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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022.

☐ 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 ☒.

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ 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, smaller reporting company or an emerging growth company. See definition of "accelerated filer", "large accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

Large Accelerated Filer ☐
Non-accelerated Filer ☒
Accelerated Filer ☐
Smaller reporting Company ☒
Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 ☒

The aggregate market value of the shares of common stock held by non-affiliates of the Registrant on June 30, 2022, was approximately $41,407,811 based upon 4,500,849 shares held by non-affiliates and an assumed fair market value of $9.20 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 valuation of the Registrant. Shares of common stock held by each officer and director, and by each other person who may be deemed to be an affiliate of the Registrant have been excluded.

As of April 17, 2023 the Registrant had 4,591,399 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE. None.

INDEX TO FORM 10-K

PART I

This Annual Report on Form 10-K for the year ended December 31, 2022 (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. is 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 IONIQ Sciences®, IONIQ Science®, IONIQ Test®, IONIQ Screen® and ProLung®. 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 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 and one 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 or bioimpedance and artificial intelligence (AI). We are developing an advanced multi-cancer screening technology for early detection of multiple cancers that may expand the therapeutic window, dramatically improve survivability and reduce the cost of healthcare. We have active projects in lung, breast and gastro-intestinal (GI) cancers. The first planned product utilizing our proprietary digital platform, the IONIQ ProLung Test™ for lung cancer, has been designated a Breakthrough Device by the U.S. FDA in February 2020. We submitted our *de novo* application to the U.S. FDA in February 2022 and we received a substantive review from the FDA outlining additional information that is required for US regulatory clearance. These items include questions and requests related to biocompatibility testing, clinical data, Indications for Use and labeling, cybersecurity documentation, electrical safety, special controls, human factors and usability, performance testing, risk analysis, software, sterility and shelf life. We remain fully-committed to gaining U.S. FDA regulatory *de novo* clearance and continue to collaborate with the US FDA so that we can satisfy their requests and subsequently commercialize the IONIQ ProLung Test for lung cancer.

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

We believe the 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 bioimpedance technology or Electrical Impedance Analytics (EIA). Our Bioimpedance technology involves a sequential scanning process that measures significant differences in electrical conductance between patients with 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 bioimpedance measurement data by means of a patented probe and disposable diaphoretic or EKG-type 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 analytic algorithm. The results are summarized in a report that can be used by the physician, in concert with other risk factors such as nodule size, family history, smoking history and gender, to evaluate patients with nodules. The IONIQ ProLung Test requires minimal preparation and can be completed in about 20 minutes. Most importantly, it guides or informs the physician's decision making without the time consuming and expensive 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.

ProLung dba IONIQ Sciences owns 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 1,400 subjects have been tested using the IONIQ ProLung Test at IONIQ's headquarters and in major cancer centers. If our *de novo* U.S. 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 IONIQ ProLung Test kit.

In the US, the push for early detection of lung cancer was greatly accelerated in 2013 and again most recently in 2020. Recognizing the dismal rate of lung cancer survival in the US, and the potential value of early detection, U.S. guidelines were established for lung cancer CT screening. The guidelines provided for CT screening for lung cancer in asymptomatic adults aged 50 to 80 who have a 20 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. In 2020, the guidelines were expanded effectively doubling the population covered. 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 bioimpedance 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 U.S. 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 U.S. clearance and recognition of the IONIQ ProLung Test a major priority, targeting lung cancer risk stratification and reducing time to treatment. The IONIQ ProLung Test has been designated a Breakthrough Medical Device by the U.S. FDA in February 2020 based on the clinical trial results from PLW-216 and the ability of the device to detect lung cancer in small lung nodules. 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.

We have developed the quality management system, as well as supply chain and the ability to fully manufacture the entire IONIQ 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. We have repeatedly expanded our intellectual property (IP) portfolio, completed the development of the IONIQ ProLung Test and manufacturing of the IONIQ System and embarked upon clinical trials to provide validation to the medical community.

The results of the clinical trial of 420 patients from 15 cancer and medical centers across the US, named PL-208, was published in early 2019. The results of another clinical trial of 486 patients from four cancer and medical centers in China, named PLW-216, was published in late 2019. We believe the results are more solid indicators 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 these Studies, the IONIQ 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 IONIQ 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 late 2019, we announced the final results of our Validation Study, named PLW-216. The validation study enrolled 486 subjects from four leading cancer and medical centers in China. The results were 84% sensitivity and 73% specificity in the 418 subjects included in the analysis.

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. 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 78%, 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.

PL-210 - ProLung Test Measurement Collection Protocols for Label Expansion (Ongoing NCT04134520)

The purpose of this Study is to identify and test different data collection methods to determine which approaches may be useful in evaluation additional cancers to lung cancer (including breast cancer) and improve the ProLung Testing procedure. Once this Study is complete, the Sponsor plans to evaluate these improvements in future follow up cancer validation studies that will assess device accuracy using the new measurement collection methods.

The address of our principal executive office is:

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Salt Lake City, Utah 84103

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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 11, 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 for 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. In March 2022, we bought out the license and now own all of the previously licensed intellectual property.

We are 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 (LDCT). 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.

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	330	94	Direct & Indirect

Symptomatic:

Each year approximately 225,500 people are diagnosed with lung cancer and approximately 90 percent of lung cancer patients are symptomatic at presentation (ACS, 2022).

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

IONIQ Sciences plans to pursue a CE mark in conjunction with US marketing clearance in the European Union and European Free Trade Association Countries, which represents approximately 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

IONIQ Sciences plans to enter the China market through its licensee (ProLung China). 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 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:

- *IONIQ 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 multiple languages. The pricing of the IONIQ System may vary upon the volume of the IONIQ ProLung Test Kits that a customer buys. We refer to the IONIQ 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 approximately $400 each, available in boxes of 10 and 40. We refer to the IONIQ ProLung Test internally as the disposable component or the razor blade in the ubiquitous razor/razor blade sales analogy.

IONIQ Sciences' novel Electrical Impedance Analytics (EIA) or bioimpedance 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 bioimpedance 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 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 about 20 minutes.

The IONIQ ProLung Test Procedure

1. 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 a self-diagnostic test.
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. IONIQ System 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 seven clinical trials at 25 clinical sites with 1,400 subjects. 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.

Algorithm Development Study a.k.a. FML-204 — Baltimore, MD (2012)

- *Description*. This single arm, single site algorithm finding and internal validation trial was designed to derive an algorithm for lung cancer detection in subjects with suspicious lung nodules.

