.17)	$ (0.22)	$ (0.47)
Weighted average common shares outstanding:			
Basic and diluted	17,081	16,398	16,773

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDARIES
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 (Deficit)	Treasury Stock	Total
Balance at January 1, 2014	16,101,006	$ 11	$ 43,607	$ (5,385)	$ (25,637)	$ 12,596
Net loss				(7,834)		(7,834)
Share-based compensation expense			472			472
Common stock issued for services performed (Note 5)	300,000		393			393
Common stock granted pursuant to a compensation plan	128,327		179			179
Common stock issued (Note 6)	3,259,727	2	4,908			4,910
Treasury stock acquired puruant to a settlement agreement (Note 6)	(3,896,764)		5,105		(5,105)	-
Balance at January 31, 2014	15,892,296	13	54,664	(13,219)	(30,742)	10,716
Net loss				(3,600)		(3,600)
Issuance of warrants in connection with secure promissory notes (Note 5)			14			14
Share-based compensation expense			135			135
Common shares issued	1,188,480		1,564			1,564
Balance at December 31, 2015	17,080,776	13	56,377	(16,819)	(30,742)	8,829
Net loss				(2,868)		(2,868)
Share-based compensation expense			1			1
Balance at December 31, 2016	17,080,776	13	56,378	(19,687)	(30,742)	5,962

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (2,868)	$ (3,600)	$ (7,834)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	426	367	277
Amortization of loan origination and warrant expenses	24		
Gain on the sale of fixed assets	-	(9)	(6)
Impairment charge	-	-	3,577
Share-based compensation expense	1	135	1,044
Changes in operating assets and liabilities:			
Accounts receivable	(1,770)	1,836	(517)
Inventory	1,595	(1,039)	(771)
Prepaid expenses and other assets	1,204	(480)	397
Accounts payable	1,166	323	(344)
Accrued advertising and other allowances	297	(1,177)	838
Other operating assets and liabilities, net	(547)	147	123
Net cash used in operating activities	(472)	(3,497)	(3,216)
Cash flows from investing activities:			
Capital expenditures	(651)	(718)	(312)
Proceeds from the sale of fixed assets	-	9	6
Net cash flows used in investing activities	(651)	(709)	(306)
Cash flows from financing activities:			
Proceeds from issuance of common stock	-	1,564	4,910
Payment of long term obligation	(100)	(100)	(100)
Secured promissory note issuance costs	-	(20)	-
Proceeds from secured promissory note	-	1,500	-
Net cash provided by (used in) financing activities	(100)	2,944	4,810
Net increase (decrease) in cash and cash equivalents	(1,223)	(1,262)	1,288
Cash and cash equivalents at beginning of year	1,664	2,926	1,638
Cash and cash equivalents at end of year	$ 441	$ 1,664	$ 2,926
Supplemental disclosures of cash flow information:			
Interest paid	$ 190	$ 6	$ 10
Issuance of warrants in connection with secured promissory notes	$ -	$ 14	$ -
Treasury stock acquired pursuant to a settlement agreement	$ -	$ -	$ 5,105
Common stock issued, in lieu of cash, as payment for service	$ -	$ -	$ 393

See accompanying 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 manufacturer, marketer and distributor of a diversified range of homeopathic and health care products that are offered to the general public. We are also engaged in the research and development of potential over-the-counter ("OTC") drug, natural based health products along with supplement, personal care and cosmeceutical products.

Our primary business is the manufacture, distribution, marketing and sale of OTC homeopathic and health care and products, particularly cold remedy products, to consumers through national chain, regional, specialty and local retail stores. Our flagship brand is Cold-EEZE ® and our principal product is Cold-EEZE ® cold remedy zinc gluconate lozenges, proven in clinical studies to reduce the duration and severity of symptoms of the common cold. In addition to Cold-EEZE ® cold remedy lozenges, we market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE ® cold remedy QuickMelts ® , (ii) Cold-EEZE ® Gummies (see below) and (iii) Cold-EEZE ® cold remedy Oral Spray. Each of our Cold-EEZE ® QuickMelts ® products are based on our proprietary zinc gluconate formulation in combination with certain (i) immune system support, (ii) energy, (iii) sleep and relaxation, and/or (iv) cold and flu symptom relieving active ingredients. We also contract manufacture for third parties their branded OTC health care lozenges, however this operation is an extension of our OTC products and as such, we operate in one segment.

In Fiscal 2014, we introduced and began shipments in June 2014 our new Cold-EEZE ® Plus Natural Multi-Symptom QuickMelts ® . In Fiscal 2015, we introduced three new Cold-EEZE ® product line extensions: (i) a Cold-EEZE ® Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE ® Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE ® Natural Allergy Relief caplets for indoor and outdoor allergies. Shipments for these three new Cold-EEZE ® product line extensions began in the third quarter of Fiscal 2015. In Fiscal 2016, we expanded our Cold-EEZE ® product line further to include (i) Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu and (ii) Cold-EEZE ® Nighttime Multi-Symptom Relief for Cold and Flu QuickMelts ® . Shipments began for these two new products in the third quarter of Fiscal 2016.

Cold-EEZE ® is an established product in the health care and cough-cold market. For Fiscal 2016, 2015 and 2014, our revenues have come principally from (i) our OTC health care and cold remedy products and (ii) were related to markets in the United States.

Our business is subject to seasonal variations thereby impacting liquidity and working capital during the course of our fiscal year.

We use a December 31 year-end for financial reporting purposes. References herein to the fiscal year ended December 31, 2016 shall be the term "Fiscal 2016" and references to other "Fiscal" years shall mean the year, which ended on December 31 of the year indicated. The term the "we", "us: or the "Company" as used herein also refer, where appropriate, to the Company, together with its subsidiaries unless the context otherwise requires.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements ("Financial Statements") include the accounts of the Company and its wholly owned subsidiaries and Phusion Laboratories LLC ("Phusion"), a variable interest entity (see Note 10). All intercompany transactions and balances have been eliminated.

Seasonality of the Business and Liquidity

Our net sales are derived principally from our OTC health care and cold remedy products. Currently, our sales have historically been subject to fluctuations and influenced by the timing, length and severity of each cold season. Generally, a cold season is defined as the period of September to March when the incidence of the common cold and flu rises as a consequence of the change in weather and other factors. We have generally experienced higher levels of net sales in the first, third and fourth quarter along with a corresponding increase in marketing and advertising expenditures designed to promote our products during the cold season. Revenues and related marketing costs are generally at their lowest levels in the second quarter when consumer demand generally declines. We track health and wellness trends and develop retail promotional strategies to align our production scheduling, inventory management and marketing programs to optimize consumer purchases.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

As a consequence of the seasonality of our business, we realize variations in operating results and demand for working capital from quarter to quarter. As of December 31, 2016, we had working capital of approximately $2.8 million, we have $1.5 million of Secured Promissory Notes due and payable on June 15, 2017 (see Note 5) and we have 2,450,000 shares of our common stock, $.0005 par value ("Common Stock") available for sale under our 2015 equity line of credit (see Note 6). In January 2017 we entered into an asset purchase agreement which would provide significant liquidity (see Note 13) to the Company. While the closing of this proposed transaction is subject to stockholder approval and therefore, there can be no assurance that this proposed sale or any strategic initiative will be consummated, we believe our current working capital and our available equity line of credit is an acceptable and adequate level of working capital to support our business for at least the next twelve months ending March 31, 2018.

