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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018.

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____

000-54600

(Commission File No.)

PROLUNG, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-1922768**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

757 East South Temple, Suite 150
Salt Lake City, Utah 84012

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (801) 736-0729

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value $.001 per share

Indicate by check mark whether 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 during the preceding 12 months (or for 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 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 Report or any amendment to this Report. [ ]

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 "accelerated filer", "large 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]
	Emerging Growth Company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): YES [ ] NO [X]

The aggregate market value of the shares of common stock held by non-affiliates of the Registrant on June 30, 2018, was approximately $26,337,002, based upon 3,617,720 shares held by non-affiliates and an assumed fair market value of $7.28 per share. The Registrant's common stock does not trade on an established market; accordingly, fair market value is estimated based upon the last private purchase of the Company's common stock prior to June 30, 2018. Shares of common stock held by each officer and director, and by each other person who may be deemed to be an affiliate of the Registrant have been excluded.

As of April 16, 2019, the Registrant had 3,861,849 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE. None.

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PART I

This Annual Report on Form 10-K for the year ended December 31, 2018 (this "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"), that involve risks and uncertainties. Purchasers of any of the shares of common stock of ProLung, Inc. are cautioned that our actual results will differ (and may differ significantly) from the results discussed in the forward-looking statements. The reader is also encouraged to review other filings made by us with the Securities and Exchange Commission (the "SEC") describing other factors that may affect future results.

In this filing, ProLung, Inc. and its consolidated subsidiary are referred to as "ProLung" in addition to as the "Company" and versions of "we" or "us." Current and all granted trademarks include ProLungdx®, Fresh Medical Laboratories®, ProLung®, EPN Scan®, Electro Pulmonary Nodule Scanner (EPN Scan)®, and EPN Scanner®. Any other trademarks and service marks used in this Report are the property of their respective holders.

Item 1. Business

We are a medical technology company specializing in predictive analytic, early stage lung cancer risk testing, which we refer to as the "ProLung Test™." Our noninvasive, rapid and radiation-free ProLung Test was developed to assess the risk of malignancy in lung nodules found in the chest by a Computed Tomography "CT" scan, which is currently the primary method used in the United States ("US") for screening lung cancer. Lung cancer is the leading cause of cancer death in the US and the world according to American Cancer Society and World Health Organization. Earlier detection makes a substantial improvement in survival in individuals at high risk of lung cancer. Timely identification of malignancy is essential for patients and their families. Currently, patients often wait from three months to three and one-half years to have the risk of malignancy assessed through periodic CT scan surveillance. Until malignancy is determined to be likely, invasive biopsy and treatment are typically delayed. Current statistics reflect an average 17% survival rate at five years for those diagnosed with lung cancer.

We believe the ProLung Test, in conjunction with the discovery of a nodule by CT scan, provides a more rapid assessment of the risk of malignancy, which must be determined prior to biopsy. Since a lung biopsy is invasive and may require life threatening thoracic surgery, physicians, patients, and insurance companies typically delay biopsy and therapy until the risk of malignancy outweighs the risk of further diagnostic procedures. For these patients, the delay can reduce the time available to treat the tumor and may cause sustained emotional trauma.

The ProLung Test is designed to enable the practitioner to promptly assess the risk of malignancy in patients with lung nodules. The ProLung Test utilizes mass-averaging bioconductive technology. Mass-averaging bioconductive technology involves a sequential scanning process that measures significant differences in electrical conductance between cancerous and benign tissue. We plan to introduce the ProLung Test to the market as a standard predictive analytic test, without the need for transmission of a physical sample or specimen to a lab for analysis.

The ProLung Test acquires bioconductance measurement data by means of a patented probe and disposable diaphoretic electrodes placed on the patient's back and arms. The ProLung Test registers and evaluates measurement data derived from numerous pathways through the chest and is processed by a predictive analytic algorithm. The results are summarized in a report that can be used by the physician, in concert with other risk factors such as nodule size, family history, smoking history and gender, to evaluate patients with nodules. The ProLung Test requires minimal preparation and can be completed in fewer than 30 minutes. Most importantly, it guides or informs the physician's decision making without the time consuming, expensive and watchful waiting period. We believe the ProLung Test provides considerable cost savings when compared with today's status quo of patients undergoing repeated CT imaging studies and potentially unnecessary surgery.

ProLung licensed and developed the intellectual property and established the clinical research plan for the ProLung Test. Beginning in 2005, we embarked on clinical research which revealed the potential of our technology. In 2011, our research demonstrated the utility of the ProLung Test in lung cancer patients. To date, more than 550 patients have been tested using the ProLung Test in major cancer centers, such as MD Anderson, Loyola, UCLA, Stanford and Huntsman Cancer Institute, among others.

In the US, the push for early detection of lung cancer was greatly accelerated in 2013. Recognizing the dismal rate of lung cancer survival in the US, and the potential value of early detection, US guidelines were established for lung cancer CT screening. The guidelines provided for CT screening for lung cancer in asymptomatic adults aged 55 to 80 who have a 30 pack-year history of smoking and who currently smoke or have quit smoking in the past 15 years. This demographic group addresses a substantial portion of individuals of high risk of lung cancer. The US health care industry has generally recognized the need for technologies that will provide for earlier detection of cancers at a lower cost. Genetic biomarkers, protein panels, and breath analysis, among others, are in various stages of development. The ProLung Test is the first bioconductive technology that has been developed for the risk stratification of lung cancer. In February 2015, the US Center for Medicare and Medicaid Services announced its coverage of lung cancer screening by CT. This newly reimbursed screening procedure increased the number of individuals with suspicious lung nodules who may be candidates for the ProLung Test.

With the arrival of lung cancer screening recommendations, the large US market and government-backed reimbursement represent near term opportunities to accelerate diagnosis and treatment of lung cancer while reducing invasive biopsies and costs. We made US clearance and recognition of the ProLung Test our major priority, targeting lung cancer risk stratification and reducing time to treatment. We intend to seek government-backed reimbursement after FDA clearance. We are also interested in improving the cost of diagnosis and treatment with capitated providers. We believe the ProLung Test can be offered at a fraction of the cost of current standard of care which is repeat periodic imaging studies.

In May 2013, we achieved an important validation of our ProLung Test by receiving the "CE" mark in Europe. This certification verifies that the ProLung Test meets the regulatory requirements for the marketing and sale of the ProLung Test in the European Economic Area and European Free Trade Association Countries representing 513 million individuals and 28-member states. Our European clinical research includes testing more than 154 patients in Italy, Switzerland and Germany. We intend to seek European reimbursement approval and accelerate our marketing in Europe following receipt of US Food and Drug Administration, ("FDA") market clearance. We believe CT screening is likely to be implemented in Europe following the completion of several lung cancer screening trials already underway.

In September of 2013, we applied for marketing clearance under Section 510(k) from the FDA. After review of the 510(k) application, the FDA issued a letter to ProLung in May 2014 indicating that the FDA believed that our 510(k) would likely be found "Not Substantially Equivalent" to a legally marketed predicate device and the FDA believed ProLung may be suitable for *de novo* classification. Subsequently, we submitted a *de novo* petition in August of 2014. In February 2015, we received a "substantive review" from the FDA requesting additional information, regarding the risk classification of the test, the study design and study analysis. We held various meetings with the FDA and agreed to complete and include an additional clinical study which was already underway. Before the FDA can grant clearance of our *de novo* application, we must resubmit the application with positive results from validation studies demonstrating efficacy and repeatability and resolve any remaining issues previously identified by the FDA as well as address possible issues that may be identified in the future. We are in the process of preparing the necessary information requested by the FDA.

We have developed the quality management system as well as supply chain and the ability to fully manufacture the entire ProLung System in our own Salt Lake City facility. We have received ISO 13485 and other clearances and made certain refinements to the intellectual property that will further our capabilities, especially the development of the underlying predictive analytic algorithm and refinements to various software and physical components. Over the last five years, we have expanded our intellectual property portfolio, completed the development of the ProLung Test and manufacturing of the ProLung System and embarked upon clinical trials to provide validation to the medical community. The preliminary results of the clinical trial of 420 patients from 15 cancer and medical centers across the US, named PL-208, was announced in early 2019. We believe the results are an indicator that our ProLung Test can be used to indicate the risk of malignancy in pulmonary nodules. With the conclusion of this Study, the ProLung Team is eager to turn its focus to validating a number of already identified hardware, software, training and data collection improvements designed to strengthen our algorithm's performance and support a future submission to the FDA. The Company is also in the midst of evaluating a number of potential strategic partnerships to accelerate our development by expanding our financial and support network.

In late 2018, we announced final results of our Repeatability Study, named PL-209. The repeatability study enrolled sixty subjects, 30 male and 30 female, half of each gender with a body mass index (BMI) of 30 or more, and half with a BMI of 28 or less. Each subject was scanned twice on Day One and twice on Day Two. All scans were done by the same operator on the same ProLung System. Fifty-nine subjects produced evaluable data. Four models (algorithms) were tested. The study was conducted by ProLung. Study objectives included quantifying the effects of gender, body mass index (BMI), day-to-day subject variability and variability of a single device when volume-averaged thoracic bioconductance was measured with the ProLung Test. The repeatability study addressed several questions regarding use of the ProLung Test. One significant limitation of this study is that no subjects with known pulmonary nodules or malignancy were enrolled. It is unknown whether pulmonary nodules or malignancy affect the repeatability of the ProLung Test. While the study showed statistically significant variability of approximately 2% when testing the same subject twice on the same day, the clinical impact of this finding is unknown because it is not anticipated that patients will receive a second test on the same day in clinical use. While we note significant day-to-day variability when using an earlier model (the algorithm used in the Johns Hopkins Study, *Journal of Thoracic Oncology, 2012*), repeatability is markedly improved when using a more refined model.

PL-209 Study Conclusions

1. Same-day variability is statistically significant (average second score is 0.0214 points lower), but the clinical impact of this finding is unclear.
2. Day-to-day variability is impacted by the model (algorithm) chosen. One particular model with age (model 1b+age) has an ICC=0.958, indicating it is very repeatable.
3. Gender and BMI do not affect test performance.
4. Average test time is 18.5 minutes, with a range of 15-24 minutes.
5. The test is well tolerated and agreeable to test subjects.

The address of our principal executive office is:

ProLung, Inc.
757 East South Temple, Suite 150
Salt Lake City, Utah 84102

Our telephone number is (801) 736 – 0729.

Our facsimile number is (801) 906 – 0333.

Our e-mail address is ItsAboutTime@ProLungInc.com.

Our website may be viewed at www.ProLungInc.com. Information included in our website is not a part of this Report.

Company Overview

The Company was incorporated on November 19, 2004, as a Delaware corporation under the name of Hilltop Group Technologies Corp. In November 2006, the Company began operations and changed its name to Fresh Medical Laboratories, Inc., and in April 2017, the Company changed its name to ProLung, Inc.

On November 15, 2006, the Company entered into an exclusive license agreement with BioMeridian Corporation ("BMC"). The license agreement allowed the Company to include the use of certain BMC technologies in the development of a medical device.
ProLung is a clinical research company. Our expertise is managing lung cancer innovation. Our focus is to develop, market, and sell precision predictive analytical devices for a life-threatening disease. Our mission is to make a difference in time for underserved lung cancer patients.

If and when the Company has the required regulatory clearances, we plan to market, and sell the ProLung Test in the US, European, Latin American, Chinese and other international markets.

Lung Cancer Market Summary

According to the American Cancer Society ("ACS"), lung cancer is the leading cause of cancer death among both men and women in the US; about one out of four cancer deaths in the US are from lung cancer. The ACS estimates that in 2017 more people in the United States will die of lung cancer than of colon, breast, and prostate cancers combined.

According to the World Health Organization ("WHO"), lung cancer is the most common cause of death from cancer worldwide and is estimated to be responsible for nearly one in five cancer related deaths. The overall ratio of mortality to incidence is 87%. Each year there are over 1.8 million new cases of lung cancer worldwide, as well as nearly 1.6 million deaths. The lifetime chance of developing lung cancer is 1:17 in women and 1:14 in men.

Until recently, asymptomatic lung cancer was detected only incidentally when looking for something else. Currently, a lung cancer screen now reimbursed by Medicare, is performed by low-dose computed tomography. This has led to a dramatic increase in number of individuals with lung nodules detected, which is intensifying the need for a risk stratification test such as the ProLung Test. The following is a summary of the principal markets for the Company's ProLung Test.

Lung Cancer Incidence and Mortality

	New Cases	Deaths
United States	222,500	155,870
European Union	313,000	268,00
China	653,000	597,000
World	1,825,000	1,590,000

Lung cancer patients face median five-year survival rates of only 17% (compared to 89% for breast cancer and 98% for prostate cancer). Survival rates of lung cancer lags behind that of other cancer rates due to a lack of early and effective detection, and a challenging biopsy. A significant amount of time is required to assess the risk under current guidelines. Should innovation reduce the time required for assessing the risk of malignancy, lung cancer mortality could approach that of other cancer rates. In those instances when lung cancer was detected in its earliest stage, the five-year survival improves to 80% or approximately an improvement of five times.

U.S. Market

Americans at high risk:

Region	***Population*** *(in millions)*	***At high risk*** *(in millions)*	**Market Channel**
United States	319	94	Direct & Indirect

Symptomatic:

Each year 225,500 are diagnosed with lung cancer. Approximately 90 percent of lung cancer patients are symptomatic at presentation.

Lung Cancer Screening:

Given the size of the US market and the progression of CT scan use in early detection, clearance and acceptance of the ProLung Test in the US is the major priority. The CDC estimates that there are 94 million Americans at risk of lung cancer (which includes current and former smokers). In the National Lung Cancer Screening Trial of 53,454 patients, approximately 24% of the CT scans performed were positive revealing a lung nodule suspicious for lung cancer that required follow-up. CT screening was recommended by the US Preventive Services Task Force on December 31, 2013, and Medicare began to pay for lung cancer screening on February 5, 2016. Based on these estimates, if the approximately 94 million Americans at risk for lung cancer received a low dose CT screen approximately 24% (or 23 million) Americans may reveal lung nodules requiring follow up. We believe these patients would be eligible to receive the ProLung Test.

In the US, 15 hospital groups participated in our clinical study (PL-208). If our *de novo* FDA clearance is granted, of which there can be no assurance, we plan to transition these hospitals involved in research to commercial placements of the ProLung Test System and consumable test kit.

European Market

ProLung plans to utilize its CE mark in conjunction with US clearance in the European Union and European Free Trade Association Countries which represents 513 million individuals and 28-member states. Europe has some of the highest smoking prevalence of any region in the world which has led to a high incidence of lung cancer. In 2012, the World Health Organization estimated that 268,000 individuals died from lung cancer and that more than 313,000 cases were diagnosed in the European Union.

It is estimated that 28% of Europeans smoke and approximately 133 million individuals are at high-risk of lung cancer. Applying the US rates in the published National Lung Screening Trial (2011), over 30 million of these individuals are estimated to have an indeterminate lung nodule and require follow-up to determine the risk of malignancy. As the number of individuals with indeterminate lung nodules continues to increase in Europe, risk stratification tools such as the ProLung Test are needed to close the gap between discovery of a nodule and the determination of malignancy.

China Market

According to the World Health Organization, the number of smokers in China is steadily growing and increasing at higher rates than any other world region. One in three of the world's cigarettes is smoked in China. The average Chinese smoker consumes 22 cigarettes per day. This is nearly a 50% increase from 1980. Overall, more cigarettes are smoked in China than in the next top 29 cigarette-consuming countries combined. Lung cancer is epidemic in China with 653,000 cases in 2012 and an estimated 597,000 deaths.

The government's smoking cessation campaign and interventions are poorly funded and weakly enforced, and certain provincial governments are somewhat dependent upon state-owned tobacco sales and taxation. However, China's Government is collaborating with pulmonology and radiology leadership to study low-dose CT screening for earlier detection of lung cancer. The government has also sponsored economic studies to investigate the reimbursement of lung cancer screening in the health insurance system.

As the number of individuals with indeterminate lung nodules continues to increase in China, risk stratification tools, such as the ProLung Test will be needed to close the gap between discovery of a nodule and the determination of malignancy. This clinical need for risk stratification may be multiplied if a lung cancer screening program is implemented in the Chinese healthcare system.

Latin American Market – potential market of 25 million patients

Nearly 10% of the world's smokers live in Latin America (i.e., more than 120 million). As yet, lung cancer screening is not widespread. As the number of individuals with indeterminate lung nodules increases in Latin America, another growing market will be available to the ProLung Test.

Latin America has an at-risk population for lung cancer of at least 120 million. In accordance with rates from the National Lung Screening Trial (2010), roughly 25 million individuals will have an indeterminate pulmonary lesion if screened and require follow up to determine the risk of malignancy. As the number of individuals with indeterminate lung nodules increases in Latin America, risk stratification tools, such as the ProLung Test, will be needed to close the gap between discovery of a nodule and the determination of malignancy.

Competition

The development and commercialization of new products to improve the accuracy and efficiency of risk stratification of lung cancer is competitive, and we expect considerable competition from major medical device companies, laboratory biomarker tests, and academic institutions that are conducting research in lung cancer. Extensive research and financial resources have been invested in the discovery and development of new lung cancer detection tests. Potential competing technologies include, but are not limited to, breath markers, sputum cytology and DNA-related markers, blood markers, radiography and CT imaging.

The timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. We believe the speed with which we can develop products, complete clinical trials and clearance processes, and supply commercial quantities to market are important competitive factors. We expect that competition among products approved for sale will be based on various factors including product efficacy, safety, reliability, availability, price, reimbursement, and patent position. We believe that our ProLung Test is superior or equivalent to existing alternatives in all of these areas, other than availability (in the US due to lack of FDA clearance) and reimbursement.

Business

ProLung Test

The ProLung Test is comprised of the following components:

- *ProLung System* - Each system, which will be sold to the customer, consists of the probe, scanner, tower, monitor, and keyboard which are all medical grade components available for sale in English, French, German, Spanish, and Italian versions. The pricing of the ProLung System may vary upon the volume of the ProLung Test Kits that a customer buys.

- *ProLung Test Kit* – ProLung Test Kit sales should provide near term and continual cash flow. Each single-use, disposable, ProLung Test Kit is sold in a nonsterile envelope that displays a unique identifier code that is required for access to a ProLung Test report, together with all the components necessary to assure precision test performance, patient comfort and hygiene. Each ProLung Test Kit includes six diaphoretic electrodes, one probe tip and one moistening sponge. Initially, ProLung plans to sell the ProLung Test Kit for $400 each, available in boxes of 10 and 40. Each ProLung Test Kit is encoded with a unique identifier number and bar code that releases a written test result to the ordering physician.

ProLung's novel mass-averaging bioconductive technology simultaneously considers data from multiple measurement pathways and utilizes a patented predictive analytic algorithm to combine the individual measurements into a weighted average composite score that indicates an increased or decreased risk of malignancy in the individual in which the nodule has been detected. No images are generated by the ProLung Test and extensive training is not required to interpret the composite score.

If required regulatory clearances are received, the ProLung Test will be introduced to the market as a standard predictive analytic test without the need for transmission of a physical sample or specimen. Instead, the ProLung Test acquires bioconductive measurement data by means of a patented probe and disposable diaphoretic electrodes placed on the back and hands. The data containing precision measurements is processed by a patented predictive analytic algorithm and a report is generated that may be used by the physician in addition to other risk factors, such as nodule size, family history, smoking history, and gender to evaluate patients with suspicious masses or lesions identified by CT scan. The ProLung Test is non-invasive, rapid and non-radiating. It requires minimal patient preparation and can be completed in fewer than 30 minutes.

The ProLung Test Procedure

1. The ProLung Test System is connected to the probe, to the electrode cables, and to the power supply. Following a brief power-on sequence, the ProLung Test completes self-diagnostics.
2. The patient is seated.
3. ProLung Test kit is opened and removed from its tamper-proof packaging.
4. Single-use diaphoretic electrodes are placed at sites on the patient's back and arms.
5. Session data is entered including technician name, physician name, report delivery method and patient data.
6. Testing begins, as prompted by the device, by applying the probe to acquire measurement data from sites on the chest, shoulders and arms.
7. Monitors the acquisition of real-time data. Should re-measurement be required, the device provides visual and audible notification that it has not received usable data.

Research and Clinical Trial Results

Our ProLung Test has been evaluated in four clinical trials and concluded a fifth clinical trial in 2018. We made modifications to the ProLung Test throughout the research process and will continue to attempt to improve its performance. A description of each clinical trial is below:

Proof of Principle - McHenry, IL (2005)

- *Description.* A blinded single-site study of 36 subjects was designed to detect differences in bioelectrical impedance measurements between biopsy-confirmed lung cancer subjects and age- and gender-matched control subjects. The trial was configured as a sequential design consisting of three individual cohorts. Following the completion of each cohort, the data was evaluated for the presence of a predictive model which would discriminate between the lung cancer patients and control subjects.