- *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 IONIQ 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 78%, 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

PL-210 - ProLung Test Measurement Collection Protocols for Label Expansion (Ongoing NCT04134520)

The purpose of this Study is to identify and test different data collection methods to determine which approaches may be useful in evaluation additional cancers to lung cancer (including breast cancer) and improve the ProLung Testing procedure. Once this Study is complete, the Sponsor plans to evaluate these improvements in future follow up cancer validation studies that will assess device accuracy using the new measurement collection methods. Preliminary results showing the feasibility of the IONIQ technology to detect breast cancer have been published in the Institute of Electrical and Electronics Engineers Journal (IEEE) in November of 2021.

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. Their 486 patient Validation Study (PLW-216) using the ProLung technology was completed in 2019. 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. Subject enrollment at these sites did not conform to research protocols utilized by ProLung. In addition, this prior research did not include IONIQ's current measurement method and algorithm improvements. The results of these studies were presented in the World Congress of Thoracic Imaging and American Thoracic Society conferences.

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 (ATS) 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. Existing patent applications are set forth below:

IONQ Sciences Company Owned Patent Summary

Title	Country	Type	Filed (6)	Application #	Patent #	Date of Patent
Company Owned Patents						
Validating Continual Probe Contact With Tissue During Bioelectric Testing	US	ORD(1)	12/11/2019	16/711,332	11,154,245 B2	10/26/2021
Conductivity Compensation Factor For Assessing Bioelectric Measurements	US	ORD(1)	10/22/2019	16/660,613	11,324,415 B2	11/06/2018
Devices, Systems And Methods For Controlling A Spring Force Exerted On A Sensor For Obtaining Bio-Conductance Readings Using A Linear Actuator	US	ORD(1)	11/28/2018	16/203,437	11,324,414 B2	9/7/2021
Multi-tip probe for obtaining bioelectrical measurements	US	ORD(1)	05/21/2018	15985378	11,109,787	
Bioconductive tip	US	ORD(1)	7/16/2018	D/656,793	D879,970	
Method for Diagnosing a Malignant Tumor	US (1)	ORD(1)	08/19/2013	13/970496	10,117,596	11/06/2018
	JP	PCT(5)	10/18/2013	2016-536073	6,337,267	
	Korea	PCT(5)	03/16/2016	10-2016-7006923	10-2035381	
	China	PCT(5)	10/18/2013	201380079729.6	ZL201380797296	
	Canada	PCT(5)	10/18/2013	2921690	2,921,690	
Enhanced surface and tip for obtaining Bioelectrical signals	US	ORD (1)	5/5/2014	14/269,248	9,526,432	12/27/2016
Method for diagnosing a disease	US	ORD (1)	10/25/2007	11/978,045	7,603,171	10/13/2009
	US	CON (2)	10/13/2009	12/578,329	8,121,677	2/21/2012
Methods for obtaining quick, repeatable and non-invasive bioelectrical signals in living organisms	US	DIV (3)	11/26/2007	11/944,696	7,536,220	5/19/2019
	US	ORD (1)	7/16/2003	10/621,178	7,542,796	
Systems and methods of utilizing electrical 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 method patents expire 20 years from the date filed.
(7) All design patents expire 15 years from the date filed.

IONIQ Sciences Patent Applications

Country	Title	Application Number
United States	Probe Having Multiple Tips And An Indicator For Obtaining Bioelectrical Signals	16/597,494
United States	Methods, Systems, And Devices For Determining And Maintaining A Consistent Ground And Ground Saturation Resistance	16/597,667
United States	Maintaining Surface Moisture To Aid In Acquiring A Consistent Ground During Bio-Conductance Testing	17/091,785
United States	Methods, Systems, And Devices For Controlling Temperature In A Bioelectric Measurement System	17/150,964
United States	Methods, Systems, And Devices For Incorporating Vibration Therapy And Vibration Feedback Into A Bioelectric Test Probe	17/163,959
Europe	Method For Diagnosing A Malignant Lung Tumor	2013789409
US	Noninvasive Medical Diagnostics Using Electrical Impedance Metrics And Clinical Predictors	17152707
PCT	Noninvasive Medical Diagnostics Using Electrical Impedance Metrics And Clinical Predictors	PCT/US21/14014
US	Noninvasively Location And Measuring Tissue Based On Real-Time Feedback	17152711
PCT	Noninvasively Location And Measuring Tissue Based On Real-Time Feedback	PCT/US21/114016

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 IONIQ 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 Regulation, or EU MDR, medical devices must meet the EU MDR requirements and receive a CE marking certification prior to marketing in the European Union, or EU. 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 MDR 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 National Medical Products Administration, or NMPA (formerly the China Food and Drug Administration). The NMPA issues registration certificates required for all medical devices sold in China. The NMPA 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 NMPA 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 NMPA 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.** The first planned product utilizing our proprietary digital platform, the IONIQ ProLung Test™ for lung cancer, has been designated a Breakthrough Device by the U.S. FDA in February 2020. We submitted our *de novo* application to the U.S. FDA in February 2022 and we received a substantive review from the FDA outlining additional information that is required for US regulatory clearance. These items include questions and requests related to biocompatibility testing, clinical data, Indications for Use and labeling, cybersecurity documentation, electrical safety, special controls, human factors and usability, performance testing, risk analysis, software, sterility and shelf life. We remain fully committed to gaining U.S. FDA regulatory *de novo* clearance and continue to collaborate with the US FDA so that we can satisfy their requests and subsequently commercialize the IONIQ ProLung Test for lung cancer.
- **China.** The NMPA (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.

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 $1,409,685 and $761,052 on company-sponsored research and development during fiscal years ending December 31, 2022, and 2021, respectively.

Employees

As of April 17, 2023 and December 31, 2022, we had nine employees.

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 an early 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, 2022 was $4,359,401 and for the year ended December 31, 2021 was $3,615,029.

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 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, 2022, we had outstanding Notes and Loans totaling $10,457,022. Nearly the entire balance of our loan obligations are scheduled to come due at the end of September 2023 as a result of an amendment with our Convertible Note holders undertaken in March 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 will not be available for sale until clinical development is completed and regulatory authorizations are obtained. We submitted a De Novo Application to the US FDA in June of 2022. The FDA has shared concerns regarding, indications for use, risks of the device, mechanism for action, device usability and repeatability, software testing documentation, cybersecurity, sterility of probe tip, electrical safety testing, biocompatibility, efficacy, PLW-216 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 to 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 IONIQ 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 has limited 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.

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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 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 a result of our prior offering activities.

In 2018, we 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 at that time. 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. We are pursuing CPT and HCPCS codes since no existing codes appear to cover the purchase and use of our device.

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 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, our licensees, or other persons engaged on our behalf, fail regulatory inspections of our manufacturing facilities requiring us to undertake corrective action or suspend or terminate our clinical trials;
- contractual or other disputes with any parties carrying out trials on our behalf;
- 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.
- Not receiving 3rd party products required to operate our device due to supply chain

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.