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 and intangible assets, impairment of property and equipment and intangible assets, 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.

Our primary product, Cold-EEZE ® cold remedy lozenges, utilizes a proprietary zinc gluconate formulation which has been clinically proven to reduce the severity and duration of common cold symptoms. Factors considered in estimating the appropriate sales returns and allowances for this product include it being (i) a unique product with limited competitors, (ii) competitively priced, (iii) promoted, (iv) unaffected for remaining shelf-life as there is no product expiration date and (v) monitored for inventory levels at major customers and third-party consumption data. In addition to Cold-EEZE ® cold remedy lozenges, we market and distribute a variety of Cold-EEZE ® cold remedy QuickMelts ® , a Cold-EEZE ® cold remedy Oral Spray, Cold-EEZE ® Natural Allergy Relief caplets, Cold-EEZE ® Daytime and Nighttime Multi-Symptom Relief in a liquid form and Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu. We also manufacture, market and distribute an organic cough drop and a Vitamin C supplement. Each of the Cold-EEZE ® cold remedy Oral Spray and QuickMelts ® products, Cold-EEZE ® Natural Allergy Relief caplets, Cold-EEZE ® liquid forms, Cold-EEZE ® Gummies Multi-Symptom Relief for Cold and Flu and organic lozenge products carry shelf-life expiration dates for which we aggregate such new product market experience data and update our sales returns and allowances estimates accordingly. Sales allowances estimates are tracked at the specific customer and product line levels and are tested on an annual historical basis, and reviewed quarterly. Additionally, we monitor current developments by customer, market conditions and any other occurrences that could affect the expected provisions relative to net sales for the period presented.

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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Inventory

Inventory is valued at the lower of cost, determined on a first-in, first-out basis (FIFO), or market. Inventory items are analyzed to determine cost and the market value and appropriate valuation adjustments are established. At December 31, 2016 and 2015, the financial statements include adjustments to reduce inventory for excess, obsolete or short-dated shelf-life inventory of $1.6 million, inclusive of adjustments of (i) $383,000 for product samples of TK Supplements ® products and (ii) $606,000 for Cold-EEZE ® Division products. At December 31, 2015, the financial statements include adjustments to reduce inventory for excess, obsolete or short-dated shelf-life inventory $501,000. The components of inventory are as follows (in thousands):

	December 31,	
	2016	2015
Raw materials	$ 1,404	$ 1,303
Work in process	466	530
Finished goods	866	2,498
	$ 2,736	$ 4,331

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. The depreciation expense is computed in accordance with the estimated asset lives (see Note 3).

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 requirements associated with the development of OTC and other personal care products in order to continue to compete on a national 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. Our OTC cold remedy 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 and trade accounts receivable.

We maintain cash and cash equivalents with certain major financial institutions. As of December 31, 2016, our cash and cash equivalents were $441,000 and our bank balance was $551,000. Of the total bank balance, $309,000 was covered by federal depository insurance and $242,000 was uninsured.

Trade accounts receivable potentially subjects us to credit risk. 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 broad range of customers includes many national chain, regional, specialty and local retail stores. During Fiscal 2016, 2015 and 2014, effectively all of our net revenues were related to domestic markets.

Our revenues are principally generated from the sale of OTC health care and cold remedy products which approximated 84%, 90% and 94% of total revenues for Fiscal 2016, 2015 and 2014, respectively. A significant portion of our business is highly seasonal, which causes major variations in operating results from quarter to quarter. The first and fourth quarters generally represent the largest sales volume for the OTC health care and cold remedy products.

Raw materials used in the production of the products are available from numerous sources. Certain raw material active ingredients used in connection with Cold-EEZE ® products are purchased from a single unaffiliated supplier. Should the relationship terminate or the vendor become unable to supply material, we believe that the current contingency plans would prevent a termination from materially affecting our operations. However, if the relationship was terminated, there may be delays in production of our products until an acceptable replacement supplier is located.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Long-lived Assets

We review the carrying value and useful lives 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 or the period over which they should be depreciated has changed. 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.

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.

Revenue Recognition

Sales are recognized at the time ownership is transferred to the customer. Revenue is reduced for trade promotions, estimated sales returns, cash discounts and other allowances in the same period as the related sales are recorded. 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.

Our return policy 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 fall 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 only accept return requests for product 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.

As of December 31, 2016 and 2015, we included a provision for sales allowances of $108,000 and $83,000, respectively, which are reported as a reduction to account receivables. Additionally, accrued advertising and other allowances as of December 31, 2016 include $1.2 million for estimated future sales returns and $1.5 million for cooperative incentive promotion costs. As of December 31, 2015, accrued advertising and other allowances include $1.4 million for estimated future sales returns and $786,000 for cooperative incentive promotion costs.

Shipping and Handling

Product sales carry shipping and handling charges to the purchaser, included as part of the invoiced price, which is classified as revenue. In all cases, costs related to this revenue are recorded in cost of sales.

Stock 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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Stock and stock options for purchase of our 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. In Fiscal 2016, 2015 and 2014, we charged to operations $1,000, $135,000 and $1.0 million, respectively, for share-based compensation expense for the aggregate fair value of stock and stock grants issued, and vested stock options earned.

Variable Interest Entity

The Joint Venture, of which we own a 50% membership interest, qualifies as a variable interest entity ("VIE") and we have consolidated the Phusion joint venture (see Note 10).

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 media advertising, presented as part of sales and marketing expense; cooperative incentive promotions and coupon program expenses, which are accounted for as part of net sales; and free product, which is accounted for as part of cost of sales. Advertising and incentive promotion costs incurred for Fiscal 2016, 2015 and 2014 were $9.7 million, $8.5 million and $10.9 million, respectively. At December 31, 2016 and 2015, prepaid expenses and other current assets included $263,000 and $854,000, respectively, relating to prepaid deposits for advertising and promotion programs scheduled principally for the first quarter of Fiscal 2017 and 2016, respectively.

Research and Development

Research and development costs are charged to operations in the period incurred. Expenditures for Fiscal 2016, 2015 and 2014 were $575,000, $1.1 million and $1.3 million, respectively. For Fiscal 2016, Fiscal 2015 and Fiscal 2014, research and development costs are related principally to new product development initiatives and costs associated with OTC health care and cold remedy products.

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 net current and non-current deferred tax asset is being provided (see Note 8).

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 uncertain tax positions will be recorded as interest or administrative expense, respectively.

The major jurisdictions for which we file income tax returns are the United States and the state of Pennsylvania.