- *Results.* The First Cohort of 12 subjects could not be utilized for statistical analysis because of an incorrectly calibrated device. An algorithm or predictive model was derived in the Second Cohort of 14 patients which fully discriminated between lung cancer patients and healthy volunteers.

  Subsequent analysis of the Third Cohort offered potentially confounding results, but ProLung felt the hypothesis of feasibility of the device had been successfully demonstrated and that sufficient evidence of feasibility existed to proceed with further research.

Reliability and Repeatability — Salt Lake City, UT (2006)

- *Description.* A single-site study to evaluate the variability of the ProLung Test in 22 healthy volunteers.

- *Results.* Measurement variables evaluated were the maximum and minimum conductance. The maximum and minimum conductance values obtained from one operator making repeated measurements with the same device on volunteer subjects over two days of testing were comparable, with slightly lower standard deviations for maximum conductance readings and extremely high reliability indices for both measures. For both data sets, the same measurement points were found to have minimal variability (and maximal reliability) indices. The Electro Pulmonary Nodule Scan showed a reliability index of 0.99 and a correlation between device replicates of 0.98.

Efficacy and Safety in the Target Indication a.k.a. FML-204 — Baltimore, MD (2012)

- *Description*. This single arm, single site algorithm finding and internal validation trial was designed to assess efficacy and safety in the risk stratification of the presence of or absence of malignancy in patients symptomatic of lung cancer who have a suspicious mass as confirmed by CT scan.

- *Results.* Final results included the identification of an algorithm capable of 90% sensitivity (correctly identifying 26 of 29 malignant masses), 92% specificity (correctly identifying 11 of 12 non-malignant masses), and Receiver Operating Characteristic ("ROC") area (combined sensitivity and specificity) of 90% (correctly identifying 37 of 41 patients overall). Final results were presented in 2011 at the World Conference of the International Association for the Study of Lung Cancer and at the Annual Congress of the European Respiratory Society and were published in the April 2012 edition of the Journal of Thoracic Oncology.

  Though not part of the original study, a subsequent subset analysis was performed on Study subjects who had indeterminate results on FDG-PET scans (n=7). In this subset (3 benign, 4 malignant) the ProLung Test correctly predicted the risk of malignancy in the index nodule being assessed. These results were presented at the International Association for the Study of Lung Cancer World Congress in Denver, CO, in September 2015 and published in volume 10, number 9, Supplement 2, Journal of Thoracic Oncology, p. S305).

Repeatability a.k.a. PL-209 —Salt Lake City, Utah (2015)

- *Description***.** The repeatability study enrolled sixty subjects, 30 male and 30 female, half of each gender with a body mass index (BMI) of 30 or more, and half with a BMI of 28 or less. Each subject was scanned twice on Day One and twice on Day Two. All scans were done by the same operator on the same ProLung System. Fifty-nine subjects produced evaluable data. Four models (algorithms) were tested. The study was conducted by ProLung. Study objectives included quantifying the effects of gender, body mass index (BMI), day-to-day subject variability and variability of a single device when volume-averaged thoracic bioconductance was measured with the ProLung Test.

- *Final Results.* (1) Same-day variability is statistically significant (average second score is 0.0214 points lower), but the clinical impact of this finding is unclear (2) Day-to-day variability is impacted by the model (algorithm) chosen. One particular model with age (model 1b+age) has an ICC=0.958, indicating it is very repeatable. (3) Gender and BMI do not affect test performance. (4) Average test time is 18.5 minutes, with a range of 15-24 minutes. (5) The test is well tolerated and agreeable to test subjects. The repeatability study addressed several questions regarding use of the ProLung Test. One significant limitation of this study is that no subjects with known pulmonary nodules or malignancy were enrolled. It is unknown whether pulmonary nodules or malignancy affect the repeatability of the ProLung Test. While the study showed statistically significant variability of approximately 2% when testing the same subject twice on the same day, the clinical impact of this finding is unknown because it is not anticipated that patients will receive a second test on the same day in clinical use. While we note significant day-to-day variability when using an earlier model (the algorithm used in the Johns Hopkins Study, Journal of Thoracic Oncology, 2012), repeatability is markedly improved when using a more refined model.

Multicenter Study of the ProLung Test aka PL-208 – Multicenter (2018)

- *Description.* ProLung concluded a multicenter study to demonstrate safety and efficacy of the ProLung Test in the lung cancer risk stratification of patients with pulmonary lesions identified by CT. This study commenced in 2012 and can be found on clinical trials.gov ID NCT01566682. There have been 420 patients enrolled. The centers include: MD Anderson, Stanford, Huntsman Cancer Institute, Henry Ford Hospital, University of California Los Angeles Medical Center, Loyola, Greater Baltimore Medical Center, Intermountain Healthcare, University of California San Diego, Wake Forest, University of Minnesota Masonic Cancer Center and Providence Healthcare, Beth Israel Deaconess, Medical University of South Carolina and the Mayo Clinic.

  There were three Specific Aims of this study:

  - Optimize and confirm the stability of the ProLung Test risk-stratification algorithm in patients with a diagnosis.
  - Externally validate the efficacy of the ProLung Test risk-stratification algorithm by comparing the test result to the conclusive patient diagnosis.
  - Assess the safety and tolerability of the ProLung Test procedures.

  Final Results.

  The primary purpose of this study was to demonstrate the accuracy or efficacy of the ProLung test by comparing the ProLung results to the actual patients' diagnoses. The study had two phases (stabilization and validation). The first phase was a stabilization phase, which was two hundred patients set aside to train and optimize a predictive algorithm. In the stabilization phase, a classifier algorithm was derived utilizing the ProLung measurements combined with the patients age. The stabilization phase classifier algorithm was locked and subsequently applied to 174 patients in a validation phase. In the validation phase the classifier algorithm obtained a sensitivity of 68%, a specificity of 49%, positive predictive value of 70%, negative predictive value of 47%, and an overall accuracy of 61%.

  Safety Analysis – Adverse Events

  The study also evaluated safety of the ProLung Test. Of the 420 patients enrolled in PL-208. There were no serious or unexpected adverse events. Among the 420 enrolled patients there were 3/175 adverse events. The first patient complained of chest wall pain at the measurement point location which resolved shortly after the test. The second patient indicated that the patient's left pinky joint was hurt during the test. The pain resolved immediately upon completion of the test. The third patient experienced bruising at some measurement locations which was determined to be caused by a clotting disorder. This patient did not complain of any discomfort during the test. All patients who experienced an adverse event stated that they would agree to undergo measurement again. Two of the three adverse events came from patients from the same device operator. The Company suspected that the Operator may be pushing too hard during device measurement. This Operator was re-trained and no additional adverse events were reported.

  We believe the PL-208 results are an indicator that the ProLung Test is capable of identifying a signal that can be used to indicate the risk of malignancy in pulmonary nodules. With the conclusion of this Study, the ProLung Team has learned of improved measurement collection techniques and improved operator training that we believe may improve future performance. The Company is eager to turn its focus to validating a number of these already identified improvements including; training, data collection, software and hardware which are designed to strengthen the ProLung test performance and support a future submission to the FDA. The Company is also in the midst of evaluating a number of potential strategic partnerships to accelerate development.

Other Research

Mexico. In 2011, ProLung supported a study with a hospital located in Mexico City. The study was administered by ProLung's partner who was pursuing a joint venture license for the Mexico territory. The partner eventually abandoned the study. After receiving preliminary test results, ProLung had reason to question the quality of the data being gathered and withdrew its support of the study.

China. We issued a license to an entity conducting research in China in 2013. This Chinese researcher has independently changed the measurement collection methodology and classifier algorithm of the device. Preliminary results of research in China have been presented at the 2017 American Thoracic Society International Conference Poster Session. Our licensee is currently conducting a 450 patient Validation Study in China using the ProLung technology with the modified measurement collection methodology and modified classifier algorithm. The study is expected to complete recruitment in 2019.

In January 2019, ProLung amended the ProLung China license. The Amendment extends the exclusivity of our licensees' license and allows ProLung to pursue a US FDA pre-submission review using the licensee's Chinese clinical Protocol. The purpose of the US FDA pre-submission is to obtain the FDA's feedback regarding the use of Chinese clinical data to demonstrate safety and efficacy for US FDA marketing clearance. ProLung may use the Chinese study data to support its US FDA application if it follows Good Clinical Practice, compliant with FDA regulations and is applicable to the US Population. The FDA recommends a pre-submission when seeking approval solely on foreign data. However, we believe it is likely FDA will require a smaller US Study replicating China results and showing repeatability. (Guidance for Industry and FDA Staff: FDA Acceptance of Foreign Clinical Studies Not Conducted Under IND Frequently Asked Studies, 21 CFR 314.106, 21 CFR 312.120).

Italy and Switzerland. Four centers in Italy and one center in Switzerland conducted research with the ProLung Test under the direction of local clinicians. At three of these sites, the research was part of a sales evaluation program for potential sale of the ProLung Test. Subject enrollment at these sites did not conform to research protocols utilized by ProLung. Consequently, the data generated by these clinics were not published by the Company.

At two other sites, Geneva and Florence, additional physician-sponsored research was conducted. It is not known whether these sites conducted research with the ProLung Test that was compliant with Good Clinical Practice or whether these patients conformed with the ProLung Test patient selection criteria. However, in June 2017, at the World Congress of Thoracic Imaging the Geneva site posted results indicating Test sensitivity of 66% and a specificity of 66%. The positive predictive value was 94% and negative predictive value was 20%. Geneva researchers concluded the ProLung Test could lower the need for invasive biopsies, especially in high risk patients. The small number of patients (n=27) precludes definitive conclusions.

Similarly, at a center in Florence, Italy, a study looked at 22 subjects undergoing the ProLung Test and PET CT scans. They reported a sensitivity of 75% and a specificity of 50%, with a positive predictive value of 94% and a negative predictive value of 17%. Researchers concluded that the high positive predictive value of the ProLung Test suggested utility in the evaluation of solitary pulmonary nodules, adding that further research was warranted. This was presented in the form of a poster at the 2017 American Thoracic Society Conference.

Intellectual Property

Protecting our intellectual property, exclusively licensed and owned, is essential to the creation of value in our business. We protect our intellectual property through confidentiality and trade secret agreements. We also have filed, and intend to continue to file, patent applications to protect key aspects of our technology.

Key Patents

Our patent protection is focused upon two key elements of the ProLung Test:

1. The proprietary design of the ProLung Test probe and related computer algorithm used to prepare its report.
2. The proprietary design of a group of algorithms or bioconductance profiles derived from our clinical research.

We intend to actively pursue our patent opportunities in the US and abroad. We have three issued US patents and license three additional US patents. Product specific patents may be filed for all final products and issuance may correspond closely with regulatory agency approval to provide the longest proprietary protection. Existing patent applications of ours and BMC, from whom we have exclusive licenses, are set forth below:

Title	Country	Type	Filed (6)	Application #	Patent #
Company Owned Patents					
Method for Diagnosing a Malignant Tumor	US (1)	ORD(1)	08/19/2013	13/970496	10,117,596 B2
	JP	PCT(5)	10/18/2013	2016-536073	6,337,267
Enhanced surface and tip for obtaining Bioelectrical signals	US	ORD (1)	5/5/2014	14/269,248	9,526,432
Method for diagnosing a disease	US	ORD (1)	10/25/2007	11/978,045	7,603,171
	US	CON (2)	10/13/2009	12/578,329	8,121,677
Licensed Patents					
Methods for obtaining quick, repeatable and non-invasive bioelectrical signals in living organisms	US	DIV (3)	11/26/2007	11/944,696	7,536,220
	US	ORD (1)	7/16/2003	10/621,178	7,542,796
Systems and methods of utilizing electrical readings in the determination of treatment	US	ORD (1)	7/20/2004	10/895,149	7,937,139
	JP	PCT (5)	1/15/2007	JP2007-522475	4,911,601

(1) Ordinary patent application - The first application for patent filed in the Patent Office without claiming priority from any application or without any reference to any other application under process in the Patent Office.
(2) Continuing patent application - A patent application which follows, and claims priority to, an earlier filed patent application.
(3) Divisional patent application - A patent application which has been divided from an existing application.
(4) International patent application - An international agreement for filing patent applications.
(5) Patent Cooperation Treaty Agreement
(6) All patents expire 20 years from the date filed.

ProLung Patent Applications

Country	Patent (Appln.) No.	Title
Australia	2013398354	Method for Diagnosing a Malignant Lung Tumor
Canada	2921690	Method for Diagnosing a Malignant Lung Tumor
China	201380079729.6	Method for Diagnosing a Malignant Lung Tumor
EP	2013789409	Method for Diagnosing a Malignant Lung Tumor
Korea	10-2016-7006923	Method for Diagnosing a Malignant Lung Tumor

Exclusive License Agreements

Effective November 2, 2006, we entered into an exclusive, worldwide, royalty-bearing License Agreement with BioMeridian Corporation ("BMC License") to use certain patents. Under the agreement, we have the right to the exclusive use of certain patents, patents pending, and related technology in its medical devices and other products until such time that we are no longer utilizing any form, in whole or in part, of the licensed technology to develop, market or sell our products or generate revenues. In return, we agree to incur, and have incurred, a minimum of $4,750,000 in costs to develop and market our products worldwide and to make royalty payments based on a percentage of the aggregate worldwide net sales (as defined in the agreement) of our medical device and other products to the extent they utilize the licensed technology. Specifically, we have licensed from BMC certain design features of the ProLung Test including the probe and system, which are described in US patent numbers 7536220, 7542796, and 7937139. In addition, pursuant to the BMC License, we have licensed from BMC the rights to the technology that controls the functionality of the probe.

Governmental Regulations

Our business is subject to extensive federal, state, local and foreign laws and regulations, including those relating to the protection of the environment, health and safety. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change, or new laws may be enacted.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations most relevant to our business.

US Food and Drug Administration regulation of medical devices.

The Federal Food, Drug and Cosmetic Act (the "FDCA") and FDA regulations establish a comprehensive system for the regulation of medical devices intended for human use. Our products include medical devices that are subject to these, as well as other federal, state, local and foreign, laws and regulations. The FDA is responsible for enforcing most of the federal laws and regulations governing medical devices in the United States.

The FDA classifies medical devices into one of three classes - Class I, Class II, or Class III depending on their level of risk and the types of controls that are necessary to ensure device safety and effectiveness. The class assignment is a factor in determining the type of premarket submission or application, if any, that will be required before marketing in the United States. We currently anticipate that the ProLung System will be classified as a Class II *de novo* medical device.

- Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to "general controls" -e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all three classes of medical devices.

- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and "special controls" -e.g., special labeling, compliance with industry standards, and post market surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification ("510(k)") process.

- The *de novo* application process provides a pathway to Class I or II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

- Class III devices present the highest risk. These devices generally are life-sustaining, life-supporting, for a use that is of substantial importance in preventing impairment of human health, present a potential unreasonable risk of illness or injury, or are not substantially equivalent to a legally marketed predicate device. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness. Class III devices are subject to general controls and typically require FDA clearance of a premarket approval ("PMA") application before marketing.

Unless it is exempt from premarket review requirements, a medical device must receive marketing authorization from the FDA prior to being commercially marketed, distributed or sold in the United States. The most common pathways for obtaining marketing authorization are 510(k) clearance and PMA.

510(k) pathway

The 510(k)-review process compares a new device to a legally marketed device. Through the 510(k) process, the FDA determines whether a new medical device is "substantially equivalent" to a legally marketed device (i.e., predicate device) that is not subject to PMA requirements. "Substantial equivalence" means that the proposed device has the same intended use as the predicate device, and either the same or similar technological characteristics as the predicate device, or if there are differences in technological characteristics, the differences do not raise different questions of safety and effectiveness as compared to the predicate, and the information submitted in the 510(k) demonstrates that the proposed device is as safe and effective as the predicate device.

To obtain 510(k) clearance, a company must submit a 510(k)-application containing sufficient information and data to demonstrate that its proposed device is substantially equivalent to a legally marketed predicate device. These data generally include non-clinical performance testing (e.g., software validation, animal testing, electrical safety testing), but clinical data may also be required. Typically, it takes six to twelve months for the FDA to complete its review of a 510(k) submission; however, it can take significantly longer and clearance is never assured. During its review of a 510(k), the FDA may request additional information, including clinical data, which may significantly prolong the review process. After completing its review of a 510(k), the FDA may issue an order, in the form of a letter, that finds the device to be either (1) substantially equivalent and states that the device can be marketed in the United States, or (2) not substantially equivalent and states that device cannot be marketed in the United States. Depending upon the reason(s) for the not substantially equivalent finding, the device may need to be approved through the PMA pathway (discussed below) prior to commercialization.

After a device receives 510(k) clearance, any modification that could significantly affect the safety or effectiveness of the device, or that would constitute a major change in its intended use, including significant modifications to any products or procedures, requires a new submission and clearance of a new 510(k). The FDA relies on each manufacturer to make and document its determination that a new 510(k) is (or is not) required, but the FDA can review any such decision and can disagree with a manufacturer's determination. If we are granted an initial 510(k), we may make minor product enhancements that we believe do not require new 510(k) clearance. If the FDA disagrees with our determination regarding whether a new 510(k) clearance was required for these modifications, we may need to cease marketing and/or recall the modified device. The FDA may also subject us to other enforcement actions, including, but not limited to, issuing a warning letter or untitled letter to us, seizing our products, imposing civil penalties, or initiating criminal prosecution.

De novo pathway

If, at the end of the FDA review of a 510(k), the FDA determines that a device is "Not Substantially Equivalent" ("NSE") due to the unavailability of a predicate device, a new intended use or different technological characteristics that raise different questions of safety and effectiveness, the FDA may indicate that the device may be suitable for review under the *de novo* classification process. If the FDA believes general controls or general and special controls may provide reasonable assurance of safety and effectiveness, the FDA may indicate in the NSE letter that the product may be appropriate for the *de novo* classification process under section 513(f)(2) of the Federal Food Drug and Cosmetic Act ("FD&C Act"). Inclusion of this language within an NSE letter does not indicate that sufficient information currently exists to support a successful *de novo* request, but simply indicates that given the risk profile of the device, it seems reasonable that *de novo* classification may be appropriate.

Alternatively, if a manufacturer believes their device is appropriate for classification into Class I or Class II and has determined, based on currently available information, there is no legally-marketed predicate device, they may submit a *de novo* request without a preceding 510(k) and NSE.

Once a *de novo* request is received (regardless of whether it is preceded by a 510(k) and NSE determination), the FDA will also check that the content of the *de novo* request includes the information required by section 513(f)(2) of the FD&C Act. *De novo* requests that lack information to determine whether a potential predicate device exists may be placed on hold. If the *de novo* request is missing information and/or data necessary to determine whether general controls or general and special controls can provide reasonable assurance of safety and effectiveness, the FDA may issue an additional information (AI) letter or request information via interactive review. If the *de novo* requestor fails to provide a complete response within 180 calendar days of the date of the AI request, the FDA will consider the *de novo* request to be withdrawn. If a *de novo* request is withdrawn due to failure to submit adequate information, a new *de novo* request is required in order to reinitiate review of the device under the *de novo* classification process.

If the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the *de novo* request. If a *de novo* request is granted, the FDA will issue you a written order granting the *de novo* request and identifying the classification of the device (either class I or class II). For class II devices, the FDA will also identify the applicable special controls. Effective on the date of the granting order, the requester may immediately begin marketing the device subject to the general controls and any identified special controls. The device may be used as a predicate device for future 510(k) submissions as appropriate.

Premarket approval pathway

Unlike the comparative standard of the 510(k) pathway, the PMA approval process requires an independent demonstration of the safety and effectiveness of a device. PMA is the most stringent type of device marketing application required by the FDA. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). A PMA application generally includes extensive information about the device including the results of clinical testing conducted on the device and a detailed description of the manufacturing process.

After a PMA application is accepted for review, the FDA begins an in-depth review of the submitted information. FDA regulations provide 180 days to review the PMA and make a determination; however, the review time is normally longer (e.g., 1-3 years). During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the data supporting the application and provide recommendations to the FDA as to whether the data provide a reasonable assurance that the device is safe and effective for its intended use. In addition, the FDA generally will conduct a preapproval inspection of the applicant's establishment to ensure compliance with the Quality System Regulation ("QSR"), which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices.