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- 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, our licensees, or other persons engaged on our behalf, fail regulatory inspections of our manufacturing facilities requiring us to undertake corrective action or suspend or terminate our clinical trials;
- contractual or other disputes with any parties carrying out trials on our behalf;
- 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.
- Not receiving 3rd party products required to operate our device due to supply chain

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 continuing coronavirus (COVID-19) outbreak or other pandemic 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 or other global pandemics 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 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 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.

Our 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. 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.

Our 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 qualified subjects, 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 may be insufficient 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 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.

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 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 IONIQ System may become obsolete.

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

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©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;
- 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 350 W. 800 N., Suite 214, Salt Lake City, Utah 84103. We currently lease this property for $3,960 a month. The lease is through August 31, 2025. 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 April 14, there are 4,591,399 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, 2022:

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	771,788	$ 5.39	0
Equity compensation plans not approved by security holders	1,344,985	$ 5.25	N/A
Total	2,116,773	$ 5.30	0

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. In April 2022, the Board authorized an additional issuance of 500,000 shares on 5/1/2022, 60,000 shares on 1/1/2023, and 60,000 to be issued 1/1/2024.

Item 6. Reserved

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 and one 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 or bioimpedance and artificial intelligence (AI). We are developing an advanced multi-cancer screening technology for early detection of multipole cancers that may expand the therapeutic window, dramatically improve survivability and reduce the cost of healthcare. We have active projects in lung, breast and gastro-intestinal (GI) cancers. 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 in February 2020 We submitted our *de novo* application to the U.S. FDA in February 2022 and we received a substantive review from the FDA outlining additional information that is required for US regulatory clearance These items include questions and requests related to biocompatibility testing, clinical data, Indications for Use and labeling, cybersecurity documentation, electrical safety, special controls, human factors and usability, performance testing, risk analysis, software, sterility and shelf life. 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, 2022 compared to Fiscal Year Ended December 31, 2021

Revenue and Cost of Revenue.

During the year ended December 31, 2022 or 2021, we had no revenue.

Operating Expenses

Research and Development Expense. Research and development expense for the year ended December 31, 2022 was $1,409,685 compared to research and development expense of $761,052 for the year ended December 31, 2021; representing an increase of $648,633. The increase was due to focused attention in support of our FDA submission. We would expect our research and development costs to remain relatively constant during 2023.

Selling, General and Administrative Expense. Selling, general and administrative expense for the year ended December 31, 2022 was $1,986,563 compared to selling, general, and administrative expense of $1,722,044 for the year ended December 31, 2021, representing an increase of $264,519. This increase was due to increases in fundraising activities, consulting in support of our FDA submission, stock compensation, and insurance rates in 2022.

Other Expense. Other expense for the year ended December 31, 2022 was $963,153 compared to $1,131,933 the year ended December 31, 2021. The in costs consists of the following:

Interest Expense – Interest decreased in 2022 to $963,153 from $1,268,823 in 2021 due to all loan costs becoming fully amortized during 2021.

Gain/ Loss on Debt Extinguishment – During 2021, the Company was able to settle various obligations at amounts less than originally accrued thus causing a gain on debt extinguishment, we did not have such items during 2022.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2022 and 2021:

	December 31,	
	2022	2021
Cash	$ 296,496	$ 745,003
Current assets	296,496	745,003
Current liabilities	(13,500,325)	(12,435,011)
Working capital deficit	$ (13,203,829)	$ (11,690,008)

We need additional capital to continue our operations. We received $1,825,582 in cash from the exercise of warrants during the year ended December 31, 2022. In order for us to continue operations we will need additional capital which will require us to issue equity securities, debt securities and rights to acquire equity securities. We have no existing commitment to provide capital, and 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 and adequacy of available funds will depend on many factors including:

- Our ability to find a commercial market for our IONIQ ProLung Test and obtain needed regulatory clearance
- Our financial results;
- the cost and availability of capital generally; and
- the occurrence of unexpected adverse expenses or events.

In March 2018, we began issuing 8% convertible promissory notes ("convertible notes"). The convertible notes are unsecured. Principal and accrued interest were originally set to mature in March 31, 2022; however, these notes, along with our other notes were amended in March 2022 to extend maturity until September 30, 2023. 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 conversion prices ranging from $3.20 to $10.53 per share. Interest accruing from the date of issuance to the conversion date shall be paid on the maturity date. Through December 31, 2022, we have issued $10,457,022 in convertible promissory 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, 2022 and 2021 is as follows:

	For the Year Ending December 31,	
	2022	2021
Operating activities	$ (2,270,185)	$ (1,799,497)
Investing activities	(3,904)	(2,137)
Financing activities	1,825,582	2,361,511
Net decrease in cash	$ (448,507)	$ 559,877

Operating Activities

For the year ended December 31, 2022, the differences between our net loss and net cash used in operating activities were due to net non-cash charges totaling $1,203,763 for stock-based compensation, amortization of debt discount, depreciation and amortization.

For the year ended December 31, 2021, the differences between our net loss and net cash used in operating activities were due to net non-cash charges totaling $1,114,803 for stock-based compensation, amortization of debt discount, depreciation and gain on debt extinguishment.

Investing Activities

During the year ended December 31, 2022, the Company purchased equipment totaling $3,904. During the year ended December 31, 2021, the Company purchased equipment totaling $2,137.

Financing Activities

During the year ended December 31, 2022, cash flows from financing activities totaled $1,825,582 related to proceeds received from the exercise of stock warrants.

During the year ended December 31, 2021, cash flows from financing activities totaled $2,361,511 related to proceeds received from the issuance of convertible notes of $3,448,779 and paid $259,069 in loan costs. We paid $864,199 to settle convertible loans that were due. We also received $36,000 in proceeds from the exercise of stock warrants.

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.

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, 2022, 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 the internal controls are considered 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, 2022, 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. Due to this material weakness, management has concluded that our internal controls over financial reporting were not effective as of December 31, 2022.

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. 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, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None noted.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

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	41	Chief Executive Officer, and Director
Michael Garff	40	Director, Chief Operating Officer
Jim Hogan	66	Director, Chairman of Finance & Compensation Committee
Don Patterson	70	Director, Chairman of Audit Committee
David Nielsen	50	Director
Aaron Dorny	47	Director
Rich McKeown	76	Director

Jared Bauer. Mr. Bauer, 41, 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 has focused his professional endeavors on the medtech industry and is also the CEO of Cibus Biotechnologies Inc. In 2012, Mr. Bauer acquired BurnFree Products, and in just two years with a focus on sustainable revenue generation, led the 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 currently serves as a trustee of The Oliver Fund, a non-profit he co-founded, Chairman of the BioUtah SLC Biotech Initiative Advisory Committee, Board member of the BioHive, and recently served as an adjunct professor of entrepreneurship at Ensign College. He holds a BS in Economics from the University of Utah, and an MBA from Boise State University.