Fair Value of Financial Instruments

Cash and cash equivalents, accounts receivable, accounts payable, accrued expense and notes payable are reflected in the Financial Statements at carrying value which approximates fair value.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Recently Issued Accounting Standards

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. The new standard provides for a single five-step model to be applied to all revenue contracts with customers as well as requires additional financial statement disclosures that will enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows relating to customer contracts. Companies have an option to use either a retrospective approach or cumulative effect adjustment approach to implement the standard. As amended by ASU No. 2015-14 issued in August 2015, this ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. We do not intend to early adopt and are currently assessing the impact of this update, but preliminarily believe that its adoption will not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". The amendments in this update state that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued, when applicable). The amendments in this update are effective for the annual reporting period beginning after December 15, 2016 and for annual periods and interim periods thereafter. Early application is permitted. The adoption of this update is not expected to have a material impact on our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11 "Simplifying the Measurement of Inventory" which requires an entity to measure inventory balances at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The adoption of this update did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02 "Leases". The new standard will require most leases to be recognized on the balance sheet which will increase reported assets and liabilities. Lessor accounting remains substantially similar to current guidance. The new standard is effective for annual and interim periods in fiscal years beginning after December 15, 2018, which for us is the first quarter of fiscal 2019 and mandates a modified retrospective transition method. We do not intend to early adopt and are currently assessing the impact of this update, but preliminarily believe that its adoption will not have a material impact on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting". The new standard simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU No. 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted for financial statements that have not already been issued. We do not intend to early adopt but preliminarily believe the adoption of this update is not expected 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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

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. The new guidance will be effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. Early adoption is permitted including adoption in an interim period. We do not intend to early adopt and we are currently assessing the impact of adoption of this update will have on our consolidated 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 should recognize the income tax consequences of an asset other than inventory when the asset transfer occurs. The new guidance will be effective for fiscal years beginning after December 15, 2017 and requires a modified retrospective adoption through a cumulative effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact of adoption of this update on our consolidated financial statements.

NOTE 3 – PROPERTY, PLANT AND EQUIPMENT

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

	December 31,		
	2016	2015	Estimated Useful Life
Land	$ 504	$ 504	
Buildings and improvements	3,016	3,016	10 - 39 years
Machinery and equipment	4,274	3,623	3 - 7 years
Computer equipment and software	319	319	3 - 5 years
Furniture and fixtures	196	196	5 years
	8,309	7,658	
Less: Accumulated depreciation	5,134	4,708	
	$ 3,175	$ 2,950	

Depreciation expense for Fiscal 2016, 2015 and 2014 was $426,000, $367,000 and $277,000, respectively.

NOTE 4 – OTHER CURRENT LIABILITIES

At December 31, 2016 and 2015, other current liabilities include $170,000 and $484,000, respectively, related to accrued compensation. At December 31, 2015, $100,000 is related to the Godfrey Settlement Agreement (see Note 5).

NOTE 5 – SECURED PROMISSORY NOTES AND OTHER OBLIGATIONS

Secured Promissory Notes

On December 11, 2015, we executed two Subscription Agreements with Investors providing for the purchase of the Notes in the aggregate principal amount of up to $3.0 million and warrants to purchase share of our Common Stock (the “Warrants”). The Warrants grant the Investors the right to purchase 17,000 shares of common stock for every $500,000 of principal amount of Notes purchased by the Investors.

NOTE 5 – SECURED PROMISSORY NOTES AND OTHER OBLIGATIONS - (continued)

Notes in the amount of $1.5 million and 51,000 Warrants, at an exercise price of $1.35 per share, which is equal to the closing price of our Common Stock on the date of investment, were issued by the Company and its wholly-owned subsidiaries Pharmaloz Manufacturing Inc. and Quigley Pharma Inc. (collectively, the "Obligors") and funded on December 11, 2015. We incurred loan origination costs of $22,000 which was recorded as a reduction of the Notes and the origination costs are charged to interest expense over the term of the loan. The Warrants have an exercise term equal to three years and are exercisable commencing on the date of issuance. The fair value of the Warrants at the date of grant was $14,000 which is recorded as a reduction of the Notes and is charged to interest expense over the term of the loan (see Note 6). At December 31, 2016, the $1.5 million Notes are reported net of $10,000 of the unamortized interest for the loan origination costs and unamortized interest for the Warrants. At December 31, 2016 and 2015, other current liabilities include $9,000 and $10,000 respectively for accrued interest under the terms of the Notes.

The Notes are secured by all of our tangible and intangible assets. The Notes bear interest at the rate of 12% per annum, payable semi-annually and the principal is due and payable on June 15, 2017. The Notes may be pre-paid at any time prior to maturity without penalty. The effective interest, inclusive of the Warrant and loan origination costs, is 14.3% per annum. At December 31, 2016 and 2015, we charged to interest expense $187,000 and $11,000, respectively, in connection with the Notes.

The offers and sales of the Notes and Warrants were made without registration under the Securities Act, or the securities laws of certain states, in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and Regulation D under the Securities Act and in reliance on similar exemptions under applicable state laws.

In connection with the issuance of the Notes, we entered into a security agreement with John E. Ligums, Jr. (an Investor and a stockholder in the Company), as collateral agent for the Investors (the "Security Agreement") to secure the timely payment and performance in full of the Obligors' obligations pursuant to the Notes. Under the Security Agreement, the Obligors grant 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 the Obligors' personal property, inventory, equipment, general intangibles, cash and cash equivalents, and proceeds.

Godfrey Settlement Agreement

In November 2004 we commenced an action against John C. Godfrey, Nancy Jane Godfrey, and Godfrey Science and Design, Inc. (together the "Godfreys") for injunctive relief regarding the ownership of the Cold-EEZE ® trademark. The Godfreys subsequently asserted against us counterclaims and sought monetary damages and injunctive and declaratory relief relative to the Cold-EEZE ® trademark and other intellectual property.

On December 20, 2012, we and the Godfreys, including the Estate of Nancy Jane Godfrey, entered into a Settlement Agreement and Mutual General Release (the "Godfrey Settlement Agreement"), pursuant to which we resolved all disputes, including claims asserted by us and counterclaims asserted against us in the action. Pursuant to the terms of the Godfrey Settlement Agreement, we paid the Godfreys $2.1 million in December 2012 and we paid four additional annual payments of $100,000 due each December of Fiscal 2013, 2014, 2015 and 2016. Each annual payment in the amount of $100,000 accrued interest at the per annum rate of 3.25%. The annual installment of $103,000, $107,000 and $110,000, inclusive of accrued interest, were paid in Fiscal 2016, 2015 and 2014, respectively. The Fiscal 2016 installment was the final required payment under the Godfrey Settlement Agreement. At December 31, 2015, other current liabilities include $100,000 related to the Godfrey Settlement Agreement. Under the Godfrey Settlement Agreement, the Godfreys assigned, transferred and conveyed to us all of their right, title, and interest in U.S. Trademark Registration No. 1,838,542 for the trademark Cold-EEZE ® , among other intellectual property associated with such trademark.

NOTE 6 – STOCKHOLDERS' EQUITY AND STOCK COMPENSATION

Our authorized capital stock consists of 50 million shares of Common Stock and 1 million shares of preferred stock, $.0005 par value ("Preferred Stock").