Based on its review, the FDA may (1) issue an order approving the PMA, (2) issue a letter stating the PMA is "approvable" (e.g., minor additional information is needed), (3) issue a letter stating the PMA is "not approvable," or (4) issue an order denying PMA. A company may not market a device subject to PMA review until the FDA issues an order approving the PMA. As part of a PMA approval (or 510(k) clearance), the FDA may impose post-approval conditions intended to ensure the continued safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution, and requiring the collection of additional clinical data. Failure to comply with the conditions of approval (or clearance) can result in materially adverse enforcement action, including withdrawal of the approval (or clearance).

Most modifications to a PMA approved device, including changes to the design, labeling, or manufacturing process, require prior approval before being implemented. Prior approval is obtained through submission of a PMA supplement. The type of information required to support a PMA supplement and the FDA's time for review of a PMA supplement vary depending on the nature of the modification.

Clinical trials

FDA generally prohibits the shipping and marketing of medical devices in the absence of a premarket clearance or approval (where required). However, the FDA's Investigational Device Exemption ("IDE") regulation exempts the provision of devices for use in certain types of clinical trials – i.e., clinical trials to collect safety and effectiveness data for investigational devices, and clinical trials evaluating new intended uses and/or certain modifications to a legally marketed device – from this prohibition. This regulation places significant responsibility on the sponsor of the clinical study including, but not limited to, choosing qualified investigators, monitoring the trial, submitting required reports, maintaining required records, and assuring investigators obtain informed consent, comply with the study protocol, control the disposition of the investigational device, submit required reports, etc.

Clinical trials of significant risk devices (e.g., implants, devices used in supporting or sustaining human life, devices of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health, or that otherwise present a serious risk to the health, safety, and welfare of a subject) require FDA and Institutional Review Board ("IRB") approval prior to starting the trial. FDA approval is requested through submission of an IDE application. Clinical trials of non-significant risk ("NSR"), devices (i.e. devices that do not meet the regulatory definition of a significant risk device) do not require FDA approval but do require IRB approval before starting. The clinical trial sponsor is responsible for making the initial determination of whether a clinical study is significant risk or NSR; however, a reviewing IRB and/or FDA may review this decision and disagree with the determination.

An IDE application must be supported by appropriate data, such as nonclinical performance data, animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the clinical study protocol is scientifically sound. There is no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place a clinical trial on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk.

As noted above, the FDA may require a company to collect clinical data on a device in the post market setting.

The collection of such data may be required as a condition of PMA approval. The FDA also has the authority to order, via a letter, a post market surveillance study for certain devices at any time after they have been cleared or approved.

Pervasive and continuing FDA regulation

After a device is placed on the market, regardless of its classification or premarket pathway, numerous additional FDA requirements generally apply. These include, but are not limited to:

- Establishment registration and device listing requirements;
- QSR, which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices;

- Labeling requirements, which mandate the inclusion of certain content in device labels and labeling, and when fully implemented, will generally require the label and package of medical devices to include a unique device identifier ("UDI"), and which also prohibit the promotion of products for uncleared or unapproved, i.e., "off-label," uses;

- Medical Device Reporting ("MDR"), regulation, which requires that manufacturers and importers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

- Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to the FDA recalls (i.e., corrections or removals) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; manufacturers and importers must keep records of recalls that they determine to be not reportable.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include, but is not limited to, the following sanctions:

- Notice of inspectional observations;

- Untitled letters or warning letters;

- Fines, injunctions and civil penalties;

- Recall or seizure of our products;

- Operating restrictions, partial suspension or total shutdown of production;

- Refusing our request for 510(k) clearance or premarket approval of new products;

- Withdrawing 510(k) clearance or premarket approvals that are already granted; and

- Criminal prosecution.

We are subject to unannounced device inspections by the FDA, as well as other regulatory agencies overseeing the implementation of and compliance with applicable state public health regulations. These inspections may include our suppliers' facilities.

Marketing Approvals Outside the United States

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

Europe

Under the European Union Medical Device Directive, or EU MDD, medical devices must meet the EU MDD requirements and receive a CE marking certification prior to marketing in the European Union, or EU, which we received for the ProLung Test in May 2013. CE marking is the uniform labeling system of products designed to facilitate the supervision and control of the EU concerning manufacturers' compliance with the various regulations and directives of the EU and to clarify the obligations imposed in the various legislative provisions in the EU. Use of a uniform product labeling indicates compliance with all the directives and regulations required for the application of such labeling, and it is effective as a manufacturer's declaration that the product meets the required criteria and technical specifications of the relevant authorities such as health, safety, and environmental protection. CE marking ensures free trade between the EU and European Free Trade Association countries (Switzerland, Iceland, Liechtenstein, and Norway) and permits the enforcement and customs authorities in European countries not to allow the marketing of similar products that do not bear the CE marking sign. Such certification allows, among other things, marking the products (according to various categories) with the CE marking and their sale and marketing in the EU.

CE marking certification requires a comprehensive quality system program, comprehensive technical documentation and data on the product, which are then reviewed by a Notified Body, or NB. An NB is an organization designated by the national governments of the EU member states to make independent judgments about whether a product complies with the EU MDD requirements and to grant the CE marking if we, and our product, comply with specified terms. After receiving the CE marking, we must pass a review carried out by the competent NB annually, under which it audits our facilities to verify our compliance with the ISO 13485 quality system standard.

Compliance with the ISO 13485 standard, for medical device quality management systems, is required for regulatory purposes. ISO standards are recognized international quality standards that are designed to ensure that we develop and manufacture quality medical devices. Other countries are also instituting regulations regarding medical devices. Compliance with these regulations requires extensive documentation and clinical reports for all our product candidates, revisions to labeling, and other requirements such as facility inspections to comply with the registration requirements.

China

China's medical device market, currently in a rapid state of expansion, is overseen by the China Food and Drug Administration, or CFDA (formerly the State Food and Drug Administration). The CFDA issues registration certificates required for all medical devices sold in China. The CFDA uses a risk-based system, and its approval process requires mandatory testing for Class II and III devices. Class II devices are moderate-risk devices and Class III devices are high-risk medical devices. Third-party review of devices is currently not allowed in China; only the CFDA is authorized to approve devices. The registration process requires the submission of a registration standard along with device samples for testing. Manufacturers of Class II and Class III medical devices are also required to demonstrate that the device has been approved by the country of origin with documents like a CE certificate, 510(k) letter and PMA approval and compliance with ISO 13485, and they may also be required to submit clinical data in support of their application. In addition to these requirements, all medical device manufacturers must also include product information in Chinese on all packaging and labeling. Manufacturers exporting medical devices to China must appoint several China-based agents to act on their behalf. These include a registration agent to coordinate the CFDA registration process, a legal agent to handle any adverse events reported with a registered device, including a product recall, and an after-sales agent to provide technical service and maintenance support.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law which prohibits, among other things, persons from knowingly and willfully soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or in return for the purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item, for which payment may be made in whole or in part under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent. The government may assert that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback law or related to off-label promotion constitutes a false or fraudulent claim for purposes of the federal false claims laws;

- the federal Health Insurance Portability and Accountability Act of 1996 fraud and abuse provisions, which prohibit executing a scheme to defraud any healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or making false statements or concealing a material fact relating to payment for healthcare benefits, items, or services;

- the Federal Physician Payments Sunshine Act within the Patient Protection and Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of protected health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Post-Marketing Regulations

Following approval of a new product, a company and the approved product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting for uses or in patient populations not described in the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such off label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, CMS, other divisions of the Department of Health and Human Services, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. Sales, marketing and scientific/educational programs must also comply with federal and state fraud and abuse laws. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of medical device products.

Our Marketing Process

We must receive separate regulatory approvals from the FDA and equivalent regulatory bodies in other countries for each of the devices before we can sell them commercially in the US or internationally. We cannot make the claims necessary to market any of our product candidates until we have completed the requirements for regulatory authorization. We do not know whether regulatory authorities will grant authorization for any of the products that we, our marketing partners, or distribution partners will develop.

A summary of the status of our marketing authorizations in the key initial markets we have identified is set forth below:

- **United States.** In September of 2013, we applied for marketing clearance under Section 510(k) from the FDA. After review of the 510(k) application, the FDA issued a letter to ProLung in May 2014 indicating that the FDA believed that our 510(k) would likely be found Not Substantially Equivalent to a legally marketed predicate device and the FDA believed ProLung may be suitable for *de novo* classification. Subsequently, we submitted a *de novo* petition in August of 2014. In February 2015, we received a Substantive Review of the *de novo* petition from the FDA requesting clarification of research to date, labeling, updated and additional safety testing, clarification of the Indications For Use (IFU) statement, software and results of the ongoing multisite trial (PL-208). We communicated with the FDA by conference call, in writing, and in a July 16, 2015, face-to-face Submission Issue Meeting. We prepared and provided a written response to the FDA, but it was never formally reviewed by the FDA because it did not include the PL-208 results and the FDA does not consider responses in a piecemeal fashion. Statutory requirements for an active FDA application mandated ProLung's withdrawal of the *de novo* petition while awaiting results of PL-208. In August 2015, the FDA considered the *de novo* petition withdrawn due to inadequate response because the written response did not include the PL-208 results, and as a result we will need to file an entirely new application. The issues that the FDA identified in the letter are as follows:

    - **Clinical and Statistical Concerns.** The FDA requested clarification on research to date and additional clinical evidence including a validation study.

    - **Risk Analysis Concerns.** The FDA asked us to address the risks associated with false positive and false negative test results.

    - **Device Description and Technology.** The FDA asked for clarification regarding the principle of operation of the device and expressed concerns regarding the accuracy of using direct current for device measurements.

    - **Electrical Safety and Electromagnetic Compatibility Concerns.** The FDA asked for additional information and specific testing mitigation for electrical shock in the event of an electrical failure.

    - **Software Concerns.** The FDA asked for additional information including a complete software description, an additional device hazard analysis and a description of unresolved anomalies.

    - **Indications for Use Concerns.** The FDA requested that the Indications For Use statement better define terms used such as "risk stratification" and "indeterminate significance" and include the clinical utility of the device.

    - **Additional Labeling Concerns.** The FDA requested that labeling include all the measurement point locations, the clinically determined accuracy of the device and the risks of false positive and false negative results.

In 2018, we pursued a pre-submission process with the FDA to get their input and buy-in on our proposed statistical analysis for the PL-208 Study. The FDA suggested that we change the endpoint of our study from relative risk to positive predictive value (PPV) and negative predictive value (NPV). FDA also had other statistical and clinical questions, concerns and recommendations.

In January 2019, ProLung amended the ProLung China license. The Amendment extends the exclusivity of our licensees' license and allows ProLung to pursue a US FDA pre-submission review using the licensee's Chinese clinical Protocol. The purpose of the US FDA pre-submission is to obtain the FDA's feedback regarding the use of Chinese clinical data to demonstrate safety and efficacy for US FDA marketing clearance. ProLung may use the Chinese study data to support its US FDA application if it follows Good Clinical Practice, compliant with FDA regulations and is applicable to the US Population. The FDA recommends a pre-submission when seeking approval solely on foreign data. However, we believe it is likely FDA will require a smaller US Study replicating China results and showing repeatability. (Guidance for Industry and FDA Staff: FDA Acceptance of Foreign Clinical Studies Not Conducted Under IND Frequently Asked Studies, 21 CFR 314.106, 21 CFR 312.120).

Before the FDA can grant clearance of our *de novo* application, we must resubmit the application with the results from the validation and repeatability studies and resolve or negotiate any existing and new issues identified by the FDA. We are hopeful regarding the resolution of any such issues. As a result of the face-to-face July 16, 2015 meeting with the FDA, submission of a new *de novo* application and possible changes in the FDA review team make it impossible to predict when, or if, clearance might occur with certainty, nor can we be certain that clearance under the *de novo* pathway or any other pathway ultimately will be granted.

- **European Union.** CE marking was granted as of May 10, 2013 for the ProLung Test which permits the product to be sold throughout the European Economic Area (European Union member states plus Iceland, Liechtenstein and Norway), Switzerland, and Turkey. CE marking requires manufacturers to maintain an ISO 13485 Quality System.

- **Latin America.** ProLung previously sponsored a pulmonary and lung cancer specific symposia in Latin America and developed relationships with key regional opinion leaders in lung cancer management. ProLung also discussed distribution and commercialization deals with distributors in Latin America. Based on primary physician feedback and response, ProLung expects a viable and strong market for a predictive analytic device such as the ProLung Test.

- **China.** The CFDA (previously known as the SFDA) roughly follows the FDA model and is the source of clearance for the marketing and sale of medical devices in China. To be sold in China, medical devices must be registered with Chinese health authorities. In February 2014, the Company's licensor in China received clearance to manufacture the device from the Beijing government. Additional clearances are required to market and sell the device in this market.

After each respective regulatory clearance is obtained, the next step in each of these markets is for insurance companies or government agencies, as applicable, to agree to reimburse providers for the ProLung Test. We have not commenced this process in the US or any other market, as we do not yet have marketing authorizations.

Manufacturing Requirements

As a manufacturer of medical devices, we must comply with the 21 CFR Part 820 Good Manufacturing Practice regulations established by the FDA. These requirements are meant to ensure that medical devices are safe and effective. We maintain a quality management system that includes standard operating procedures for key processes such as design, manufacturing, packaging, labeling, storage, installation, servicing, record keeping, complaint handling and corrective and preventative action. Our quality management system is currently ISO 13485 certified and is intended to meet the 21 CFR Part 820 Good Manufacturing Practice regulations. We will also be subject to similar requirements imposed by other countries.

Manufacturing

We currently manufacture the ProLung Test and the ProLung Test Kit. When volume requirements exceed current manufacturing capacity, we intend to utilize contract manufacturers for the physical manufacturing of our products. This may afford us numerous benefits, including:

- the ability to ramp up production quickly;

- access to leading technologies, supply chain networks and best-in-class manufacturing processes for its products;

- flexibility to use one or many manufacturers in many regions of the world to optimize costs, production volumes, material availability, lead times, and to meet various regional regulations.

We have interviewed, performed site visits, and qualified multiple, redundant contract manufacturers which may be required to produce our products. We have no contractual obligations with such contract manufacturers for the manufacturing of our products.

Our prospective contract manufacturers will source our product components from multiple specialized vendors that supply plastics, sheet metal, machining, cables, wire harnesses, and other computer hardware components. We maintain our own design control and ISO 13485 quality system.

Research and Development

The Company spent $2,036,792 and $1,630,837 on company-sponsored research and development during fiscal years ending December 31, 2018, and 2017, respectively.

Employees

As of April 16, 2019, we had six employees.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates.

We believe we will remain an "emerging growth company" through at least December 31, 2019.

Item 1A. Risk Factors

Our business, operations, and financial condition are subject to certain risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, our actual results will vary, and may vary materially, from those anticipated, estimated, projected, or expected. Among the key factors that may have a direct bearing on our business, operations or financial conditions are the factors identified below:

RISKS RELATED TO OUR STAGE OF DEVELOPMENT

We are a development stage company with limited revenue and no assurance of earning significant revenue over the long term.

We were organized in 2004 and since that date have experienced significant losses from operations. We are in the process of commercializing our proprietary ProLung Test in the US and Europe and seeking marketing clearance for the ProLung Test in the United States and expect to incur additional operating losses in the near term. We have generated limited revenue from the sale of our products and services. The amount of losses we will incur, and whether we will become profitable at all, are highly uncertain. Our net loss for the year ended December 31, 2017 was $5,369,312 and for the year ended December 31, 2018 was $7,709,282.

Our future success depends on our ability to begin generating revenues on a regular and continuing basis and to properly manage costs. Our ability to generate revenues depends on several factors, some of which are outside our control. These factors include our ability to obtain necessary government and regulatory marketing authorizations, our ability to successfully commercialize the ProLung Test, our ability to protect intellectual property related to the ProLung Test, our ability to obtain coverage and reimbursement for the test procedure from Medicare and other third- party payers, and our ability to effectively market our products. If we cannot expand our revenue significantly over the long term, we will not be profitable.

We are dependent upon financings to fund our operations and may be unable to continue as a going concern.

We do not generate sufficient cash flows from operations to meet the cash requirements of our operations and other commitments without raising funds through the sale of debt and/or equity securities. We do not expect to generate enough cash, if any, from operations to meet our requirements in the near term. Proceeds raised from funding activities, including the net proceeds from this offering, are required for us to have funds to meet our obligations for the foreseeable future. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing and generate positive cash flow from operations, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and it may not be able to continue operations.

We will need significant capital to execute our business plan.

We currently generate no revenue, and we require at least $2.0 million in capital each year to operate our business. We also anticipate requiring additional capital to conduct additional clinical studies prior to submitting an application for FDA clearance for our ProLung Test. If we obtain FDA clearance, of which there is no assurance, we will need to obtain significant additional capital in order to roll out our marketing plan.

As of December 31, 2018, we had a cash balance and pre-paid expenses totaling $273,539 and current liabilities of $507,353. We do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, could increase our expenses and require that our assets secure such debt. Moreover, any debt we incur must be repaid regardless of our operating results. Equity financing, if obtained, could result in dilution to our then existing stockholders. If such financing is not available on satisfactory terms, or at all, we may be required to delay, scale back or eliminate our testing and developing activities or, if we obtain FDA clearance, marketing efforts, which will harm our operations and financial condition, if we are unable to secure sufficient capital to fund our operations, we may have to discontinue operations and liquidate (and we anticipate that our liquidation value would be nominal).

We have issued significant indebtedness, and, if we are unable to repay or refinance it, our creditors could force us into bankruptcy.

As of December 31, 2018, we had outstanding Notes of $4,189,681. The balances of our loan obligations are scheduled to come due in 2020 and 2022. If we default under our loan obligations, and we do not have sufficient cash resources to repay the loan, our creditors would have the ability to force us into bankruptcy. As a result of any bankruptcy proceeding, if cash resources were depleted, it is doubtful that there will be any amount available for distribution to our stockholders.

Risks Related to Our Business and Industry

We are in the early stages of commercialization and our ProLung Test may never achieve commercial market acceptance.

Our ProLung Test is approved and commercially available only in a limited number of countries and will not be available for sale in other countries, including the United States, until clinical development is completed and regulatory authorizations are obtained. Following our *de novo* application for marketing clearance for the ProLung Test from the FDA, in February 2015, we received a letter from the FDA identifying many issues, questions, and concerns in our submission, including issues regarding our proposed risk classification for the test, the study design and analysis plan for the clinical trial intended to support our submission, along with certain other questions. In subsequent communications and meetings with the FDA, we succeeded in addressing a number of the FDA's concerns, and we were asked to complete a clinical study. In 2018, before breaking the study data blind and analyzing the amassed clinical data for our PL-208 study, we collaborated with the FDA through two formal Pre-Submission Meetings regarding our PL-208 Study Statistical Analysis Plan, study design, device output and statistical approaches. We received significant comments from the FDA, some but not all of which have been resolved.

The FDA will likely require additional clinical study work and resolve or negotiate the removal of the remaining issues previously identified by the FDA, as well as address issues to be identified in the future, before clearing the ProLung Test for marketing. This may never occur. Moreover, the successful commercialization of our product will require significant, time-consuming and costly sales and marketing efforts. If the commercialization of our ProLung Test is unsuccessful or we are unable to market our ProLung Test due to market developments, failure to obtain and maintain the regulatory authorizations necessary for our business to be commercially viable, development of alternative diagnostics or otherwise, we will be required to expend significant additional resources on research and development to improve our ProLung Test. The development of a new test will be subject to the risks of failure inherent in the creation of any innovative new medical technology. These risks include the possibilities that our test will not be effective or of acceptable quality, will fail to receive necessary regulatory authorizations, will be uneconomical to manufacture or market or does not achieve broad market acceptance, and that third parties market a superior or equivalent product. Even if our test is effective, it may not be accepted by patients or physicians. The failure of our research and development activities to result in any commercially viable products would have a material adverse effect on our business and financial condition.

We are reliant on a single product and if we are not successful in commercializing the ProLung Test and are unable to develop additional products, our business will not succeed.

We have no experience commercializing the ProLung Scan System and ProLung Test. In addition, we currently have one central product, our ProLung Test. We currently have no other product available for sale. If the ProLung Test is not successful at a level sufficient to generate a profit and we are unable to develop additional products, our business will not succeed.

The ability to add to the product suite is subject to the availability of additional funds and certain factors not in our control, such as government policy. We may eventually want to expand the ProLung Test to other cancer targets. ProLung does not have clinical data suggesting that the ProLung Test is effective in other cancers and the ProLung Test may not be effective in other cancers.

We are subject to litigation risk if our ProLung Test is not effective.

