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, 2019.

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

001-38362
(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.)

350 W. 800 N., Suite 214
Salt Lake City, Utah
84103

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common	**None**	**None**

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 [ ] NO [X]

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 [ ]
Non-accelerated Filer [X]
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, 2019, was approximately $12,167,917 based upon 3,802,474 shares held by non-affiliates and an assumed fair market value of $3.20 per share. The Registrant's common stock does not trade on an established market; accordingly, fair market value is estimated based upon the most recent conversion rate of the Company's convertible debt issued prior to June 30, 2019. 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 June 26, 2020, the Registrant had 4,083,557 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, 2019 (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," "IONIQ Sciences" or "IONIQ" in addition to as the "Company" and versions of "we" or "us." On May 27, 2020, ProLung, Inc. announced we had filed a dba IONIQ Sciences ("IONIQ" or the "Company") to reflect our expanded early cancer detection strategy. Current and all granted trademarks include ProLungdx®, ProLung®, EPN Scan®, Electro Pulmonary Nodule Scanner (EPN Scan) ®, IONIQ Sciences®, IONIQ Science®, IONIQ Test® and IONIQ Screen®. 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 with a mission to dramatically improve cancer outcomes by the development of our modern screening technology for the early detection of multiple cancers, which has the potential to expand therapeutic windows, significantly improve survivability, and reduce treatment costs. Half of all Americans will be diagnosed with cancer during their lifetimes and one in five of those diagnosed with cancer will die from it. Clinical literature shows that early detection can save lives and money. The first planned product utilizing our proprietary analytic platform, the IONIQ ProLung Test™ for lung cancer, has been designated a Breakthrough Device by the U.S. FDA. We remain fully committed to gaining U.S. FDA regulatory *de novo* clearance and subsequently commercializing the IONIQ ProLung Test for 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. Current statistics reflect an average 17% survival rate at five years for those diagnosed with lung cancer. Early detection substantially improves rates of survival. Patients at high risk of lung cancer are recommended to undergo regular Computed Tomography "CT" chest scans to detect nodules. Due to the risks and costs associated with assessing malignancy by current technology, patients now normally wait from three months to 3.5 years to have the risk of malignancy assessed upon detection of a nodule by CT chest scan. Our IONIQ ProLung Test was developed to provide a non-invasive, rapid and radiation-free option for assessing the risk of malignancy in lung nodules found in the chest by CT scans.

We believe the IONIQ 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 IONIQ ProLung Test is designed to enable the practitioner to promptly assess the risk of malignancy in patients with lung nodules. The IONIQ ProLung Test utilizes mass-averaging bioconductive technology or Electrical Impedance Analytics (EIA). 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 IONIQ 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 IONIQ 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 IONIQ ProLung Test registers and evaluates measurement data derived from numerous pathways through the chest and is processed by a predictive analytical 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 IONIQ ProLung Test requires minimal preparation and can be completed in 20 minutes. Most importantly, it guides or informs the physician's decision making without the time consuming, expensive and watchful waiting period. We believe the IONIQ ProLung Test provides considerable cost savings when compared with today's status quo of patients undergoing repeated CT imaging studies and potentially unnecessary surgery.

We licensed and developed the intellectual property and established the clinical research plan for the IONIQ 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 IONIQ ProLung Test in lung cancer patients. To date, more than 1,200 subjects have been tested using the IONIQ ProLung Test at our headquarters and in major cancer centers, such as MD Anderson, Loyola, Wake Forest and Huntsman Cancer Institute, among others. If our *de novo* FDA clearance is granted, of which there can be no assurance, we plan to transition the hospitals that participated in our clinical trials to commercial placements of the IONIQ ProLung Test System and consumable ProLunt Test kits.

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 IONIQ ProLung Test is the first bioconductive technology that has been developed for the risk stratification of lung cancer. In February 2015, the US Centers for Medicare& Medicaid Services (CMS) 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ ProLung Test by receiving the “CE” mark in Europe. This certification verifies that the IONIQ ProLung Test meets the regulatory requirements for the marketing and sale of the IONIQ 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 of the requested study 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 IONIQ 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 another solid indicator that our IONIQ ProLung Test is capable of identifying a signal that can be used to indicate the risk of malignancy in pulmonary nodules by non-invasively measuring their bioconductance biomarker. With the conclusion of this Study, the ProLung Team is eager to turn its focus to validating a number of already identified hardware, software 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 IONIQ ProLung Test. The repeatability study addressed several questions regarding use of the IONIQ 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 IONIQ 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.

In February 2020, the FDA designated the IONIQ ProLung Test a Breakthrough Device. Through the Breakthrough Device program, the FDA will provide ProLung with expedited reviews and the Centers for Medicare & Medicaid Services (CMS) has provisions for a simpler and faster pathway to reimbursement. This is not a marketing clearance.

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.

PL-208 Study – (2012-2019)

Three Validation studies have been completed for the IONIQ ProLung Test. The first is PL-208 which enrolled 420 patients across 15 US centers (ID: NCT01566682). This study was two-phased, with a 200-patient open-labelled training set to test and optimize an algorithm, followed by testing of the optimized algorithm on the diagnosis-blinded 174-patient validation set. Forty-six (46) subjects (11%) were excluded for being lost to follow up or having an inconclusive diagnosis, missing or inadequate device data. The predictive algorithm utilized the patient's bioconductance measurements coupled with the patient's age and a binary cut-off point of 0.5 was chosen to distinguish between high and low likelihood of cancer. The algorithm was locked and applied to a blinded validation set of 174 patients and yielded a Sensitivity of 69% Specificity of 49%, Positive Predictive Value (PPV) of 70%, Negative Predictive Value (NPV) of 47% and overall Accuracy of 61%.

PLW-208 Study – (2015-2016)

The second validation trial (PLW-208) was completed by the Company's licensor (ProLung Wuxi). This study enrolled 138 subjects at 2 centers in China. This study was similar in design to the US PL-208 Study and obtained a Sensitivity of 77%, Specificity of 60%, PPV of 82%, NPV of 41% and an Accuracy of 73%. In reviewing this study, the Sponsor determined that test method and operator training needed to be improved to obtain better results.

PLW-216 Study – (2017-2019)

Ultimately, the Study Sponsor (ProLung Wuxi) improved the device operator training, test method and device predictive algorithm. The Sponsor concluded the PLW-208 Study and initiated PLW-216, utilizing improved training, test method and a modified locked predictive algorithm. This PLW-216 Study was a single-phase validation study whereby the predictive algorithm was locked prior to the first patient being enrolled and the IONIQ ProLung Test results were provided to site investigators prior to knowing the subject's actual diagnosis. The PLW-216 Study enrolled 486 subjects in China at 4 centers led by Dr. Bai, the Chair of the Chinese Alliance against lung Cancer and Director of the Shanghai Respiratory Research Institute (ID: NCT 02726633, registration No 20170226). The Validation Study demonstrated improved performance yielding a Sensitivity of 84% Specificity of 73%, Positive Predictive Value (PPV) of 79%, Negative Predictive Value (NPV) of 80% and overall Accuracy of 79% from the US Study PL-208 (ID NCT0156668). This performance is comparable to other diagnostic cancer devices such as Mammogram (~sensitivity of 75%, specificity of 71%) and was demonstrated in a large sample size of 418 subjects included in the final analysis.

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Our facsimile number is (801) 906 – 0333.

Our e-mail address is info@IONIQsciences.com.

Our website may be viewed at www.IONIQsciences.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. In May 2020, the Company filed a dba IONIQ Sciences.

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 IONIQ ProLung Test in the US, European, 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 IONIQ ProLung Test. The following is a summary of the principal markets for the Company's IONIQ ProLung Test.

Lung Cancer Incidence and Mortality

	New Cases	Deaths
United States	222,500	155,870
European Union	313,000	268,000
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 IONIQ 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 IONIQ ProLung Test.

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 IONIQ 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 IONIQ 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.

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, 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 IONIQ 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

IONIQ ProLung Test

The IONIQ ProLung Test is comprised of the following two 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 IONIQ ProLung Test Kits that a customer buys. We refer to the ProLung System internally as capital equipment or the razor handle in the ubiquitous razor/razor blade sales analogy.

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

ProLung's novel Electrical Impedance Analtyics 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 IONIQ ProLung Test and extensive training is not required to interpret the composite score.

If required regulatory clearances are received, the IONIQ 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 IONIQ 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 IONIQ ProLung Test is non-invasive, rapid and non-radiating. It requires minimal patient preparation and can be completed in fewer than 30 minutes.

The IONIQ ProLung Test Procedure

1. The IONIQ ProLung Test System is connected to the probe, to the electrode cables, and to the power supply. Following a brief power-on sequence, the IONIQ ProLung Test completes self-diagnostics.
2. The patient is seated.
3. IONIQ 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 IONIQ ProLung Test has been evaluated in five completed clinical trials through 2019. We made modifications to the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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-208 Study – (2012-2019)

- *Description.* Three Validation studies have been completed for the IONIQ ProLung Test. The first is PL-208 which enrolled 420 patients across 15 US centers (ID: NCT01566682). This study was two-phased, with a 200-patient open-labelled training set to test and optimize an algorithm, followed by testing of the optimized algorithm on the diagnosis-blinded 174-patient validation set. Forty-six (46) subjects (11%) were excluded for being lost to follow up or having an inconclusive diagnosis, missing or inadequate device data. The predictive algorithm utilized the patient's bioconductance measurements coupled with the patient's age and a binary cut-off point of 0.5 was chosen to distinguish between high and low likelihood of cancer.

- *Final Results.* The algorithm was locked and applied to a blinded validation set of 174 patients and yielded a Sensitivity of 69% Specificity of 49%, Positive Predictive Value (PPV) of 70%, Negative Predictive Value (NPV) of 47% and overall Accuracy of 61%.

PLW-208 Study – (2015-2016)

- *Description.* The second validation trial (PLW-208) was completed by the Company's licensor (ProLung Wuxi). This study enrolled 138 subjects at 2 centers in China.

- *Final Results.* This study was similar in design to the US PL-208 Study and obtained a Sensitivity of 77%, Specificity of 60%, PPV of 82%, NPV of 41% and an Accuracy of 73%. In reviewing this study, the Sponsor determined that test method and operator training needed to be improved to obtain better results.

PLW-216 Study – (2017-2019)

- *Description.* Ultimately, the Study Sponsor (ProLung Wuxi) improved the device operator training, test method and device predictive algorithm. The Sponsor concluded the PLW-208 Study and initiated PLW-216, utilizing improved training, test method and a modified locked predictive algorithm. This PLW-216 Study was a single-phase validation study whereby the predictive algorithm was locked prior to the first patient being enrolled and the IONIQ ProLung Test results were provided to site investigators prior to knowing the subject's actual diagnosis. The PLW-216 Study enrolled 486 subjects in China at 4 centers led by Dr. Bai, the Chair of the Chinese Alliance against lung Cancer and Director of the Shanghai Respiratory Research Institute (ID: NCT 02726633, registration No 20170226).

- *Final Results.* The Validation Study demonstrated improved performance yielding a Sensitivity of 84% Specificity of 73%, Positive Predictive Value (PPV) of 79%, Negative Predictive Value (NPV) of 80% and overall Accuracy of 79% from the US Study PL-208 (ID NCT0156668). This performance is comparable to other diagnostic cancer devices such as Mammogram (~sensitivity of 75%, specificity of 71%) and was demonstrated in a large sample size of 418 subjects included in the final analysis.

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. Their 486 patient Validation Study in China using the ProLung technology with the modified measurement collection methodology and modified classifier algorithm was completed in 2019. Preliminary results of the completed research in China have been presented at the 2017 American Thoracic Society International Conference Poster Session, as well as the 2019 International Symposium on Respiratory Diseases (ISRD) & American Thoracic Society (ATS) Joint Medical Conference.

In January 2019, ProLung amended the ProLung China license. The second addendum 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).

In August 2019, ProLung announced that it amended the ProLung China license. The third addendum supports an expanded full collaboration business relationship wherein Prolung China Co. ("Prolung China") and subsidiary (ProLung Biotech Wuxi) agree to provide all ProLung Biotech Wuxi Know-How and Improvements and clinical data which are used in Clinical Trials in China (PLW-208 and PLW-216) to ProLung, and other matters

Italy and Switzerland. Four centers in Italy and one center in Switzerland conducted research with the IONIQ 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 IONIQ 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 IONIQ ProLung Test that was compliant with Good Clinical Practice or whether these patients conformed with the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ ProLung Test:

1. The proprietary design of the IONIQ 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:

ProLung Patent Applications

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	10,117,596B2
	JP	PCT(5)	10/18/2013	2016-536073	6,337,267
	Korea	PCT(5)	03/16/2016	10-2016-7006923	10-2035381
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	US	DIV (3)	11/26/2007	11/944,696	7,536,220
non-invasive bioelectrical signals in living organisms	US	ORD (1)	7/16/2003	10/621,178	7,542,796
Systems and methods of utilizing electrical	US	ORD (1)	7/20/2004	10/895,149	7,937,139
readings in the determination of treatment	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 Application 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
US	62/962,484	Noninvasively Locating and Measuring the Lymphatic system
US	62/962,482	Noninvasive Diagnostic Screening and Monitoring of the Body
US	62/962,475	Noninvasive Medical Diagnostics using Electrical Impedance Metrics and Clinical Predictors

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 IONIQ 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 IONIQ 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.