Preferred Stock

On June 16, 2015, our stockholders approved the change our state of incorporation from the State of Nevada to the State of Delaware pursuant to a plan of conversion ("Conversion Plan") and the filing of a certificate of incorporation in the State of Delaware. 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, 2016, no shares of Preferred Stock have been issued. Our board of directors has the full authority permitted by law to establish, without further stockholder approval, one or more series 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 amend from time to time our certificate of incorporation and bylaws to increase the number of authorized shares of Preferred Stock or Common Stock or to make other changes or additions.

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.

2014 Equity Line of Credit

On May 28, 2014, we entered into an equity line of credit agreement (such arrangement, the "2014 Equity Line") with Dutchess whereby Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,000,000 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. On May 29, 2014, we filed a registration statement with the SEC to register for sale up to 3,000,000 shares of our Common Stock and the registration statement was declared effective by the SEC on June 4, 2014.

NOTE 6 – STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

During the period June 4, 2014 through September 30, 2014, we sold an aggregate of 2,561,520 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of $3.7 million. In June 2015, we sold an aggregate of 438,480 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of $524,000. The sales of the shares under the 2014 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Section 4(a)(2) (or Regulation D promulgated thereunder). At June 30, 2015, there were no shares of our Common Stock available for sale under the terms of the 2014 Equity Line. As a consequence of the utilization of the 2014 Equity Line, on July 23, 2015 we filed a post-effective amendment to the underlying registration statement for the 2014 Equity Line to terminate the registration statement.

2015 Equity Line of Credit

On July 30, 2015, we entered into a new equity line of credit agreement (such arrangement, the "2015 Equity Line") with 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. On August 4, 2015, we filed a registration statement for the underlying shares of the 2015 Equity Line with the SEC and the registration statement was declared effective by the SEC on August 21, 2015.

We may, at our discretion, draw on the 2015 Equity Line from time to time, as and when we determine appropriate in accordance with the terms and conditions of the 2015 Equity Line. The maximum number of shares that we are entitled to put to Dutchess in any one draw down notice shall not exceed 500,000 shares with a purchase price calculated in accordance with the 2015 Equity Line. We may deliver a notice for a subsequent put from time to time, following the one day pricing period for the prior put.

The purchase price is set at ninety-five percent (95%) of the volume weighted average price (VWAP) of the Common Stock during the one trading day immediately following our put notice. We have the right to withdraw all or any portion of any put, except that portion of the put that has already been sold to a third party, including any portion of a put that is below the minimum acceptable price set forth on the put notice, before the closing. In the event Dutchess receives more than a five percent (5%) return on the net sales for a specific put, Dutchess must remit such excess proceeds to us; however, in the event Dutchess receives less than a five percent (5%) return on the net sales for a specific put, Dutchess has the right to deduct from the proceeds of the put amount on the applicable closing date so Dutchess's return will equal five percent (5%).

There are put restrictions applied on days between the draw down notice date and the closing date with respect to a particular put. During such time, we are entitled to deliver another draw down notice. In addition, Dutchess is not obligated to purchase shares if Dutchess' total number of shares beneficially held at that time would exceed 4.99% of the number of shares of Common Stock as determined in accordance with Rule 13d-1(j) of the Securities Exchange Act of 1934, as amended. In addition, we are not permitted to draw on the facility unless there is an effective registration statement to cover the resale of the shares.

During the period from August 21, 2015 through December 31, 2015, we sold an aggregate of 750,000 shares of our Common Stock to Dutchess under and pursuant to the 2015 Equity Line and we derived net proceeds of $1.0 million. The sales of the shares under the 2015 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Section 4(2) (or Regulation D promulgated thereunder). At December 31, 2016 we have 2,450,000 shares of our Common Stock available for sale to Dutchess, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

The 2010 Equity Compensation Plan

On May 5, 2010, our stockholders approved the 2010 Equity Compensation Plan which was subsequently amended, restated and approved by stockholders on April 24, 2011, and further amended and approved by stockholders on May 6, 2013, and further amended and approved by stockholders on May 24, 2016 (the "2010 Plan"). The 2010 Plan, as amended on May 24, increased the total number of shares of Common Stock that may be issued under the 2010 Plan by 700,000 to an aggregate equal to 3.2 million shares. At December 31, 2016, there were 1,699,000 options outstanding under the 2010 Equity Compensation Plan (see *"Stock Options"* below).

NOTE 6 – STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

Stock Options and Warrants Fair Value

All of our employees, including employees who are officers or members of the Board are eligible to participate in the 2010 Plan. Consultants and advisors who perform services for us are also eligible to participate in the 2010 Plan. For Fiscal 2016 and 2015, there were no options granted under the 2010 Plan. For Fiscal 2015, we issued 51,000 Warrants pursuant to the terms of the Subscription Agreements for the Notes (see Note 5). For Fiscal 2016 and 2014, there were no warrants issued. For Fiscal 2014 we granted, 147,500 options, to employees to acquire our Common Stock pursuant to the terms of 2010 Plan. Presented below is a summary of the terms of the grant of options and Warrants:

	Year Ended December 31,		
	2016	2015	2014
Number of options granted	-	-	147,500
Number of Warrants granted	-	51,000	-
Vesting period	-	none	none
Maximum term of option or Warrants from date of grant	-	3 years	7 years
Exercise price per share	-	$ 1.35	$ 1.39
Weighted average fair value per share of options and Warrants granted during the year	-	$ 0.26	$ 0.59

We used the Black-Scholes option pricing model during Fiscal 2015 and 2014 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 a range between 2.5 to 6.5 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.

Presented below is a summary of assumptions used in determining the fair value of the stock options and Warrants at the date of grant:

	Year Ended December 31,		
	2016	2015	2014
Expected option or Warrant life	-	3 years	3.5 years
Weighted average risk free rate	-	0.88%	0.10%
Dividend yield	-	0%	0%
Expected volatility	-	26.42%	52.43%

The fair value of the stock options and Warrants at the time of the grant in Fiscal 2015 and 2014 was $14,000 and $87,000, respectively. For Fiscal 2015 and 2014, stock options and Warrants granted were not subject to a vesting period. Additionally, the remaining vesting period for options originally issued in Fiscal 2010 of 200,000 was accelerated to be fully vested at December 31, 2014. The aggregate fair value of $217,000 for each of the stock options granted in Fiscal 2014 and the accelerated vesting period of previously issued options of $255,000 were charged to operations in Fiscal 2014. For Fiscal 2016, 2015 and 2014, we charged to operations $1,000, $135,000 and $472,000, respectively, for share-based compensation expense for the aggregate fair value of the vested stock options earned.

Stock Options

At December 31, 2016, all 1,699,000 of the options granted under the 2010 Equity Compensation Plan were vested. At December 31, 2016, there are 733,659 options available for grant to purchase shares of Common Stock that may be issued pursuant to the terms of the 2010 Plan.