The nature of the ProLung Test as a medical technology platform and the general litigious environment of the market should be regarded as potential risks that could significantly and adversely affect our financial condition and results of operations in the future. If the ProLung Test does not perform as demonstrated in well controlled clinical trials and as reviewed by the FDA, there could be significant, even life-threatening, adverse consequences. We may be subject to claims against us as a result of the failure of the ProLung Test or other devices. We may also be subject to claims even though the injury is due to the actions of others, such as manufacturers or medical personnel. If we are sued, we may not have the resources to defend any such lawsuit or pay any related judgments. In addition, even the existence of a lawsuit will divert management's attention from the development and commercialization of the ProLung Test. Any insurance obtained by us may not adequately cover the amount or nature of any claim asserted against us and we are exposed to the risk that claims may be excluded from insurance coverage and that insurers may become insolvent. Moreover, there may not be any insurance available that would adequately cover all such risks.

We are subject to litigation risk as result of recent offering activities.

We recently experienced a very public proxy battle for control of the board of directors. In that process, both sides of the proxy battle made numerous allegations of wrongdoing by a former officer/director of ProLung. The allegations have led to expressions of frustration and anger by existing shareholders, certain of which have threatened to file lawsuits against ProLung, its former executives and various current and former directors. Complaints by shareholders and former employees have also led to an investigation being opened by the Utah Division of Securities related to the Company's and individuals' activities. If any of the threats, allegations and investigations lead to legal actions against the Company or its current or former officers and directors, we will be significantly limited in our ability to raise capital and will be required to expend management time and financial resources on such legal actions. It is unlikely that we would be able to continue as a going concern following any such legal actions.

We may incur substantial product liability expenses due to manufacturing or design defects, or the use or misuse of our products.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of medical products. We may face liability to our distributors and customers if our products are not manufactured as per specifications or if such specifications cause the products to become unsafe or fail to function as marketed or sold. We may also face substantial liability for damages if our products produce adverse side effects or defects are identified with any of our products that harm patients and other users. Any such failures or defects may lead to a breakdown in our relationships with distributors and purchasers leading to a substantial decline in or collapse of our market. In addition, if any judgments or liabilities are material in size, we may be unable to satisfy such liabilities. Any product liability could harm our operations and a large judgment could force us to discontinue our operations.

We are subject to the risk of product recalls if our products are defective.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding where there is a reasonable probability that the device would cause serious adverse health consequences or death. A government- mandated recall or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects, or other issues. Recalls, which include corrections as well as removals, of any of our products would divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation with customers, and reduce our ability to achieve expected revenues.

Lack of adequate third-party coverage and reimbursement for our customers could delay or limit the adoption of our products.

We may experience limited or no sales growth resulting from limitations on coverage and reimbursement for the diagnostic procedures performed with our products by third-party payors, and we cannot assure you that our sales will not be impeded and our business harmed if third-party payors fail to provide reimbursement for such procedures that customers view as adequate.

In the US, the ProLung Test will be purchased primarily by medical institutions, which will perform the diagnostic procedure using our product and bill various third-party payors, such as Medicare and other government programs and private insurance plans, for the health care services provided to their patients. Acute care hospitals are generally reimbursed by Medicare for items and services provided to hospital inpatients under the Medicare hospital inpatient prospective payment system. Under the Medicare hospital inpatient prospective payment system, acute care hospitals receive a fixed payment amount for each covered hospitalized patient admission based upon the Diagnosis- Related Group ("DRG") to which the inpatient stay is assigned, regardless of the actual cost of the services provided during that admission. If hospitals do not receive sufficient reimbursement from Medicare during an encounter in which our product is used, then a medical institution would have to absorb the cost of our products. At this time, we do not know the extent to which medical institutions would consider current Medicare inpatient payment levels adequate to cover the cost of our products, and we cannot assure you that such amounts are adequate. Failure by hospitals to receive an amount that they consider to be adequate reimbursement for the patient admissions during which our products are used could deter them from purchasing our products and limit our revenue growth. Moreover, DRG-based payments may decline over time, which could deter medical institutions from purchasing our products in the future. If medical institutions are unable to justify the costs of our products, they may refuse to purchase them, which would significantly harm our business.

Under current Medicare hospital inpatient reimbursement policies, the Centers for Medicare & Medicaid Services ("CMS") offers a process whereby manufacturers may apply for temporary add-on payment for a new medical technology when the applicable DRG-based inpatient prospective payment rate is inadequate to cover the cost of a new product. To obtain add-on payment, a technology must be considered "new," represent an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries, and data reflecting the cost of the new technology must not yet be available in the data used to recalibrate the DRGs and the sponsor much show that admissions involving the furnishing of the technology exceed cost thresholds established by CMS for each applicable DRG. If an application is approved, "new technology" add-on payments are made to hospitals for no less than two years and no more than three years. We must demonstrate the safety and effectiveness of our technology to the FDA in addition to CMS requirements before add- on payments can be made, and cannot assure you that CMS will agree to provide such incremental payments for the ProLung Test. Even if the ProLung Test receives FDA and other required regulatory clearances or approvals, the diagnostic procedure performed with the test may not receive incremental reimbursement in the foreseeable future, if at all.

Moreover, many private payors look to Medicare in setting their reimbursement policies and amounts. If Medicare does not offer adequate reimbursement for the services offered using our products, this may affect reimbursement determinations by certain private payors.

The absence of, or limits on, reimbursements may affect our revenues and our ability to achieve profitability.

The cost of a significant portion of healthcare is funded by governmental, and other third-party, insurance programs. It is possible that our products will not be covered or adequately reimbursed by governments or insurance providers, which will seriously harm our ability to generate revenue. In addition, even if payers cover our products (or the services in which our products are used), limits on reimbursement imposed by such programs may adversely affect the ability of hospitals and others to purchase our products. In addition, limitations on reimbursement for procedures which utilize our products could adversely affect our business.

If the ProLung Test is not accepted by physicians and patients, we will be unable to achieve market acceptance.

Patients may be unwilling to depart from the current standard of care and opt not to undergo the ProLung Test. In addition, physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products. Physicians may not recommend or order the ProLung Test until there is long-term clinical evidence to convince them to alter their existing patient management methods, there are recommendations from prominent physicians that the ProLung Test is safe, effective, and clinically useful, and that reimbursement or insurance coverage is available. We cannot predict when, if ever, physicians and patients may adopt the use of the ProLung Test. If the ProLung Test does not achieve an adequate level of acceptance by patients, physicians and healthcare payors, we may not generate significant product revenue and we may not become profitable.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by early commercial stage companies. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully execute our current business plan for the commercialization of the ProLung Test, or that our business plan is sound;
- successfully contract for and establish a commercial supply of components for the manufacture of the ProLung Test and the ProLung Scan System;
- achieve market acceptance of the ProLung Test; and
- attract and retain experienced personnel.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We are a small company and may be unable to compete with larger or better-funded companies that promote competitive technologies.

There are a number of competitive technologies currently being developed as well as refinements being made to existing competitive technologies. Technologies being developed or obtaining limited commercialization for the same intended use as our test include, methylated DNA tests, micro RNA tests, panels of proteins and minimally invasive biopsy. These include the current standard of care for the indication to be claimed for the ProLung Test; the use of serial chest CT views over a period often ranging from three months to three and one-half years. To the extent that any of these technologies or refinements result in products that successfully address some of the shortcomings of existing products, or result in quality products that are less expensive, safer or outperform existing tests and the ProLung Test, future demand for the ProLung Test may be reduced or eliminated.

The future market for our products is characterized by rapidly changing technology. Our future financial performance will, in part, be dependent on our ability to develop and manufacture new products or improvements to existing products on a cost-effective basis, to introduce them to the market on a timely basis, and to have them accepted by physicians. We may not be able to keep pace with technological change or to develop viable new products in a timely fashion. Factors that could delay the release of potential products or even cancellation of our plans to produce and market these new products could include delays in research and development, delays in securing future regulatory authorizations, or changes in the competitive landscape.

Many competitors offer a range of products in areas other than those in which we propose to compete, which may make such competitors and their products more attractive to surgeons, hospitals, group purchasing organizations, and other potential customers. Many competitors also have significantly more financial resources than us. Competitive pricing pressures or the introduction of new products by competitors could have an adverse effect on our ability to establish market acceptance for the ProLung Test. We cannot predict future markets for the ProLung Test or other products, and we may not be able to shift production to other products in the event of a lack of market demand for the ProLung Test, leading to an accompanying adverse effect on our profitability.

We are dependent upon contract manufacturers to safely and timely manufacture our products.

If we commercialize our ProLung test, we will need to establish arrangements with contract manufacturers to manufacture, package, label, and deliver our products. Our business will suffer if there are delays or difficulties in establishing relationships with manufacturers to manufacture, package, label, and deliver our products, or if the prices charged by such manufacturers are higher than anticipated. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by FDA. If any such manufacturers fail to comply with FDA requirements, they may be unable to manufacture our products. In addition, such manufacturers may fail to manufacture our products in accordance with specifications or may fail to meet delivery timelines, which may cause problems in our customer or distributor relationships and potentially lead to defaults or an obligation to pay damages. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our dependence upon third parties for the manufacturing of our products may harm our ability to generate significant revenues or acceptable profit margins and our ability to develop and deliver such compliant products on a timely and competitive basis.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our product. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of the ProLung Test, increase our cost of goods sold and result in lost sales.

We are dependent upon third parties for marketing and other aspects of our business.

We have limited experience in sales, marketing and distribution of our products and are just beginning the process of developing a sales and marketing organization, which includes an establishment of a distributor network. Our lack of experience could negatively impact our ability to enter into or maintain collaborative arrangements or other third-party relationships which are important to the successful commercialization of our products and potential profitability. We may be unable to establish or maintain adequate sales and distribution capabilities.

In developing a preliminary commercialization plan, much of our strategy for the commercialization of the ProLung Test will also rely on us entering into various arrangements with licensors, distributors, and other third parties. We have entered into an exclusive license agreement with BioMeridian Corporation to use technology owned by BioMeridian, although such license agreement is subject to claims of breach and likely renegotiation. We have also entered into an agreement with a distributor in Europe to distribute the ProLung Test. This distribution agreement is currently in the process of being renegotiated. We may be unable to enter into necessary distribution and licensing agreements to market the product. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of third parties. Failure to enter into or maintain these arrangements with third parties or failure to develop our own sales and marketing infrastructure could substantially impair or even eliminate our ability to market the ProLung Test. Our reliance on collaboration with others may adversely affect our ability to continue to operate, pursue our technology development program, or to achieve profitability.

Any clinical trials that we conduct may not be completed on schedule, or at all, or may be more expensive than we expect, which could prevent or delay regulatory authorization(s) of our products or impair our financial position.

The commencement or completion of any clinical trials that we conduct may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities suspend or place on hold a clinical trial, or do not give us the authorization required to start a clinical trial;
- the data and safety monitoring committee or applicable hospital institutional ethics review board recommends that a trial be placed on hold or suspended;
- fewer patients meet our clinical study criteria and our enrollment rate is lower than we expected;
- patients do not return for follow-up as expected;
- clinical trial sites decide not to participate or cease participation in a clinical trial;
- patients experience adverse side effects or events related to our ProLung Test or for unrelated reasons;
- third-party clinical investigators do not perform our clinical trials on schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- we fail regulatory inspections of our manufacturing facilities requiring us to undertake corrective action or suspend or terminate our clinical trials;
- governmental regulations require additional testing not currently contemplated in our pivotal trial or implement administrative actions;
- pre-clinical or clinical data are interpreted by third parties in unanticipated ways; or
- our trial design is considered inadequate to demonstrate safety and/or efficacy of the product.

Patient enrollment in clinical trials and completion of patient follow-up in clinical trials depend on many factors, including the size of the target patient population, the nature of the trial protocol, the proximity of patients to clinical sites and patient compliance. Delays in patient enrollment or failure of patients to continue to participate in a study may cause an increase in costs and delays or result in the failure of the trial.

Our clinical trial costs will increase if we have material delays in those trials or if we need to perform more or larger trials than planned. Adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel an entire program. Should our clinical development plan be delayed, this could have a material adverse effect on our operations and financial condition.

We engage in related party transactions, which result in a conflict of interest involving our management.

We have engaged in the past, and may continue to engage, in related party transactions. Related party transactions present difficult conflicts of interest, could result in disadvantages to our company and may impair investor confidence, which could materially and adversely affect us. Related party transactions could also cause us to become materially dependent on related parties in the ongoing conduct of our business, and related parties may be motivated by personal interests to pursue courses of action that are not necessarily in the best interests of our company and our stockholders.

ProLung tests may produce false positive and false negative results.

A patient may have a low composite risk score as measured by the ProLung Test and still have lung cancer. A low composite risk score does not preclude risk for lung cancer. This patient, however, based upon a false negative ProLung Test, may be subject to less stringent clinical vigilance. The ProLung Test is to be used in conjunction with all available clinical risk factors and findings including physician/health practitioner judgment. Nonetheless, a false negative result generated from the ProLung Test may contribute to a patient not receiving a timely diagnosis of or treatment for existing lung cancer.

By contrast, a patient may have a high composite risk score but not have lung cancer. Such a patient may be subject to greater clinical vigilance or unnecessary invasive procedures, such as biopsy, thus subjecting the patient to greater morbidity and potential mortality due to a falsely positive ProLung Test. Again, since the ProLung Test is to be used in conjunction with other clinical findings, and not as a stand-alone diagnostic test, such a case would be unlikely. Nonetheless, a false positive result generated from the ProLung Test may contribute to a patient receiving unnecessary procedures such as CT Scans and lung biopsies. False positive and false negative results would likely erode market acceptance of the ProLung Test and would thus harm our business, cash flows and operations.

Our clinical studies may produce unfavorable results.

Unfavorable results could prevent the ProLung Test from obtaining FDA and other regulatory authorizations. Unfavorable clinical results may also prevent the Company from adequately commercializing the ProLung Test in foreign markets such as the European Union which would harm our business, cash flows and operations. The Company may not have a cost-effective resolution to overcome either of these obstacles.

Our success depends upon our ability to effectively market our products.

If the ProLung Test does not achieve market acceptance, we will be unable to generate significant revenues. The commercial success of the ProLung Test will depend primarily on convincing healthcare providers to adopt and use the ProLung Test. To accomplish this, we, together with any other marketing or distribution collaborators, will need to convince members of the medical community the benefits of the ProLung Test through, for example, published papers, presentations at scientific conferences, and additional clinical data. Medical providers will not use our product unless we can demonstrate that our product consistently produces results comparable or superior to existing products and has acceptable safety profiles and costs. If we are not successful in these efforts, market acceptance of the ProLung Test could be limited. Even if we demonstrate the effectiveness of the ProLung Test, medical practitioners may still use other products. If the ProLung Test does not achieve broad market acceptance, we will be unable to generate significant revenues, which would have a material adverse effect on its business, cash flows, and results of operations.

We are dependent on key personnel, who may terminate their employment at any time.

Our success depends, in large part, upon the talents and skills of company management and other key personnel. During the past year, we have experience high turnover in our executive management team, including the positions of CFO and CEO, as well as a majority of the board of directors. The CEO was terminated for cause, and the other officers and directors resigned as part of the turmoil that followed. We have filled some, but not all vacated positions and are at risk of losing additional employees in the future. There can be no assurance that we would be able to find suitable replacements for all such personnel or that suitable personnel could be obtained for an amount that we could afford. In the future, a need for additional qualified personnel is expected in order to operate the business successfully. There can be no assurance that we will be able to attract employees of adequate qualification or that we would be able to afford such personnel.

Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Members of our management, scientific and medical teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition.

Other medical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize our product would be limited.

Risks Related to Our Regulatory and Legal Environment

We must obtain regulatory clearance or approval in the US and other non-European Union markets to be able to commence marketing and sales in those markets.

In many countries, we are required to obtain government clearance or approval before we can market and sell a medical device like the ProLung Test. Obtaining the necessary clearance or approval is a complex, costly, and time-consuming process, which differs from country-to-country. Failure to comply with the premarket authorization requirements of a country can result in serious penalties, including fines, recalls, seizure of product, suspension of sales, refusal to grant other approvals or clearances, increased requirements for quality control or (in severe cases) criminal prosecution. The imposition of any of the afore-mentioned penalties would adversely affect our business.

We have received a CE Mark for the marketing of the ProLung Test in the European Union. We are seeking clearance to sell the ProLung Test in the US and plan to seek clearance in other markets. Each market has unique regulatory requirements. In the US, FDA marketing clearance will be required before the ProLung Test may be marketed in the US. We expect to be subject to the premarket notification or *de novo* clearance pathway, but may be subject to premarket approval, which would substantially lengthen (and substantially increase the costs associated with) the regulatory process beyond that which is currently anticipated. As with the FDA review process, there are numerous risks associated with the review of medical devices by foreign regulatory agencies. The foreign regulatory agencies may request additional data to demonstrate the clinical safety and efficacy of a product. It is possible that we may not obtain the clearance or approval required to market the ProLung Test in the US or another significant potential market, which would harm our long-term revenue potential.

Even if marketing clearance (or approval) is granted, such clearance (or approval) may include significant limitations on the indicated use(s) for which the product may legally be marketed – i.e., the clearance may not allow us to make the type of claims that we believe we need to make for the ProLung Test to be commercially viable. Delays in obtaining regulatory clearance(s) or approval(s) would also harm our financial condition. A failure to obtain required clearances for our desired indication(s) in a timely fashion, particularly in the US, would significantly harm our long-term ability to continue as a going concern.

Even if we receive regulatory clearance or approval for the ProLung Test, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

The commercial success of the ProLung Test will depend on its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of the ProLung Test will depend on a number of factors, including:

- demonstration of clinical safety, efficacy, and utility;
- relative convenience and ease of use;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to order the ProLung Test and of the target patient population to try new medical devices;
- the introduction of any new products that in the future may become available to compete with the ProLung Test;
- pricing and cost-effectiveness;
- the inclusion or omission of the ProLung Test in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-cleared (or approved) labeling;
- our ability to obtain and maintain sufficient third-party coverage and reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

In addition, even if we obtain regulatory clearances or approvals, the timing or scope of any clearances or approvals may prohibit or reduce our ability to commercialize the ProLung Test successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory clearance (or approval) we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the ProLung Test not commercially viable. For example, third-party payers may deny coverage for the test or set reimbursement for the ProLung Test procedure at a rate that is insufficient to cover provider costs, or regulatory authorities may grant clearance or approval contingent on ProLung's performance of costly post-marketing clinical trials. Moreover, product clearances and approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of the ProLung Test.

If we obtain FDA clearance, we will be subject to Medical Device Reporting ("MDR") requirements, which may lead to inquiries, injunctions, or liabilities.

Under the FDA MDR regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has caused or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the European Economic Area are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the regulatory agency, or other Competent Authority, in whose jurisdiction the incident occurred. Were we to learn of a reportable adverse event, we would submit the required information to the relevant regulatory agency, to which the agency may respond with additional request(s) for information if the agency has any questions.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Existing US regulatory laws and cost-saving initiatives may harm our revenues and create additional expenses.

To the extent that we market the ProLung Test in the US, federal healthcare reform may adversely affect the results of our domestic operations. The Patient Protection and Affordable Care Act, or the Affordable Care Act, was enacted in March 2010. The Affordable Care Act included several provisions intended to reduce the volume of medical procedures, which, in turn, could result in reduced demand for our products and increased downward pricing pressure. While the Affordable Care Act is intended to expand health insurance coverage to uninsured persons in the US, the impact of any overall increase in access to healthcare on potential sales of the ProLung Test is uncertain at this time. Further, we cannot predict with any certainty what other impact the Affordable Care Act may have on our business.

Recently proposed healthcare reform measures could hinder or prevent the commercial success of our products.

The pricing and reimbursement environment may change in the future and become more challenging as a result of any of one several possible regulatory developments, including policies advanced by the United States government, new healthcare legislation, repeal or reform of the Affordable Care Act, or fiscal challenges faced by government health administration authorities. The US government has shown significant interest in pursuing healthcare "reform" and reducing healthcare costs. For example, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year were implemented starting in 2013. Any government-adopted reform measures that further decrease the amount of reimbursement our customers receive from governmental and other third-party payers could potentially adversely affect our business.

We will be subject to healthcare fraud and abuse law regulations.

Our operations may be directly or indirectly affected by various broad federal, state or foreign healthcare fraud and abuse laws. In particular, the US federal Anti-Kickback Statute prohibits any person from knowingly and willfully soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or in return for the ordering, leasing, purchasing, or arranging for or recommending the ordering, purchasing or leasing of any good, facility, item or service, for which payment may be made in whole or in part under federal healthcare programs, such as the Medicare and Medicaid programs. We are also subject to the fraud and abuse provisions of the US federal HIPAA statute, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or making false statements or concealing a material fact relating to payment for health-care benefits, items or services, and federal "sunshine" laws that require transparency regarding financial arrangements with healthcare providers, such as the reporting and disclosure requirements imposed by the Affordable Care Act on certain medical device manufacturers regarding any "transfer of value" made or distributed to prescribers and other healthcare providers.

