

---

---

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

---

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (date of earliest event reported): **July 10, 2018**

**Prolung, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**000-54600**

(Commission  
File Number)

**20-1922768**

(IRS Employer  
Identification No.)

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

(Address of Principal Executive Offices)

**84102**

(Zip Code)

Registrant's Telephone Number, Including Area Code:

**(801) 736-0729**

**N/A**

(Former name, former address, and formal fiscal year, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
- 
-

**Item 7.01. Regulation FD Disclosure**

On July 10, 2018, ProLung, Inc. (the “Company”) released responses to frequently asked questions related to recent management changes at the Company. A copy of the questions and responses is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The Company is furnishing the information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) pursuant to Regulation FD promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such information shall not be deemed “filed” for purposes of the Exchange Act or otherwise subject to the liabilities of that section, and is not deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Frequently Asked Questions dated July 10, 2018</a>

---

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Prolung, Inc.

Dated: July 11, 2018

By /s/ Michael Garff  
Michael Garff, Chief Executive Officer

---



**ProLung, Inc. Frequently Asked Questions**  
**July 10, 2018**

We have announced via Form 8-K the termination of the employment of Steven C. Eror, our former Chief Executive Officer, the resignation of certain directors and the appointment of a new interim Chief Executive Officer and two directors. We understand that stockholders are concerned about what these changes mean for the future of ProLung. Set forth below are certain frequently asked questions and responses to those questions. We hope you understand that, as a result of privacy, confidentiality, legal and strategic concerns, we may be unable to provide answers to all of your questions.

**Q: Who is the new CEO at ProLung?**

The ProLung Board of Directors has appointed Michael Garff as interim Chief Executive Officer. Mr. Garff has served as our Chief Operating Officer since 2009. In that capacity, Mr. Garff has had primary responsibility for the operational side of our business, including our pending clinical validation study, and has worked closely with the rest of our team of qualified professionals to move our product development efforts forward. As a result of his experience and long tenure with ProLung, Mr. Garff is especially well-suited to oversee our near-term operations, including the completion of our clinical validation study and our application for FDA marketing authorization.

As ProLung makes progress on its clinical validation study and an application to the FDA for marketing authorization, the Board of Directors intends to commence a search for a CEO with the skills and experience needed to lead the Company past FDA marketing authorization, toward global commercialization and/or strategic partnerships.

**Q: How will the change in management affect the development and commercialization of the ProLung Test?**

The change in management will not delay or hinder the development and commercialization of the ProLung Test. The testing and development of the ProLung Test has been overseen by Michael Garff, historically our Chief Operating Officer, Dr. Rex Yung, Chief Science Officer, and Dr. Jeff O'Driscoll, Chief Medical Officer. This in-house cross-functional team of professionals remains intact and, subsequent to our creating a direct reporting line from this team to the Science and Technology Committee of our Board of Directors in May 2018, we have experienced enhanced productivity and improved results. Dr. John D. Ruckdeshel, previously Chair of the Science and Technology Committee of our Board of Directors, continues to provide oversight of our in-house team as a consultant. We also continue to work with the same outside statisticians, FDA experts and other supporting advisers. Despite the change in our Chief Executive Officer, we continue to retain access to all of the skills and resources necessary to complete our near-term targets of finalizing our clinical validation study and seeking FDA marketing authorization.

---

**Q: What is the status of the clinical validation study?**

As previously disclosed, we have completed enrollment of patients for our clinical validation study and have entered the data review and analysis phase. Subsequent to the filing of our most recent Quarterly Report on Form 10-Q, we have submitted a request to the FDA for a review of our Statistical Analysis Plan (“SAP”), which review we intend to obtain prior to commencing data analysis. We have an appointment with representatives of the FDA on August 16, 2018. We expect the FDA to have some questions and/or concerns, but hope to finalize our SAP in the weeks following that appointment. Upon finalization of the SAP following FDA review, we plan to immediately begin processing accumulated data and, assuming favorable results, to complete and submit an application with the FDA for marketing authorization of the ProLung Test.