Michael Garff. Mr. Garff, 40, 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 Department of Biomedical Informatics of the University of Utah and 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.

Don Patterson. Mr. Don Patterson, 70, 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, 50, is currently a partner at Whiteknob consulting, which is a medtech product development company. 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 is currently a partner at Whiteknob, which is a medtech product development company based in Salt Lake City, Utah. Mr. Nielsen holds a BS degree in Mechanical Engineering from Brigham Young University, and a Master of Mechanical Engineering from the University of Utah.

Aaron Dorny. Mr. Dorny, 47, joined the Board in late-2021. He has dedicated his career to improving the operational and financial standing of companies of all sizes by utilizing his expertise in strategy, finance, and leadership. His work has crossed multiple industries, international borders and business disciplines, including accounting, finance, manufacturing, intellectual property, product development, restructuring and corporate strategic planning. His leadership and business skills have been enhanced by time spent with great colleagues at strong companies, such as Innovative Coatings, EP Minerals, EaglePicher and Ernst & Young Corporate Finance, as well as in advisory roles for many other organizations. Mr. Dorny holds a Master of Accountancy from the Marriott School of Business at Brigham Young University.

Rich McKeown. Mr. Rich McKeown, 76, is the co-founder of Leavitt Partners. 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. 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.

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 directors are Don Patterson and Michael Garff. Their terms will expire at the 2022 annual meeting of stockholders tentatively slated for June 2023
- The Class II directors are Jim Hogan and Aaron Dorny. Their terms will expire at the 2023 annual meeting of stockholders
- The Class III directors are David Nielsen, Rich McKeown and Jared Bauer. Their terms will expire at the 2024 annual meeting of stockholders.

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 seven 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), Aaron Dorny 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), Aaron Dorny and Michael Garff. Our Board of Directors has determined that Mr. Patterson, Mr. Dorny 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. Patterson. 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 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 and our current CEO have, during the past ten years, been involved in 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 the1total compensation of the Company's named executive officers during the years ended December 31, 2022, and 2021.

The Company's named executive officers are (a) each person who served as the Company's Chief Executive Officer during 2022 and 2021, (b) the next two most highly compensated executed officers serving as of December 31, 2022, 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, 2022 or 2021.

Summary Compensation Table

Name & Principal Position	Year	Salary	Bonus	Option Awards	All Other (1)	Total
Jared Bauer, Chief Executive Officer(2, 3)	2022	$ 145,000	$ 50,000	$ 290,635	$ -	$ 485,635
	2021	$ 120,000	$ -	$ 146,743	$ -	$ 266,743
Michael Garff, Chief Operating Officer (4)	2022	$ 165,316	$ -	$ 98,518	$ -	$ 263,834
	2021	$ 161,288	$ -	$ 88,524	$ -	$ 249,804

(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 was 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 at which point he became a salaried employee of the Company.

(3) Includes the aggregate grant date fair value of options to purchase 44,956 and 23,000 shares of common stock issued to Mr. Bauer during 2022 and 2021, respectively in accordance with FASB ASC. Options related to Mr Baur's service as CEO during the years ended December 31, 2022 and 2021 totaled 36,956 and 15,000, respectively. Options related to service as a director during 2022 and 2021 totaled 8,000 for each year.

(4) Includes the aggregate grant date fair value of options to purchase 15,741 and 14,241 shares of common stock issued to Mr. Garff during 2022 and 2021, respectively in accordance with FASB ASC. Options related to Mr Garff's service as COO during the years ended December 31, 2022 and 2021 totaled 7,741 and 6,241, respectively . Options related to service as a director during 2022 and 2021 totaled 8,000 for each year.

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, 2022:

Compensation Table for Non-Executive Directors

Name & Principal Position	Fees Earned or Paid	Stock Awards	Option Awards	Other	Total
David Nielsen (1)	$ -	$ -	$ 47,724	$ -	$ 47,724
Don Patterson (2)	$ -	$ -	$ 60,037	$ -	$ 60,037
Jim Hogan (3)	$ -	$ -	$ 60,037	$ -	$ 60,037
Rich McKeown (4)	$ -	$ -	$ 47,724	$ -	$ 47,724
Aaron Dorny (5)	$	$	$ 84,179	$	$ 84,179

(1) Represents the aggregate grant date fair value of options to purchase 8,000 shares of common stock issued in accordance with FASB ASC Standards.

(2) Represents the aggregate grant date fair value of options to purchase 10,000 shares of common stock issued in accordance with FASB ASC Standards.

(3) Represents the aggregate grant date fair value of options to purchase 10,000 shares of common stock issued in accordance with FASB ASC Standards.

(4) Represents the aggregate grant date fair value of options to purchase 8,000 shares of common stock issued in accordance with FASB ASC Standards.

(5) Represents the aggregate grant date fair value of options to purchase 14,000 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 April 14 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 4,591,399 shares of our common stock issued and outstanding as of April 14. Unless otherwise indicated, the address of each person listed is in care of ProLung, 350 W. 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 [3]	483,164	10.2%
ProLung China	278,053	6.1%
Michael Garff, Chief Operating Officer [4]	161,611	3.4%
Jared Bauer, Chief Executive Officer[5]	279,956	5.7%
Don Patterson[6]	219,064	4.6%
Aaron Dorny[7]	81,985	1.8%
Other Directors	214,500	4.6%
All Executive Officers and Directors as a Group (seven persons)	957,115	20.1%

(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 the assumed conversion of convertible debt into 142,475 shares of common stock. Also, includes 12,500 shares issuable upon the exercise of stock warrants that are currently exercisable or exercisable within 60 days.

(4) Includes 102,236 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(5) Includes 279,956 shares issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(6) Includes the assumed conversion of convertible debt into 144,139 shares of common stock. Also, includes 40,000 shares issuable upon the exercise of stock options and warrants that are currently exercisable or exercisable within 60 days. Includes 34,925 shares of common stock held.

(7) Includes the assumed conversion of convertible debt into 18,985 shares of common stock. Also, includes 38,000 shares issuable upon the exercise of stock options and warrants that are currently exercisable or exercisable within 60 days. Includes 15,000 shares of common stock held.

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

Certain Relationships and Related Transactions

Other than compensation arrangements described herein, since January 1, 2020, 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, Aaron Dorny and Rich McKeown are independent.

Item 14. Principal Accounting Fees and Services

The following table summarizes the fees of 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.