In addition, the US federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

Many states and other countries have also adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, as well as laws that restrict our marketing activities with physicians, and require us to report consulting and other payments to physicians. Some states and other countries mandate implementation of commercial compliance programs to ensure compliance with these laws. We also are subject to foreign fraud and abuse laws, which vary by country.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

ProLung clinical study designs have not been reviewed by the FDA.

Our PL-208 clinical study was designed without input from the FDA. In 2018, before breaking the study data blind and analyzing the amassed clinical data for our PL-208 study, we collaborated with the FDA through two formal Pre-Submission Meetings regarding our PL-208 Study Statistical Analysis Plan, Study design, device output and statistical approaches. We received significant comments from the FDA, some but not all of which have been resolved. There can be no assurance that the FDA will approve the design of PL-208 or any future study, or agree that the results generated in our PL-208 trial is sufficient for FDA to approve or clear the ProLung Test for our desired indication for use. Even if our clinical studies produce favorable results, the FDA may refuse regulatory clearance and or require additional research causing delays in the launch and commercialization of the ProLung Test in the US.

Prolung clinical studies have resulted in statistically significant variability and the results may be insufficient to gain marketing clearance from the FDA.

Our clinical studies may produce unfavorable results which could prevent or delay ProLung from obtaining FDA and other regulatory clearances. In November 2018, we reported our PL-209 study results indicating day-to-day variability is repeatable; however, same-day variability is statistically significant with a 2% difference in scores though the clinical impact is unclear. In January 2019, we announced preliminary results for our PL-208 study. In the Validation Set (n=174 subjects), the ProLung Test demonstrated a sensitivity of 68%, specificity of 49%, Positive Predictive Value (PPV) of 70%, Negative Predictive Value (NPV) of 47% and an Accuracy of 61%. The performance from PL-208 and PL-209 are unlikely to be sufficient to gain marketing clearance from the FDA.

Risks Related to Our Intellectual Property

We may be unable to protect our intellectual property rights, which are important to the potential value of our products and company.

We have obtained patent protection, through ownership and licensing, for aspects of the ProLung Test in a limited number of jurisdictions, and there is no guarantee that such protection will be available for the ProLung Test in all jurisdictions, or, that once obtained, we would be able to enforce such rights. Disputes may arise between us and others as to the scope, validity and ownership rights of patents. Any defense of patents could prove to be costly and time consuming and we may not be in a position, or may deem it unadvisable, to carry on such a defense. In addition, the owner of patented technology that we license may fail to maintain underlying patents or may breach its obligations to us.

There can be no assurance that any patent applications that we or our licensors file will result in patents being issued or that, if issued, the patents will afford protection against competitors with similar technology. There can also be no assurance that any patents issued to us or that we license will not be infringed on or circumvented by others, or that others will not obtain patents that we would need to license or circumvent. Our patents may not contain claims that are sufficiently broad to prevent others from using our technologies or developing competing products. Competitors may be able to use technologies in competing products that perform substantially the same as our technologies but avoid infringing on our patent claims. Under these circumstances, our patents would be of little commercial value.

Additionally, there can be no assurance that patents, even after issuance, will be upheld by applicable courts. There can be no assurance that licenses, which might be required for our processes or products, would be available on reasonable terms, or that patents issued to others would not prevent us from developing and marketing its products. To the extent that we also rely on un-patented trade secrets, there can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology. Disclosure of our trade secrets would impair our competitive position and adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. Further, to the extent that our employees, consultants or contractors use trade secret technology or know-how owned by others in their work for us, disputes may arise as to the ownership of related inventions.

We rely on an exclusive license maintained by the licensor, and if the licensor does not adequately defend the license our business may be harmed.

We currently have one exclusive license to US patents. We rely on the licensor to maintain these patents and otherwise protect the intellectual property covered by this license. We have limited control over these activities or over any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that activities by the licensor have been or will be conducted in compliance with applicable laws and regulations. We may have no control or input over whether, and in what manner, our licensor may enforce or defend the patents against a third-party. The licensor may enforce or defend the patent less vigorously than if we had enforced or defended the patents ourselves. Further, the licensor may not necessarily seek enforcement in scenarios in which we would feel that enforcement was in our best interests. For example, the licensor may not enforce the patents against a competitor of ours who is not a direct competitor of the licensor. If our in-licensed intellectual property is found to be invalid or unenforceable, then the licensor may not be able to enforce the patents against a competitor of ours. If we fail to meet our obligations under the license agreement, then the licensor may terminate the license agreement. If the license agreement is terminated, the former licensor may seek to enforce the intellectual property against us. We may choose to terminate the license agreement, and doing so would allow a third party to seek and obtain an exclusive license to the patents. If a third party obtains an exclusive license to intellectual property formerly licensed to us, then the third party may seek to enforce the intellectual property against us.

We may incur significant costs and liability if we infringe, or are accused of infringing on, the intellectual property rights of others.

We may incur significant liability if we infringe the patents and other proprietary rights of third parties, including damages, inability to sell or license the ProLung Test without obtaining a license from the patent holder, which may not be available at commercially reasonable terms or at all, and we may have to redesign the ProLung Test so that it does not infringe on the third-party patent, which redesign may not be possible or could require substantial funds or time. Although no third party has asserted a claim of infringement against us, in the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of any product that uses these technologies. There may be patents held by others of which we are unaware that contain claims that our product or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Even if we are ultimately successful in our defense of an infringement case, the costs of litigation would significantly harm our business.

We may need to market the ProLung Test under a different name in the EU to avoid the risk of infringement.

We are aware of a company that markets an assay to be used as a liquid biopsy test for lung cancer detection under the name Epi proLung, which is trademarked in the EU. If we market the ProLung Test in the EU, we may be subject to the risk of infringement. If we determine, at the time we choose to market the ProLung Test in the EU, that we may infringe on this trademark, we might need to change the name under which we market the ProLung Test in the EU.

Parts, components, and software incorporated in the ProLung System may become obsolete.

The ProLung System consists of both custom and off the shelf parts and software. As off the shelf components age they may become obsolete requiring ProLung to procure, test and validate replacement components, parts and software for the ProLung System.

Risks Related to Capital Stock

Our SEC Reports contain projections and forward-looking statements that may not prove to be accurate.

Our SEC Reports, including those delivered herewith, contain projections that are based on our assumptions and judgments as of the date of such reports concerning future events and are subject to significant uncertainties and contingencies, many of which are beyond our control. Our actual results may materially differ from the results we have projected. In addition, our SEC Reports contain forward-looking statements that involve known and unknown risks and uncertainties. All statements other than those of historical facts, including those regarding business strategy, plans and objectives of management, projected costs, and expected benefits are forward-looking statements. These forward-looking statements are based on information and expectations as of the date of the respective SEC Report. Important factors that could cause our results to differ materially from expectations include those set forth in this "Risk Factors" section and elsewhere in our SEC Reports. We disclaim any obligation or intent to update these forward- looking statements.

Many of our directors have failed to timely file required reports with the SEC.

Section 16(a) of the Securities Exchange Act requires our officers, directors and persons who own more than 10% of our common stock to file reports concerning their ownership of common stock with the SEC and to furnish us copies of such reports. We believe that several of our directors have not timely filed all stock ownership and trading reports required by SEC rules. However, we believe that all of our officers and directors have currently filed all such required reports. The failure of the officers and directors to file such reports could lead to legal action by the SEC or third parties against the directors and potentially against the Company. Any such legal actions would be disruptive, consume financial and personnel resources, and harm the reputation of the Company including its ability to continue to raise capital. This may inhibit the ability of the Company to execute its business plan and continue as a going concern.

There is no trading market for our common stock, and it is possible that no trading market will develop.

There is currently no public trading market for the Company's common stock, and there is no assurance that a public market for the Company's common stock will exist in the future. We do not currently meet the listing requirements of the Nasdaq Stock Market or any other exchange. We do meet the requirements for listing on an over- the-counter market; however, an application for quotation in the over-the-counter market must be submitted by one or more market makers who: 1) are approved by the Financial Industry Regulatory Authority, 2) who agree to sponsor the security, and 3) who demonstrate compliance with SEC Rule 15(c)2-11 before initiating a quote in a security on the over-the-counter market.

If our common stock commences trading in the over-the-counter market, it will likely be subject to penny stock rules, which may restrict liquidity.

If our common stock becomes tradable in the secondary market, it may be subject to the penny stock rules adopted by the SEC that require brokers to provide extensive disclosure to their customers prior to executing trades in penny stocks. These disclosure requirements may cause a reduction in the trading activity of the Company's common stock, which in all likelihood would make it difficult for our shareholders to sell their securities. Penny stocks generally are equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or quoted on the Nasdaq Stock Market). Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The broker-dealer must also make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit their market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell the Company's common stock and may affect the Purchaser's ability to resell the common stock.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our Board of Directors. The provisions in our charter documents include the following:

- a classified Board of Directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our Board of Directors;
- the prohibition on removal of directors without cause;
- the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our Board of Directors to alter our bylaws without obtaining stockholder approval;
- the requirement that a special meeting of stockholders may be called only by the President of the Company or by the Board of Directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the Board of Directors has approved the transaction.

We are subject to various regulatory regimes, and may be adversely affected by inquiries, investigations and allegations that we have not complied with governing rules and laws.

In light of our status as a reporting company and the early stage of our business, we are subject to a variety of laws and regulatory regimes in addition to those applicable to all businesses generally. For example, we are subject to the reporting requirements applicable to U.S. reporting issuers, such as the Sarbanes-Oxley Act of 2002, and certain state and provincial securities laws. In addition, because we are in an early stage of development and intend on issuing securities to raise capital and use acquisitions for growth, our actions will be governed by state and federal securities laws and laws governing the issuance of securities, which are complex. In connection with such laws, we may be subject to periodic audits, inquiries, and investigations. Any such audits, inquiries, and investigations may divert considerable financial and human resources and adversely affect the execution of our business plan.

Through such audits, inquiries, and investigations, we, or a regulator, may determine that we are out of compliance with one or more governing rules or laws. Remedying such non-compliance diverts additional financial and human resources. In addition, in the future, we may be subject to a formal charge or determination that we have materially violated a governing law, rule, or regulation. We may also be subject to lawsuits as a result of alleged violation of the securities laws or governing corporate laws. Any charge or allegation, and particularly any determination, that we had materially violated a governing law would harm our ability to enter into business relationships, recruit qualified officers and employees, and raise capital.

If a market develops for our common stock, we expect the market price to be volatile.

The market prices of securities of smaller companies tend to be highly volatile. If a market develops for our common stock, of which there can be no assurance, our stock price may change dramatically as the result of announcements of our quarterly results, slow revenue growth, absence of profits, the rate of our expansion, significant litigation or other factors or events that would be expected to affect our business or financial condition, results of operations, and other factors specific to our business and future prospects. In addition, the market price for our common stock may be affected by various factors not directly related to our business, including the following:

- intentional manipulation of our stock price by existing or future stockholders;
- short selling of our common stock or related derivative securities;
- a single acquisition or disposition, or several related acquisitions or dispositions, of a large number of our shares of common stock;
- the interest, or lack of interest, of the market in our business sector;
- the adoption of governmental regulations and similar developments in the U.S. or abroad that may affect our ability to offer our products and services or affect our cost structure; and
- economic and other external market factors, such as a general decline in market prices due to poor economic indicators or investor distrust.

We have never paid, and do not intend to pay in the future, dividends on our common stock.

We have never declared nor paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. It is unlikely that investors will derive any current income from ownership of our stock. This means that the potential for economic gain from ownership of our stock depends on appreciation of our stock price and will only be realized by a sale of the stock at a price higher than the purchase price.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently maintain a corporate office at 757 East South Temple, Suite 150, Salt Lake City, Utah 84102. We currently lease this property for $4,140 a month. This location is approximately 4,657 square feet of office space.

Item 3. Legal Proceedings

We know of no existing or pending legal proceedings against us, nor are we involved as a plaintiff in any proceeding or pending litigation. There are no proceedings in which any of our directors, officers or any of their respective affiliates, or any beneficial stockholder is an adverse party or has a material interest adverse to our interest.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters.

(a) Market Information

Our common stock is not listed or traded on any exchange or other market.

(b) Holders

As of December 31, 2018, there are 3,861,849 shares outstanding held by approximately 800 stockholders of record.

(c) Dividends

We have not declared or paid dividends on our common stock since our formation, and we do not anticipate paying dividends in the foreseeable future. Declaration or payment of dividends, if any, in the future, will be at the discretion of our Board of Directors and will depend on our then current financial condition, results of operations, capital requirements and other factors deemed relevant by the Board of Directors. There are no contractual restrictions on our ability to declare or pay dividends.

(d) Securities Authorized for Issuance under Equity Compensation Plans

In April 2017 the Board of Directors approved the ProLung Inc. Stock Incentive Plan (the "Plan"). The shareholders approved the Plan in July 2017. The Plan authorizes the Board Compensation Committee to grant incentive stock options, non-incentive stock options, stock bonuses, restricted stock, and performance-based awards to directors, officers, employees and non-employee agents, consultants, advisers, and independent contractors of the Company or any parent or subsidiary of the Company. The following table sets forth certain information with respect to the Plan and any other plans plan as of December 31, 2018:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	310,635	$ 7.41	231,865
Equity compensation plans not approved by security holders	1,227,809	$ 5.21	N/A
Total	1,538,444	$ 5.65	231,865

The total number of initial shares of Common Stock authorized for issuance under the Plan was 500,000 shares; the authorized shares will automatically increase on January 1st of each year, for ten consecutive years, commencing on January 1, 2018, by the lesser of (i) 40,000 shares of Common Stock (i.e., 8% of the shares of the shares originally authorized to be issued), or (ii) such number of shares of common stock (if any) the Board may earlier designate in writing. If the automatic increases are not limited by the Board, there will be 900,000 shares of common stock authorized under the Plan in January 1, 2027.

Item 6. Selected Financial Data

This item is not applicable to the Company because the Company is a smaller reporting company.

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

The following discussion of our plan of operation should be read in conjunction with the financial statements and related notes that appear elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements. All forward-looking statements speak only as of the date on which they are made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

Certain statements in this Report constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, among others, uncertainties relating the following: general economic and business conditions; receipt or denial of marketing clearance from the FDA and similar agencies; receipt or denial of reimbursement from government agencies and insurance companies; demand for our products and services; developments and announcements by our competitors; potential delays in the development, market acceptance, or installation of our products and services; changes in government regulations; availability of management and other key personnel; availability, terms and deployment of capital; relationships with third-party equipment suppliers; and worldwide political stability and economic growth. The words "believe", "expect", "anticipate", "intend", "plan", and similar expressions identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made.

Overview

We are a medical technology company specializing in predictive analytic, early stage lung cancer risk testing, which we refer to as the "ProLung Test." Our noninvasive, rapid and radiation-free ProLung Test was developed to assess the risk of malignancy in lung nodules found in the chest by a Computed Tomography ("CT") scan, which is currently the primary method used for the early detection of lung cancer. As lung cancer is the leading cause of cancer death, early detection makes a substantial improvement in survival in a large population group. Timely identification of malignancy is essential for patients and their families. Currently, patients often wait from three months to three and one-half years to have the risk of malignancy assessed through periodic CT scan surveillance. Until malignancy is determined to be likely, invasive biopsy and treatment are significantly delayed. Current statistics reflect a 17% survival rate at five years for those diagnosed with lung cancer.

We believe the ProLung Test, in conjunction with the discovery of a nodule by CT scan, provides a more rapid assessment of the risk of malignancy, which must be determined prior to biopsy. Since a lung biopsy is invasive and may require life threatening thoracic surgery, physicians, patients, and insurance companies typically delay biopsy and therapy until the risk of malignancy outweighs the risk of further diagnostic procedures. For these patients, the delay reduces the treatment opportunity window and may cause sustained emotional trauma.

Results of Operations

The following discussion is included to describe our consolidated financial position and results of operations. The consolidated financial statements and notes thereto contain detailed information that should be referred to in conjunction with this discussion.

Fiscal Year Ended December 31, 2018, compared to Fiscal Year Ended December 31, 2017

Revenue and Cost of Revenue.

During the year ended December 31, 2018 or 2017, we had no revenue.

Operating Expenses.

Research and Development Expense. Research and development expense for the year ended December 31, 2018 was $2,036,792 compared to research and development expense of $1,630,837 for the year ended December 31, 2017; representing an increase of $405,955. The net increase was due to the following events:

During 2018, we entered into an agreement with our Chief Medical Officer resulting in a total additional expense of approximately $300,000. We also recorded approximately $450,000 of stock-based compensation during 2018 related to our 2017 stock option grant to our employees classified as research and development employees in full or in part. Due to the options being granted during the last quarter of 2017, we only recorded approximately $200,000 of stock based compensation during 2017.

Due to the uncertainty of when the Company would receive revenue and in anticipation of future research projects, on December 31, 2018 the Company reassigned all of inventory to research and development supplies. This resulted in approximately an additional $264,000 of research and development expense.

The above increase was offset by a decrease in research and development salary expense. In an effort to best utilize our resources we scaled back our employees to only essential personal with a major reduction in force at the end of the third quarter. We also had decreased consulting and clinical costs during 2018. Our on-site clinical trials began winding down at the end of 2017 and early part of 2018. Our focus during 2018 was to obtain FDA clearance, which was done mostly with our in-house personnel.

Selling, General and Administrative Expense. Selling, general and administrative expense for the year ended December 31, 2018, was $2,494,455, compared to selling, general, and administrative expense of $3,615,495 for the year ended December 31, 2017, representing a decrease of $1,121,040. This decrease was due to the following events:

During 2017, we commenced an offering of our common stock whereby we incurred significant up-front travel, legal, professional and consulting expense during 2017. These costs primarily related to advisory fees, investor relations and brand awareness as we commenced the offering process and were not included as part of deferred offering costs. In February 2018, we elected to terminate our relationship with our underwriter and postponed and, ultimately cancelled, the offering. We did not incur these costs during the majority of the year ended December 31, 2018. We also had decreased salary expense during 2018. In June 2018, our CEO was terminated for cause, which was followed by other administrative personnel either resigning or were asked to leave to minimize personnel cost. During 2018, we updated our estimate on when our former CEO would vest in his performance based stock options. It was decided these options would not vest and resulted in us reversing all expense recognized in 2017.

Offsetting these decreases was an increase in stock based compensation related to our 2017 stock option grant to our employees classified as administrative employees. During 2018, we had a full year of vesting expense compared to a partial year during 2017.

Other Expense. Other expense for the year ended December 31, 2018 was $3,178,035 as compared to $122,980 for the year ended December 31, 2017. The increase costs consist of the following:

- *Interest Expense* – From March through May 2018, we issued approximately $3 million in 8% convertible promissory notes. The convertible notes were issued with a beneficial conversion feature and cash and equity loan costs. Under these new notes, we incurred both interest and the amortization of discount which we did not have during the year ended December 31, 2017. We anticipate our interest expense during 2019 will be consistent with 2018. However, if the convertible notes are converted, any unamortized discount will be immediately charged against interest.

- *Write-Off of Deferred Offering Costs* – During 2017 and 2018, the Company filed a Registration Statement and numerous amendments related to a potential public offering of the Company's common stock. There was no assurance that any shares would be offered and sold pursuant to such Registration Statement. Through February 2018, the Company incurred cash offering costs totaling $303,401 which were to be offset against the proceeds received if such offering was completed. In February 2018, the Board suspended the offering, and in June 2018, the Board decided not to pursue the public offering in the near future and the Company wrote-off the deferred offering costs to expense.

- *Impact of Warrant Restructure* – In December 2018, the Board decided to lower the exercise price of certain warrants issued in 2016 and 2017 with an original exercise price of $12 to $5.20 per share. The Company recorded the $2,179,612 difference in fair value of the warrants before and after the change as an impact of warrant restructure.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2018, and 2017:

	December 31,2018	December 31, 2017
Cash	$ 249,286	$ 636,639
Current assets	273,539	971,884
Current liabilities	(507,353)	(321,320)
Working (deficit) capital	$ (233,814)	$ 650,564

We need additional capital to continue our operations. During the year ended December 31, 2018, we completed a financing in which we were able to satisfy our capital requirements. We continue to need additional funds to fund operations and obtain FDA clearance to market the ProLung Test. If we receive FDA clearance, of which there can be no assurance, we expect that our need for capital will expand. Given our early stage of development, we may be unable to raise sufficient capital when needed and, in any case, will likely be required to pay a high price for capital.