  Before the FDA can grant clearance of our *de novo* application, we must resubmit the application with the results of our clinical 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.

  In February 2020, the FDA designated the IONIQ ProLung Test a Breakthrough Device. Through the Breakthrough Device program, the FDA will provide ProLung with expedited reviews and the Centers for Medicare Medicaid Services (CMS) has provisions for a simpler and faster pathway to reimbursement. This is not a marketing clearance. Furthermore, in 2020 we have received feedback from the FDA regarding the PLW-216 Study. The FDA has shared concerns regarding, indications for use, risks of the device, mechanism of action, device usability and repeatability, efficacy, PLW-Study design and applicability of the PLW-216 study results to the US population. We have ongoing meetings with the FDA to address these significant comments from the FDA many of which have not yet been resolved.

- **European Union.** CE marking was granted as of May 10, 2013 for the IONIQ 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.

- **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 IONIQ 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 IONIQ ProLung Test and the IONIQ 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 $2,099,463 and $2,036,792 on company-sponsored research and development during fiscal years ending December 31, 2019, and 2018, respectively.

Employees

As of December 31, 2019, we had six employees. As of June 26, 2020, we had eight 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.

As of December 31, 2019, we remain an "emerging growth Company. We believe we will remain an "emerging growth company" through at least December 31, 2020.

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 IONIQ ProLung Test in the US and Europe and seeking marketing clearance for the IONIQ 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, 2018 was $7,709,282 and for the year ended December 31, 2019 was $4,619,887.

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 IONIQ ProLung Test, our ability to protect intellectual property related to the IONIQ 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 IONIQ ProLung Test, If we obtain FDA clearance, of which there is no assurance, we will need to obtain significant additional capital in order to execute our sales and marketing go-to-market plan.

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, 2019, we had outstanding Notes and Loans totaling $6,260,484. The balances of our loan obligations are scheduled to come due between 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 IONIQ ProLung Test may never achieve commercial market acceptance.

Our IONIQ 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 IONIQ 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. Furthermore, in 2020 we have received feedback from the FDA regarding the PLW-216 Study. The FDA has shared concerns regarding, indications for use, risks of the device, mechanism of action, device usability and repeatability, efficacy, PLW-Study design and applicability of the PLW-216 study results to the US population. We have ongoing meetings with the FDA to address these significant comments from the FDA many of which have not yet 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 IONIQ 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 IONIQ ProLung Test is unsuccessful or we are unable to market our IONIQ 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 IONIQ 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 IONIQ ProLung Test and are unable to develop additional products, our business will not succeed.

We have no experience commercializing the ProLung System and IONIQ ProLung Test. We currently have no products available for sale. If the IONIQ ProLung Test or our other products in development are 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 IONIQ ProLung Test to other cancer targets. ProLung does not have clinical data suggesting that the IONIQ ProLung Test is effective in other cancers and the IONIQ ProLung Test may not be effective in other cancers.

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

The nature of the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 our prior 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 former officers and directors 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.

On April 23, 2019, the Utah Division of Securities (the "***Division***") filed a Notice of Agency Action and an Order to Show Cause before the Division of Securities of the Department of Commerce of the State of Utah against the Company, Jared Bauer and former Board Members (Clark Campbell, Tim Treu, Todd Morgan and Robert Raybould).

In January 2020, the Division issued a Stipulation and Consent Order which set forth the following: 1) the Company agrees to settle the matter with the Division by way of the Stipulation and Consent Order; 2) the Stipulation and Consent Order fully resolves all claims the Division has against the Company pertaining to the Order to Show Cause; 3) the Division, ProLung and Bauer, agree to promptly file a stipulation and joint motion to dismiss ProLung and Bauer from this administrative action, with respect to Count 1 against ProLung and Bauer (the only claim brought against Bauer); 4) In or about April 2014, the Company Board of Directors circulated a consent agreement regarding the issuance of 582,102 (72,763 post-split) ProLung stock certificates to select members of the ProLung Board of Directors in connection with "financing services provided" by those members; 5) In or about April 2014, ProLung issued stock grants of 216,000 (27,000 post-split) shares to Robert W. Raybould, 16,350 (2,044 post-split) shares to Steve Eror, 63,750 (7,968 post-split) shares to Treu; 193,500 (24,118 post-split) shares to Campbell; and 97,500 (12,188 post-split) shares to Morgan; 6) Subsequent to issuance of those shares, ProLung was informed by counsel of potential consequences for Pro Lung employing unlicensed agents and individuals receiving the shares as compensation directly for sale of securities without a securities license, as opposed to receiving shares as compensation for generalized board service. Subsequently, no further shares were issued as compensation for fundraising. Mr. Eror returned his shares to the Company. However, Raybould, Treu, Campbell and Morgan did not return their shares to the Company. ProLung did not disclose the potential licensing violation until on or about December 3, 2018, in its Note Purchase Agreements.

As set forth by the Company in its Form 8-K dated November 27, 2019, Campbell, Treu, Morgan, and Raybould entered into Stipulation and Consent Orders wherein they returned shares of stock to the Company's treasury and paid fines to the Division of Securities.

On January 9, 2020, the Division entered an order as follows: 1) entering certain Findings and Conclusions by the Division, which ProLung admitted via a Stipulation and Consent Order; 2) ordering ProLung to cease and desist from violating Utah Uniform Securities Act (the "***Act")*** and to comply with the requirements of the Act in all future business in the state of Utah; 3) ordering ProLung to disclose the contents of the order to investors and prospective investors in all future capital raising efforts and disclosure documents of ProLung; and 4) Ordering ProLung to pay a fine of $55,000 to the Division.

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 IONIQ 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 IONIQ ProLung Test. Even if the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ ProLung Test. If the IONIQ 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 IONIQ ProLung Test, or that our business plan is sound;
- successfully contract for and establish a commercial supply of components for the manufacture of the IONIQ ProLung Test and the ProLung Scan System;
- achieve market acceptance of the IONIQ 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 IONIQ 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 IONIQ ProLung Test, future demand for the IONIQ 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 IONIQ ProLung Test. We cannot predict future markets for the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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.

IONIQ ProLung Tests may produce false positive and false negative results.

A patient may have a low composite risk score as measured by the IONIQ 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 IONIQ ProLung Test, may be subject to less stringent clinical vigilance. The IONIQ 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 IONIQ 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 IONIQ ProLung Test. Again, since the IONIQ 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 IONIQ 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 IONIQ ProLung Test and would thus harm our business, cash flows and operations.

Our clinical studies may produce unfavorable results.

Unfavorable results could prevent the IONIQ ProLung Test from obtaining FDA and other regulatory authorizations. Unfavorable clinical results may also prevent the Company from adequately commercializing the IONIQ 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 IONIQ ProLung Test does not achieve market acceptance, we will be unable to generate significant revenues. The commercial success of the IONIQ ProLung Test will depend primarily on convincing healthcare providers to adopt and use the IONIQ 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 IONIQ 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 IONIQ ProLung Test could be limited. Even if we demonstrate the effectiveness of the IONIQ ProLung Test, medical practitioners may still use other products. If the IONIQ 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. 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.

The recent novel coronavirus (COVID-19) outbreak could materially adversely affect our financial condition and results of operations

The novel strain of the coronavirus (COVID 19) identified in China in late 2019 has globally spread throughout other areas such as Asia, Europe, the Middle East, and North America and has resulted in authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and shutdowns. The spread of COVID-19 has caused us to modify our business practices (including employee travel, employee work locations, and cancellation of physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers, partners, and suppliers. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and our ability to perform critical functions could be harmed.

The degree to which COVID-19 impacts our operations and financial results will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume.

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 IONIQ 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 IONIQ ProLung Test in the European Union. We are seeking clearance to sell the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ ProLung Test;
- pricing and cost-effectiveness;
- the inclusion or omission of the IONIQ 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 IONIQ 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 IONIQ ProLung Test not commercially viable. For example, third-party payers may deny coverage for the test or set reimbursement for the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 and PLW-216 clinical studies were designed without input from the FDA. We have 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 and PLW-216 or any future study, or agree that the results generated in our PL-208 and PLW-216 trial is sufficient for FDA to approve or clear the IONIQ 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 IONIQ 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 IONIQ 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%. In, the fall of 2019 we announced the results of PLW-216. In the study of 486 subjects with 418 effective, the IONIQ ProLung Test returned results of 84% sensitivity, 73% specificity, 78% Positive Predictive Value (PPV) and 80% Negative Predictive Value (NPV). The performance from PL-208, PL-209 and PLW-216 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 IONIQ ProLung Test in a limited number of jurisdictions, and there is no guarantee that such protection will be available for the IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ 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 IONIQ ProLung Test in the EU, that we may infringe on this trademark, we might need to change the name under which we market the IONIQ 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.

We rely on the proper function, availability and security of information technology systems to operate our business, and a material disruption of critical information systems or a material breach in the security of our systems may adversely affect our business and customer relationships.

We rely on information technology systems (including technology from third-party providers) to process, transmit, and store electronic information in our day-to-day operations, including sensitive personal information and proprietary or confidential information. Our internal information technology systems, as well as those systems maintained by third-party providers, may be subjected to computer viruses or other malicious code, unauthorized access attempts, and cyber-attacks, any of which could result in data leaks or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent, and there can be no assurance that our protective measures have prevented or will prevent security breaches, any of which could have a significant impact on our business, reputation and financial condition, particularly attacks that result in our intellectual property and other confidential information being accessed or stolen. We rely on third-party vendors to supply and support certain aspects of our information technology systems. These third-party systems could also become vulnerable to cyber-attacks, malicious intrusions, breakdowns, interference or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems. Cyber-attacks could also result in unauthorized access to our systems and products, including personal information of individuals, which could trigger notification requirements, encourage actions by regulatory bodies, result in adverse publicity, prompt us to offer credit support products or services to affected individuals and lead to class action or other civil litigation. [We currently do not maintain cybersecurity insurance.] If we fail to monitor, maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could, lose customers, be subject to fraud, breach our agreements with or duties toward customers, physicians, other health care professionals and employees, be subject to regulatory sanctions or penalties, incur expenses or lose revenues, sustain damage to our reputation or suffer other adverse consequences. Unauthorized tampering, adulteration or interference with our products may also create issues with product functionality that could result in a loss of data, risk to patient safety, and product recalls or field actions. Any of these events could have a material adverse effect on our business, operations or financial condition.

Our business is subject to complex and evolving U.S., state and international laws and regulations regarding privacy and data protection. Many of these laws and regulations are subject to change and uncertain interpretation and could result in claims, changes to our business practices, penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

The U.S. and many other countries in which we conduct our operations have adopted laws and regulations protecting certain data, including medical and personal data, and requiring data holders and controllers to implement administrative, logical and technical controls and procedures in order to protect the privacy of such data. Individual states have also begun to enact data privacy laws. For example, California's Consumer Protection Act went into effect on January 1, 2020, giving consumers the right to demand certain information and actions from companies who collect personal information. Internationally, some countries have also passed laws and regulations that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. In addition, regulatory authorities around the world are considering a number of additional proposals concerning data protection. These laws and regulations have been, and may continue to be, inconsistent with each other, requiring different approaches in different jurisdictions. In addition, the interpretation and application of medical and personal data protection laws and regulations in the U.S., Europe, China and elsewhere are often uncertain and in flux. Further, we may incur significant expense in connection with our efforts to comply with those laws and regulations. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our data practices, possibly resulting in fines or orders requiring that we change our data practices, which could have an adverse effect on our business and results of operations. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business. Legal developments in Europe have created compliance uncertainty regarding certain transfers of personal data from the EU to the U.S. and other non-EU jurisdictions. For example, the GDPR, which came into application in the EU on May 25, 2018, applies to our activities conducted from an establishment in the EU or related to products and services that we offer to EU users. The GDPR created a range of new compliance obligations, which could cause us to change our business practices, and significantly increases financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements).