	2022	2021
Audit Fees	$ 57,248	$ 55,450
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total	$ 57,248	$ 55,450

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 2022 and 2021 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:

- Report of Independent Registered Public Accounting Firm
- Balance Sheets as of December 31, 2022 and 2021
- Statements of Operations for the years ended December 31, 2022 and 2021
- Statements of Stockholders' Deficit for the years ended December 31, 2022 and 2021
- Statements of Cash Flows for the years ended December 31, 2022 and 2021
- Notes to the 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.

INDEX TO FINANCIAL STATEMENTS

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 balance sheets of ProLung, Inc. ("the Company") as of December 31, 2022 and 2021, the related statements of operations, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2022 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, 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 incurred substantial and recurring losses to date from operations, continues to have a stockholders' deficit and is currently dependent on debt and equity financing, which creates substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) related to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgements. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Equity-Based Instruments

Critical Audit Matter Description

During the year ending December 31, 2022, the Company issued common stock and stock options which required management to assess the fair value of these instruments in order to record and disclose the equity-based compensation in these transactions. The Company's stock does not actively trade on an active market. The Company utilized a valuation methodology that incorporated various assumptions including replacement cost and also utilized a third-party valuation specialist to assist in the determination of the fair value of the Company's common stock.

We identified auditing the valuation of the equity-based compensation as a critical audit matter due to the significant judgements used by the Company in determining the value of its common stock. Auditing the determination and valuation of the common stock involved a high degree of auditor judgement, specialized skills and knowledge.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures related to the following:

- We evaluated the reasonableness and appropriateness of the choice of valuation methodology and model used for valuing the common stock.
- We tested the reasonableness of the assumptions used by the Company in the valuation model, including scenario weighting, replacement cost assumptions and discount rates.
- We tested the accuracy and completeness of data used in developing the assumptions used in the valuation model.
- We evaluated the accuracy and completeness of the Company's presentation of these instruments in the financial statements and related disclosures, including evaluating whether such disclosures were in accordance with relevant accounting standards.
- Professionals with specialized skill and knowledge were utilized by the Firm to assist in the evaluation of the valuation models deployed by management.

/s/ Sadler, Gibb & Associates, LLC

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

Draper, UT
April 17, 2023

ProLung, Inc. (dba IONIQ Sciences)
Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash	$ 296,496	$ 745,003
Total Current Assents	296,496	745,003
Property and equipment, net	6,274	21,183
Operating lease right of use asset	123,431	-
Intangible assets, net	108,368	117,929
Total Assets	$ 534,569	$ 884,115
Liabilities and Stockholders' Deficit		
Current Liabilities		
Accounts payable	$ 76,540	$ 13,733
Accrued liabilities	2,610,804	1,775,849
Operating lease liability - current	40,959	-
Payable for research and development - current	315,000	315,000
Convertible notes payable, related party - current	439,000	434,687
Convertible notes payable - current	10,018,022	9,895,742
Total Current Liabilities	13,500,325	12,435,011
Long-Term Liabilities		
Operating lease liability - long term	83,748	-
Total Long-Term Liabilities	**83,748**	-
Total Liabilities	**13,584,073**	12,435,011
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; 4,591,399 and 4,122,130 shares issued and outstanding, respectively	4,591	4,122
Additional paid-in capital	31,497,065	28,571,741
Subscription receivable	(65,000)	-
Accumulated deficit	(44,486,160)	(40,126,759)
Total Stockholders' Deficit	**(13,049,504)**	(11,550,896)
Total Liabilities and Stockholders' Deficit	$ 534,569	$ 884,115

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

ProLung, Inc.
Statements of Operations

	For the Year Ended December 31,	
	2022	**2021**
Revenues:		
Revenue	$ -	$ -
Total revenue	-	-
Cost of revenue:	-	-
Gross margin	-	-
Operating expenses:		
Research and development expense	1,409,685	761,052
Selling, general and administrative expense	1,986,563	1,722,044
Total operating expenses	3,396,248	2,483,096
Loss from operations	(3,396,248)	(2,483,096)
Other income (expense):		
Gain on debt extinguishment	-	136,890
Interest expense	(963,153)	(1,268,823)
Total other expense	(963,153)	(1,131,933)
Net loss	$ (4,359,401)	$ (3,615,029)
Basic and diluted loss per share	$ (0.97)	$ (0.88)
Weighted-average common shares outstanding, basic and diluted	4,498,453	4,109,444

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

ProLung, Inc.
Statements of Stockholders' Deficit
For the Years Ended December 31, 2022 and 2021

	Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance, December 31, 2020	4,084,916	$ 4,085	$27,662,507	$ -	$ (36,511,730)	$ (8,845,138)
Exercise of warrants	10,000	10	35,990	-	-	36,000
Conversion of notes payable to common stock	27,214	27	87,058	-	-	87,085
Stock-based compensation	-	-	730,887	-	-	730,887
Warrants issued to convertible debt placement agent	-	-	55,299	-	-	55,299
Net loss	-	-	-	-	(3,615,029)	(3,615,029)
Balance, December 31, 2021	4,122,130	4,122	28,571,741	-	(40,126,759)	(11,550,896)
Exercise of warrants for cash	351,074	351	1,825,231	-	-	1,825,582
Cashless exercise of warrants	52,174	52	(52)	-	-	-
Exercise of warrants for acquired research and development	19,414	19	113,731	-	-	113,750
Additional shares of common stock issued to warrant holders	27,671	28	254,546	-	-	254,574
Exercise of warrants for subscription receivable	12,667	13	65,861	(65,874)	-	-
Issuance of common stock acquired for research and development	6,436	6	59,205	-	-	59,211
Return of shares for settlement of subscription receivable	(167)	-	(874)	874	-	-
Stock-based compensation	-	-	607,676	-	-	607,676
Net loss	-	-	-	-	(4,359,401)	(4,359,401)
Balance, December 31, 2022	4,591,399	$ 4,591	$31,497,065	$ (65,000)	$ (44,486,160)	$ (13,049,504)