**Q: Why was the employment of the Chief Executive Officer terminated?**

It has been anticipated and discussed at the Board level for some time that ProLung would seek a new CEO with the strategic and marketing skills and experience needed to lead the Company past FDA marketing authorization toward global commercialization and strategic partnerships. Mr. Eror has led ProLung for many years in its research and development phase and was, for many years, instrumental in the development of our ProLung Test and raising the capital to keep our business moving forward. However, as ProLung moves toward commercialization, the Board intends to hire a CEO with experience and skills suited for leading the build-out of distribution and manufacturing networks for the ProLung Test, assuming our clinical study results are positive and we obtain required FDA marketing authorization.

While the change in CEO has occurred earlier than would have otherwise been anticipated, it is consistent with the long-term expectations of our directors. In late April 2018, the Chairman of our Audit Committee received a number of confidential communications from employees identifying concerns of various types associated with our Chief Executive Officer, Mr. Eror. The Audit Committee promptly initiated an investigation and provided frequent updates to all of the independent directors from and after May 7, 2018. Following numerous meetings of the independent directors, and after giving due weight to both the information reported by the Audit Committee and the inquiries to which Mr. Eror elected to respond, and considering a number of alternative means for addressing the issues raised, on June 26, 2018, the Board of Directors voted to terminate Mr. Eror’s employment for cause. For legal and confidentiality reasons, we cannot provide the specific bases for the decision of the Board of Directors.

**Q: Why did a majority of the directors resign in connection with this decision?**

None of the directors, including Mr. Eror, were asked or pressured to resign, and none of the directors identified to management the reasons for his or her resignation. Each director made his or her own decision for his or her own reasons, which reasons were not disclosed to management. That said, we do know that in the process up to the decision to terminate the employment of Mr. Eror, the independent directors processed disheartening information, held numerous meetings and engaged in frequent and occasionally challenging discussions about how to proceed. This process was time consuming, stressful and disruptive of relationships among the directors and the directors’ lives outside of ProLung.

**Q: Who is on the Board of Directors at ProLung now?**

Robert Raybould and Scott Nixon remain on the ProLung Board of Directors. Mr. Raybould has served on the Board of Directors for six years and is the Chairman of the Compensation Committee. Mr. Nixon has served on the Board of Directors for one year and nine months, and is the Chairman of the Audit Committee.

ProLung’s interim Chief Executive Officer, Michael Garff, and its Chief Financial Officer, Mark Anderson, have also been added to the Board of Directors in order to create a quorum and to facilitate the formal governance of the Company. Each is a leader within ProLung and brings to the meetings of the Board of Directors first-hand knowledge about the operations and needs of ProLung, as well as his knowledge and experience.

---

The Board of Directors has begun a search for new Board members with the intent of adding to the Board of Directors a diversity of background, skills and experience that that can best position ProLung for success. In particular, as we hire an outside CEO, we anticipate that this individual will draw on his or her own relationships and vision in shaping our Board of Directors over time.

**Q: What are the objectives of the current Board of Directors?**

The objectives of the current Board of Directors are the same as the previous Board of Directors. Specifically, the objectives are to support the entire company, including the stockholders and investors, employees, and consultants; to work collaboratively to move the ProLung technology toward FDA authorization in order to help lung cancer patients gain faster treatment and, thereby, help to extend lives; and to increase the value of the business for the benefit of the stockholders. This can be done through an increased emphasis on collaboration and synergism throughout the organization. During the past two months, employee collaboration and synergy have significantly improved, which assists with moving ProLung toward its objectives.

***For further information, contact:***

Andy Robertson | +1801-503-9231 | [acr@prolunginc.com](mailto:acr@prolunginc.com)  
ProLung Chief Marketing Officer  
ProLung  
757 E.South Temple Suite 150  
Salt Lake City, Utah 84102  
USA  
[www.prolunginc.com](http://www.prolunginc.com)  
Follow ProLung, Inc. on [Twitter](#), [Facebook](#) and [LinkedIn](#): @ProLungInc

***Forward-Looking Statements***

This FAQ may contain forward-looking statements regarding projected business performance, operating results, financial condition and other aspects of ProLung. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipates,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should” and “would,” as well as similar expressions, may identify forward-looking statements, but the absence of these words does not mean a statement is not forward looking. The forward-looking statements contained in this FAQ are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties, or assumptions, many of which are beyond our control that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Important factors that could cause these differences include the following:

---

- We are a development stage company with limited revenue and no assurance of earning significant revenue over the long term.
  - We will need significant capital to execute our business plan, particularly as we continue to seek authorization from the FDA to market our ProLung Test.
  - We are dependent upon financings to fund our operations and may be unable to continue as a going concern.
  - We have issued indebtedness and, if we are unable to repay or refinance it, our creditors could foreclose on our assets and force us into bankruptcy.
  - We are in the early stages of commercialization, and our ProLung Test may never receive marketing authorization from the FDA or achieve commercial market acceptance.
  - Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.
  - We are reliant on a single product and if we are not successful in commercializing the ProLung Test and are unable to develop additional products, our business will not succeed.
  - We are subject to litigation risk for product liability if our ProLung Test is not effective.
  - We may incur substantial product liability expenses due to manufacturing or design defects, or the use or misuse of our products.
  - We are subject to the risk of product recalls if our products are defective.
  - We may not obtain any, or adequate, third-party coverage and reimbursement for our prospective customers.
  - The absence of, or limits on, reimbursements may affect our revenues and our ability to achieve profitability.
  - If the ProLung Test is not accepted by physicians and patients, we will be unable to achieve market acceptance.
  - We are a small company and may be unable to compete with competitive technologies.
  - We are dependent upon our suppliers to safely and timely manufacture our products.
  - We are dependent upon third parties for marketing and other aspects of our business.
  - Any clinical trials that we conduct, including our ongoing trial, 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.
  - We engage in related party transactions, which result in a conflict of interest involving our management.
  - ProLung tests may produce false positive and false negative results.
  - Our clinical studies, including our ongoing clinical study, may produce unfavorable results.
-

- Our success depends upon our ability to effectively market our products.
  - We are dependent on key personnel, whose employment may be terminated by the Company or the employee at any time, which could cause significant disruption in our business and lead to significant expenses.
  - We must obtain regulatory authorization in the US and other non-European Union markets to be able to commence marketing and sales in those markets.
  - Even if we receive regulatory authorization for the ProLung Test, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.
  - If we obtain FDA authorization, we will be subject to Medical Device Reporting.
  - Recently proposed healthcare reform measures could hinder or prevent the commercial success of our products.
  - We will be subject to healthcare fraud and abuse law regulations.
  - Our business is subject to complex and evolving U.S. and international laws and regulation 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.
  - ProLung clinical study designs have not been reviewed by the FDA, and there is a risk that the FDA will not agree with our study designs or results.
  - We may be unable to protect our intellectual property rights, which are important to the potential value of our products and company.
  - We rely on an exclusive license maintained by the licensor, and if the licensor does not adequately defend the license our business may be harmed.
  - We may incur significant costs and liability if we infringe, or are accused of infringing on, the intellectual property rights of others.
  - We may need to market the ProLung Test under a different name in the EU to avoid the risk of infringement.
  - If outstanding warrants are exercised, or Convertible Debentures are converted, stockholders will be diluted.
  - Our officers and directors have significant voting power and may take actions that may not be in the best interests of other stockholders.
  - Our common stock is not quoted or traded in any market, limiting liquidity opportunities for investors.
-

- 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.
- 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.
- If a market develops for our common stock, we expect the market price to be volatile and trading in our common stock to be of limited volume.
- We have never paid, and do not intend to pay in the future, dividends on our common stock.
- We are uncertain when or if full clinical results will be complete and when they will be submitted to the FDA.
- We expect to be dependent upon contract manufacturers to safely and timely manufacture our products.
- While we have completed the on-site procedures for the clinical trials, we do not intend to conduct data analysis until our statistical analysis plan is reviewed by the FDA; we submitted a request for review of our statistical analysis plan in June 2018 and expect a review to take approximately three months, although there can be no assurance of that timeline.
- If we receive FDA confirmation of our statistical plan, of which there can be no assurance, we will then need to complete the analysis of the study results; we anticipate this will take one month, but can provide no assurance as to this timing.
- There is no guarantee that FDA authorization will lead to the ProLung Test being approved by payors for reimbursement.
- Our ProLung Test may produce false positive and false negative results.

In addition, please review the other, and more detailed, risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Forward-looking statements speak only as of the date they are made. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions, or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

---