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 350W. 800 N., Suite 214, Salt Lake City, Utah 84103. We currently lease this property for $3,600 a month. This location is approximately 3,635 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 June 26, 2020, there are 4,083,557 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, 2019:

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	526,135	$ 5.86	53,865
Equity compensation plans not approved by security holders	1,255,667	$ 5.17	N/A
Total	1,781,802	$ 5.37	53,865

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 with a mission to dramatically improve the cancer landscape with a modern solution for the early detection of multiple cancers thereby expanding the therapeutic window, significantly improving survivability, and reducing the cost of healthcare. One in two Americans will be diagnosed with cancer during their lifetime an done in five will die. Clinical literature shows that early detection can save lives and money. We operate at the confluence of our Electrical Impedance Analytics (EIA) technology and artificial intelligence (AI). We are developing an advanced multi-cancer screening technology for early detection that will expand the therapeutic window, dramatically improve survivability and reduce the cost of healthcare. The first planned product utilizing our proprietary analytic platform, the IONIQ ProLung Test™ for lung cancer, has been designated a Breakthrough Device by the U.S. FDA. We remain fully committed to gaining U.S. FDA regulatory de novo clearance and subsequently commercializing the IONIQ ProLung Test™ for lung cancer.

We believe the IONIQ ProLung Test for lung cancer, 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, 2019, compared to Fiscal Year Ended December 31, 2018

Revenue and Cost of Revenue.

During the year ended December 31, 2019 or 2018, we had no revenue.

Operating Expenses

Research and Development Expense. Research and development expense for the year ended December 31, 2019 was $2,099,463 compared to research and development expense of $2,036,792 for the year ended December 31, 2018; representing an increase of $62,671. The increase was due to the following events:

During 2019, we amended a license agreement with ProLung China. The license agreement was amended whereby ProLung China will provide us its clinical trial data, know-how and improvements which we will use outside the greater China area. As part of this agreement we committed to pay ProLung China $560,000 and issue shares based on the completion of certain milestones. During 2019 we recorded apporoximately $1,450,000 of expense under this agreement.

During 2018, we entered into an agreement with our then 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. Also, during 2018, 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.

Selling, General and Administrative Expense. Selling, general and administrative expense for the year ended December 31, 2019, was $1,464,515, compared to selling, general, and administrative expense of $2,494,455 for the year ended December 31, 2018, representing a decrease of $1,029,940. This decrease was due to allocating our limited cash resources to essential activities and eliminating all non-essential administrative activities. During 2018, we incurred significant travel, legal, professional and consulting expense related to investor relations, public relations, company awareness and indirect costs incurred as we concluded the public offering process. However, in February 2018, we elected to terminate our relationship with our underwriters and cancelled the offering.

Other Expense. Other expense for the year ended December 31, 2019 was $1,055,909 as compared to $3,178,035 for the year ended December 31, 2018. The decrease costs consist of the following:

- *Interest Expense / Loss on Debt Extinguishment* – 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. Interest decreased from 2019 ($407,358) to 2018 ($695,022) due to a higher amortization of the discount during 2018. However, during 2019, we reduced the conversion price of the convertible notes which resulted in a debt extinguishment whereby we recorded a loss of $648,551.

- *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, 2019 and 2018:

	December 31,	
	2019	2018
Cash	$ 207,421	$ 249,286
Current assets	212,848	273,539
Current liabilities	(2,535,877)	(507,353)
Working capital deficit	$ (2,323,029)	$ (233,814)

We need additional capital to continue our operations. During the year ended December 31, 2019, 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 IONIQ 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 IONIQ 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 IONIQ 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, 2019, 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 $3.20 per share. Interest accruing from the date of issuance to the conversion date shall be paid on the maturity date. Through December 31, 2019, we have issued $5,643,243 in convertible promissory notes and incurred cash fees of $391,400 and issued 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, 2019 and 2018 is as follows:

	For the Year Ending December 31,	
	2019	2018
Operating activities	$ (1,394,115)	$ (3,056,367)
Investing activities	-	8,539
Financing activities	1,352,250	2,660,475
Net decrease in cash	$ (41,865)	$ (387,353)

Operating Activities

For the fiscal year ended December 31, 2019, the differences between our net loss and net cash used in operating activities were due to net non-cash charges totaling $2,734,209 for impact of stock-based compensation, amortization of research and development agreement, loss on debt restructure, and depreciation.

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.

Investing Activities

In the year ended December 31, 2019, we had no investing activities. During 2018, we had nominal investing activities.

Financing Activities

During the year ended December 31, 2019 and 2018, cash flows from financing activities totaled $1,352,250 and $2,660,475 related to proceeds received from the issuance of convertible notes and short term loans, net of loan costs paid. During 2019, we also made an initial $150,000 payment on a long-term commitment.

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.

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, 2019, 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 and therefore not effective. 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, 2019, 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 weakness, management has concluded that our internal controls over financial reporting were not effective as of December 31, 2019.

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, 2019 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 IONIQ Sciences, 350 W. 800 N., Suite 214, Salt Lake City, Utah 84103.

Name and Business Address	Age	Position
Jared Bauer	38	Chief Executive Officer, and Director
Michael Garff	37	Director, Chief Operating Officer
Jim Hogan	63	Director
Don Patterson	67	Director
David Nielsen	48	Director
Rich McKeown	73	Director

Jared Bauer. Mr. Bauer, 38, was promoted from interim Chief Executive Officer to Chief Executive Officer of ProLung in October 2019. He was appointed to the ProLung Board of Directors in August 2018 and appointed interim CEO one month later. 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.

Jim Hogan. Mr. Jim Hogan, 63, served his entire professional career in the medtech industry in multiple locations in the USA and abroad. After rising to the role of Director of Sales and Marketing for Pfizer Europe in London, he successfully founded two medtech companies and led two others. These four start-up medtech companies were all successfully exited. Mr. Hogan recently retired from Medtronic, one of the world's largest medtech companies, where he was President of Medtronic Latin America, corporate Vice President, and appointed to the company's Sr. Executive Committee. Mr. Hogan has deep operational, sales, marketing, and general management expertise with medical devices and therapeutics in some of the smallest and largest medtech companies in the world. Mr. Hogan remains dedicated to health-related philanthropic endeavors from his home in Park City, Utah. Mr. Hogan holds a BA in Chemistry and Psychology in addition to a MBA from the University of Minnesota.

Don Patterson. Mr. Don Patterson, 67, comes to the Board with a broad range of experience. He began his professional career in public accounting and worked for both large and small firms as a CPA for 24 years. During this time, he developed expertise in financial analysis and was significantly involved in merger and acquisition (M&A) activities. He has been involved in multiple boards of directors for companies ranging in size from small, closely-held companies to large privately-held, publicly listed companies. In one instance where he served on the boards of two NASDAQ-listed and affiliated firms as the Chair of the Audit Committee and a member of the Compensation Committee, he was directly involved in the sales negotiation to an investment bank. He has also been one of the founders in various entrepreneurial ventures, including manufacturing, distribution, intellectual property (IP) development and prosecution. His primary pursuit for the past 19 years has been in the development and licensing of patents involving manufacturing processes used in the home products industry. Mr. Patterson currently resides in Gilbert, Arizona and holds a BA degree in accounting from Arizona State University.

David Nielsen. Mr. David Nielsen, 48, is currently a partner at SaltRidge consulting, which is a medtech product development company and Chair/COO of Advanced Conceptions, a start-up in the fertility space. He has 20 years of R&D and leadership experience at BioFire and BioFire Defense (formerly named Idaho Technology), which sold to bioMérieux in 2014. As one of the original Idaho Technology employees, Mr. Nielsen worked in various roles in engineering, management, and business development rising to the position of Vice President of Product Development. He managed a team of more than 70 scientists and engineers who were responsible for developing and launching new medical diagnostic products and supporting the complex regulatory clearance process in the US, EU, and other jurisdictions. Mr. Nielsen holds a BS degree in Mechanical Engineering from Brigham Young University, a Master of Mechanical Engineering from the University of Utah and a MBA from the University of Utah.

Rich McKeown. Mr. Rich McKeown, 73, is the co-founder and Chairman of the Leavitt Partners Board of Directors. Mr. McKeown is re-joining the ProLung Board, as the Leavitt Partners' corporate designee, after previously serving on the ProLung Board from 2014-2017. Leavitt Partners is a health care intelligence business that understands the emerging role of value in health care. In previous roles, Mr. McKeown served as chief of staff for Mike Leavitt at the U.S. Department of Health and Human Services (HHS). At HHS, he directed and coordinated the activities of the largest department in the federal government, serving as the Secretary's day-to-day manager for a department that employed 67,000 people and had an annual budget in excess of $840 billion. He also led the negotiations between China and the FDA regarding Drug, Device and Food issues which led to landmark agreements in 2008 and paved the way for the placement of US-FDA offices around the world. Mr. McKeown also served as senior counselor and chief of staff to Administrator Mike Leavitt at the U.S. Environmental Protection Agency (EPA). Mr. McKeown co-authored with Mike Leavitt the highly-acclaimed book titled Finding Allies, Building Alliances. Prior to his public service in Washington, D.C., Mr. McKeown served as chief of staff to Governor Mike Leavitt and as commissioner of the Utah State Tax Commission. Mr. McKeown currently resides in Salt Lake City, Utah and received his juris doctorate from the University of Utah and bachelor's degree from Ohio University.

Michael Garff. Mr. Garff, 37, has served as our Chief Operating Officer since May 2009. At IONIQ, he obtained US FDA Breakthrough Device Designation and European regulatory approval (CE Mark) for the IONIQ ProLung Test, organized and operates manufacturing, acquired clinical sites at premier cancer hospitals, and designed and implemented a certified ISO 13485 quality management system. Currently, he oversees IONIQ's product development, manufacturing, clinical studies, regulatory affairs, FDA submissions, quality audits, data analysis, and patents. Prior to IONIQ, he was involved with the Pierre Lassonde Entrepreneur Center where he served as a Director. While there he helped launch several biomedical companies. He holds a BS in Business Finance and an MBA from the University of Utah.

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 Jim Hogan. His term will expire at the annual meeting of stockholders to be held later in 2020;
- The Class II directors is David Nielsen, Rich McKeown and Jared Bauer. Their terms will expire at the annual meeting of stockholders to be held in 2021;
- The Class III directors are Don Patterson and Michael Garff. Their terms will expire at the annual meeting of stockholders to be held in 2022.

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 Jim Hogan, David Nielsen and Rich McKeown representing three of our six 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. The remaining Board of Directors have determined that Jared Bauer (CEO), Michael Garff (COO) and Don Patterson 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 Don Patterson (chair) and Michael Garff. Our Board of Directors has determined that Mr. Patterson and Mr. Garff are independent under Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The chair of our audit committee is Mr. Nixon. Our Board of Directors has determined that Mr. Patterson is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulations 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.

Finance and 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 Jim Hogan (chair), David Nielsen and Rich McKeown. Our Board of Directors has determined that Mr. Hogan, Mr. Nielsen and Mr. McKeown 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 Finance and Compensation committee is Mr. Hogan.

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, four of our former directors or executive officers and one current director 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.

On April 23, 2019, the Utah Division of Securities (the "***Division***") filed a Notice of Agency Action and an Order to Show Cause before the Division of Securities of the Department of Commerce of the State of Utah against the Company, Jared Bauer and former Board Members (Clark Campbell, Tim Treu, Todd Morgan and Robert Raybould).

In January 2020, the Division issued a Stipulation and Consent Order which set forth the following: 1) the Company agrees to settle the matter with the Division by way of the Stipulation and Consent Order; 2) the Stipulation and Consent Order fully resolves all claims the Division has against the Company pertaining to the Order to Show Cause; 3) the Division, ProLung and Bauer, agree to promptly file a stipulation and joint motion to dismiss ProLung and Bauer from this administrative action, with respect to Count 1 against ProLung and Bauer (the only claim brought against Bauer); 4) In or about April 2014, the Company Board of Directors circulated a consent agreement regarding the issuance of 582,102 (72,763 post-split) ProLung stock certificates to select members of the ProLung Board of Directors in connection with "financing services provided" by those members; 5) In or about April 2014, ProLung issued stock grants of 216,000 (27,000 post-split) shares to Robert W. Raybould, 16,350 (2,044 post-split) shares to Steve Eror, 63,750 (7,968 post-split) shares to Treu; 193,500 (24,118 post-split) shares to Campbell; and 97,500 (12,188 post-split) shares to Morgan; 6) Subsequent to issuance of those shares, ProLung was informed by counsel of potential consequences for Pro Lung employing unlicensed agents and individuals receiving the shares as compensation directly for sale of securities without a securities license, as opposed to receiving shares as compensation for generalized board service. Subsequently, no further shares were issued as compensation for fundraising. Mr. Eror returned his shares to the Company. However, Raybould, Treu, Campbell and Morgan did not return their shares to the Company. ProLung did not disclose the potential licensing violation until on or about December 3, 2018, in its Note Purchase Agreements.

As set forth by the Company in its Form 8-K dated November 27, 2019, Campbell, Treu, Morgan, and Raybould entered into Stipulation and Consent Orders wherein they returned shares of stock to the Company's treasury and paid fines to the Division of Securities.