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

ProLung, Inc.
Statements of Cash Flows

	For the Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (4,359,401)	$ (3,615,029)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	28,374	61,676
Amortization of right of use asset	13,585	-
Share-based compensation	607,676	730,887
Exercise of warrants for acquired research and development	113,750	-
Additional shares of common stock issued to warrant holders	254,574	-
Issuance of common stock for acquired research and development	59,211	-
Amortization of loan discount/loan fees	126,593	459,131
(Gain) loss on debt extinguishment	-	(136,891)
Change in assets and liabilities:		
Prepaid expenses	-	5,427
Accounts payable	62,807	(84,058)
Accrued liabilities	834,955	779,360
Operating lease liability	(12,309)	-
Net cash flows used in operating activities	(2,270,185)	(1,799,497)
Cash flows from investing activities:		
Purchase of equipment	(3,904)	(2,137)
Net cash flows used in investing activities	(3,904)	(2,137)
Cash flows from financing activities:		
Proceeds from convertible notes payable	-	3,448,779
Proceeds from warrant exercise	1,825,582	36,000
Payment to placement agent for convertible notes payable	-	(259,069)
Payment on convertible note payable	-	(864,199)
Net cash flows provided by financing activities	1,825,582	2,361,511
Net decrease in cash	(448,507)	559,877
Cash at beginning of period	745,003	185,126
Cash at end of period	$ 296,496	$ 745,003
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest	$ -	$ 30,693
Supplemental disclosure of non-cash investing and financing activities:		
Exercise of warrants for subscription receivable	$ 65,874	$ -
Return of shares in satisfaction of subscription receivable	$ 874	$ -
Common stock issued for cashless exercise of warrants	$ 52	$ -
Addition of right of use asset/liability	$ 137,016	$ -
Debt discount on convertible notes - warrants	$ -	$ 292,409
Partial settlement of research and development liability	$ -	$ 50,000
Transfer of accrued interest to convertible notes payable	$ -	$ 43,931
Conversion of debt to equity	$ -	$ 87,085
Transfer of short term loans payable to convertible note payable	$ -	$ 100,181

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

ProLung, Inc
Notes to 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 11, 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.

Going Concern – The accompanying 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 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 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 places its cash with a high credit quality financial institution. At December 31, 2022, the Company had $46,496 of cash in their accounts that exceeded the $250,000 Federally Insured Limit ($250,000).

Fair Value of Financial Instruments – For the notes payable and convertible debentures, 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, 2022 and 2021.

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 3 to these 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, 2022 and 2021.

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.

Stock-based Compensation – The Company measures the cost of employee and non-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 and non-employee is required to provide service in exchange for the award, usually the vesting period.

The Company computes the fair value of stock options granted and placement agent warrants using the Black Scholes pricing model. The following the assumptions used under the Black Scholes pricing model:

Fair Value of Common Stock - The Company's shares are not quoted in an active market, therefore the fair value of the Company's issued shares is based on valuation methods and techniques generally recognized as standard within the industry in which observable data have been used to the extent practicable.

Expected Term - The Company utilizes the "simplified" method to develop an estimate of the expected term of option and warrant grants.

Volatility - The Company does not currently have a sufficient trading history to support its historical volatility calculations. Accordingly, the Company is utilizing an expected volatility figure based on a review of the historical volatility of comparable entities over a period of time equivalent to the expected life of the instrument being valued.

Risk Free Interest Rate - Is determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

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, 2022 and 2021, 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, 2022, and 2021, the following items were excluded from the computation of diluted net loss per common share as their effect is anti-dilutive:

	December 31,	
	2022	2021
Warrants to purchase shares	299,761	1,344,985
Stock options	917,066	771,788
Convertible notes	3,362,791	3,150,387
	4,579,618	5,267,160

Related Parties – The Company discloses related party transactions which are in the normal course of operations and are measured at the exchange amount.

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 have been effective for the Company's 2019 fiscal year; however, since the Company was an Emerging Growth Company and made the election to adopt certain accounting standards when they would be applicable for private companies which was the fiscal year beginning January 1, 2022. The Company used the modified retrospective basis. During 2022, the Company entered into lease agreement related to a building. See Note 11 for the effects of implementing ASU 2016-02.

Recent Accounting Pronouncements

Convertible Notes Payable – In August 2020, the FASB issued ASU 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)," which simplifies the accounting for convertible instruments, reduces complexity for preparers and practitioners and improves the decision usefulness and relevance of the information provided to financial statement users. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company has elected to implement this standard effective January 1, 2022. There does not appear to be any prior period effects for the Company implementing this standard.

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 – Property and Equipment

Property and equipment consist of the following at December 31, 2021, and 2020:

		December 31,	
	Life	2022	2021
Leasehold improvements	3 Years	$ 133,553	$ 133,553
Computer equipment	3 years	31,392	31,392
Office equipment	3 to 5 years	28,781	24,877
Tooling	5 years	92,228	92,228
		285,954	282,050
Less accumulated depreciation		(279,680)	(260,867)
Property and equipment, net		$ 6,274	$ 21,183

Depreciation expense for the years ended December 31, 2022 and 2021, was $18,813 and $52,114, respectively.

Note 3 – 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, 2022 and 2021, the Company recognized amortization expense of $9,562 each year. At December 31, 2022, there was accumulated amortization of $66,932. The intangibles will be amortized at the above $9,562 yearly amount over the next 11.3 years

Note 4 – Accrued Liabilities

Accrued liabilities consists of the following at December 31, 2022 and 2021:

	December 31,	
	2022	2021
Accrued interest	$ 2,551,006	$ 1,714,446
Accrued royalties	17,873	17,873
Accrued payroll and payroll taxes	41,925	43,530
Accrued liabilities	$ 2,610,804	$ 1,775,849

Note 5 –Notes Payable

Convertible Note Issuances prior to 2021

Prior to 2021 the Company issued a total $7,008,243 in convertible notes; $439,000 of which was from a current board members. These notes are unsecured, bear interest at 8% and are convertible at amounts ranging from $3.20 per share ($6,788,467) to $10.53 per share ($219,767). If at any time prior to the maturity date, the Company completes an initial registered public offering (IPO) of its common stock, all unpaid amounts shall automatically be converted into common stock at the lower of (i) $3.20 per share and (ii) 90% of the IPO price. Interest accruing from the date of issuance to the conversion date shall be paid on the maturity date. In March 2022, these and all of the Company's convertible notes were amended with the following new terms: (1) the maturity date was extended to September 30, 2023 and (2) there is an expanded automatic contingent conversion to include a qualified financing of at least $10M and (3) added a three month bonus interest payment in the event an automatic contingent conversion is triggered.

2021 Other Convertible Note Issuances

During the year ended December 31, 2021, the Company issued $3,448,779 of new convertible notes. These new convertible notes pay interest at 8% and are due March 31, 2022. The notes are convertible as follows: $851,848 at $3.20 per share and $2,596,931 at $10.53 per share. Interest accruing from the date of issuance to the conversion date shall be paid on the maturity date. In March 2022, these and all of the Company's convertible notes were amended with the following new terms: (1) the maturity date was extended to September 30, 2023 and (2) there is an expanded automatic contingent conversion to include a qualified financing of at least $10M and (3) added a three month bonus interest payment in the event an automatic contingent conversion is triggered.