NOTE 6 – STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

A summary of the status of our stock options granted pursuant the 2010 Plan as of December 31, 2016, 2015 and 2014 and changes during the years then ended is presented below (in thousands, except per share data):

	Year Ended December 31,					
	2016		2015		2014	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding - beginning of year	1,713	$ 1.21	1,740	$ 1.40	1,638	$ 1.60
Granted		-	-		148	1.39
Exercised	-	-			-	-
Cancelled	(14)	1.44	(27)	13.50	(46)	9.50
Options outstanding - end of year	1,699	$ 1.20	1,713	$ 1.21	1,740	$ 1.40
Options granted and subject to future vesting	-	$ -	4	$ 1.48	263	$ 1.54
Exercisable, at end of year	1,699		1,709		1,477	
Available for grant	734		20		20	

The following table summarizes information about stock options outstanding and stock options exercisable at December 31, 2016 (in thousands, except remaining life and per share data):

	Options Outstanding and Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share
$0.87 - $1.17	1,130	1.1	$ 1.02
$1.36 - $1.65	569	3.2	$ 1.57
Total	1,699		$ 1.37

The aggregate intrinsic value of (i) options outstanding, (ii) options outstanding and expected to vest in the future and (iii) options outstanding and exercisable at December 31, 2016 was $1.2 million, zero and $1.2 million, respectively.

Stock Option Exercises

There were no stock options exercised in Fiscal 2016, 2015 or 2014.

Stock Grants and Other Issuances

In December 2014, we issued 300,000 shares of our Common Stock valued at $1.31 per share for an aggregate of $393,000, as payment for a portion of the litigation costs incurred prior to December 31, 2014 related to the Settlement Agreement (defined below). The 300,000 shares of our Common Stock were issued pursuant to an exemption from registration under the Securities Act, by virtue of Section 4(2) of the Securities Act and by virtue of Rule 506 of Regulation D under the Securities Act.

In December 2014, the Compensation Committee of the Board of Directors granted Mr. Karkus 100,000 shares of Common Stock under the 2010 Plan valued at $139,000 as payment for a portion of his Fiscal 2014 bonus.

NOTE 6 – STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

The 2010 Directors Equity Compensation Plan

On May 5, 2010, our stockholders approved the 2010 Directors' Equity Compensation Plan which was subsequently amended and approved by stockholders on May 6, 2013 (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 425,000 shares. We did not grant shares to Directors in Fiscal 2016 or 2015 for director compensation. In Fiscal 2014 we granted 28,327 shares of our Common Stock valued at $41,000, for director compensation. At December 31, 2016, there are 147,808 shares of Common Stock that may be issued pursuant to the terms of the 2010 Directors' Equity Compensation Plan.

Treasury Stock Acquired Pursuant to a Settlement Agreement

Effective September 4, 2014, we consummated a definitive, global Settlement Agreement ("Settlement Agreement") resolving all of our litigation with certain of the Company's former managers and with certain stockholders. The cases that have been settled include *ProPhase Labs, Inc. v. Quigley, et al.* , Court of Common Pleas of Bucks County, Pennsylvania, Civ. A. No. 2010-08227; *ProPhase Labs, Inc. v. Quigley, et al.* , Court of Common Pleas of Bucks County, Pennsylvania, Civ. A. No. 2011-09815; the appeal filed by the plaintiff in the matter *Quigley v. ProPhase Labs. Inc.'s Officers and Directors, el al* , Court of Common Pleas of Philadelphia County, December Term, 2011, No. 111200409; together with certain ancillary litigation.

The Settlement Agreement amicably resolved these matters and provided, in part, that the parties adverse to the Company in the two Bucks County cases (i) returned to the Company 3,896,764 shares of the Company's Common Stock for which they were listed as the record owners to the Company; and (ii) paid $440,000 to the Company. In addition, the Company paid $500,000 to the benefit of one of the defendants and $37,000 to a third party, to defray certain costs and expenses associated with the Settlement Agreement. Exclusive of legal related costs, the payments received and the payments made pursuant to the Settlement Agreement resulted in a net charge to administrative expense of $97,000 for Fiscal 2014. Pursuant to the Settlement Agreement, the parties also agreed to (i) a mutual release of all claims, (ii) a standstill agreement whereby, for a period of ten years, the adverse parties will not acquire Company shares, and (iii) the dismissal of all pending litigation involving the Company, its directors and affiliates on the one hand, and the other parties.

The 3,896,764 shares of Common Stock received pursuant to the terms of the Settlement Agreement were recorded as treasury stock and as an additional contribution to our additional paid-in capital, valued at $5.1 million, or $1.31 per share, representing the fair value of the shares at September 4, 2014.

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 2016, 2015 and 2014 were $121,000, $134,000 and $101,000, respectively.

NOTE 8 – INCOME TAXES

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

	Year Ended December 31,		
	2016	2015	2014
Current			
Federal	$ -	$ -	$ -
State	-	-	-
	-	-	-
Deferred			
Federal	(936)	(1,403)	(2,471)
State	(66)	(73)	(74)
	(1,002)	(1,476)	(2,545)
Total	$ (1,002)	$ (1,476)	$ (2,545)
Income taxes from continuing operations before valuation allowance	$ (1,002)	$ (1,476)	$ (2,545)
Change in valuation allowance	1,002	1,476	2,545
Income tax (benefit)	-	-	-
Total	$ -	$ -	$ -

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

	Year Ended December 31,		
	2016	2015	2014
Statutory rate - federal	$ (975)	$ (1,224)	$ (2,662)
State taxes, net of federal benefit	(41)	(305)	(51)
Permanent differences and other	14	53	168
Income tax from continuing operation before valuation allowance	(1,002)	(1,476)	(2,545)
Change in valuation allowance	1,002	1,476	2,545
Income tax (benefit)	-	-	-
Total	$ -	$ -	$ -

The components of permanent and other differences are as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Permanent items:			
Meals and Entertainment	$ 14	$ 7	$ 7
Return to provision adjustment	-	-	-
Charitable contributions	-	-	1
Share-based compensation expense for stock options granted	-	46	160
	$ 14	$ 53	$ 168

NOTE 8 – INCOME TAXES - (continued)

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,		
	2016	2015	2014
Net operating loss and capital loss carryforward	$ 18,019	$ 16,921	$ 14,983
Consulting-royalty costs	-	(8)	39
Trademark	576	671	752
Investment in Phusion	938	1,103	(483)
Depreciation	(304)	(103)	(45)
Other	1,159	802	2,508
Valuation allowance	(20,388)	(19,386)	(17,754)
Total	$ -	$ -	$ -

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 loss ("NOL") carryforwards could be used can be predicted to be more likely than not. The net change in the valuation allowance for Fiscal 2016, 2015 and 2014 was $1.0 million, $1.6 million and $2.7 million, respectively. Certain exercises of options and warrants, and restricted stock issued for services that became unrestricted resulted in reductions to taxes currently payable and a corresponding increase to additional-paid-in-capital for prior years. In addition, certain tax benefits for option and warrant exercises totaling $6.5 million are deferred and will be credited to additional-paid-in-capital, and not income tax expense, if the NOL's attributable to these exercises are utilized. The net operating loss carry-forwards currently approximate $47.1 million for federal purposes will expire beginning in Fiscal 2020 through 2036. Additionally, there are net operating loss carry-forwards of $22.1 million for state purposes that will expire beginning in Fiscal 2020 through 2036.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

Employment Agreements

On January 14, 2015, we entered into new employment agreements, effective as of January 1, 2015, with Mr. Karkus and Mr. Cuddihy. These January 2015 employment agreements supersede the 2012 Employment Agreements that had been scheduled to terminate on July 15, 2015. On May 29, 2015 we entered into amended and restated employment agreements with each of Mr. Karkus and Mr. Cuddihy (the "2015 Employment Agreements"). The Employment Agreements supersede the employment agreements of Messrs. Karkus and Cuddihy, dated January 1, 2015. The 2015 Employment Agreements were approved by our Compensation Committee.