On January 9, 2020, the Division entered an order as follows: 1) entering certain Findings and Conclusions by the Division, which ProLung admitted via a Stipulation and Consent Order; 2) ordering ProLung to cease and desist from violating Utah Uniform Securities Act (the "***Act")*** and to comply with the requirements of the Act in all future business in the state of Utah; 3) ordering ProLung to disclose the contents of the order to investors and prospective investors in all future capital raising efforts and disclosure documents of ProLung; and 4) Ordering ProLung to pay a fine of $55,000 to the Division.

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.

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, 2019, and 2018. The Company's named executive officers are (a) each person who served as the Company's Chief Executive Officer during 2019, (b) the next two most highly compensated executed officers serving as of December 31, 2019, 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, 2019.

Summary Compensation Table

Name & Principal Position	Year	Salary	Bonus	Option Awards	All Other	Total
					(1)	
Jared Bauer (2)	2019	$ 96,000	$ -	$ 361,129(5)	$ -	$ 457,129
	2018	$ 32,000	$ -	$ 231,191(5)	$ -	$ 263,191
Steven C. Eror, Former CEO	2018	$ 161,069	$ -	$ -	$ 12,000	$ 173,069
Mark Anderson, Former CFO and Director (3)	2019	$ -	$ -	$ 13,794(6)	$ -	$ 13,794
	2018	$ 112,276	$ -	$ 23,140(6)	$ -	$ 135,416
Michael Garff, Chief Operating Officer (4)	2019	$ 161,288	$ -	$ 24,977(7)	$ -	$ 186,265
	2018	$ 160,868	$ -	$ 23,140(7)	$ -	$ 184,008

(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 and promoted to CEO in October 2019. Mr. Bauer is being compensated under a consulting contract of $8,000 per month, which was increased by the Board to $10,000 per month in June 2020.

(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 and resigned in June 2019.

(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 127,000 and 50,000 shares of common stock issued Mr. Bauer during 2019 and 2018, respectively in accordance with FASB ASC. Options related to Mr Baur's service as CEO during the years ended December 31, 2019 and 2018 totaled 119,000 and 45,000, respectively. Options related to service as a director during 2019 and 2018 totaled 8,000 and 5,000, respectively.

(6) Includes the aggregate grant date fair value (per FASB ASC guidelines) of options to purchase 5,000 and 5,000 shares of common stock issued to Mr. Anderson for his service as a director during 2019 and 2018, respectively.

(7) Includes the aggregate grant date fair value (per FASB ASC guidelines) of options to purchase 9,000 and 5,000 shares of common stock issued to Mr. Garff for his service as a director during 2019 and 2018, respectively.

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, 2019:

Compensation Table for Non-Executive Directors

Name & Principal Position	Fees Earned or Paid	Stock Awards	Option Awards	Other	Total
David Nielsen (1)	$ -	$ -	$ 16,887	$ -	$ 16,887
Don Patterson (2)	$ -	$ -	$ 21,109	$ -	$ 21,109
Jim Hogan (3)	$ -	$ -	$ 21,109	$ -	$ 21,109
Rich McKeown (4)	$ -	$ -	$ 11,183	$ -	$ 11,183
Robert Raybould, Former Director (5)	$ -	$ -	$ 26,377	$ -	$ 26,377
J. Scott Nixon, Former Director (6)	$ -	$ -	$ 20,690	$ -	$ 20,690

(1) Represents the aggregate grant date fair value of options to purchase 6,000 shares of common stock issued in accordance with FASB ASC Standards.

(2) Represents the aggregate grant date fair value of options to purchase 7,500 shares of common stock issued in accordance with FASB ASC Standards.

(3) Represents the aggregate grant date fair value of options to purchase 7,500 shares of common stock issued in accordance with FASB ASC Standards.

(4) Represents the aggregate grant date fair value of options to purchase 4,000 shares of common stock issued in accordance with FASB ASC Standards.

(5) Represents the aggregate grant date fair value of options to purchase 9,500 shares of common stock issued in accordance with FASB ASC Standards.

(6) Represents the aggregate grant date fair value of options to purchase 7,500 shares of common stock issued in accordance with FASB ASC Standards.

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 June 29, 2020, 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 4,083,557 shares of our common stock issued and outstanding as of June 26, 2020. Unless otherwise indicated, the address of each person listed is in care of ProLung, 350W. 800 N., Suite 214, Salt Lake City, Utah 84103.

Name of Beneficial Owner, Officer or Director	Amount and Nature of Beneficial Ownership [1] [2]	Percentage of Shares Beneficially Owned
Eric Sokol	328,189	8.0%
ProLung China	278,053	6.8%
Michael Garff, Chief Operating Officer [3]	108,625	2.6%
Jared Bauer[4]	186,000	4.4%
Don Patterson[5]	100,625	2.4%
All Executive Officers and Directors as a Group (nine persons)	425,750	9.6%

(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.

(3) Includes 49,250 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(4) Includes 186,000 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 88,125 shares of common stock. Also, includes 10,000 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, 2019, 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 and Michael Garff are not independent due to current and former employment with the Company. All other directors, namely Jim Hogan, David Nielsen, Don Patterson and Rich McKeown are independent.

Item 14. Principal Accounting Fees and Services

The following table summarizes the fees of MaloneBailey, LLP ("MaloneBailey") and Sadler, Gibb & Associates LLC (Sadler Gibb), 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. The Company switched from MaloneBailey to Sadler Gibb after the 2Q19 10-Q.

	2019	2018
Audit Fees	$ 45,000	$ 59,000
Audit-Related Fees	-	28,000
Tax Fees	-	-
All Other Fees	-	-
Total	$ 45,000	$ 87,000

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 2019 and 2018 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, 2019 and 2018
- Consolidated Statements of Operations for the years ended December 31, 2019 and 2018
- Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2019 and 2018
- Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018
- 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

SADLERGIBB
CERTIFIED PUBLIC ACCOUNTANTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of ProLung, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ProLung, Inc. ("the Company") as of December 31, 2019, the related consolidated statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2019 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

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 generated minimal revenues and has incurred substantial and recurring losses to date from operations, which 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audit included performing procedures to assess the risks of material misstatement of the 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 audit 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 audit provides a reasonable basis for our opinion.

Sadler Gibb & Assoc.

We have served as the Company's auditor since 2020.

Salt Lake City, UT
July 15, 2020

office 801.783.2950
fax 801.783.2960

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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 the related consolidated statements of operations, stockholders' deficit, and cash flows for the year 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 the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

Our audit included performing procedures to assess the risks of material misstatement of the 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 audit 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 audit provides 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,	
	2019	**2018**
Assets		
Current Assets		
Cash	$ 207,421	$ 249,286
Prepaid expenses	5,427	24,253
Total Current Assets	212,848	273,539
Property and equipment, net	135,633	46,699
Intangible assets, net	137,054	146,614
Total Assets	$ 485,535	$ 466,852
Liabilities and Stockholders' Deficit		
Current Liabilities		
Accounts payable	$ 387,739	$ 263,620
Accrued liabilities	636,207	243,733
Short term loans payable	105,000	-
Payable for research and development - current	200,000	-
Convertible notes payable - current	1,206,931	-
Total Current Liabilities	2,535,877	507,353
Long-Term Liabilities		
Payable for research and development agreement - long term	210,000	-
Convertible notes payable, related party, net - long-term	193,346	150,000
Convertible notes payable, net - long-term	4,242,966	3,386,868
Total Long-Term Liabilities	4,646,312	3,536,868
Total Liabilities	7,182,189	4,044,221
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; 4,068,557 and 3,861,849 shares issued and outstanding, respectively	4,069	3,862
Additional paid-in capital	27,083,391	25,582,996
Accumulated deficit	(33,784,114)	(29,164,227)
Total Stockholders' Deficit	(6,696,654)	(3,577,369)
Total Liabilities and Stockholders' Deficit	$ 485,535	$ 466,852

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,	
	2019	**2018**
Revenues:		
Revenue	$ -	$ -
Total revenue	-	-
Cost of revenue:	-	-
Gross margin	-	-
Operating expenses:		
Research and development expense	2,099,463	2,036,792
Selling, general and administrative expense	1,464,515	2,494,455
Total operating expenses	3,563,978	4,531,247
Loss from operations	(3,563,978)	(4,531,247)
Other income (expense):		
Loss on debt extinguisment	(648,551)	-
Warrant restructure	-	(2,179,612)
Write-off of deferred offering costs	-	(303,401)
Interest expense	(407,358)	(695,022)
Total other expense	(1,055,909)	(3,178,035)
Net loss	$ (4,619,887)	$ (7,709,282)
Basic and diluted loss per share	$ (1.19)	$ (2.00)
Weighted-average common shares outstanding, basic and diluted	3,895,673	3,861,848

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 2019

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance, December 31, 2017	3,861,849	$ 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	3,861,849	3,862	25,582,996	(29,164,227)	(3,577,369)
Shares issued under research and development agreement	278,053	278	889,492	-	889,770
Shares cancelled by former directors	(71,345)	(71)	71	-	-
Stock-based compensation	-	-	559,122	-	559,122
Warrants issued to convertible debt placement agent	-	-	51,710	-	51,710
Net loss	-	-	-	(4,619,887)	(4,619,887)
Balance, December 31, 2019	4,068,557	$ 4,069	$ 27,083,391	$ (33,784,114)	$ (6,696,654)

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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (4,619,887)	$ (7,709,282)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	54,179	38,996
Gain on sale of equipment	-	(3,294)
Share-based compensation	559,122	1,276,213
Shares issued under research agreement	889,770	-
Amortization of research and development agreement	560,000	-
Transfer of inventory to research and development	-	263,999
Loss on debt extinguishment	648,551	-
Amortization of loan discount/loan fees	22,857	408,726
Warrant restructure	-	2,179,612
Write-off of deferred offering costs	-	303,401
Change in assets and liabilities:		
Inventory	-	(8,362)
Prepaid expenses	18,826	7,591
Accounts payable	79,993	(32,298)
Accrued liabilities	392,474	218,331
Net cash flows used in operating activities	(1,394,115)	(3,056,367)
Cash flows from investing activities:		
Proceeds from sale of equipment	-	8,539
Net cash flows provided by investing activities	-	8,539
Cash flows from financing activities:		
Payment for placement of convertible notes payable	(25,000)	(322,275)
Payment on long-term payable	(150,000)	-
Proceeds from short term notes payable	105,000	-
Proceeds from convertible notes payable - related party	50,000	-
Proceeds from convertible notes payable	1,372,250	2,982,750
Net cash flows provided by financing activities	1,352,250	2,660,475
Net decrease in cash	(41,865)	(387,353)
Cash at beginning of period	249,286	636,639
Cash at end of period	$ 207,421	$ 249,286
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest	$ 48,145	$ 48,277
Supplemental disclosure of non-cash investing and financing activities:		
Debt discount on convertible notes - warrants	$ 95,835	$ 275,281
Payment of research and development agreement with long term payable	$ 560,000	$ -
Leasehold improvements purchased through convertible note	$ 133,553	$ -
Cancellation of former board shares	$ 71	$ -
Beneficial conversion feature	$ -	$ 463,983

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." In May 2020, the Company announced a dba IONIQ Sciences. 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. Subsequent to December 31, 2019, the Company dissolved this entity.

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 and no revenue during the current period. Until the Company receives Food and Drug Administration ("FDA") approval, the Company will not achieve its planned level of operations in the United States. The Company does have a Conformité Européene or CE mark for Europe and has licensed a portion of its technology to an entity located in China. The Company has incurred substantial and recurring losses to date from operations, continues to have a stockholders' deficit 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 for a period of one year from the issuance of these financial statements. The accompanying condensed 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, 2019 and 2018 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, 2019 or 2018.

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. During 2018 we wrote off all inventory amounts to research and development expense.

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. Leasehold improvements are amortized over the shorter of the life of the lease or the service life of the improvements. Maintenance, repairs, and renewals that neither materially add to the value of the property nor appreciably prolong its life are charged to expense as incurred. Gains or losses on dispositions of property and equipment are included in the results of operations.

Intangible Assets – As further discussed in Note 5 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 are being amortized over an estimated useful life of eighteen years, with periodic evaluation for impairment.

Impairment or Disposal of Long-Lived Assets **-** Long-lived assets are reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. When necessary, impaired assets are written down to estimated fair value based on the best information available. Estimated fair value is generally based on either appraised value or measured by discounting estimated future cash flows. Considerable management judgment is necessary to estimate discounted future cash flows. Accordingly, actual results could vary significantly from such estimates. We did not record an asset impairment charge for either of the years ended December 31, 2019 and 2018.

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, 2019 and 2018, 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, 2019 and 2018, the following items were excluded from the computation of diluted net loss per common share as their effect is anti-dilutive:

	December 31,	
	2019	2018
Warrants to purchase shares	1,255,667	1,227,809
Stock options	526,135	310,635
Convertible notes	1,774,351	698,919

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 2019 or 2018.