Our future capital requirements, adequacy of available funds and ability to raise necessary capital will depend on many factors including:

- our completion of our current clinical study and the extent to which the results are positive;
- our ability to obtain regulatory clearance in markets outside of Europe, including in the US;
- our ability to successfully commercialize our ProLung Test, ProLung System, and related products and the market acceptance of these products;
- the timing of our orders, if any, and the pricing and payment terms of those orders;
- reimbursement for our ProLung Test by Medicaid, Medicare and private third-party payors;
- our ability to establish and maintain collaborative arrangements with distributors for the development and commercialization of certain product opportunities;
- the cost of manufacturing and production scale-up;
- our financial results;
- the cost and availability of capital generally; and
- the occurrence of unexpected adverse expenses or events.

Notes Payable

Since our inception, the principal source of our financing has come from the issuance of equity securities and from debt financing. As of December 31, 2018, our outstanding debt financing includes the following notes payable.

Convertible Notes Payable

In March 2018, we began issuing 8% convertible promissory notes ("convertible notes"). The convertible notes are unsecured. Principal and accrued interest are due two years from the date of issuance. The holder of the convertible note is entitled, at its option, to convert all, or any portion of the outstanding principal and interest, into shares of our common stock at a conversion price of $6.30 per share. Interest accruing from the date of issuance to the conversion date shall be paid on the maturity date. If the Company completes a public offering of its common stock, the convertible promissory notes and accrued interest automatically convert into common stock at the lower of i) 90% of the public offering price or ii) $6.30 per share. Through December 31, 2018, we have issued $2,982,750 in convertible promissory notes and paid fees of $322,275 related to these notes.

Cash provided by (used in) operating, investing and financing activities

Cash provided by (used in) operating, investing and financing activities for the fiscal years ended December 31, 2018 and 2017 is as follows:

	Year Ended December 31,	
	2018	2017
Operating activities	$ (3,056,367)	$ (4,637,581)
Investing activities	8,539	(26,801)
Financing activities	2,660,475	5,272,099
Net increase (decrease) in cash	$ (387,353)	$ 607,717

Operating Activities

For the fiscal year ended December 31, 2018, the differences between our net loss and net cash used in operating activities were due to net non-cash charges totaling $4,467,653 for impact of warrant restructure, stock-based compensation, amortization of debt discount, depreciation and the write-off of deferred offering costs

For the fiscal year ended December 31, 2017, the differences between our net loss and net cash used in operating activities were due to net non-cash charges primarily related to stock-based compensation and depreciation.

Investing Activities

In the year ended December 31, 2017, the company invested $26,801 in equipment. During 2018, we had nominal investing activities.

Financing Activities

During the year ended December 31, 2018, cash flows from financing activities totaled $2,660,475 related to proceeds received from the issuance of convertible notes, net of loan costs paid.

During the year ended December 31, 2017, cash flows from financing activities totaled $5,272,099 related to proceeds of 1) $6,531,568 from the issuance of 544,300 equity units consisting of, one share of common stock and one warrant to purchase stock at a price of $12.00, per unit less $924,080 for offering and deferred offering costs, 2) less $285,389 for payments on notes payable, and 3) less $50,000 of net repayments of related-party notes payable.

Critical Accounting Policies and Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and contingencies as of the date of the financial statements and reported amounts of revenues and expenses during the reporting periods. We evaluate our estimates on an on-going basis. We base our estimates on historical experience and on other assumptions that are believed to be reasonable under the circumstances. However, future events may cause us to change our assumptions and estimates, which may require adjustment. Actual results could differ from these estimates. We have determined that for the periods reported in this Annual Report on Form 10-K the following accounting policies and estimates are critical in understanding our financial condition and results of operations.

Revenue Recognition – Revenue is recognized by the Company when a binding sales or service agreement exists between the parties, services have been rendered, the price for the services is fixed or determinable, collection is reasonably assured, and the Company has no significant obligations remaining with respect to the arrangement.

Inventory – Inventory is valued at the lower of cost or market value, with cost determined based on the first-in-first-out method. Management evaluates inventory for obsolescence based on expectations about future demand and marketability of products, and if necessary, reduces inventory to the lower of cost or market through the use of an inventory valuation account for obsolescence. The estimated cost of inventory not expected to be converted to cash within one year is reflected as "Inventory, noncurrent" in the consolidated balance sheet. Due to the uncertainty of when the Company would receive revenue and in anticipation of future research projects, on December 31, 2018 the Company reassigned all inventory to research and development.

Long-lived Assets – Long-lived assets, including property and equipment, and intangible assets are tested for recoverability whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. When such events occur, we compare the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset or asset group to the carrying amount of the long-lived asset or asset group. If this comparison indicates that there is an impairment, the amount of the impairment is calculated based on fair value.

Stock-based Compensation – The Company measures the cost of employee and consulting services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The awards issued are valued using a fair value-based measurement method. The resulting cost is recognized over the period during which an employee or consultant is required to provide services in exchange for the award, usually the vesting period.

Emerging Growth Company – We are an "emerging growth company" under the federal securities laws and will be subject to reduced public company reporting requirements. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Although we have not delayed the adoption of any accounting standards, we may choose to take advantage of the extended transition period for complying with new or revised accounting standards in the future.

Off Balance Sheet Arrangements

The Company has not had any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

This item is not applicable to the Company because the Company is a smaller reporting company.

Item 8. Financial Statements and Supplementary Data

Financial Statements

Reference is made to the consolidated financial statements and accompanying notes included in this report, which begin on page F-1.

Supplemental Financial Data

This item is not applicable to the Company because the Company is a smaller reporting company.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired control objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018, and concluded that the disclosure controls and procedures were not effective, because certain deficiencies involving internal controls constituted material weaknesses as discussed below. The material weaknesses identified did not result in the restatement of any previously reported financial statements or any other related financial disclosure, nor does management believe that it had any effect on the accuracy of our financial statements for the current reporting period.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes, in accordance with GAAP. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Additionally, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal accounting officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control—Integrated Framework (2013). Based on its evaluation, our management concluded that there are material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2018, the following material weaknesses existed:

The Company did not maintain effective entity-level internal controls as defined by the framework issued by COSO. Specifically, the Company did not effectively segregate certain accounting duties due to the small size of the Company's accounting staff. In addition, there were lapses in the Company's expense documentation and related controls. Due to this material weaknesses, management has concluded that our internal controls over financial reporting were not effective as of December 31, 2018.

In order to mitigate these material weaknesses to the fullest extent possible we engage a third-party accounting firm to provide additional expertise in accounting. Furthermore, regular meetings are held with the audit committee and the audit committee approves all audit functions. If at any time, we determine a new control can be implemented to mitigate these risks at a reasonable cost, it is implemented as soon as possible.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to Commission rules that permit the Company to provide only management's report in this annual report.

This report shall not be deemed to be filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred in the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None noted

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

Set forth below are the names, ages, and present principal occupations or employment, and material occupations, positions, offices, or employments for the past five years of our current Directors and executive officers. Unless otherwise indicated, the mailing address of each person listed is in care of ProLung, Inc, 757 East South Temple, Suite 150, Salt Lake City, Utah 84102.

Name and Business Address	Age	Position
Jared Bauer	37	Interim Chief Executive Officer, and Director
Michael Garff	36	Director, Chief Operating Officer
Rex Yung, MD	62	Chief Science Officer
Robert W. Raybould	82	Director
J. Scott Nixon	59	Director
Mark V. Anderson	50	Director, Former Chief Financial Officer

Jared Bauer. Mr. Bauer, 37, is currently the interim Chief Executive Officer of ProLung. He was appointed to the ProLung Board of Directors in August 2018 and was appointed interim CEO in September 2018. Mr. Bauer is also Chief Executive Officer of ApolloDx, LLC, an in vitro mobile point-of-care diagnostic company, and the Chief Executive Officer of CibusDx Inc., a company delivering technology that improves food safety testing. In 2012, Mr. Bauer founded Exuro Medical and acquired BurnFree Products. At the time, BurnFree was insolvent, riddled with legal issues and had not shipped product in nearly six months. In just two years with a focus on sustainable revenue generation, he led the Exuro Medical team to expand BurnFree distribution to 58 countries, managing regulatory processes, re-working quality systems and making BurnFree the second largest burn treatment product line in the world. Mr. Bauer also co-founded and led the Idaho Business Council, which is a pioneering, non-partisan collaboration between the state's business community and all of its research universities to promote Idaho-based research and economic development. Mr. Bauer also serves as a trustee at The Oliver Fund, which is a non-profit he co-founded with his wife.

Mark V. Anderson. Mr. Anderson, Certified Public Accountant (CPA), 50, was our Chief Financial Officer from June 2017 through September 2018. He was appointed to the ProLung Board of Direcotors in July 2018. Mr. Anderson is now a Partner at Haynie and Company. Prior to joining ProLung as our Chief Financial Officer, Mr. Anderson was a partner with Eide Bailly LLP and previously Hansen, Barnett and Maxwell, both public accounting firms. During Mr. Anderson's 24 years in public accounting his roles included Quality Control Director and engagement partner over public and private companies in many industries, including work on filings with the Securities and Exchange Commission on behalf of his clients. Mr. Anderson holds both a Bachelor of Science and Masters of Professional Accounting degree from Weber State University.

Michael Garff. Mr. Garff, 36, has served as our Chief Operating Officer since May 2009. Prior to joining us, he worked at the Pierre Lassonde New Venture Development Center where he served as a Director from 2007 to 2009. Mr. Garff worked as a business analyst for the Biomedical Informatics Department of the University of Utah from 2008 to 2009. Mr. Garff was a project manager at US Bank from 2005 to 2008. Mr. Garff received a BA in Business Finance and an MBA from the University of Utah.

Rex Yung. MD Dr. Yung, 62, became our Chief Scientific Officer in August 2017. Dr. Yung was the Director of Pulmonary Oncology and Director of Bronchoscopy at Johns Hopkins University School of Medicine (JHU). Dr. Yung remains an adjunct faculty in the Department of Oncology at JHU. Dr. Yung is a fellow of the American College of Chest Physicians. He is board certified in Internal Medicine, Pulmonary and Critical Care Medicine and has served on the executive and editorial boards of the American Association of Bronchology and Interventional Pulmonology and Journal of Bronchology and Interventional Pulmonology. Dr. Yung graduated from Harvard University and received his MD from the University of California at Los Angeles (UCLA).

Robert W. Raybould. Mr. Raybould, 82, has served as one of our directors since January 2012. Mr. Raybould began his career in the US Army and Eastman Kodak and became a financial planner. In 1971, he co-founded Realvest (a real estate investment company) and then sold its holdings between 1981 and 1984. Realvest again syndicated real estate in the early 1990's and sold in 1997. In 1987, Mr. Raybould assisted in founding TRI Capital Corporation (a mortgage-banking firm) and served as a member of its Board of Directors until 2005. In 1995, he assisted in the formation of DTM Research, LLC and served as Chairman of the Board from its formation until 2006. In 1999, he founded Greenhill Financial (now Arlington Value Capital, LLC) and served as one of its managing partners until 2006. From 2007 to present, Mr. Raybould has been actively investing in companies. Mr. Raybould holds a BS in Banking and Finance and an MBA from the University of Utah. Due to Mr. Raybould's successful financial, entrepreneurial, and business experience, the Board of Directors has concluded that Mr. Raybould is qualified to serve as a director of the Company.

J. Scott Nixon. Mr. Nixon, a Certified Public Accountant (CPA), 59, has served as one of our directors since November 2016. Mr. Nixon retired in 2015 as a partner with PricewaterhouseCoopers (PwC) where he spent over 31 years in various roles including Office Managing Partner and engagement partner over public and private companies in many industries. His career involved providing audit and business advisory services. Mr. Nixon was involved in numerous complex filings with the Securities and Exchange Commission on behalf of his clients. In 2007, Mr. Nixon returned from a four-year assignment in São Paulo, Brazil where he represented various interests of the PwC global firm to the 18-member firms in South and Central America and led the implementation and compliance of the Sarbanes-Oxley requirements in those countries. Mr. Nixon serves on the Board of Directors for USANA Health Sciences, Inc. (NYSE: USNA) as well as several boards of directors of private entities and is a National Association of Corporate Directors (NACD) Leadership Fellow. He holds both a BA and Master of Accounting from Utah State University. The Board of Directors believes that Mr. Nixon's expertise in accounting, particularly with respect to public companies, and his management experience with PricewaterhouseCoopers qualify him for service as a member of the Company's Board of Directors.

Board Composition

Our bylaws provide that the Board of Directors shall consist of one or more members, with such number to be determined by the Board of Directors. The whole Board of Directors currently consists of seven members. In accordance with our amended and restated certificate of incorporation, our Board of Directors is divided into three classes. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I director is Robert W. Raybould. His term will expire at the annual meeting of stockholders to be held in 2020;
- The Class II directors are J. Scott Nixon and Jared Bauer. Their terms will expire at the annual meeting of stockholders to be held in 2021;
- The Class III directors are Michael Garff and Mark Anderson. Their terms will expire at the annual meeting of stockholders to be held in 2019.

We expect that any additional directorships resulting from an increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board of Directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Our Board of Directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that Robert W. Raybould and J. Scott Nixon representing two of our five directors, do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined in the Listing Rules of the Nasdaq Stock Market. Due to being interim Chief Executive Officer, former Chief Financial Officer and Chief Operating Officer the remaining Board of Directors have determined that Jared Bauer, Mark Anderson and Michael Garff are not independent under the applicable rules and regulations of the SEC, respectively. In making this determination, our Board of Directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our Board of Directors has established an audit committee, a compensation committee a nominating and governance committee and a science and technology committee. Our Board of Directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board of Directors. Each committee has adopted a written charter which we post on our website at www.prolunginc.com.

Audit Committee

The audit committee is responsible for assisting our Board of Directors in its oversight of the integrity of our financial statements, the qualifications and independence of our independent auditors and our internal financial and accounting controls. The audit committee has direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the audit committee. The audit committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement.

Our audit committee consists of J. Scott Nixon and Robert W. Raybould. Our Board of Directors has determined that Mr. Nixon and Mr. Raybould are independent under Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, of the Exchange Act. The chair of our audit committee is Mr. Nixon. Our Board of Directors has determined that Mr. Nixon is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our Board of Directors has also determined that each member of our audit committee can read and understand fundamental financial statements, in accordance with applicable requirements. In arriving at these determinations, the Board of Directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

Compensation Committee

The compensation committee approves the compensation objectives for the Company, the compensation of the chief executive officer and approves, or recommends to our Board of Directors for approval, the compensation for other executives. The compensation committee reviews all compensation components, including base salary, bonus, benefits and other perquisites.

Our compensation committee consists of J. Scott Nixon and Robert W. Raybould. Our Board of Directors has determined that Mr. Nixon and Mr. Raybould are independent and are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act and are "outside directors" as that term is defined in Section 162(m) of the US Internal Revenue Code of 1986, as amended, or Section 162(m). The chair of our compensation committee is Mr. Raybould.

Nominating and Governance Committee

The nominating and governance committee makes recommendations regarding corporate governance, the composition of our Board of Directors, identification, evaluation and nomination of director candidates and the structure and composition of committees of our Board of Directors. In addition, the nominating and governance committee is responsible for developing and recommending corporate governance guidelines to our Board of Directors, as applicable to the Company.

Our nominating and governance committee consists of Mark Anderson and Robert W. Raybould. The chair of our nominating and governance committee is Mr. Anderson. Each member of the nominating and governance committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act. Mr. Raybould is independent, as determined under Nasdaq Listing Rules. Based on his former employment with the Company, Mr. Anderson is not considered independent under Nasdaq Listing Rules.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to all our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions, and agents and representatives. The full text of our code of business conduct and ethics is posted on our website at www.prolunginc.com. The nominating and governance committee of our Board of Directors will be responsible for overseeing our code of business conduct and ethics and any waivers applicable to any director, executive officer or employee. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and agents and representatives, on our website identified above.

Involvement in Legal Proceedings

To the best of our knowledge, none of our directors or executive officers have, during the past ten years, been involved in any legal proceedings described in subparagraph (f) of Item 401 of Regulation S-K.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's officers, directors and persons who own more than 10% of the Company's common stock to file reports concerning their ownership of common stock with the SEC and to furnish the Company with copies of such reports. Based upon the Company's review of the reports required by such persons and amendments thereto furnished to the Company, the Company believes that all reports required to be filed pursuant to Section 16(a) of the Exchange Act have been timely filed other than as follows. Based on the records of the Company of transactions involving the Company, the Company believes that the following persons filed the following number of late reports, or failed to file the following reports, during the fiscal year ended December 31, 2018: Mark Anderson filed a late Form 3 and a late Form 4; Scott Nixon filed a late Form 3 and a late Form 4; Robert Raybould filed two late Forms 4.

Item 11. Executive Compensation

Executive Compensation

Summary Table. The following table provides details with respect to the total compensation of the Company's named executive officers during the years ended December 31, 2018, and 2017. The Company's named executive officers are (a) each person who served as the Company's Chief Executive Officer during 2018, (b) the next two most highly compensated executed officers serving as of December 31, 2018, whose total compensation exceeds $100,000 and (c) any person who could have been included under (b) except for the fact that such persons were not an executive officer on December 31, 2018.

Summary Compensation Table

Name & Principal Position	Year	Salary	Bonus	Option Awards	All Other	Total
				(5)(6)	(1)	
Jared Bauer (2)	2018	$ 32,000	$ -	$ 231,191	$ -	$ 263,191
Steven C. Eror, Former CEO	2018	$ 161,069	$ -	$ -	$ 12,000	$ 173,069
	2017	$ 290,000	$ 16,667	$ 533,337	$ 24,000	$ 864,004
Mark Anderson, Former CFO (3)	2018	$ 112,276	$ -	$ 23,140	$ -	$ 135,416
	2017	$ 94,731	$ -	$ 213,019	$ -	$ 307,750
Michael Garff, Chief Operating Officer (4)	2018	$ 160,868	$ -	$ 23,140	$ -	$ 184,008
	2017	$ 158,400	$ -	$ 213,019	$ -	$ 371,419

(1) The amounts represent fees paid or accrued by us to the executive officers for service as a Director on the Board of Directors

(2) Mr. Bauer was appointed as our interim Chief Executive Officer in August 2018. Mr. Bauer is being compensated under a consulting contract of $8,000 per month.

(3) Mr. Anderson was appointed as Chief Financial Officer in June 2017 and resigned in September 2018. Mr. Anderson was appointed to the Board of Directors in June 2018.

(4) Mr. Garff was appointed to the Board of Directors in June 2018.

(5) Includes the aggregate grant date fair value of options to purchase 31,250 and 31,250 shares of common stock issued Mr. Anderson and Mr. Garff during 2017, respectively in accordance with FASB ASC.

(6) Includes the aggregate grant date fair value of options to purchase 50,000, 5,000 and 5,000 shares of common stock issued to Mr. Baurer, Mr. Anderson and Mr. Garff during 2018 for their service on the board of directors. Includes the aggregate grant date fair value of options to purchase 5,000 shares of common stock issued in 2017 to Mr. Eror as compensation for his service on our board of directors.

None of the other named executive officers are party to written employment agreements.

Compensation of Non-Executive Directors

Summary Table. The following table sets forth information concerning the annual and long-term compensation awarded to, earned by, or paid to our non-executive directors for all services rendered in all capacities to our company, or any of its subsidiaries, for the year ended December 31, 2018:

Compensation Table for Non-Executive Directors

Name & Principal Position	Fees Earned or Paid	Stock Awards	Option Awards	Other	Total
		(2)	(2)		
Robert Raybould, Director (1)	$ 15,000	$ -	$ 58,698	$ -	$ 73,698
J. Scott Nixon, Director (1)	$ -	$ -	$ 77,205	$ -	$ 77,205

(1) The amounts represent fees paid or accrued by us during the past year pursuant to service as a Director on the Board of Directors.

(2) Represents the aggregate grant date fair value of options to purchase 8,356 and 11,404 shares of common stock issued to Mr. Raybould and Mr. Nixon, in May and December, respectively in accordance with FASB ASC Standards. Options were granted as compensation for service as Directors on the Board of Directors.

Director Compensation Arrangements

Currently there are no formal arrangements for compensation to the members of the Board of Directors.

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

Security Ownership of Certain Beneficial Owners and Management.

The following table lists, as of April 16, 2019, the number of shares of common stock of our Company that are beneficially owned by (i) each person or entity known to our Company to be the beneficial owner of more than 5% of the outstanding common stock; (ii) each named executive officer and director of our Company; and (iii) all officers and directors as a group. Information relating to beneficial ownership of common stock by our principal shareholders and management is based upon information furnished by each person using beneficial ownership concepts under the rules of the Securities and Exchange Commission. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or direct the voting of the security, or investment power, which includes the power to vote or direct the voting of the security. The person is also deemed to be a beneficial owner of any security of which that person has a right to acquire beneficial ownership within 60 days. Under the Securities and Exchange Commission rules, more than one person may be deemed to be a beneficial owner of the same securities, and a person may be deemed to be a beneficial owner of securities as to which he or she may not have any pecuniary beneficial interest. Except as noted below, each person has sole voting and investment power.