Under his new amended and restated employment agreement, Mr. Karkus agreed to an annual base salary of $675,000 as Chief Executive Officer. Mr. Karkus is eligible to receive an annual increase in base salary and may be awarded a bonus in the sole discretion of the Compensation Committee and also will receive regular benefits routinely provided to other senior executives of the Company. In the event of the termination by the Company of the employment of Mr. Karkus without cause or due to a voluntary resignation by Mr. Karkus with Good Reason (as defined in his employment agreement), Mr. Karkus will be paid 1.5 times his base salary ("Mr. Karkus Severance"), with one-half of such amount as a lump sum severance payment in cash and the remaining one-half paid in 12 equal consecutive, monthly installments commencing on the first business day of the month following the effective date of the termination; and all of the stock options and/or restricted stock held by Mr. Karkus will automatically vest concurrently upon such termination of employment, regardless of any prior existing vesting schedules. If Mr. Karkus is terminated without cause or leaves with Good Reason in contemplation of (or within 24 months following) a change in control of the Company, then, in lieu of the Mr. Karkus Severance payment described above, Mr. Karkus will instead receive a one-time severance payment in cash equal to the greater of (i) $1.5 million, and (ii) 199 percent of his average annual total Form W-2 compensation for the three calendar years immediately preceding the date of termination.

NOTE 9 – COMMITMENTS AND CONTINGENCIES - (continued)

Under his new amended and restated employment agreement, Mr. Cuddihy agreed to an annual base salary of $350,000 as Chief Financial Officer and Chief Operating Officer. Mr. Cuddihy is eligible to receive an annual increase in base salary and may be awarded a bonus in the sole discretion of the Compensation Committee and also will receive regular benefits routinely provided to other senior executives of the Company. In the event of the termination by the Company of the employment of Mr. Cuddihy without cause or due to a voluntary resignation by Mr. Cuddihy with Good Reason (as defined in his Employment Agreement), Mr. Cuddihy will be paid 1.5 times his base salary ("Mr. Cuddihy Severance"), with one-half of such amount as a lump sum severance payment in cash and the remaining one-half paid in 12 equal consecutive, monthly installments commencing on the first business day of the month following the effective date of the termination; and all of the stock options and/or restricted stock held by Mr. Cuddihy will automatically vest concurrently upon such termination of employment, regardless of any prior existing vesting schedules. If Mr. Cuddihy is terminated without cause or leaves with Good Reason in contemplation of (or within 24 months following) a change in control of the Company, then, in lieu of the Mr. Cuddihy Severance payment described above, Mr. Cuddihy will instead receive a one-time severance payment in cash equal to the greater of (i) $900,000 and (ii) 199 percent of his average annual total Form W-2 compensation for the three calendar years immediately preceding the date of termination.

Future Obligations

We have approximate future obligations over the next five years as follows (in thousands):

Year	Employment Agreements	Notes	Total
2017	$ 1,025	$ 1,500	$ 2,525
2018	512	-	512
2019	-	-	-
2020	-	-	-
2021	-	-	-
Total	$ 1,537	$ 1,500	$ 3,037

Direct Response Contract

On June 30, 2015, we executed a Direct Response Production Agreement ("DRPA") with Pacific Custom Video Productions Inc. ("PCV") to produce a series of direct response television commercials for certain TK Supplements ® products at a cost of $300,000 which was charged to operations in Fiscal 2016 due to the expansion of our future consumer engagement strategy which is expected to include both e-commerce (direct-to-consumer) sales and traditional retail store distribution. In addition, we agreed to pay to PCV a three percent performance incentive in the form of a royalty (aka commission) of net sales collected, as defined in the agreement, of certain TK Supplements ® products marketed and promoted with PCV. For Fiscal 2016 and Fiscal 2015, we charged to operations $2,000 and zero for performance incentive fees pursuant to terms of the DRPA. The DRPA terminated effective February 2017.

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 10 – JOINT VENTURE

On March 22, 2010, we, Phosphagenics Limited ("PSI Parent"), an Australian corporation, Phosphagenics Inc. ("PSI"), a Delaware corporation and subsidiary of PSI Parent, and Phusion, a Delaware limited liability company, entered into a Limited Liability Company Agreement (the "LLC Agreement") of the Phusion joint venture and additional related agreements for the purpose of developing and commercializing, for worldwide distribution and sale, a wide range of non-prescription remedies using PSI Parent's proprietary patented TPM™ technology ("TPM"). TPM facilitates the delivery and depth of penetration of active molecules in pharmaceutical, nutraceutical, and other products. Pursuant to the LLC Agreement, we and PSI each own a 50% membership interest in the Phusion joint venture.

NOTE 10 – JOINT VENTURE – (continued)

In connection with the LLC Agreement, PSI Parent granted to us, pursuant to the terms of a License Agreement, dated March 22, 2010 (the "Original License Agreement"), (i) an exclusive, royalty-free, world-wide (subject to certain limitations), paid-up license to exploit OTC drugs and certain other products that embody certain of PSI Parent's TPM-related patents and related know-how (collectively, the "PSI Technology") and (ii) a non-exclusive, royalty-free, world-wide (subject to certain limitations), paid-up license to exploit certain compounds that embody the PSI Technology for use in a product combining one or more of such compounds with an OTC drug or in a product that is part of a regimen that includes the application of an OTC drug.

Pursuant to the Original License Agreement, we issued 1,440,000 shares of our Common Stock having an aggregate value of approximately $2.6 million to PSI Parent (such shares, the "PSI Shares", which PSI no longer owns), and made a one-time payment to PSI Parent of $1.0 million. We recorded an intangible asset valued at $3.6 million in March 2010 for the acquisition of the PSI Technology license.

In September 2014, we began implementing a series of new product development and pre-commercialization initiatives principally in the dietary supplement category. While several of our product development initiatives have advanced, including those specific to the dietary supplement category, our Phusion product development initiatives had not progressed to management's satisfaction.

During the third quarter of Fiscal 2014, our evaluation of the Company's progress in its new product development pipeline and delays in Phusion product development caused management to reassess projections (including income projections) relied upon in December 2013. Accordingly, management performed an impairment analysis for the period ended September 30, 2014 for the licensed technology. As a consequence of our impairment assessment, we determined that a full impairment occurred of the intangible asset, licensed technology. As a consequence, we charged to operations a $3.6 million impairment charge during the third quarter of Fiscal 2014.