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

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.

Leases – 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 would be effective for the Company's 2019 fiscal year; however, since the Company is an Emerging Growth Company and has made the election to adopt certain accounting standards when they would be applicable for private companies which is the fiscal year beginning January 1, 2020. The Company will use the modified retrospective basis. The Company entered into a three year lease agreement in May 2019 and management is evaluating how the implementation of this standard will affect its 2020 balance sheet and statement operations.

Stock Compensation – In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The new ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. Since the Company is an Emerging Growth Company this standard is applicable fiscal years beginning after December 15, 2019. The Company is evaluating the effect that the updated standard will have on its financial statements and related disclosures.

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. 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 research projects, on December 31, 2018 the Company reassigned all inventory to research and development supplies.

Note 3 – Research and Development Agreement

On July 29, 2019, the Company amended a license agreement dated April 10, 2013 between the Company and ProLung Biotech Wuxi / ProLung China (Wuxi). The original agreement allowed Wuxi to utilize the Company's technology in China in return for royalty payments based on ProLung China's revenues. Wuxi has yet to earn any revenue but has been conducting clinical trials. The license agreement was amended whereby Wuxi will provide the Company its clinical trial data, know-how and improvements which the Company will use outside the greater China area. This amendment further requires full collaboration (i.e., protocols and methodologies) between the two entities. In consideration for such trial data and know-how, the Company will make cash payments to Wuxi of up to $560,000 and issue up to 347,566 shares of common stock upon the completion of certain events.

The Company will issue and value the shares as the following conditions are met:

- 139,027 shares upon Wuxi delivering their know-how and improvements to the Company plus up to 200 hours of operator training. This condition was met in October 2019.
- 69,513 shares upon delivering information and materials from Wuxi's Clinical Trial Data (PLW-216) for the purpose of review and monitoring which are sufficient for the Company to use in the US FDA Pre-sub mission review process. This condition was met in December 2019.
- 69,513 shares upon Wuxi transferring to the Company upon the Company's request for the completed China Clinical Trial Data (PLW-216). This condition was met in December 2019.
- 69,513 shares upon Wuxi losing the sites of the validation study utilizing Wuxi know how and improvements for submission to the US FDA for approval. This condition has yet to be met.

Through December 31, 2019, 278,053 shares had been issued based on conditions being met for a value of $889,770. The value of the stock issued was based on the conversion rate of convertible debt being issued at the time the conditions were met. The final 69,513 shares will be issued once the final milestone is met.

The cash payments are payable as follows: $150,000 in October 2019; $100,000 in April 2020; $85,000 in October 2020; $100,000 in April 2021; $100,000 in October 2021; and $25,000 in April 2022. The Company made $150,000 in payments through December 31, 2019 the remaining $410,000 is payable through April 2022. Once the initial milestone was met in October 2019 the entire $560,000 was recorded as research and development expense.

Note 4 – Property and Equipment

Property and equipment consists of the following at December 31, 2019 and 2018:

	Life	December 31, 2019	2018
Leasehold improvements	3 Years	$ 133,553	$ -
Computer equipment	3 years	31,392	31,393
Office equipment	3 to 5 years	19,152	19,151
Tooling	5 years	92,228	92,228
		276,325	142,772
Less accumulated depreciation		(140,692)	(96,073)
Property and equipment, net		$ 135,633	$ 46,699

Depreciation expense for the years ended December 31, 2019 and 2018 was $44,619 and $29,434, respectively.

Note 5 – 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, 2019 and 2018 the Company recognized amortization expense of $9,562 each year. At December 31, 2019, there was accumulated amortization of $38,246.

Note 6 – Accrued Liabilities

Accrued liabilities consists of the following at December 31, 2019 and 2018:

	December 31, 2019	2018
Accrued interest	$ 524,136	$ 187,779
Accrued royalties	17,873	17,873
Accrued settlement	55,000	-
Accrued payroll and payroll taxes	39,198	38,081
Accrued liabilities	$ 636,207	$ 243,733

Note 7 –Notes Payable

Short-term loans payable

The Company issued short term loans totaling $105,000 during 2019 for working capital. These loans are due on demand and accrue interest at 14.5%. The principal is due in cash and the accrued interest can be paid either in cash or common shares. At December 31, 2019, there was $5,982 in accrued interest related to these notes.

Convertible Notes Payable

2015 Convertible Note Issuances

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.

2018 Convertible Note Issuances

During 2018, the Company issued 8% convertible notes. The convertible notes were unsecured. Principal and accrued interest were 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 originally 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. Under the original terms, if the Company completed a public offering of its common stock, the convertible 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 notes; $150,000 of which from a current board member.

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 $275,321 ($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 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.

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. Due to the significance of the change in conversion price $2,862,750 of notes payable were considered extinguished and reissued. The Company recognized interest expense of $4,263 and a loss of $633,628 related to the deemed extinguishment.

On April 15, 2019, the Board agreed to decrease the conversion rate of certain convertible notes to $3.20 per share. Due to the significance of the change in conversion price, $3,232,750 of notes payable ($2,982,750 of 2018 issuances and $250,000 in 2019 convertible notes described below) were considered extinguished and reissued. The Company recognized an additional loss of $14,923 as a result of this deemed extinguishment. These modifications did not require recording a beneficial conversion feature.

2019 Convertible Note Issuances

During the year ended December 31, 2019, the Company issued $1,555,803 in convertible notes; $50,000 of which from a current board member. The Company received cash proceeds of $1,422,250 and settled $133,553 in leasehold improvements. These notes are unsecured, bear interest at 8% and are convertible at $3.20 per share ($250,000 of these notes were originally convertible at $5.20 and reduced in April 2019 as described above). The notes are due March 2022. Since these notes had a conversion price that was not "in the money" upon issuance there was no beneficial conversion feature recorded. 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 incurred $69,125 of loan costs and issued 21,608 warrants to a broker related to these loans. These warrants are exercisable at $3.20 and expire in ten years. The value of the warrants was $51,710 ($2.39 per warrant), derived utilizing the Black-Scholes Pricing Model with the following weighted average assumptions:

Expected life	5.0 years
Exercise price	$ 3.20
Expected volatility	100%
Expected dividends	n/a
Risk-free interest rate	1.83%

The $120,835 in loan costs incurred will be amortized as a component of interest expense over the term of the convertible notes. During the year ended December 31, 2019, the Company recognized interest expense of $18,594 related to the amortization of the loan costs. As of December 31, 2019, the unamortized balance loan costs is $102,241.

Convertible notes payable is summarized as follows :

	December 31, 2019	December 31, 2018
Convertible notes payable; unsecured; interest at 8%; due March 2020 (included related party amount of $150,000); balance transferred to March 2022 notes	$ -	$ 2,982,750
Convertible notes payable; unsecured; interest at 8%; due March 2022 (includes related party amount of $200,000)	4,538,553	-
Convertible notes payable; unsecured; interest at 8.00%; due November 2020	1,206,931	1,206,931
Unamortized discount and loan costs (includes related party amount of $6,654)	(102,241)	(652,813)
Notes payable, net	$ 5,643,243	$ 3,536,868
Less: current portion, net	(1,206,931)	-
Convertible notes payable - long term, net	$ 4,436,312	$ 3,536,868

Note 8 – 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, 2019, and 2018, the Board has not designated any series of preferred stock and there are no shares of preferred stock issued or outstanding.

Note 9 – Common Stock

Common Stock Issued for Services

See Note 3 for common stock issued under a research and development agreement.

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.

Return of Former Board Member Shares

As part of a settlement with the Utah Division of Securities (further discussed in Note 12), certain former directors of the Company returned 71,345 shares of common stock. There was no consideration given to these shareholders for the return of the shares.

Warrant Restructure

During 2016 and through May 2017, the Company issued equity under a private placement agreement. As part of the offering, a total of 697,293 warrants were issued with an initial exercise price of $12 per share. 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 $2,179,612 difference in fair value as a warrant restructure expense. The fair value(s) were derived using the Black Scholes pricing model with the value before being $0.31 per warrant ($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 per warrant ($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.

Note 10 – 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. At December 31, 2019 there were 53,865 options available under the plan.

Issuance of Stock Options under the Plan

2019 Board and Employee Option Grants

In June 2019, the Board's approved the issuance of 135,000 options to employees of the Company at an exercise price of $3.20 per option. These options vest monthly over one year. The fair value of these options was $2.87 per option or $387,730 and will be expensed over the relative vesting period. During 2019, 2,500 of these options have been forfeited.

As part of an agreement for their service during 2019 current and former Board members accepted the issuance of 83,000 options to Board members at exercise prices ranging from $3.20 to $5.20 per option. These options vested upon issuance. The fair value of these options was $2.77 per option or $230,047 and was expensed upon grant.

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 $2.93 and $5.47 per option for the year ended December 31, 2019 and 2018. The fair value was computed using the Black Scholes method using the following weighted-average assumptions:

	2019	2018
Expected life	5.3 years	5.0 years
Exercise price	$ 3.64	$ 6.75
Expected volatility	138%	132%
Expected dividends	n/a	n/a
Risk-free interest rate	1.82%	2.71%

The Company recorded an expense of $549,747 and $1,410,409 for the year ended December 31, 2019 and 2018 related to these options. The $164,240 remaining unrecognized expense will be recognized through June 2020.

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. 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.

A summary of option activity for the years ended December 31, 2019 and 2018 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, 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	9.2 years	$ -
Vested at December 31, 2018	276,823	$ 7.34	9.2 years	$ -
Outstanding at December 31, 2018	310,635	$ 7.41	9.2 years	
Issued	218,000	$ 3.59		
Adjustment	-	$ -		
Forfeited/Expired	(2,500)	$ 3.20		
Outstanding at December 31, 2019	526,135	$ 5.85	8.7 years	$ -
Vested at December 31, 2019	461,135	$ 6.23	8.6 years	$ -

Total stock-based compensation expense from options and warrants (Note 11) and related amortization have been included in the consolidated statements of operations as follows:

	For the Year Ending December 31,	
	2019	2018
Research and development expense	$ 97,433	$ 634,205
Selling, general and administrative expense	461,689	642,008
Total share-based compensation	$ 559,122	$ 1,276,213

Note 11 – Common Stock Warrants

The Company has issued warrants to purchase its common stock for equity, debt and compensation reasons. See Note 7 for 21,608 and 47,186 warrants issued as part of loan issuance costs during the years ended December 31, 2019 and 2018, respectively.

In August 2019 the Company and a former consultant reinstated a consulting agreement whereby this consultant, based on services rendered, will receive 1,875 warrants a month through May 2020. A member of this consulting firm is also on the Board. Through December 31, 2019, 9,375 warrants had been issued. The warrants have an exercise price of $4.00 and vest upon issuance and expire October 2024. The fair value of the warrant shares issued was $21,803 and recorded as an expense during the period. The weighted-average assumptions used for these warrant shares were risk-free interest rate of 1.56%, expected volatility of 146%, expected life of 2.5 years, and expected dividend yield of zero.

A summary of warrant activity for the years ended December 31, 2019 and 2018 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, 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	
Issued	30,983	$ 3.44		
Exercised	-			
Expired/Forfeited	(3,125)	$ 4.00		
Outstanding at December 31, 2019	1,255,667	$ 5.17	2.5 years	

Note 12 – Commitments and Contingencies

Research and Development Agreement

See Note 3 Research & Development Agreement for commitment to ProLung China under a research and development agreement.

Lease Agreement

In May 2019 the Company entered into a new lease agreement for its office space. The lease amount is $3,600 per month and expires in April 2022. The Company inhabited the office in September and incurred $14,400 in lease expense as it relates to this lease during the remainder of 2019. The remaining minimum lease expense is expected to be $43,200 for 2020 and 2021and $14,400 for 2022.

The Company also incurred $133,553 in leasehold improvements that were settled with a convertible note payable (Note 7). These improvements will be amortized through April 2022.

Utah Division of Securities

On April 23, 2019, the Utah Division of Securities (the "***Division***") filed a Notice of Agency Action and an Order to Show Cause before the Division of Securities of the Department of Commerce of the State of Utah against the Company, Jared Bauer (Bauer) and former Board Members (Clark Campbell, Tim Treu, Todd Morgan and Robert Raybould).