The percentages below are calculated based on 3,861,849 shares of our common stock issued and outstanding as of April 16, 2019. Unless otherwise indicated, the address of each person listed is in care of ProLung, 757 East South Temple, Suite 150, Salt Lake City, Utah 84102.

Name of Beneficial Owner, Officer or Director	Amount and Nature of Beneficial Ownership [1] [2]	Percentage of Shares Beneficially Owned
Michael Garff, Chief Operating Officer [3]	87,813	2.2%
Mark V. Anderson, Chief Financial Officer [4]	36,250	0.9%
Robert W. Raybould, Director [5]	218,589	5.4%
J. Scott Nixon, Director [6]	28,518	0.7%
Jared Bauer[7]	50,000	1.3%
All Executive Officers and Directors as a Group (nine persons)	421,170	9.8%

(1) The number of shares included on this table includes those shares owned by the beneficial owner's spouse, and entity or trust controlled by the beneficial owner, or owned by another person in the owner's household.

(2) Each current member of the Board of Directors has been awarded options to purchase shares of common stock for services on the Board. There is no current plan in place to compensate those serving on the Board of Directors.

(3) Includes 28,438 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(4) Includes 36,250 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(5) Includes the assumed conversion of convertible debt into 19,230 shares of common stock. Also, includes 14,606 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(6) Includes the assumed conversion of convertible debt into 9,614 shares of common stock. Also, includes 18,904 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(7) Includes 50,000 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

Other than compensation arrangements described herein, since January 1, 2017, there has not been, nor is there currently proposed, any transaction or series of similar transactions to which we were or are a party in which the amount involved exceeds the lesser of (1) $120,000 and (2) one percent of the average of our total assets at year-end for the last two completed fiscal years, in which any director, executive officer or beneficial holder of more than 5% of any class of our voting securities or members of such person's immediate family or household had or will have a direct or indirect material interest, other than the transactions described below.

Director Independence

Our securities are not listed on a national securities exchange or on any inter-dealer quotation system which has a requirement that a majority of directors be independent. Our Board of Directors has undertaken a review of the independence of each director by the standards for director independence of the Nasdaq Stock Market. Under these rules, Jared Bauer, Mark Anderson and Michael Garff are not independent due to current and former employment with the Company. All other directors, namely Robert Raybould and J. Scott Nixon are independent.

Item 14. Principal Accounting Fees and Services

The following table summarizes the fees of MaloneBailey, LLP ("MaloneBailey"), our independent auditors, billed to us for each of the last two fiscal years for audit services and billed to us in each of the last two years for other services.

	2018	2017
Audit Fees	$ 59,000	$ 53,000
Audit-Related Fees	28,000	50,404
Tax Fees	-	-
All Other Fees	-	-
Total	$ 78,000	$ 103,404

Audit Fees. Audit Fees consist of amounts billed for professional services rendered for the audit of our annual consolidated financial statements included in our Annual Report on Forms 10-K, reviews of our interim consolidated financial statements included in our Quarterly Reports on Forms 10-Q, and related matters.

Audit-Related Fees. Audit-Related Fees consist of fees billed for professional services that are reasonably related to the performance of the audit or review of our consolidated financial statements but are not reported under "Audit Fees."

Tax Fees. Tax Fees consist of fees billed for professional services for tax compliance activities, including the preparation of federal and state tax returns and related compliance matters.

All Other Fees. All other fees consist of aggregate fees billed for products and services provided by the independent auditor, other than those disclosed above.

The Audit Committee has established pre-approval policies and procedures requiring that the Audit Committee (or the Board of Directors, functioning as the Audit Committee) approve in advance any engagement of the independent auditors to render audit or non-audit services. As a result, all engagements during 2018 and 2017 were approved by the Audit Committee (or the Board of Directors, functioning as the Audit Committee).

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. *Financial Statements*. The following Consolidated Financial Statements of the company and Auditors' reports are filed as part of this Annual Report on Form 10-K:

- Reports of Independent Registered Public Accounting Firms
- Consolidated Balance Sheets as of December 31, 2018 and 2017
- Consolidated Statements of Operations for the years ended December 31, 2018 and 2017
- Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2018 and 2017
- Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017
- Notes to the Consolidated Financial Statements

2. *Financial Statements Schedule.* Not applicable.

3. *Exhibits*. The information required by this item is set forth on the exhibit index that follows the signature page of this report.

PROLUNG, INC. AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
ProLung, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ProLung, Inc. and its subsidiary (collectively, the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2015.
Houston, Texas
April 16, 2019

ProLung, Inc. and Subsidiary
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current Assets		
Cash	$ 249,286	$ 636,639
Prepaid expenses	24,253	31,844
Deferred offering costs	-	303,401
Total Current Assets	273,539	971,884
Inventory, noncurrent	-	255,637
Property and equipment, net of accumulated depreciation	46,699	81,378
Intangible assets, net of accumulated amortization	146,614	156,176
Total Assets	$ 466,852	$ 1,465,075
Liabilities and Stockholders' Deficit		
Current Liabilities		
Accounts payable	$ 263,620	$ 295,918
Accrued liabilities	243,733	25,402
Total Current Liabilities	507,353	321,320
Long-Term Liabilities		
Notes payable, net of discount	3,536,868	1,206,931
Total Long-Term Liabilities	3,536,868	1,206,931
Total Liabilities	4,044,221	1,528,251
Stockholders' Deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; none issued and outstanding	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized; 3,861,848 shares issued and outstanding	3,862	3,862
Additional paid-in capital	25,582,996	21,387,907
Accumulated deficit	(29,164,227)	(21,454,945)
Total Stockholders' Deficit	(3,577,369)	(63,176)
Total Liabilities and Stockholders' Deficit	$ 466,852	$ 1,465,075

The accompanying notes are an integral part of these consolidated financial statements.

ProLung, Inc. and Subsidiary
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2018	**2017**
Revenues:		
Revenue	$ -	$ -
Total revenue	-	-
Cost of revenue:	-	-
Gross margin	-	-
Operating expenses:		
Research and development expense	2,036,792	1,630,837
Selling, general and administrative expense	2,494,455	3,615,495
Total operating expenses	4,531,247	5,246,332
Loss from operations	(4,531,247)	(5,246,332)
Other income (expense):		
Impact of warrant restructure	(2,179,612)	-
Write-off of deferred offering costs	(303,401)	-
Interest expense	(695,022)	(122,980)
Net loss	$ (7,709,282)	$ (5,369,312)
Basic and diluted loss per share	$ (2.00)	$ (1.49)
Weighted-average common shares outstanding, basic and diluted	3,861,848	3,608,472

The accompanying notes are an integral part of these consolidated financial statements.

ProLung, Inc. and Subsidiary
Consolidated Statements of Stockholders' Deficit
For the Years Ended December 31, 2018 and 2017

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2016	3,000,815	$ 3,001	$ 13,247,054	$ (16,085,633)	$ (2,835,578)
Stock-based compensation	-	-	808,307	-	808,307
Common stock issued for cash and warrants, net of offering costs	544,300	545	5,866,571	-	5,867,116
Common stock issued upon conversion of debt and accrued interest (which includes the conversion of $60,000 of related party debt and accrued interest)	254,834	255	1,415,536	-	1,415,791
Common stock issued to placement agent	55,372	55	(55)	-	-
Common stock issued for services	6,250	6	50,494	-	50,500
Rounding due to reverse stock split	277	-	-	-	-
Net loss	-	-	-	(5,369,312)	(5,369,312)
Balance, December 31, 2017	3,861,848	3,862	21,387,907	(21,454,945)	(63,176)
Stock-based compensation	-	-	1,276,213	-	1,276,213
Revaluation of warrants	-	-	2,179,612	-	2,179,612
Warrants issued to convertible debt placement agent	-	-	275,281	-	275,281
Beneficial conversion feature	-	-	463,983	-	463,983
Net loss	-	-	-	(7,709,282)	(7,709,282)
Balance, December 31, 2018	3,861,848	$ 3,862	$ 25,582,996	$ (29,164,227)	$ (3,577,369)

The accompanying notes are an integral part of these consolidated financial statements.

ProLung, Inc. and Subsidiary
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (7,709,282)	$ (5,369,312)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	38,996	37,212
Stock-based compensation	1,276,213	858,807
Transfer of inventory to research and development	263,999	-
(Gain) loss on sale of equipment	(3,294)	690
Amortization of loan discount	408,726	-
Impact of warrant restructure	2,179,612	-
Write-off of deferred offering costs	303,401	-
Change in assets and liabilities:		
Inventory	(8,362)	35,922
Prepaid expenses	7,591	(23,013)
Accounts payable	(32,298)	(106,332)
Accrued liabilities	218,331	(71,555)
Net cash flows from operating activities	(3,056,367)	(4,637,581)
Cash flows from investing activities:		
Proceeds from sale of equipment	8,539	394
Payments for equipment	-	(27,195)
Net cash flows from investing activities	8,539	(26,801)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants	-	6,531,568
Payment for placement of convertible notes payable	(322,275)	-
Payment of stock offering costs	-	(924,080)
Payment on notes payable and convertible debentures	-	(285,389)
Proceeds from notes payable	2,982,750	-
Proceeds from related party notes payable	-	35,000
Payment on related party notes payable	-	(85,000)
Net cash flows from financing activities	2,660,475	5,272,099
Net increase (decrease) in cash	(387,353)	607,717
Cash at beginning of period	636,639	28,922
Cash at end of period	$ 249,286	$ 636,639
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest	$ 48,277	$ 189,644
Supplemental disclosure of non-cash investing and financing activities:		
Beneficial conversion feature	$ 463,983	$ -
Warrants issued to convertible debt placement agent	$ 275,281	$ -
Conversion of convertible debt and interest	$ -	$ 1,355,791
Conversion of related party debt and interest	$ -	$ 60,000
Deferred offering costs accrued	$ -	$ 43,773

The accompanying notes are an integral part of these consolidated financial statements.

ProLung, Inc. and Subsidiary
Notes to Consolidated Financial Statements

Note 1 – Organization and Summary of Significant Accounting Policies

Organization – ProLung, Inc. (the "Company"), is a Delaware corporation that was incorporated on November 22, 2004 and is doing business as "ProLung." The Company's headquarters are located in Salt Lake City, Utah. The Company's business is the marketing and sales of precision predictive analytical medical devices specializing in lung cancer. The Company's principal activities are primarily developing products, seeking FDA clearance for its products, developing markets and securing strategic alliances and obtaining financing.

Principles of Consolidation – During the year ended December 31, 2012, the Company formed a wholly-owned subsidiary, Hilltop Acquisition Corporation, Inc., which has had no activity since its inception and is included in the accompanying financial statements from the date of its formation.

Going Concern –The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has generated minimal revenues thus far from its operations. Until the Company receives FDA approval, the Company will not achieve its planned level of operations in the United States. The Company does have a CE mark for Europe and has licensed a portion of its technology to an entity located in China. The Company's focus and use of funds during 2018 was on obtaining FDA approval and building an infrastructure to launch in the United States market. The Company has incurred substantial and recurring losses to date from operations, continues to have a stockholders' deficit, has negative working capital and is currently dependent on debt and equity financing. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result relating to the recoverability and classification of the asset carrying amounts or the amount and classification of liabilities that might result from the outcome of this risk and uncertainty.

The ability of the Company to continue as a going concern is dependent on the Company successfully obtaining additional funding, developing products that can be sold profitably, and generating cash through operating activities. Management's plans include issuing equity or debt securities to fund capital requirements and developing ongoing operations.

Use of Estimates – The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Concentration of Credit Risk – Financial instruments that potentially subject the Company to a concentration of credit risk consists principally of cash. The Company has cash balances during the years ended December 31, 2018 and 2017 in excess of federally insured limits. The Company places its cash with a high credit quality financial institution.

Fair Value of Financial Instruments – For the notes payable and convertible debentures classified as long-term liabilities, the estimated fair value is approximately equal to the carrying value based on the interest rates and other terms of debt.

Cash and Cash Equivalents – The Company considers all unrestricted highly liquid investments purchased with a maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of December 31, 2018 or 2017.

Trade Receivables and Credit Policies – Accounts receivable are recorded at the invoiced amount, with foreign currencies reflected in U.S. dollars (based on the exchange rate on the date of sale and adjusted to current exchange rates at the end of each reporting period), and do not bear interest. The Company uses an allowance for doubtful accounts to reflect the Company's best estimate of the amount of probable credit losses in accounts receivable. Account balances will be charged off against the allowance when the account receivable is considered uncollectible.

Inventory – Inventory is valued at the lower of cost or market value, with cost determined based on the first-in-first-out method. The estimated cost of inventory not expected to be converted to cash within one year is reflected as "Inventory, noncurrent" in the consolidated balance sheets, although all inventory is ready and available for sale at any moment. Due to the uncertainty of when the Company would receive revenue and in anticipation research projects, the Company reassigned inventory to research and development.

Property and Equipment – Property and Equipment is stated at cost and depreciated using the straight-line method over useful lives of 3 to 5 years.

Intangible Assets – As further discussed in Note 4 to these consolidated financial statements, intangible assets consist of rights to certain patent applications acquired in December 2015 under a Patent Assignment Agreement. These intangible assets will be amortized over an estimated useful life of eighteen years, with periodic evaluation for impairment.

Research and Development – The Company expenses research and development costs as incurred. Research and development costs primarily consist of clinical study costs, consulting fees, compensation of employees related to activities to obtain regulatory approval for the Company's devices, and materials and supplies.

Employee Stock-based Compensation – The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award and to recognize it as compensation expense over the period the employee is required to provide service in exchange for the award, usually the vesting period.

Non-Employee Stock-based Compensation – The Company accounts for non-employee stock-based compensation at fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

Income Taxes – The Company accounts for income taxes under the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and for operating loss and tax credit carry-forwards. Deferred income tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. The Company has established a valuation allowance to reduce deferred income tax assets to their realizable values based on whether it is more likely than not that such deferred income tax assets will be realized. At December 31, 2018 and 2017, the Company has recorded a full valuation allowance against the net deferred tax assets related to temporary differences and operating losses because there is significant uncertainty as to the realizability of the deferred tax assets.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. The Company currently believes that all significant filing positions are above this threshold and therefore, the Company has no significant reserves for uncertain tax positions and no adjustments to such reserves are required by generally accepted accounting principles. No interest or penalties have been levied against the Company and none are anticipated; therefore, no interest or penalty has been included in our provision for income taxes in the statements of operations.

Basic and Diluted Loss Per Share – The Company computes basic loss per share by dividing net loss by the weighted-average number of common shares outstanding during the period. The Company computes diluted loss per share by dividing net loss by the sum of the weighted-average number of common shares outstanding and the weighted-average dilutive common share equivalents outstanding. The computation of diluted loss per share does not assume exercise or conversion of securities that would have an anti-dilutive effect. As of December 31, 2018, and 2017, the following items were excluded from the computation of diluted net loss per common share as their effect is anti-dilutive:

	For the Year Ended December 31,	
	2018	2017
Warrants to purchase shares	1,227,809	1,184,998
Stock options	310,635	331,000
Convertible notes	698,919	201,155

Foreign Currency Policy – Transactions in foreign currencies are initially recorded at the rates of exchange prevailing on the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are retranslated into the Company's functional currency at the rates prevailing on the balance sheet date. Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are reported as other income (expense) and included in net loss for the period. The Company had no foreign currency transactions during 2018 or 2017.
Related Parties – The Company discloses related party transactions which are in the normal course of operations and are measured at the exchange amount.

Recent Accounting Pronouncements – In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was amended with ASU No. 2015-14, ASU No. 2016-08, ASU No. 2016-10, ASU No. 2016-11, ASU No. 2016-12 and ASU No. 2016-20. These new standards supersede all existing revenue recognition requirements, including most industry specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The Company currently has no revenue and the implementation of this standard has no current effect.

In February 2016, the FASB issued ASU No. 2016-02: *Leases* ASU 2016-02 requires companies to generally recognize on the balance sheet operating and financing lease liabilities and corresponding right-of-use assets. ASU 2016-02 will be effective for the Company's fiscal year beginning January 1, 2020 on a modified retrospective basis and earlier adoption is permitted. Management is currently evaluating the impact of the pending adoption of ASU 2016-02 on the Company's consolidated financial statements and based on the Company's one month-to-month lease agreement does not anticipate a material impact.

The Company has reviewed other recent accounting pronouncements and has determined that they will not significantly impact the Company's results of operations or financial position.

Note 2 – Inventory

Inventory principally consisted of the cost of materials purchased and assembled during the years ended December 31, 2018 and 2017. The cost of inventory also included the costs of direct labor for the assembly and certain indirect costs incurred in connection with purchasing of parts and the assembly of products. Due to the uncertainty of when the Company would receive revenue and in anticipation of research projects, on December 31, 2018 the Company reassigned all $263,939 of inventory to research and development. Inventory consisted of the following at December 31, 2018 and 2017:

	December 31,	
	2018	2017
Raw materials	$ -	$ 66,417
Work in progress	-	12,465
Finished goods	-	176,755
Total inventory	-	255,637
Less: carrying value of inventory not deemed to be a current asset	-	255,637
Inventory, included in current assets	$ -	$ -

Note 3 – Property and Equipment

Property and equipment consists of the following at December 31, 2018 and 2017:

	Life	December 31, 2018	December 31, 2017
Computer equipment	3 years	$ 31,393	$ 38,134
Office equipment	3 to 5 years	19,151	19,151
Tooling	5 years	92,228	92,228
		142,772	149,513
Less accumulated depreciation		(96,073)	(68,135)
Property and equipment, net		$ 46,699	$ 81,378

Depreciation expense for the years ended December 31, 2018 and 2017 was $29,434 and $27,650, respectively.

Note 4 – Intangible Assets

In December 2015, the Company purchased patents for a probe as well as enhanced surface and tips for obtaining bioelectrical signals for $175,300. These patents will be amortized over 220 months (18.3 years), at a rate of $797 per month, or $9,562 per year. During the years ended December 31, 2018 and 2017 the Company recognized amortization expense of $9,562 each year. At December 31, 2018, there was accumulated amortization of $28,686.

Note 5 – Accrued Liabilities

Accrued liabilities consists of the following at December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Accrued interest	$ 187,779	$ -
Accrued royalties	17,873	17,873
Accrued payroll and payroll taxes	38,081	7,529
Accrued liabilities	$ 243,733	$ 25,402

Note 6 –Notes Payable

2018 Transactions

In March 2018, the Company began issuing 8% convertible promissory notes (“convertible notes”). The convertible notes are unsecured. Principal and accrued interest are due two years from the date of issuance. The holder of the convertible note is entitled, at its option, to convert all, or any portion of the outstanding principal and interest, into shares of the Company’s common stock at a conversion price of $6.30 per share. Interest accruing from the date of issuance to the conversion date shall be paid on the maturity date. If the Company completes a public offering of its common stock, the convertible promissory notes and accrued interest automatically convert into common stock at the lower of i) 90% of the public offering price or ii) $6.30 per share. During 2018, the Company issued $2,982,750 in convertible promissory notes and as of December 31, 2018 had accrued interest totaling $187,779.

On the date the convertible notes were issued, the fair value of the Company’s stock was estimated to be $7.28 per share which was greater than the conversion rate of $6.30. The $0.98 per share difference is considered a beneficial conversion feature. The beneficial conversion feature related to the convertible notes was $463,983. On the date of issuance, the Company also assessed the conversion feature for possible derivative treatment (under ASC 815) and determined the conversion feature was indexed to the Company’s common stock and thus not a derivative.

The Company utilized a placement agent in connection with the offering which entitled them to a cash commission of 10% of the convertible notes issued, $25,000 for non-accountable expenses and warrants to purchase 10% of the potential conversion shares of stock associated with the principal portion of convertible notes issued by the Company (47,186 warrants). Pursuant to this agreement, the Company incurred cash commission fees to the placement agent of $322,275. The value of the 47,186 warrants was $275,281 ($5.83 per warrant), derived utilizing the Black-Scholes Pricing Model with the following weighted average assumptions:

Expected life	2.5 years
Exercise price	$ 7.29
Expected volatility	160%
Expected dividends	n/a
Risk-free interest rate	2.35%

The $597,596 in loan costs incurred was added to the $463,983 beneficial conversion feature creating a debt discount ("discount") of $1,061,579. The accompanying consolidated balance sheet reflects the convertible notes net of the discount. The discount will be amortized as a component of interest expense over the term of the convertible notes. During the year ended December 31, 2018, the Company recognized interest expense of $408,726 related to the amortization of the beneficial conversion feature and loan costs. As of December 31, 2018, the unamortized balance of the beneficial conversion feature and loan costs is $652,813.