PROPHASE LABS, INC. PROPHASE LABS, INC. FOR THE BENEFIT OF PHUSION LABORATORIES, LLC vs. Phosphagenics, Inc., Phosphagenics, LTD and Phusion Laboratories, LLC as a nominal defendant

On October 17, 2014, we initiated a demand for arbitration with the American Arbitration Association, case number 01-14-0001-7373. This demand for arbitration pertains to our Phusion joint venture and the matter is against PSI Parent and PSI (collectively known as the "Phosphagenics Entities").

In November 2016, the arbitration case was resolved and is now concluded. The arbitrator rejected all of the counterclaims asserted by Phosphagenics that ProPhase pay damages to Phosphagenics. The arbitrator also awarded to ProPhase recovery of approximately $350,000 (net of the payment of certain wind down expenses) that had been invested in the Phusion joint venture entity; terminated the intellectual property license that had been granted to Phusion from Phosphagenics; and directed the wind down and termination of Phusion Laboratories LLC, the joint venture entity.

Phusion a variable interest entity ("VIE)" and its financial statements are consolidated with the Company's financial statements for each period presented. As a consequence of Phusion qualifying as a VIE, the $350,000 award was effected through the transfer of cash from the Phusion bank account to the Company's solely controlled bank account and no gain or loss is realized as a result of the award. The steps to wind down and terminate Phusion Laboratories LLC, the joint venture entity, were initiated in December 2016 and it is expected to be completed in the first half of Fiscal 2017. The operations of the Phusion VIE, other than the impairment of the intangible asset (see above), were not material to any of Fiscal 2016, 2015 or 2014.

NOTE 11 – EARNINGS PER SHARE

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Diluted EPS also utilizes the treasury stock method which prescribes a theoretical buy back of shares from the theoretical proceeds of all options and warrants outstanding during the period. Since there is a large number of options and Warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

For Fiscal 2016, 2015 and 2014, diluted earnings per share is 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"), would have an anti-dilutive effect on the loss per share. For Fiscal 2016, 2015 and 2014, there were Common Stock Equivalents in the amount of 430,636, 337,186 and 598,609, respectively, which were in-the-money that were excluded in the earnings per share computation due to their dilutive effect. In addition, for Fiscal 2016, 2015 and 2014, there were Common Stock Equivalents in the amount of 403,000, 420,500 and 26,500, respectively, which were out-of-the-money (the exercise price of the stock option was greater than the average market price for the period), that were excluded in the earnings per share computation due to their dilutive effect.

NOTE 12 – SIGNIFICANT CUSTOMERS

Our products are distributed through national chain, regional, specialty and local retail stores throughout the United States. We also provide contract manufacturing services to third parties. Revenues for Fiscal 2016, 2015 and 2014 were $21.0 million, $20.6 million and $22.1 million, respectively. Two retail customers and one third party contract manufacturing customer accounted for 13.6%, 12.1% and 10.5%, respectively, of our Fiscal 2016 revenues. Two retail customers accounted for approximately 15.8% and 11.3%, respectively, of our Fiscal 2015 revenues. Three retail customers accounted for approximately 18.9%, 16.9% and 11.3%, respectively, of our Fiscal 2014 revenues. The loss of sales to any one or more of these large retail or 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 22% and two customers represented 25% of our total trade receivable balances at December 31, 2016 and 2015, respectively. Management believes that the provision for possible losses on uncollectible accounts receivable is adequate for our credit loss exposure. The allowance for doubtful accounts was zero for both December 31, 2016 and 2015.

NOTE 13 – SUBSEQUENT EVENT

Strategic Initiatives

In August 2016, management initiated a process to explore and evaluate a wide range of strategic initiatives and alternatives to further enhance stockholder value. These include the possible sale of core assets of the Company as well as a range of potential acquisitions. We engaged Bourne Partners, a boutique investment bank focused on the consumer health and pharmaceutical industries, to assist in our strategic review. This process has been approved by the Board of Directors.

On January 9, 2017, we announced that we had signed an asset purchase agreement, pursuant to which we have agreed to sell our Cold-EEZE ® Division to Mylan for $50 million before taking into account taxes, transaction costs and related deal expenses, restructuring costs and post-closing escrow requirements. We will retain ownership of our manufacturing facility and manufacturing business in Lebanon, Pennsylvania, and our headquarters in Doylestown, Pennsylvania, and our assets related to our ORXx and TK Supplements ® brands, product lines and operations. As part of the transaction, PMI will enter into a manufacturing and supply agreement with Mylan pursuant to which Mylan will purchase the current inventory of the Cold-EEZE ® Division and PMI will manufacture certain of the Cold-EEZE ® products for Mylan.

NOTE 13 – SUBSEQUENT EVENT – (continued)

The closing of the proposed sale, which is currently expected to occur in late March or April of 2017, is subject to the approval of the stockholders of the Company and other customary closing conditions. In connection with the execution of the asset purchase agreement, our executive officers and directors executed voting agreements. The voting agreements provide, among other things, for our executive officers and directors to vote all of the shares owned by them in favor of the proposed sale. The shares subject to the voting agreements represent approximately 24.1% of the outstanding common stock of the Company.

Since the proposed sale has not been approved by our stockholders and is subject to other conditions to be completed by Mylan and the Company prior closing, the Cold-EEZE ® Division does not meet the criterion for classification of an asset held for sale or as discontinued operations. As there can be no assurance that this proposed sale or any strategic initiative will be consummated, we intend to operate our business as discussed throughout these financial statements.

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 the Company's disclosure controls and procedures were 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). Based upon our review, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that the Company's internal controls over financial reporting were effective as of December 31, 2016.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during Fiscal 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 to the Company's Proxy Statement for the 2017 Annual Meeting of Stockholders (the "2017 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, 2016 and is hereby incorporated by reference.

Item 11. Executive Compensation

The information required under this item is incorporated by reference to the 2017 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 to the 2017 Proxy Statement.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated by reference to the 2017 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated by reference to the 2017 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Exhibits:

3.1	Certificate of Incorporation of the Company, (incorporated by reference to Exhibit 3.3 of Form 8-K filed on June 19, 2015).
3.2	By-laws of the Company as amended and restated effective June 18, 2015 (incorporated by reference to Exhibit 3.4 of Form 8-K filed on June 19, 2015).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Form 10-KSB/A filed on April 4, 1997).
4.2	Amended and Restated Rights Agreement, dated June 18, 2014 between the Company and American Stock Transfer and Trust Company, LLC (incorporated by reference to Exhibit 4.1 of Form 8-K filed on June 19, 2014).
4.3	Amended No. 1 to Amended and Restated Rights Agreement, dated January 6, 2017 between the Company and American Stock Transfer and Trust Company, LLC (incorporated by reference to Exhibit 4.2 of Form 8-K filed on January 9, 2017).
4.4	Form of Warrant (incorporated by reference to Exhibit 10.3 of Form 8-K filed on December 16, 2015).
4.5	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 Form 8-K filed on January 9, 2017).
10.1	Exclusive Representation and Distribution Agreement dated May 4, 1992 between the Company and Godfrey Science and Design, Inc. et al (incorporated by reference to Exhibit 10.2 of Form 10-KSB/A filed on April 4, 1997).
10.2	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 Form 8-K filed on August 19, 2009).
10.3	Limited Liability Company Agreement, dated March 22, 2010, between the Company, Phosphagenics Limited, Phosphagenics Inc., and Phusion Laboratories, LLC. (incorporated by reference to Exhibit 10.11 of Form 10-K filed on March 24, 2010).
10.4	Contribution Agreement, dated March 22, 2010, between the Company, Phosphagenics Limited, Phosphagenics Inc., and Phusion Laboratories, LLC. (incorporated by reference to Exhibit 10.12 of Form 10-K filed on March 24, 2010).
10.5	License Agreement, dated March 22, 2010, between the Company and Phosphagenics Limited. (incorporated by reference to Exhibit 10.13 of Form 10-K filed on March 24, 2010).
10.6	Amended and Restated License Agreement, dated March 22, 2010, between the Company, Phosphagenics Limited, Phosphagenics Inc., and Phusion Laboratories, LLC. (incorporated by reference to Exhibit 10.14 of Form 10-K filed on March 24, 2010).