In January 2020, the Division issued a Stipulation and Consent Order which set forth the following: 1) the Company agrees to settle the matter with the Division by way of the Stipulation and Consent Order; 2) the Stipulation and Consent Order fully resolves all claims the Division has against the Company pertaining to the Order to Show Cause; 3) the Division, the Company and Bauer, agree to promptly file a stipulation and joint motion to dismiss the Company and Bauer from this administrative action, with respect to Count 1 against the Company and Bauer (the only claim brought against Bauer); 4) In or about April 2014, the Company Board of Directors circulated a consent agreement regarding the issuance of 72,763 Company stock certificates to select members of the Company Board of Directors in connection with "financing services provided" by those members; 5) In or about April 2014, the Company issued stock grants of 27,000 shares to Robert W. Raybould, 2,044 shares to Steve Eror, 7,969 shares to Tim Treu; 24,188 shares to Clark Campbell; and 12,188 shares to Todd Morgan; 6) Subsequent to issuance of those shares, ProLung was informed by counsel of potential consequences for Pro Lung employing unlicensed agents and individuals receiving the shares as compensation directly for sale of securities without a securities license, as opposed to receiving shares as compensation for generalized board service. Subsequently, no further shares were issued as compensation for fundraising. Mr. Eror returned his shares to the Company. However, Raybould, Treu, Campbell and Morgan did not return their shares to the Company. The Company did not disclose the potential licensing violation until on or about December 3, 2018, in its Note Purchase Agreements.

As set forth by the Company in its Form 8-K dated November 27, 2019, Campbell, Treu, Morgan, and Raybould entered into Stipulation and Consent Orders wherein they returned shares of stock to the Company's treasury and paid fines to the Division of Securities.

On January 9, 2020, the Division entered an order as follows: 1) entering certain Findings and Conclusions by the Division, which ProLung admitted via a Stipulation and Consent Order; 2) ordering ProLung to cease and desist from violating Utah Uniform Securities Act (the "***Act")*** and to comply with the requirements of the Act in all future business in the state of Utah; 3) ordering ProLung to disclose the contents of the order to investors and prospective investors in all future capital raising efforts and disclosure documents of ProLung; and 4) Ordering ProLung to pay a fine of $55,000 to the Division.

Note 13 – 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, 2019 and 2018:

	December 31,	
	2019	2018
Net operating losses	$ 6,190,000	$ 5,309,400
Research and development credit carryforward	209,900	177,800
Depreciation and amortization	(8,100)	(8,500)
Valuation allowance	(6,391,800)	(5,478,700)
Net Deferred Tax Asset	$ -	$ -

As of December 31, 2019, 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, 2019 and 2018 is set forth below:

	For the Year Ended December 31,	
	2019	2018
Net loss	$ (1,201,000)	$ (2,004,000)
Non-deductible expenses and other	287,900	976,600
Change in valuation allowance	913,100	1,027,400
Benefit from income taxes	$ -	$ -

As of December 31, 2019, the Company has a net operating loss carry-forward for U.S. federal income tax purposes of approximately $23.8 million. This carry-forward is available to offset future taxable income, if any, and will expire, if not used, from 2023 through 2039. 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, 2016. The Company is no longer subject to Utah state tax examinations for tax years before and including December 31, 2014. During the years ended December 31, 2019 and 2018, the Company did not incur interest and penalties.

Note 14 – Subsequent Events

Subsequent to December 31, 2019, the Company has raised approximately $1.6M in convertible notes. These notes are convertible at $3.20 per share bear interest at 8% and mature in March 2022. As part of the proceeds received 52,947 warrants were issued as part of loan issuance costs.

During 2020, the Company applied for and received funding from the Payroll Protection Program (the "PPP Loan") in the amount of $126,000. under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The PPP Loan matures in April 2025 and bears interest at a rate of 1.0% per annum. Monthly amortized principal and interest payments are deferred for six months after the date of disbursement. The Promissory Note contains events of default and other provisions customary for a loan of this type. The Paycheck Protection Program provides that the use of PPP Loan amount shall be limited to certain qualifying expenses and may be partially or wholly forgiven in accordance with the requirements set forth in the CARES Act.

The Company is closely monitoring the impact of the 2019 novel coronavirus, or COVID-19. COVID-19 was declared a global pandemic by the World Health Organization on March 11, 2020 and the President of the United States declared the COVID-19 outbreak a national emergency. The future impacts of the pandemic and any resulting economic impact are largely unknown and evolving. It is possible that the COVID-19 pandemic, the measures taken by the governments of countries affected and the resulting economic impact may materially and adversely affect the Company's results of operations, cash flows and financial position as well as its customers.

In May 2020, the Company issued 15,000 shares to a consultant for services rendered.

At March 31, 2020 and June 30, 2020 the Company issued 13,000 options, for a total of 26,000 options, to Directors for their services rendered. These options have exercise prices ranging from $2.47 to $3.20 per share.

As part of a consulting agreement discussed in Note 11 we issued 11,250 warrants at $4.00 per share during 2020 to satisfy this agreement.

In May 2020, the Company issued 73,887 options to employees at an exercise price of $2.47. These options vest over four years and expire in 10 years.

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.

July 15, 2020
Date

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

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	Chief Executive Officer (Principal Executive and Accounting Officer)	July 15, 2020
/s/ Don Patterson Don Patterson	Director	July 15, 2020
/s/ Michael Garff Michael Garff	Director	July 15, 2020
/s/ Jim Hogan Jim Hogan	Director	July 15, 2020
/s/ David Nielsen David Nielesen	Director	July 15, 2020
/s/ Rich McKeown Rich McKown	Director	July 15, 2020

Exhibit Index

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation, as amended by Certificate of Amendment dated October 10, 2017*
3.2	Amended and restated By-Laws[(1)]
4.1	Description of Securities
10.13	Lease agreement*
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 8-K filed with the SEC on July 19, 2017.

Exhibit 3.1

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "PROLUNG, INC.", FILED IN THIS OFFICE ON THE NINETEENTH DAY OF JULY, A.D. 2017, AT 2:50 O`CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

Jeffrey W. Bullock, Secretary of State

3885078 8100
SR# 20175314714

Authentication: 202920282
Date: 07-20-17

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 02:50 PM 07/19/2017
FILED 02:50 PM 07/19/2017
SR 20175314714 - File Number 3885078

THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF PROLUNG, INC.

ProLung, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify:

1. The original Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on November 19, 2004. The original name of the Corporation was Hilltop Group Technologies Corp. The present name of the corporation is ProLung, Inc.

2. This Third Amended and Restated Certificate of Incorporation has been duly approved by the Board of Directors of the Corporation and the stockholders of the Corporation in accordance with Section 242 and Section 245 of the Delaware General Corporation Law.

3. This Third Amended and Restated Certificate of Incorporation restates, integrates and further amends the Certificate of Incorporation of the Corporation. The text of the Certificate of Incorporation is hereby amended and restated to read in full as set forth on Exhibit A attached hereto.

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed by the duly authorized officer identified below on July 19, 2017.

ProLung, Inc.

By _____
Mark V. Anderson, Chief Financial Officer

EXHIBIT A

THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF PROLUNG, INC.

FIRST: The name of this Corporation is ProLung, Inc. (the "Corporation").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, Wilmington, County of New Castle, DE 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH: The total number of shares of capital stock which the Corporation shall have authority to issue is one hundred thirty million (130,000,000), of which one hundred twenty (120,000,000) shall be shares of common stock, par value $.001 per share (the "Common Stock"), and ten million (10,000,000) shall be shares of preferred stock, par value $.001 per share (the "Preferred Stock"). Fully paid stock of the Corporation shall not be liable to any further call or assessment. The Corporation shall from time to time in accordance with the laws of the State of Delaware increase the authorized amount of its Common Stock if at any time the number of shares of Common Stock remaining unissued and available for issuance is not sufficient to permit conversion of the Preferred Stock. The relative powers, preferences, special rights, qualifications, limitations, and restrictions granted to or imposed on the respective classes of shares of capital stock or the holders thereof are as follows:

A. COMMON STOCK.

1. Dividends. Subject to the rights of the holders of the Preferred Stock, and subject to any other provisions of this Third Amended and Restated Certificate of Incorporation (the "Restated Certificate"), holders of the Common Stock shall be entitled to receive such dividends and other distributions in cash, stock or property of the Corporation as may be declared thereon by the Board from time to time out of assets or funds of the Corporation legally available therefor.

2. Liquidation; Dissolution. In the event of any liquidation, dissolution or winding up of the affairs of the Corporation, whether voluntary or involuntary, after payment or provision for payment of the debts and other liabilities of the Corporation and after payment of provision for payment to the holders of each series of the Preferred Stock of all amounts required in accordance with this Article IV, the remaining assets and funds of the Corporation shall be divided among and paid to the holders of the Common Stock.

3. Voting.

a. Subject to Section 3(c) of this Article IV.B and the provisions of Article IV.C below, at every meeting of the stockholders of the Corporation, every holder of Common Stock shall be entitled to one vote in person or by proxy for each share of such Common Stock standing in such stockholder's name on the stock transfer records of the Corporation.

b. No holder of shares of the Common Stock shall have the right to cumulate votes in election of directors.

c. Except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Restated Certificate (including any certificate of designations relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Restated Certificate (including any certificate of designations relating to any series of Preferred Stock).

4. Preemptive Rights. No holder of shares of Common Stock shall, as such holder, be entitled as of right to subscribe for, purchase or receive any part of any new or additional issue of stock of any class, whether now or hereafter authorized, or of bonds, debentures or other securities convertible into or exchangeable for stock, but all such additional shares of stock of any class, or bonds, debentures or other securities convertible into or exchangeable for stock, may be issued and disposed of by the Board on such terms and for such consideration, so far as may be permitted by law, and to such persons, as the Board in its absolute discretion may deem advisable.

B. PREFERRED STOCK

1. Number Series. The Preferred Stock may be issued in one or more series, from time to time, with each such series to have such designation, powers, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof, as shall be stated and expressed in an amendment to this Restated Certificate providing for the issue of such series. The Board is hereby expressly vested with authority to amend this Restated Certificate, without stockholder action or approval, to: (a) create one or more series of the Preferred Stock, fix the number of shares of each such series (within the total number of authorized shares of the Preferred Stock available for designation as a part of such series), and designate and determine, in whole or part, the preferences, limitations and relative rights of each series of the Preferred Stock, all before the issuance of any shares of such series; (b) alter or revoke the preferences, limitations and relative rights granted to or imposed upon any wholly unissued series of the Preferred Stock; and (c) increase or decrease the number of shares constituting any series of the Preferred Stock (the number of shares of which was originally fixed by the Board) either before or after the issuance of shares of such series, provided that the number may not be decreased below the number of shares of such series then outstanding, or increased above the total number of authorized shares of the Preferred Stock available for designation as part of such series. Without limiting the foregoing, the authority of the Board with respect to each such series shall include, but not be limited to, the determination or fixing of the following:

a. The dividend rate of such series, the conditions and times upon which such dividends shall be payable, the relation which such dividends shall bear to the dividends and/or

other payments payable on or with respect to any other class or classes of stock or series thereof, or on the other series of the Preferred Stock, and whether dividends shall be cumulative or noncumulative;

b. The conditions upon which the shares of such series shall be subject to redemption by the Corporation and the times, prices and other terms and provisions upon which the shares of such series may be redeemed;

c. Whether or not the shares of such series shall be subject to the operation of retirement or sinking fund provisions to be applied to the purchase or redemption of such shares and, if such retirement or sinking fund be established, the annual amount thereof and the terms and provisions relative to the operation thereof and the relation payments on such retirement or sinking fund shall bear to any payments and/or distributions on or with respect to each other class or classes of stock or series thereof, or on or with respect to the other series of the Preferred Stock;

d. Whether or not the shares of such series shall be convertible into or exchangeable for shares of any other class or classes, with or without par value, or of any other series of the Preferred Stock and, if provision is made for conversion or exchange, the times, prices, rates, adjustments and other terms and conditions of such conversion or exchange;

e. Whether or not the shares of the series shall have voting rights, in addition to the voting rights provided by law, as such voting rights granted by law may be modified or limited in the provisions designating such series, and, if so, subject to the limitations hereinafter set forth, the terms of such additional voting rights; and

f. The rights of the shares of such series in the event of voluntary or involuntary liquidation, dissolution or upon distribution of assets of the Corporation.

2. General Voting Rights. Except as specifically provided herein or otherwise required by law, the holder of each share of Preferred Stock shall be entitled to vote on all matters and shall be entitled to the number of votes equal to the number of shares of Common Stock into which each share of Preferred Stock could be converted, as contemplated hereby, at the record date for the determination of the stockholders entitled to vote on such matters or, if no such record date is established, at the date such vote is taken, such votes to be counted together with all other shares of stock of the Corporation having general voting power and not separately as a class. Fractional votes shall not, however, be permitted and any fractional voting rights resulting from the above formula shall be rounded to the nearest whole number (with one-half rounded upward to one).

3. Preemptive Rights. Except as otherwise provided by an amendment to this Restated Certificate, or by any agreement approved by the Board and to which the Company is a party, providing for the issuance of any series of the Preferred Stock, no holder of shares of the Preferred Stock shall, as such holder, be entitled as of right to subscribe for, purchase or receive any part of any new or additional issue of stock of any class, whether now or hereafter authorized, or of bonds, debentures or other securities convertible into or exchangeable for stock, but all such additional shares of stock of any class, or bonds, debentures or other securities convertible into or exchangeable for stock, may be issued and disposed of by the Board on such terms and for such

consideration, so far as may be permitted by law, and to such persons, as the Board in its absolute discretion may deem advisable.