Since these convertible 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 $237,110 of cash loan costs related to the issuance of the convertible notes during the year ended December 31, 2021. Also, during 2021, the Company issued 22,540 warrants to a broker related to the issuance of the convertible notes. These warrants are exercisable at prices between $3.20 and $10.53 per share and expire in ten years. The initial fair value of these warrants on the date of grant was $55,299 ($2.45 per warrant) for the year ended December 31, 2021. The fair value was derived utilizing the Black-Scholes Pricing Model with the following weighted average assumptions:

	2021
Expected life	5 years
Exercise price	$ 10.53
Expected volatility	185% - 191%
Weighted average volatility	188%
Expected dividends	n/a
Risk-free interest rate	0.76%

The loan costs incurred will be amortized as a component of interest expense over the original term of the convertible notes. During the year ended December 31, 2022 and 2021, the Company recognized interest expense of $126,593 and $459,131 related to the amortization of the loan costs, respectively. As of December 31, 2022, the unamortized balance loan costs is zero.

Convertible notes payable is summarized as follows:

	December 31,	
	2022	2021
Convertible notes payable; unsecured; interest at 8%; due September 2023 (includes related party amounts of $439,000)	$ 10,457,022	$ 10,457,022
Unamortized discount and loan costs (includes related party amount of $- and $4,313)	-	(126,593)
Notes payable, net	$ 10,457,022	$ 10,330,429
Less: current portion, net	(10,457,022)	(10,330,429)
Convertible notes payable - long term, net	$ -	$ -

Note 6 – 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, 2022 and 2021, the Board has not designated any series of preferred stock and there are no shares of preferred stock issued or outstanding.

Note 7 – Stockholders' Equity

Biomeridian License Purchase (OT Acceptance)

On March 3, 2022, the Company acquired from OT Acceptance, LLC ("OT Acceptance") certain intellectual property formerly licensed to the Company by OT Acceptance. As a result of this acquisition, the Company now owns, rather than having license rights, to all of the intellectual property used by it with respect to early cancer detection. The aggregate consideration paid by the Company to OT Acceptance under the Agreement was $134,211, which was paid $75,000 in cash and the issuance of 6,436 shares of the Company's common stock at $9.20 per share totaling $59,211. The Company considers the acquisition of intellectual property as research and development and expensed the acquisition as research and development.

Vine Medical Asset Purchase

On March 30, 2022 the Company acquired from Vine Medical LLC ("Vine") certain intellectual property and designs that are expected to accelerate IONIQ Sciences' product development efforts. The aggregate consideration paid by the Company to Vine Medical LLC under the Agreement was $313,750, which was $200,000 in cash and the seller's exercise of 19,414 previously issued warrants, in the amount of $113,750 which represents forgone cash proceeds that would have otherwise been received. The Company considers the acquisition of intellectual property as research and development and expensed upon issuance.

Exercise of Warrants

During the year ended December 31, 2022, warrant holders exercised 503,785 warrants for 435,162 shares of common stock as follows:

- 351,704 common shares were issued upon the cash exercise of 351,704 warrants with a $5.20 per share exercise price. The Company received $1,825,582 in cash proceeds.
- 19,414 common shares were issued upon the non-cash exercise of 19,414 warrants with a $5.20 per share exercise price as part of the Vine Medical Asset Purchase mentioned above.
- The exercise of 12,667 warrants with a value of $65,874 for the issuance of 12,667 shares of common stock had signed exercise agreements but the cash proceeds were not initially received, and a subscription receivable was recorded. During 2022, 167 shares were returned, and the subscription receivable decreased by $874. On December 31, 2022, the balance of the subscription receivable was $65,000. The subscription receivable was settled in cash subsequent to December 31, 2022.
- 120,000 warrants with exercise prices of $5.20 were exercised cashless based on the fair value of common stock of $9.20 per share, resulting in 52,174 common shares being issued.

During the year ended December 31, 2022, for professional services rendered 27,671 shares valued at $254,574 ($9.20 per share) were issued. The value of these shares was included in the statement of operations.

During the year ended December 31, 2021, 10,000 warrants were exercised for cash proceeds of $36,000 ($3.60 per share).

Note 8 – 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. In May 2020, the Plan was modified by the Board.

2022 Board and Employee Option Grants

As part of an agreement for their service during the year ended December 31, 2022 current Board members and advisors accepted the issuance of 80,463 options at exercise prices between $9.20 and $9.86 per option. These options vested upon issuance. The fair value of these options was $5.66 per option or $455,323 and was expensed upon grant.

In July 2022, the Board's approved the issuance of 64,815 options to employees of the Company at an exercise price of $9.20 per option. These options vest quarterly over four years. The fair value of these options was $6.56 per option or $425,292 and will be expensed over the relative vesting period.

2021 Board and Employee Option Grants

As part of an agreement for their service during the year ended December 31, 2021 current Board members and advisors accepted the issuance of 73,600 options at per option exercise price of $2.47 (16,600 options), $6.73 (33,200 options) and $9.20 (23,800 options), respectively. These options vested upon issuance. The fair value of these options was $5.92 per option or $435,664 and was expensed upon grant. The fair value was computed using the Black Scholes method.

In May 2021, the Board's approved the issuance of 40,678 options to employees of the Company at an exercise price of $6.73 per option. These options vest quarterly over four years. The fair value of these options was $6.37 per option or $259,104 and will be expensed over the relative vesting period.

The fair value was computed using the Black Scholes method using the following weighted-average assumptions:

	2022	2021
Weighted average fair value	$ 8.64	$ 6.11
Expected life	5.6 years	5.1 years
Exercise price	$ 9.28	$ 4.94
Expected volatility	68% to 78%	140% to 188%
Weighted average volatility	75%	176%
Expected dividends	n/a	n/a
Risk-free interest rate	3.21%	1.00%

A summary of option activity for the year ended December 31, 2022 and 2021 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, 2020	663,016	$ 5.16	8.1 years	
Issued	114,278	$ 6.63		
Adjustment	-	$ -		
Forfeited/Expired	(5,506)	$ 2.47		
Outstanding at December 31, 2021	771,788	$ 5.39	6.8 years	
Vested at December 31, 2021	698,707	$ 5.52	6.6 years	
Outstanding at December 31, 2021	771,788	$ 5.39	6.8 years	
Issued	145,308	$ 9.28		
Adjustment	-	$ -		
Forfeited/Expired	-	$ -		
Outstanding at December 31, 2022	917,096	$ 6.01	6.7 years	$ 3,530,341
Vested at December 31, 2022	815,099	$ 5.87	6.4 years	$ 3,251,642

The above intrinsic value is based on an assumed fair value of the Company's stock of $9.84 per share. The Company recorded an expense of $606,676 and $542,690 for the year ended December 31, 2022 and 2021 related to these options, respectively. The $571,352 remaining unrecognized expense will be recognized through June 2026 with a weighted average term of 3.4 years.