10.7* Amended and Restated 2010 Equity Compensation Plan (incorporated by reference to Exhibit B of the Company's Annual Proxy Statement on Schedule 14A filed on April 18, 2016).

10.8* 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit C of the Company's Annual Proxy Statement on Schedule 14A filed on April 2, 2010).

10.9* Amendment to 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.3 of Form 8-K filed on May 10, 2010).

10.10* Form of Option Agreement pursuant to 2010 Equity Compensation Plan (incorporated by reference to Exhibit 10.4 of Form 8-K filed on May 10, 2010).

10.11* Form of Option Agreement pursuant to 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.5 of Form 8-K filed on May 10, 2010).

10.12* Form of Restricted Stock Award Agreement pursuant to 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.6 of Form 8-K filed on May 10, 2010).

10.13 Redemption Agreement with Phosphagenics Ltd. (incorporated by reference to Exhibit 10.1 of Form 8-K filed on September 23, 2011).

10.14 Investment Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of May 28, 2014 (incorporated by reference to Exhibit 10.1 of Form 8-K filed on May 28, 2014).

10.15 Registration Rights Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of May 28, 2014 (incorporated by reference to Exhibit 10.2 of Form 8-K filed on May 28, 2014).

10.16 Settlement Agreement and Mutual Release between ProPhase Labs, Inc. f/k/a The Quigley Corporation and John C. Godfrey, the Estate of Nancy Jane Godfrey, and Godfrey Science and Design, Inc. dated December 20, 2012. (incorporated by reference to Exhibit 10.25 of Form 10-K filed on March 28, 2013).

10.17* Amendment to 2010 Directors' Equity Compensation Plan (incorporated by reference to Appendix B of the Company's Annual Proxy Statement on Schedule 14A filed on April 3, 2013).

10.18* Global Settlement Agreement between ProPhase Labs, Inc. and certain of the Company's former managers and with certain shareholders dated September 4, 2014 resolving all litigation matters between the parties (incorporated by reference to Exhibit 99.3 of Form 8-K dated September 4, 2014)

10.19* Employment Agreement dated May 29, 2015 between Ted Karkus and the Company (incorporated by reference to Exhibit 99.2 of Form 8-K filed on June 1, 2015).

10.20* Employment Agreement dated May 29, 2015 between Robert V. Cuddihy, Jr. and the Company (incorporated by reference to Exhibit 99.1 of Form 8-K filed on June 1, 2015).

10.21 Registration Rights Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of July 30, 2015 (incorporated by reference to Exhibit 4.2 of the registration statement on Form S-8 filed on August 5, 2015).

10.22 Investment Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of July 30, 2015 (incorporated by reference to Exhibit 4.1 of the registration statement on Form S-8 filed on August 5, 2015).

10.23 Subscription Agreements by and between ProPhase Labs, Inc. and John Ligums and Justin Leonard dated December 11, 2015 (incorporated by reference to Exhibit 10.1 of Form 8-K filed on December 16, 2015).

10.24 Form of 12% Secured Promissory Note dated December 11, 2015 (incorporated by reference to Exhibit 10.2 of Form 8-K filed on December 16, 2015).

10.25 Form of Security Agreement by and between ProPhase Labs, Inc. and John Ligums dated December 11, 2015 (incorporated by reference to Exhibit 10.4 of Form 8-K filed on December 16, 2015).

14.1 Code of Ethics (incorporated by reference to Exhibit II of the Proxy Statement on Schedule 14A filed on March 31, 2003).

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

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

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
Registrant

Date: February 24, 2017

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

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

Principal Executive Officer

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

Principal Financial and Accounting Officer

By: */s/ Robert V. Cuddihy, Jr.*
Robert V. Cuddihy, Jr.
Chief Operating Officer and
Chief Financial Officer

Date: February 24, 2017

Directors

/s/ Jason Barr
Jason Barr

/s/ Mark Burnett
Mark Burnett

/s/ Louis Gleckel
Louis Gleckel

/s/ Mark Leventhal
Mark Leventhal

/s/ James McCubbin
James McCubbin

Date: February 24, 2017

EXHIBIT 21.1

SUBSIDIARIES OF PROPHASE LABS, INC.

Subsidiaries	State or other Jurisdiction of Incorporation	Ownership Percentage
Pharmaloz Manufacturing Inc.	Delaware	100%
Phusion Laboratories, LLC	Delaware	50%
Phusion Labs Manufacturing, 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, 2016.

EXHIBIT 23.1

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 Forms S8 (No. 333-73456, No. 333-61313, No. 333-10059, No. 333-14687, No. 333-26589, No. 333-132770 and No. 333-169697), 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) of our report dated February 24, 2017, on our audits of the consolidated financial statements of ProPhase Labs, Inc. and Subsidiaries as of December 31, 2016 and 2015 and for each of the years in the three-year period ended December 31, 2016, which report is included in this Annual Report on Form 10-K to be filed on or about February 24, 2017.

/s/ EISNERAMPER LLP

Iselin, New Jersey
February 24, 2017

EXHIBIT 31.1

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

I, Ted Karkus, certify that:

1. I have reviewed this 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: February 24, 2017

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

EXHIBIT 31.2

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

I, Robert V. Cuddihy, Jr., 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: February 24, 2017

By: */s/ Robert V. Cuddihy, Jr.*
Robert V. Cuddihy, Jr.
Chief Operating Officer and Chief Financial Officer
(Principal Accounting and Financial Officer)

EXHIBIT 32.1

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

I, Ted Karkus, Chief Executive Officer of ProPhase Labs, Inc., a Delaware corporation (the "Registrant"), in connection with the Registrant's Annual Report on Form 10-K for the period ended December 31, 2016, 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)

February 24, 2017

EXHIBIT 32.2

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

I, Robert V. Cuddihy, Jr., 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, 2016, 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/ Robert V. Cuddihy, Jr.

Robert V. Cuddihy, Jr.
Chief Operating Officer and
Chief Financial Officer
(Principal Accounting and Financial Officer)

February 24, 2017