4. Issuance. Each share of Preferred Stock shall be issued for such consideration as the Board may determine. Once duly issued for the consideration called for by resolution of the Board, shares of Preferred Stock shall be deemed fully paid and nonassessable.

FIFTH: Unless and except to the extent that the Bylaws of the Corporation shall so require, the election of directors of the Corporation need not be by written ballot.

SIXTH: In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board is expressly authorized and empowered to make, alter and repeal the Bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any Bylaw whether adopted by them or otherwise.

SEVENTH: A director of the Corporation shall not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the Delaware General Corporation Law as the same exists or may hereafter be amended. Any amendment, modification or repeal of the foregoing sentence shall not adversely affect any right or protection of a director of the Corporation existing hereunder with respect to any act or omission occurring prior to the time of such amendment, modification or repeal.

EIGHTH: The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Restated Certificate, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Restated Certificate in its present form or as hereafter amended are granted subject to the rights reserved in this article.

NINTH: The directors of the Corporation shall be divided, with respect to the time for which they severally hold office, into three classes, designated as Class I, Class II, and Class III, respectively (the "Classified Board"). The Board may assign members of the Board already in office at the time this provision becomes effective to the Classified Board, which assignments shall become effective at the same time the Classified Board becomes effective. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board, with the number of directors in each class to be divided as nearly equal as reasonably possible. The initial term of office of the Class I directors shall expire at the Corporation's 2017 annual meeting of stockholders, the initial term of office of the Class II directors shall expire at the Corporation's 2018 annual meeting of stockholders, and the initial term of office of the Class III directors shall expire at the Corporation's 2019 annual meeting of stockholders. At each annual meeting of stockholders (from the 2017 annual meeting of stockholders, onward), directors elected to succeed those directors of the class whose terms then expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election.

Exhibit 4.1

DESCRIPTION OF CAPITAL STOCK

As of the date of this prospectus, our authorized capital stock consists of 120,000,000 shares of common stock, $0.001 par value, and 10,000,000 shares of preferred stock, $0.001 par value. A description of material terms and provisions of our amended and restated certificate of incorporation and amended and restated bylaws affecting the rights of holders of our capital stock is set forth below. The description is intended as a summary, and is qualified in its entirety by reference to our amended and restated certificate of incorporation and our amended and restated bylaws.

On October 25, 2017, we effected a 1-for-8 reverse stock split of our registered and outstanding common stock under which every 8 shares of common stock, par value $0.001 per share, was consolidated into one share of common stock par value $0.001 per share.

General

Prior to this offering, there has not been an established public trading market for our common stock.

Common Stock

As of December 31, 2019, there were approximately 800 holders of our common stock. The holders of our common stock are entitled to equal dividends and distributions per share with respect to the common stock when, as and if declared by our board of directors from funds legally available therefor. No holder of any shares of our common stock has a preemptive right to subscribe for any of our securities, nor are any common shares subject to redemption or convertible into other securities. Upon liquidation, dissolution or winding-up of our company, and after payment of creditors and preferred stockholders, if any, the assets will be divided pro rata on a share-for-share basis among the holders of the shares of our common stock. All shares of our common stock now outstanding are fully paid, validly issued and non-assessable. Each share of our common stock is entitled to one vote with respect to the election of any director or any other matter upon which stockholders are required or permitted to vote.

Preferred Stock

Our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. There are currently no shares of preferred stock issued or outstanding. The issuance of preferred stock, while providing flexibility in connection with financings, possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, discouraging or preventing a change in control of our company, may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock, and may reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation.

Warrants

As of December 31, 2019, warrants for the issuance of 1,255,667 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of $5.17 per share.

Options

As of December 31, 2019, total options outstanding were 526,135 at a weighted exercise price of $5.85. At December 31, 2019 options for the issuance of 461,135 shares of our common stock were vested which are exercisable at a weighted average exercise price of $6.23 per share.

Anti-Takeover Provisions

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below:

- 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 acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval; and
- 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.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (1) persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Action Stock Transfer Company. The transfer agent and registrar's address is 2469 Fort Union Blvd #214, Cottonwood Heights, UT 84121. Its phone number is (801) 274-1088.

Exhibit 10.13

Northgate Park LLC

825 N 300 W #C160 · Salt Lake City, UT 84103
(801) 983-8000

1. NORTHGATE PARK, LLC LEASE AGREEMENT with ProLung

1.1 LEASOR AND LEASEE

This lease is made as of Date 05/21/2019 by and between Northgate Park, LLC ("Landlord") and ProLung ("Tenant").

1.2 LEASED PREMISES.

The leased premises (the "Leased Premises") consist of _ 214 __ (_3635_) rentable square feet of office space located in building at 214 (825 North 300 West OR 350 West 800 North), Salt Lake City, Utah 84103 ("The Building");

See Lease Amendment A for Convertible Debenture agreement for Leasehold Imporovements

1.3 TERM AND RENT

Landlord leases the above-identified premises for a term, commencing 05/31/2019 and terminating on 04/30/2022 or sooner as provided herein at the monthly rental of $ $3,600.00 payable on the first day of each month for that month's rental, during the term of this lease. All rental payments shall be made to Landlord, using the Appfolio tenant portal. The following late fees will apply for payment made after grace period:

Late fee rule: A late fee charge in the amount of $25.00 or 5% of monthly rent, whichever is greater, if rent is received after the 5th of the month.

We may change the terms of this lease in accordance with applicable law, including rent increases and other modifications to the terms of the contract. All rental payments shall be made to Landlord, at its office at 825 North 300 West, Suite C-160, Salt Lake City, Utah, 84103.

1.4 USE.

The Leased Premises shall be used only for general office purposes or _lab, production and office space. The premises shall be used for no other purpose without the written permission from Landlord. Landlord represents that the premises may lawfully be used for such purpose.

1.5 SECURITY DEPOSIT.

Tenant shall deposit with Landlord on the signing of this lease the sum of $3,600.00 Dollars as security deposit for the performance of Tenant's obligations under this lease, including without limitation, the surrender of possession of the premises to Landlord as herein provided. If Landlord applies any part of the deposit to cure any default of Tenant, Tenant shall on demand deposit with Landlord the amount so applied so that Landlord shall have the full deposit on hand at all times during the term of this lease.

1.6 CONDITION, CARE, AND MAINTENANCE OF PREMISES

Tenant acknowledges that Tenant has a right to inspect prior to entering into the present lease and that the leased premises are in good order and repair, unless otherwise indicated herein. Any Noted Exceptions to Good Condition of the Premises: _____
_____

Tenant shall, at his own expense and at all times, maintain the premises in good and safe condition, including electrical wiring, plumbing, and any other system or equipment upon the premises, and shall surrender the same at termination hereof, in as good condition as received, normal wear and tear excepted. Tenant shall be responsible for all repairs required, excepting the roof, exterior walls, structural foundations, and heating and cooling systems. Tenant shall make, at its sole cost and expense, such repairs to the Leased Premises as are necessitated by Tenant's use of the Leased Premises, as and when needed to preserve them in good working order and condition, ordinary wear and tear and damage by fire, earthquake, act of God, or the elements excepted. All damage or injury to the Leased Premises and its fixtures, appurtenances, and equipment caused by Tenant moving property in or out of the Building or by installation or removal of furniture, fixtures, or other property shall be repaired, restored, or replaced promptly by Tenant at its sole cost and expense, to the satisfaction of the Landlord. All of said repairs, restoration, and replacements shall be in a quality and class equal to the original work or installations. If Tenant fails to make such repairs, restorations, or replacements, the same may be made by Landlord at the expense of Tenant, and such expense shall be collectible as additional rent and shall be paid by Tenant within ten (10) days after Tenant's receipt of a bill therefor.

1.7 ALTERATIONS.

Tenant shall not, without first obtaining the written consent of Landlord, make any alterations, additions, or improvements, in, to or about the premises. Any such alterations conditionally permitted by Landlord shall be done only by contractors approved by Landlord. Tenant shall present to Landlord written plans and specifications at the time Landlord's consent hereunder is sought. Tenant shall not change any locks, add to, disturb, or change any plumbing or wiring, and shall not install any trade fixtures, floor coverings, lighting, plumbing fixtures, curtains, draperies, shades, or awnings without Landlord's prior written consent.

1.8 ORDINANCES AND STATUTES.

Tenant, at its expense, shall comply with all laws, orders, statutes, and regulations of Federal, State, County and municipal authorities, and with any direction of any public officer or offices, pursuant to law, which shall impose any violation, order, or duty upon Landlord or Tenant with respect to the Leased Premises or the use or occupation thereof.

1.9 ASSIGNMENT AND SUBLETTING.

Tenant will not assign, mortgage or encumber this Lease in whole or in part, nor sublet all or any part of the Leased Premises, or suffer or permit the Leased Premises or any part thereof to be used by others, without the prior written consent of Landlord, and any attempt to do so without Landlord's prior written consent shall be null and void and of no force and effect and, at the option of the Landlord, may be grounds for the termination of this lease.

1.10 UTILITIES

All applications and connections for necessary utility services on the demised premises shall be made in the name of Tenant only, and Tenant shall be solely liable for utility charges as they become due, including internet and telephone services.

1.11 ENTRY AND INSPECTION.

Landlord, or its legal representatives, shall have free access to the Leased Premises, at reasonable times and with reasonable notice, for the purpose of making needed repairs or alterations of the Leased Premises that Landlord may see fit to make. Tenant will permit Landlord at any time within sixty (60) days prior to the expiration of this lease, to place upon the premises any usual "To Let" or "For Lease" signs, and permit persons desiring to lease the same to inspect the premises thereafter.

1.12 POSSESSION

If Landlord is unable to deliver possession of the premises at the commencement hereof, Landlord shall not be liable for any damage caused thereby, nor shall this lease be void or voidable, but Tenant shall not be liable for any rent until possession is delivered. Tenant may terminate this lease if possession is not delivered within 5 days of the commencement of the term hereof.

1.13 INDEMNIFICATION OF LANDLORD

Tenant shall defend and indemnify Landlord and hold Landlord harmless from and against any and all liability, damages, cost, or expenses, including attorney's fees, arising from any negligent act or omission, of said parties, or the officers, contractors, licensees, agents, servants, employees, guests, invitees, or visitors of said parties in or about the Leased Premises.

1.14 INSURANCE.

Tenant shall be responsible for obtaining and paying for such insurance as Tenant may desire on Tenant's leasehold improvements, trade fixtures, and personal property from time to time in or upon the Leased Premises, and Landlord shall not be liable for damage to or loss or theft of property of Tenant or others. To the maximum extent permitted by insurance policies which may be owned by Landlord or Tenant, Tenant and Landlord, for the benefit of each other, waive any and all rights of subrogation which might otherwise exist.

1.15 EMINENT DOMAIN.

If the premises or any part thereof or any estate therein, or any other part of the building materially affecting Tenant's use of the premise, shall be taken by eminent domain, this lease shall terminate on the date when title vests pursuant to such taking. The rent, and any additional rent, shall be apportioned as of the termination date, and any rent paid for any period beyond that date shall be repaid to Tenant. Tenant shall not be entitled to any part of the award for such taking or any payment in lieu thereof, but Tenant may file a claim for any taking of fixtures and improvements owned by Tenant, and for moving expenses.

1.16 DESTRUCTION OF PREMISES.

In the event of a partial destruction of the premises during the term hereof, from any cause, Landlord shall forthwith repair the same, provided that such repairs can be made within sixty (60) days under existing governmental laws and regulations, but such partial destruction shall not terminate this lease, except that Tenant shall be entitled to a proportionate reduction of rent while such repairs are being made, based upon the extent to which the making of such repairs shall interfere with the business of Tenant on the premises. If such repairs cannot be made within said sixty (60) days, Landlord, at his option, may make the same within a reasonable time, this lease continuing in effect with the rent proportionately abated as aforesaid, and in the event that Landlord shall not elect to make such repairs which cannot be made within sixty (60) days, this lease may be terminated at the option of either party. In the event that the building in which the demised premises may be situated is destroyed to an extent of not less than one-third of the replacement costs thereof, Landlord may elect to terminate this lease whether the demised premises be injured or not. A total destruction of the

1.17 NO WASTE OR NUISANCE BY TENANT.

Tenant shall use and occupy the Leased Premises solely for the purposes previously described and for no other purpose. Tenant shall continually use and occupy the Leased Premises for the entire Term and will not permit any part of the Leased Premises to be used for any unlawful purposes or for any purpose or use which may constitute a public or private nuisance or which creates a hazard. Tenant will not commit or suffer to be committed any waste upon the Leased Premises. Furthermore, Tenant will not commit or suffer to be committed any act or thing which may disturb the quiet enjoyment of any other tenant in the Building.Tenant covenants not to introduce any hazardous or toxic materials onto the Building or surrounding property without a) first obtaining Landlord's written consent and b) complying with all applicable federal, state and local laws or ordinances pertaining to the transportation, storage, use or disposal of such materials, including but not limited to obtaining roper permits.