Total stock-based compensation expense from amortization of options, warrants (Note 9) and common stock issuances have been included in the statements of operations as follows:

	For the Year Ending December 31,	
	2022	2021
Research and development expense	$ 455,640	$ 45,271
Selling, general and administrative expense	579,571	685,616
Total share-based compensation	$ 1,035,211	$ 730,887

Note 9 – Common Stock Warrants

See Note 7 for common stock warrants exercised during the year ended December 31, 2022 and 2021.

The Company has issued warrants to purchase its common stock for equity, debt and compensation reasons. See Note 5 for 22,540 warrants issued as part of loan issuance costs during the year ended December 31, 2021.

On September 30, 2021 the Company issued a consultant 30,000 warrants for financial advisory services rendered to the Company. These warrants vested upon grant, are exercisable at $10.53 and expires in 10 years. The fair value of the warrant shares issued was $192,161 and expensed upon issuance. The assumptions used for these warrant shares were risk-free interest rate of 0.98%, expected volatility of 184%, expected life of 5 years, and expected dividend yield of zero.

	Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value of Vested Warrants
Outstanding at December 31, 2020	1,305,595	$ -	-	
Issued	52,540	$ 10.53		
Exercised	(10,000)	$ 3.60		
Adjustment	(25)			
Expired/Forfeited	(3,125)	$ 3.60		
Outstanding at December 31, 2021	1,344,985	$ 5.25	1.1 years	
Outstanding at December 31, 2021	1,344,985	$ 5.25	1.1 years	
Issued	-	$ -		
Exercised	(503,785)	$ 5.21		
Expired/Forfeited	(541,439)	$ 5.22		
Outstanding at December 31, 2022	299,761	$ 5.16	4.4 years	$ 1,444,240

Note 10 – Commitments and Contingencies

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 Wuxi'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 $575,000 and issue up to 347,566 shares of common stock upon the completion of certain events.

Through December 31, 2022, 278,053 shares had been issued based on conditions being met. The final 69,513 shares will be issued once the final milestone is met. Through December 31, 2021, $210,000 in payments had been made plus $50,000 in equipment (see below) with the remaining $315,000 currently payable.

Settlement of Liabilities

During the year ended December 31, 2021, the Company recorded $136,890 in gains from settlement of liabilities. Write-down of accounts payable related to agreed-to settlement accounted for $86,890 with the remaining $50,000 attributed to the agreed to value of equipment transferred to Wuxi.

Note 11 – Leases

In September 2022, the Company renegotiated their office space lease from a month-to-month lease to a long-term operating lease agreement. The lease agreement is for 36 months requiring monthly payments as follows:

On *January 1, 2022,* the Company adopted Topic *842, Leases* which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. The Company determined that the fair value of the lease asset and liability at the inception of the leases was $137,016 using a discount rate of 8% which was the cost of capital for the Company.

Beginning Date		Ending Date		Payment
September 2022	-	August 2023	$	3,960
September 2023	-	August 2024	$	4,356
September 2024	-	August 2025	$	4,487

During the year ended December 31, 2022, the Company made payments resulting in a $3,047 reduction in the lease liability. As of December 31, 2022 the lease liability amounted to $124,707. Topic 842 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. The right-of-use asset on December 31, 2022 was $123,431, net of amortization of $13,585. The remaining term of the lease is 32 months on December 31, 2022.

The lease expense related to this lease for the year ended December 31, 2022 and 2021, which includes the portion under a month-to-month agreement was $32,880 and $43,200, respectively.

Maturities of the Company's lease liability is as follows:

Year Ending December 31,		
2023	$	49,500
2024		52,796
2025		35,896
Less: Imputed interest/ present value discount		(13,485)
	$	124,707

The above liability is presented on the accompanying balance sheet as follows:

Lease liability - current	$	40,959
Lease liability - long-term	$	83,748

Note 12 – Income Taxes

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

The significant components of net deferred tax assets (liabilities) were as follows at December 31, 2022, and 2021:

	December 31,	
	2022	2021
Net operating losses	$ 8,628,300	$ 7,730,700
Research and development credit carryforward	209,900	209,900
Depreciation and amortization	(100)	(2,400)
Valuation allowance	(8,838,100)	(7,938,200)
Net Deferred Tax Asset	$ -	$ -

As of December 31, 2022, 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, 2022 and 2021 is set forth below:

	For the Year Ended December 31,	
	2022	2021
Net loss	$ (1,133,000)	$ (940,000)
Non-deductible expenses and other	233,100	201,400
Change in valuation allowance	899,900	738,600
Benefit from income taxes	$ -	$ -

As of December 31, 2022, the Company has a net operating loss carry-forward for U.S. federal income tax purposes of approximately $33.2 million. This carry-forward is available to offset future taxable income, if any, and will expire, if not used, from 2023 through 2041. 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, 2019. The Company is no longer subject to Utah state tax examinations for tax years before and including December 31, 2017. During the years ended December 31, 2022, and 2021, the Company did not incur interest and penalties.

Note 13 – Subsequent Events

Convertible Note Bridge Financing

In February 2023, the company initiated a $2M bridge financing round. As of April 14, $736,124 in financing has been received with the remaining expected by the end of the second quarter.

Board and Employee Options Grant

In the first quarter of 2023, the board approved the issuance of 16,624 options for board members and advisors as part of their agreed compensation.

SIGNATURES

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

PROLUNG, INC.

April 17, 2023
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)	April 17, 2023
/s/ Don Patterson Don Patterson	Director	April 17, 2023
/s/ Michael Garff Michael Garff	Director	April 17, 2023
/s/ Jim Hogan Jim Hogan	Director	April 17, 2023
/s/ David Nielsen David Nielesen	Director	April 17, 2023
/s/ Rich McKeown Rich McKown	Director	April 17, 2023
/s/ Aaron Dorny Aaron Dorny	Director	April 17, 2023

Exhibit Index

Exhibit Number	**Description**
3.2	Amended and restated By-Laws[(1)]
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	Inline XBRL Instance Document*
101 SCH	Inline XBRL Schema Document*
101 CAL	Inline XBRL Calculation Linkbase Document*
101 LAB	Inline XBRL Labels Linkbase Document*
101 PRE	Inline XBRL Presentation Linkbase Document*
101 DEF	Inline XBRL Definition Linkbase Document*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

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, 2022.

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

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

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

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

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

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

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

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

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

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

Dated: April 17, 2023

/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, 2022, as filed with the Securities and Exchange Commission (the "Report"), I, Jared Bauer, interim Chief Executive Officer and Principal Accounting Officer of the Company, hereby certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Dated: April 17, 2023

/s/ Jared Bauer
Jared Bauer, Chief Executive Officer