2017 Transactions

In 2015, the Company issued $2,000,000 in convertible debentures. The holder of the convertible debentures was entitled, at its option, to convert all or any portion of the outstanding principal of the convertible debentures into shares of the Company's common stock at a conversion price of $5.20 per share. As of December 31, 2016, there was an unpaid balance principal balance of $1,257,050. During the year ended December 31, 2017 the Company repaid $164,000 in principal along with $25,700 in related accrued interest. Also, during December 31, 2017, convertible debentures holders converted the remaining $1,093,050 in principal along with $162,741 in related interest into 241,500 shares of common stock. Additionally, upon the conversion of the convertible debentures, the Company was required to issue the placement agent warrants to acquire shares of the Company's common stock at an exercise price of $5.20 per share. The placement agent was to be issued a warrant to purchase one share of common stock for each $6.48 of principal converted into common stock. The term of the warrants is for a period of 36 months from the date of issuance. During the year ended December 31, 2017, 215,772 warrants were issued to the placement agent.

On December 31, 2016 the Company was obligated under the terms of a master note to an individual related to an executive officer of the Company in the amount of $189,389. The note was secured by all the assets of the Company, bore interest at 15% and required the Board of Directors ("Board") to retain the current management as long as the note is outstanding. During the year ended December 31, 2017, $89,389 of principal was repaid along with interest of $39,071. In addition, the noteholder elected to convert the remaining $100,000 of principal for 8,334 shares of common stock as well as 8,334 warrants to purchase stock at a price of $12 per unit.

During the year ended December 31, 2016, the Company issued notes payable to a member of the Board and a former Board member. These notes bore interest between 8% and 10%, were unsecured and due on demand. During the year ended December 31, 2017, $105,000 was settled along with interest of $5,000 as follows. The Company repaid $50,000 in cash, and the remaining $60,000 was converted into 5,000 shares of common stock, and 5,000 warrants to purchase stock, at a price of $12 per share. Also, during the year ended December 31, 2017, the same Board member made a short-term advance of $35,000 that did not bear interest. This amount was repaid during the year ended December 31, 2017.

Convertible Notes Payable

In 2015, the Company issued two convertible promissory notes (the "convertible notes") in the aggregate principal amount of $1,206,931 to two investment entities controlled by a single family. The convertible notes are unsecured and accrue interest at the rate of 8% per annum, with interest payable on the last day of each calendar quarter. The principal amount under the convertible notes is due on the five-year anniversary of the issue date. The convertible notes are convertible at any time prior to maturity at the option of the holders at a conversion rate of $6.00 per share. If the Company's common stock commences trading and closes at a price of $28.00 per share for five consecutive trading days, the principal amount under the convertible notes automatically converts into common stock at the rate of $6.00 per share.

Notes payable is summarized as follows:

	December 31,	
	2018	2017
Convertible notes payable net of $652,813 in discount and loan costs; unsecured; interest at 8.00%; due between March 2020 through March 2022	$ 2,329,937	$ -
Convertible notes payable; unsecured; interest at 8.00%; due November 2020	1,206,931	1,206,931
Notes payable	$ 3,536,868	$ 1,206,931

Note 7 – Preferred Stock

The stockholders of the Company have authorized 10,000,000 shares of preferred stock, par value $0.001 per share. The preferred stock may be issued in one or more series. The Board has the right to fix the number of shares of each series (within the total number of authorized shares of the preferred stock available for designation as a part of such series), and designate, in whole or part, the preferences, limitations and relative rights of each series of preferred stock. As of December 31, 2018, and 2017, the Board has not designated any series of preferred stock and there are no shares of preferred stock issued or outstanding.

Note 8 – Common Stock

Public Offering of Common Stock of the Company

During 2017 through February 2018, the Company filed a Registration Statement and subsequent amendments on Form S-1 (the "Registration Statement"). The Registration Statement related to a potential public offering of the Company's common stock. There was no assurance that any shares would be offered and sold pursuant to such Registration Statement. Through February 2018, the Company incurred cash offering costs totaling $303,401 which were to be offset against the proceeds received if such offering was completed. In February 2018, the Board suspended the offering, and in June 2018, the Board decided not to pursue the public offering in the near future and the Company wrote-off the deferred offering costs to expense.

Private Placement of Common Stock of the Company

During 2016 and through May 2017, the Company issued equity under a private placement agreement. The Company engaged two separate placement agents during different time periods in connection with the offering, which placement agents were entitled to a cash commission of ten percent of the issuance price of the common stock sold in the offering, and one share of common stock of the Company for each ten shares of the Company's common stock sold in the offering. During the year ended December 31, 2017, the Company received subscriptions for 544,300 units and received proceeds of $6,531,568. The Company paid $664,452 in offering costs and issued 55,372 shares of common stock to the placement agents for the year ended December 31, 2017.

As part of this offering each investor was given a warrant for each share of stock purchased at a price of $12 per share. As part of the offering, a total of 697,293 warrants were issued. In December 2018, the Board decided to lower the exercise price of these warrants to $5.20 and extended the maturity date to March 2022. The Company recorded the difference in fair value of the warrants before and after the change as an impact of warrant restructure expense. Using the Black Scholes pricing model the value before was $0.31 per option ($212,987) based on an exercise price of $12, risk-free interest rate of 2.39%, expected volatility of 156%, expected life of 0.20 years, and expected dividend yield of zero; the value after was $3.43 ($2,392,599) based on an exercise price of $5.20 risk-free interest rate of 2.66%, expected volatility of 147%, expected life of 1.64 years, and expected dividend yield of zero. The resulting difference of $2,179,612 was recorded as an expense.

Common Stock Issued for Services

During the year ended December 31, 2017, the Company issued 6,250 shares of common stock with a total value of $50,500 to a Board member and a consultant for services rendered. The consultants and director could not provide a reliable value on the services rendered and agreed the value of the common shares was more reliable. As the Company did not have an active trading market for its common shares, the shares' fair value was based on the allocated value of the common stock being issued in the Private Placement mentioned above.

Total stock-based compensation expense from all sources for the year ended December 31, 2018 and 2017, including stock-based compensation for the options, warrants and related amortization discussed in Note 9 and Note 10 below, have been included in the consolidated statements of operations as follows:

	For the Year Ended December 31,	
	2018	2017
Research and development expense	$ 634,205	$ 196,211
Selling, general and administrative expense	642,008	662,596
Total share-based compensation	$ 1,276,213	$ 858,807

Note 9 – Common Stock Options

Equity Incentive Plan

In April 2017, the Board, contingent on shareholder approval, approved the ProLung, Inc. Stock Incentive Plan (the "Plan"). The shareholders approved the Plan in July 2017. The Plan authorizes the Board compensation Committee to grant incentive stock options, non-incentive stock options, stock bonuses, restricted stock, and performance-based awards to directors, officers and employees and non-employee agents, consultants, advisers and independent contractors of the Company or any parent or subsidiary of the Company.

The total number of initial shares of Common Stock authorized for issuance under the Plan is 500,000 shares. The authorized shares will automatically increase on January 1 of each year, for ten consecutive years, commencing on January 1, 2018, by the lesser of (i) 40,000 shares of Common Stock (i.e., 8% of the shares of the shares originally authorized to be issued), or (ii) such number of shares of common stock (if any) the Board may earlier designate in writing. If the automatic increases are not limited by the Board, there will be 900,000 shares of common stock authorized under the Plan in January 1, 2027.

Issuance of Stock Options under the Plan

2017 Board and Key Employee Option Grants

In August 2017, the Board's compensation committee approved the issuance of 52,500 options to directors of the Company at exercise prices ranging from $8 to $10 per option. One half of the options vest immediately with the remaining half vesting quarterly through August 2018.

In November 2017, the Board's compensation committee approved the issuance of 203,500 options to certain key employees and a consultant. These options have an exercise price of $8 and vest quarterly through September 2019.

2018 Board and Key Employee Option Grants

In May 2018, as part of a bonus agreement the Board approved the issuance of 30,000 options to our Chief Medical Officer with an exercise price of $8 per option. These options vested upon issuance.

At various Board meetings during the year ended December 31, 2018, the Board approved the issuance of stock options as payment for their 2018 Board fees in lieu of cash. The Company issued 115,954 options to these Board members with exercise prices ranging from $5.20 to $8.00 per share and vested through 2018.

During 2018, certain employees separated from the Company and several directors resigned resulting in 40,222 options being forfeited and $140,303 of future expense being eliminated.

During 2018, as part of a reduction in force, certain employees either resigned or separated from the Company. As part of their separation, the Board elected to fully vest these individuals' stock options. Also, the Board agreed to allow these options to expire at their original expiration date. As a result 32,343 options vested and the Company immediately recognized all unvested expense related to these options.

The fair value of these options was $5.47 and $6.06 per option for the year ended December 31, 2018 and 2017. The fair value was computed using the Black Scholes method using the following weighted-average assumptions:

	For the Year Ended December 31,	
	2018	2017
Expected life	5.03 Years	5.43 Years
Exercise price	$ 6.75	$ 8.07
Expected volatility	132%	118%
Expected dividends	None	None
Risk-free interest rate	2.71%	2.00%

The Company recorded an expense of $1,410,409 and $601,056 for the year ended December 31, 2018 and 2017 related to these options. The $90,963 remaining unrecognized expense will be recognized through September 30, 2019.

CEO Stock Option Incentive

In August 2017, the Company granted the Company's former CEO stock option incentives related to FDA approval. The stock option shall expire 10 years after the grant date and shall vest with respect to a number of options of Common Stock upon the receipt of FDA marketing authorization (as defined below), with such number of options to be as follows:

- 112,500 options if FDA marketing authorization is obtained after January 1, 2018 and on or before July 1, 2018;
- 75,000 options if FDA marketing authorization is obtained after July 1, 2018 and on or before January 1, 2019;
- 37,500 options if FDA marketing authorization is obtained after January 1, 2019 and on or before January 1, 2020.

The Company considers these options to be performance based. Solely for accounting purposes, the Company originally estimated FDA marketing authorization would be obtained by December 2018. Based on this estimate, the most probable number of options to be issued would have been 75,000. On the date of issuance the Company computed the value of these options using the Black-Scholes Pricing Model using the following assumptions:

Expected life	5.70 Years
Exercise price	$ 8.00
Expected volatility	116%
Expected dividends	None
Risk-free interest rate	1.84%

The resulting value of $472,000 ($6.29 per option) would be amortized over the vesting period which was estimated to be through December 31, 2018. Through December 31, 2017, the Company recorded $134,196 of expense.

During 2018, the Company concluded it was improbable that FDA marketing authorization would be obtained by December 31, 2019. The Company updated their estimate whereby the conditions for vesting will not be met by December 31, 2019. Based on the estimate, the number of options decreased from 75,000 to zero and the resulting value from $472,000 to zero. As a result, $134,196 of compensation expense recognized during the year ended December 31, 2017 was reversed during the year ended December 31, 2018.

As of December 31, 2018, there are currently 231,865 options available for issuance under the Plan. As noted above, we have issued performance-based options to our CEO, whereby we could issue up to 37,500 options; which are included in the above options available for issuance under the Plan.

A summary of option activity for the years ended December 31, 2018 and 2017 is presented below:

	Shares Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value of Vested Options
Outstanding at December 31, 2016	-			
Issued	331,000	$ 8.05		
Forfeited/Expired	-			
Outstanding at December 31, 2017	331,000	$ 8.05	10.0 years	
Issued	145,954	$ 6.75		
Adjustment	(75,000)	$ 12.00		
Forfeited/Expired	(91,319)	$ 8.19		
Outstanding at December 31, 2018	310,635	$ 7.41	9.16 years	$ -
Vested at December 31, 2018	276,823	$ 7.34	9.20 years	$ -

Note 10 – Common Stock Warrants

The Company has issued warrants to purchase its common stock for payment of consulting services, in connection with the extension of a note payable, as incentives to investors, and for cash. The fair value of warrants issued for consulting services is recognized as consulting expense at the date the warrants become exercisable.

The Company values non-vested warrants utilizing the Black-Scholes method and records compensation over the requisite service period which is usually the vesting period. As part of a consulting contract, the Company issued warrants monthly as part of the compensation. The fair value of the warrants that vested during the year ended December 31, 2017, was $6.32 per warrant. The weighted-average assumptions used for these warrants was a risk-free interest rate of 1.84%, expected volatility of 122%, expected life of 4.5 years, and expected dividend yield of zero. The Company recognized $69,927 as share-based compensation related to the vesting of warrants for the year ended December 31, 2017. The consultant terminated this agreement effective July 1, 2017 and forfeited the remaining 20,625 warrants under the contract.

In September 2017, the Company issued 1,250 warrants to a consultant for investor relation services rendered. The warrants have an exercise price of $12 per warrant, vest immediately and expire in September 2020. The fair value of these warrants was $3,359 or $2.69 per warrant and was immediately recognized as an expense. The fair value was computed using the Black Scholes method using the a risk-free interest rate of 1.33%, expected volatility of 107%, expected life of 1.5 years, and expected dividend yield of zero.

A summary of warrant activity for the years ended December 31, 2018 and 2017 is presented below:

	Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value of Vested Warrants
Outstanding at December 31, 2016	430,938	$ 7.04	4.2 years	
Issued	774,656	$ 10.11		
Exercised	-			
Expired/Forfeited	(20,625)	$ 4.00		
Rounding	29			
Outstanding at December 31, 2017	1,184,998	$ 9.16	1.9 years	
Issued	47,186	$ 7.29		
Exercised	-			
Expired/Forfeited	(4,375)	$ 8.57		
Outstanding at December 31, 2018	1,227,809	$ 5.21	3.4 years	$ 174,582

The intrinsic value at December 31, 2018 is calculated at $5.20 per share less the exercise price, based on the management's latest estimate of the fair value of the shares of common stock, which is the latest price the Company's Board estimated the price to be.

Note 11 – Commitments and Contingencies

Lease Agreement

The Company leases office space under an agreement that is currently month to month. Monthly rental payments as of December 31, 2018 are $4,140 per month.

Lease expense charged to operations for the years ended December 31, 2018 and 2017 was $49,677 and $48,871, respectively.

License Agreement

The Company has a license agreement with a party related through a shareholder and former member of the Board. Under the agreement, the Company has the right to the exclusive use of certain patents and related technology in its medical devices and other products for an indefinite term. The Company agreed to make royalty payments based on a percentage of the aggregate worldwide net sales (as defined in the agreement) of its medical device and other products that utilize the technology. At December 31, 2018 and 2017, accrued royalties under this license agreement was $17,873. The Company asserts the amount payable is to be offset against costs the Company has incurred to maintain and keep the patents current. The costs to maintain the patents exceeds the amount accrued for royalty payments; however, no receivable amount is recorded in the accompanying financial statements.

Note 12 – Income Taxes

The Company provides for income taxes using an asset and liability-based approach. Deferred income tax assets and liabilities are recorded to reflect the future tax consequences of temporary differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. The Tax Cuts and Jobs Act was enacted on December 22, 2017 which reduced the U.S. corporate statutory tax rate from 35% to 21%. The Company changed its effective federal rate to 21% as the expected rate for our deferred tax items. Our effective state rate is unchanged at 5%.

The significant components of net deferred tax assets (liabilities) were as follows at December 31, 2018 and 2017:

	December 31,	
	2018	2017
Net operating losses	$ 5,309,400	$ 4,316,700
Research and development credit carryforward	177,800	145,700
Depreciation and amortization	(8,500)	(11,100)
Valuation allowance	(5,478,700)	(4,451,300)
Net Deferred Tax Asset	$ -	$ -

As of December 31, 2018, the Company had no unrecognized tax benefits that, if recognized, would affect the Company's effective income tax rate over the next 12 months. A reconciliation of the expected income tax benefit at the U.S. Federal income tax rate to the income tax benefit actually recognized for the years ended December 31, 2018 and 2017 is set forth below:

	For the Year Ended December 31,	
	2018	2017
Net loss	$ (2,004,000)	$ (1,396,000)
Non-deductible expenses and other	976,600	217,700
Effect due to decrease in tax rates	-	1,716,000
Change in valuation allowance	1,027,400	(537,700)
Benefit from income taxes	$ -	$ -

As of December 31, 2018, the Company has a net operating loss carry-forward for U.S. federal income tax purposes of approximately $20.4 million. This carry-forward is available to offset future taxable income, if any, and will expire, if not used, from 2018 through 2038. The utilization of the net operating loss carry-forward is dependent upon the tax laws in effect at the time the net operating loss carry-forward can be utilized and may be limited by changes in ownership control of the Company. The Company's U.S. federal and Utah income tax returns, constituting the returns of the major taxing jurisdictions, are subject to examination by the taxing authorities for all open years as prescribed by applicable statute. No income tax waivers have been executed that would extend the period subject to examination beyond the period prescribed by statute. The Company is no longer subject to U.S. federal tax examinations for tax years before and including December 31, 2015. The Company is no longer subject to Utah state tax examinations for tax years before and including December 31, 2013. During the years ended December 31, 2018 and 2017, the Company did not incur interest and penalties.

Note 13 – Other Related Party Transactions

Effective February 1, 2017, the Company entered into a consulting agreement with a member of the Board. Under the agreement, the individual agreed to provide advisory services related to our clinical assets, capital markets, public company related issues and other matters as agreed. The agreement had an original term of twelve months with compensation of $120,000. In November 2017, the term was modified to nine months and the compensation adjusted to $90,000. There was also the issuance of 3,750 shares issued to the related party which was valued at $30,000. This agreement has currently expired.

Note 14 – Subsequent Events

In January 2019, the Board proposed, and a majority of the note holders agreed to, a modification to the convertible notes by extending the maturity date to March 2022 and decreasing the conversion price to $5.20 per share which was deemed to be the fair value of the common stock on the date of the modification. Subsequently on April 15, 2019, the Company agreed to decrease the conversion rate to $3.20 per share. The Company is still computing the effect of this change.

The Company received $150,000 in convertible notes from certain Board Members in March 2019. These notes bear interest at 8% and are convertible at $5.20 per share and subject to the same modification disclosed above. The notes are due March 2022.

The Company evaluated all subsequent events that occurred after the balance sheet date through April 16, 2019 the date the financial statements were available to be issued, and concluded there were no additional events and transactions occurring during this period that required recognition or disclosure in the financial statements.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

PROLUNG, INC.

April 16, 2019
Date

By: */s/ Jared Bauer*
Jared Bauer
Interim Chief Executive Officer (Principal Executive and Accounting Officer), Director

ADDITIONAL SIGNATURES

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

Signature	Title	Date
/s/ Jared Bauer Jared Bauer	Interim Chief Executive Officer (Principal Executive and Accounting Officer), Director	April 16, 2019
/s/ Mark V. Anderson Mark V. Anderson	Director	April 16, 2019
/s/ J. Scott Nixon J. Scott Nixon	Director	April 16, 2019
/s/ Robert W. Raybould Robert W. Raybould	Director	April 16, 2019
/s/ Michael Garff Michael Garff	Director	April 16, 2019

Exhibit Index

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation, as amended by Certificate of Amendment dated October 10, 2017(1)
3.2	Amended and restated By-Laws(2)
21.1	List of Subsidiaries
31.1	Certification Pursuant to Rule 13a-14 and 15d-14 under the Securities Exchange Act of 1934, as amended*
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101 INS	XBRL Instance Document*
101 SCH	XBRL Schema Document*
101 CAL	XBRL Calculation Linkbase Document*
101 LAB	XBRL Labels Linkbase Document*
101 PRE	XBRL Presentation Linkbase Document*
101 DEF	XBRL Definition Linkbase Document*

* Filed herewith
(1) Incorporated by reference from our Current Report on Form 10-K filed with the SEC on April 17, 2018.
(2) Incorporated by reference from our Current Report on Form 8-K filed with the SEC on July 19, 2017.

Exhibit 21.1

List of Subsidiaries

Hilltop Acquisition Corporation, Inc., a Delaware corporation (100% owned)

Exhibit 31.1

CERTIFICATION

I, Jared Bauer, certify that:

1. I have reviewed this Annual Report on Form 10-K of ProLung, Inc. for the year ended December 31, 2018.

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer(s) 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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

Dated: April 16, 2019

/s/ Jared Bauer

Jared Bauer, interim Chief Executive Officer and Principal Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ProLung, Inc. (the "Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (the "Report"), I, Jared Bauer, interim Chief Executive Officer and Principal Accounting Officer of the Company, hereby certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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 this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 16, 2019

/s/ Jared Bauer
Jared Bauer, interim Chief Executive Officer