Tenant shall not, without the prior written consent of Landlord, use any apparatus or device in the Leased Premises, including, without limitation, electronic data processing machines, punch card machines, vending, printing, and other types of machines using electric current in excess of 110 volts which will in any way increase the amount of electricity or utilities usually furnished or supplied for the use of the Leased Premises as general office space, nor shall Tenant connect with electric current or other utility supply facilities except through existing electrical outlets in the Leased Premises or other facilities, any apparatus or device for the purpose of using electric current or other utilities. Landlord reserves the right to separately meter or sub-meter Tenant's Leased Premises for determining appropriate payment by Tenant for Operating Expenses and Taxes.

Tenant shall not, without the prior written consent of Landlord, use any heat-generated machines or equipment in the Leased Premises which affect the temperature otherwise maintained by the heating or air conditioning systems. Tenant will not, without Landlord's prior written consent, permit the cooking of food upon the Leased Premises which will create odors discernible beyond the Leased Premises. Tenant will not use any apparatus, machinery, equipment or device in or about the Leased Premises (nor conduct its business upon the Leased Premises in a manner) which will cause any noise or vibration beyond the Leased Premises. If any of Tenant's apparatus, machines, equipment, or devices beyond standard office equipment or Tenant's use of the Leased Premises should disturb the use and enjoyment of any other Tenant in the Building, Tenant will provide adequate insulation or take such other action as may be requested by Landlord to eliminate the disturbance.

1.18 DEFAULT.

(a) Each of the following events shall be a default by Tenant and a breach of this Lease;

(i) Abandonment or surrender of the Leased Premises or of the leasehold estate or failure or refusal to pay when due any installment of rent, taxes, insurance, or any other sum required by this Lease to be paid by Tenant, or to perform as required or conditioned by any other covenant or condition of this Lease.

(ii) The subjection of any right or interest of Tenant in the Leased Premises to attachment, execution or other levy, or to seizure under legal process if not released within ten (10) days.

(iii) The appointment of a receiver to take possession of the Leased Premises or improvements or of Tenant's interest in the leasehold estate or of Tenant's operations on the Leased Premises for any reason, including, but not limited to, assignment for benefit of creditors or voluntary or involuntary bankruptcy proceedings.

(iv) An assignment by Tenant for the benefit of creditors or the filing of a voluntary or involuntary petition by or against Tenant under any law for the purpose of adjudicating Tenant bankrupt; or for extending time for payment, adjustment, or satisfaction of Tenant's liabilities; or for reorganization, dissolution, or arrangement on account of or to prevent bankruptcy or insolvency; unless the assignment or proceedings, and all consequent orders, adjudications, custodies, and supervision are dismissed, vacated, or otherwise permanently stayed or terminated within thirty (30)days after the assignment, filing or other initial event.

(b) If the alleged default is nonpayment of rent, taxes, insurance, or other sums to be paid by Tenant as provided in this Lease, said nonpayment shall constitute a default if the amounts are not paid within three (3) days from the date they are due and payable. For any other default, Tenant shall promptly and diligently after written notice commence during the default and shall complete the cure within thirty (30) days after such notice plus any additional period that is reasonably required for the curing of the default (or if the default is of such a character as to require more than thirty (30) days to cure, then Tenant shall use reasonable diligence in curing such default)

1.19 LANDLORD'S REMEDIES ON DEFAULT.

After expiration of the applicable time for curing a particular default, if any such cure period is provided herein, or before the expiration of that time in the event of emergency, Landlord may, at Landlord's election, but is not obligated to, make any payment required of Tenant under this Lease or perform or comply with any covenant or condition imposed on Tenant under this Lease, and the amount so paid plus the reasonable cost of any such performance or compliance, plus interest on such sum at the rate of four (4) percentage points over the prime rate quoted by Wells Fargo Bank per annum from the date of payment, performance, or compliance (herein called "act") shall be deemed to be additional rent payable by Tenant with the next succeeding installment of rent. No such act shall constitute a waiver of default or of any remedy for default or render Landlord liable for any loss or damage resulting from any such act. If any default by Tenant shall continue uncured following notice of default, if any, as required by this Lease, for the period applicable to the default under the applicable provision of this Lease, Landlord has the following remedies in addition to all of the rights and remedies provided hereunder, and at law or equity, to which Landlord may resort cumulatively or in the alternative:

(a) Landlord may, at Landlord's election, terminate this Lease by giving Tenant notice of termination. On the giving of the notice, all of Tenant's right in the Leased Premises and in all improvements thereon shall terminate. Promptly after notice of termination Tenant shall surrender and vacate the Leased Premises and all improvements in broom-clean condition, and Landlord may re-enter and take possession of the Leased Premises and all remaining improvements and eject all parties in possession or eject some and not others or eject none. Termination under this subparagraph shall not relieve Tenant from the payment of any sum then due to Landlord or from any claim for damages previously accrued or then accruing to date of termination against Tenant.

(b) Landlord may, at Landlord's election, re-enter the Leased Premises, and, without terminating this Lease, at any time and from time to time relet the Leased Premises and improvements or any part or parts of them for the account and in the name of Tenant or otherwise. Landlord may, at Landlord's election, eject all persons or eject some and not others or eject none. Landlord shall apply all rents from reletting as hereinafter provided. Any reletting may be for the remainder of the Term or for longer or shorter periods. Landlord may execute any leases made under this provision either in Landlord's name or in Tenant's name and shall be entitled to all rents from the use, operation, or occupancy of the Leased Premises or improvements or both. Tenant shall nevertheless pay to Landlord on the due dates specified in this Lease the equivalent of all sums required of Tenant under this Lease, plus Landlord's reasonable expenses, of any reletting. No act by or on behalf of Landlord under this provision shall constitute a termination of this Lease unless Landlord gives Tenant a notice of termination.

(c) Landlord may, at Landlord's election, use Tenant's personal property and trade fixtures or any of such property and fixtures without compensation and without liability for use or damage, or store them for the account and at the cost of Tenant. The election of one remedy for any one item shall not foreclose an election of any other remedy for another item or for the same item at a later date.

(d) Landlord shall be entitled, at Landlord's election, to each installment of rent or to any combination of installments for any period before termination, plus interest at the rate of eighteen percent (18%) per annum from the due date of each installment until paid. Avails of reletting shall be applied, when received, as follows:

(1) to Landlord to the extend that the avails for the period covered do not exceed the amount due from and charged to Tenant for the same period, and

(2) the balance to Tenant.

(e) Landlord shall be entitled, at Landlord's election, to damages equal to all amounts that would have fallen due as rent between the time of termination of this Lease and the time of the claim, judgment or other award, less the avails of all relettings plus interest on the balance at the rate of eighteen percent (18%) per annum from the date of the expiration of the applicable time for curing a particular default.

(f) Tenant assigns to Landlord all sub-rents and other sums falling due from subtenants, licensees, and concessionaires (herein call "subtenants") during any period in which Landlord has the right under this Lease, whether exercised or not, to re-enter the Leased Premises for Tenant's default, and Tenant shall not have any right to such sums during that period. Landlord may, at Landlord's election, re-enter the Leased Premises and improvements with or without process of law, without terminating this Lease, and collect these sums and/or bring action for the recovery of the sums directly from such obligors. Landlord shall receive and collect all sub-rents and avails from reletting, applying them: first, to the payment of reasonable expenses (including attorney's fees or broker's commissions or both) paid of incurred by or on behalf of Landlord in recovering possession, placing the Leased Premises and improvements in good condition, and preparing or altering the Leased Premises or improvements for reletting; second, to the reasonable expense of securing new tenants; third, to the fulfillment of Tenant's covenants to the end of the Term; and fourth, to Landlord's uses and purposes. Tenant shall nevertheless pay to Landlord on the due dates specified in this Lease the equivalent of all sums required of Tenant under this Lease, plus Landlord's expenses, less the avails of the sums assigned and actually collected under this provision.

1.20 TAX INCREASE.

In the event there is any increase during any year of the term of this lease in the City, County or State real estate taxes over and above the amount of such taxes assessed for the tax year during which the term of this lease commences, whether because of increased rate or valuation, Tenant shall pay to Lesser upon presentation of paid tax bills an amount equal to 50% of the increase in taxes upon the land and building in which the leased premises are situated. In the event that such taxes are assessed for a tax year extending beyond the term of the lease, the obligation of Tenant shall be proportionate to the portion of the lease term included in such year.

1.21 ATTORNEY'S FEES.

In case suit should be brought for recovery of the premises, or for any sum due hereunder, or because of any act which may arise out of the possession of the premises, by either party, the prevailing party shall be entitled to all costs incurred in connection with such action, including a reasonable attorney's fee.

1.22 NOTICES.

Any notice which either party may, or is required to give, shall be given by mailing the same, postage prepaid, to Tenant at the premises, or Landlord at the address previously specified in Section Number 2 of this Agreement.

1.23 HEIRS, ASSIGNS, SUCCESSORS.

This lease is binding upon and inures to the benefit of the heirs, assigns and successors in interest to the parties.

1.24 EXPIRATION OF LEASE AND HOLDOVER

At the expiration of the Term (where either renewal or a new lease has not previously been reached), Tenant shall surrender the Leased Premises in the same condition as the Leased Premises were in upon delivery or possession thereof under this Lease, reasonable wear and tear excepted, and shall surrender all keys for the Leased Premises to Landlord at the place then fixed for the payment of rent and shall inform Landlord of all combinations on locks, safes, and vaults, if any, in the Leased Premises. Tenant shall remove all of its trade fixtures, and upon request of Landlord, shall remove any alterations or improvements as
provided in this Lease and shall repair any damage to the Leased Premises caused thereby. Tenant's obligation to observe or perform this covenant shall survive the expiration or other termination of the Lease. If Tenant shall remain in possession of the Leased Premises after the expiration of the Term or any extension of renewal thereof, such possession shall be deemed to be a month-to-month tenancy. During such month-to-month tenancy, rent shall be payable in advance on the first day of each month in an amount equal to current market rents for similar space. All other terms, conditions, and covenants herein specified shall remain the same.

1.25 SUBORDINATION.

This lease is and shall be subordinated to all existing and future liens and encumbrances against the property.

1.26 TIME IS OF THE ESSENCE.

It is expressly stipulated and agreed that time shall be of the essence of this Lease.

By initialing below, you acknowledge and agree to the terms in Section 1.

X JBB
ProLung

2. Policies and Procedures

2.1 COMPLIANCE WITH THE LANDLORD RULES AND REGULATIONS

Tenant shall observe all rules and regulations as may be adopted and published by Landlord for the comfortable use and care of the Building and Leased Premises and the safety, care, and cleanliness thereof and the preserving of good order therein. Tenant shall be responsible for compliance with said Rules and Regulations which may be posted on the Internet as long as Tenant has received notification of the web address where such Rules and Regulations are posted.

By initialing below, you acknowledge and agree to the terms in Section 2.

X JBB
ProLung

3. Responsibilities

3.1 LANDLORD IMPROVEMENTS

Landlord's Improvements. Landlord shall install new VCT flooring or carpet in standard colors in Suite 214. Landlord shall remove all wallpaper, graphic art, boards and displays from all walls and replace with new paint. Paint color shall be selected by Tenant from Landlord's standard paint colors. All trim, moldings and door frames shall be touched up as needed. Landlord shall build and or install new office walls of wood, drywall and or glass based on the agreed upon office layout including conference room. Lab space layout will be designed by tenant (ProLung) and finished buildout will be approved by tenant (ProLung). The build out will be done by the Landlord, all cost of including but not limited to materials, labor, contracting, management oversight and overhead will be paid by the Landlord. All costs will be signed off by tenant (ProLung) and reimbursed by tenant (ProLung) to the Landlord using the convertible debenture in article "A"

By initialing below, you acknowledge and agree to the terms in Section 3.

X JBB
ProLung

4. General Clauses

4.1 ENTIRE AGREEMENT

The foregoing constitutes the entire agreement between the parties and may be modified only by a writing signed by both parties.

By initialing below, you acknowledge and agree to the terms in Section 4.

X JBB
ProLung

5. Sign and Accept

5.1 1

1

X Jared B. Bauer
Lessee
IP Address: 162.218.216.158
05/30/2019 11:08am MDT

X Richard Reed
Lessor
IP Address: 162.218.220.101
05/30/2019 01:15pm MDT

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, 2019.

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: July 15, 2020

/s/ Jared Bauer

Jared Bauer, 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, 2019, 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: July 15, 2020

/s/ Jared Bauer
Jared Bauer, Chief Executive Officer