
**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): September 13, 2018

ProLung, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

001-38362

(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)

(801) 736-0729

(Registrant's Telephone Number, Including Area Code)

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))
 - 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 12(a) of the Exchange Act
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Item 8.01. Other Events.

Press Release

On September 13, 2018, ProLung, Inc. (the “Company”) issued a press release announcing changes to the Company’s executive leadership team and corporate strategy. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	ProLung, Inc. Press Release dated September 13, 2018

SIGNATURES

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

Date: September 13, 2018

ProLung, Inc.

By: /s/ Jared Bauer

Name: Jared Bauer

Title: Interim Chief Executive Officer



**PRESS RELEASE
FOR IMMEDIATE RELEASE**

**ProLung, Inc. Announces Organizational Changes to Sharpen Focus on Achieving FDA Approval
and Successful Commercialization**

Jared Bauer Named Interim CEO and Details Seven-Point Go-Forward Strategy

Salt Lake City, UT, September 13, 2018 – ProLung, Inc. (“ProLung” or the “Company”) today announced the Company is taking significant steps to better align its product, regulatory, marketing, and consulting functions by focusing upon research and development. This realignment will strengthen the Company’s ability to bring the product through FDA approval and to successful commercialization. The Company also announced its appointment of Jared Bauer as interim CEO, as well as additional executive changes.

The ProLung Test shows great promise helping extend lung cancer patient lives. Over the past few months, the Company has enjoyed many successes on its path to market, including finalizing its FDA De Novo application and securing an appointment with the FDA for September of 2018.

Unfortunately, thirteen years under the former CEO Steve Eror’s “slow play” strategy have taken their toll on the Company’s operations. Mr. Eror’s strategy has led ProLung into a costly and unwieldy corporate structure. Under the previous leadership, ProLung allocated heavy resources to marketing, accounting and medical teams while underfunding, understaffing and outsourcing key technical functions. This approach has failed shareholders. The Company’s key differentiators – its hardware and software capabilities – have been outsourced.

Your Board and the senior leadership team is realigning the business to address these shortcomings with every available resource in an expeditious manner, while continuing to pursue ProLung’s uninterrupted development. The Company will be applying medical technology industry-demonstrated best practices to reframe ProLung as a lean, energetic company with an experienced product-focused staff and a strong research and development focus. These changes will allow the Company to effectively improve lung cancer diagnostics and responsibly return value to its shareholders.

- Robert Raybould, Vice Chair of the Board of Directors

Executive Changes

The Company is pleased to announce that it has appointed Jared Bauer as interim CEO. Mr. Bauer brings over a decade of leadership in the medical device industry and looks forward to steering ProLung through this transitional phase and further along the path to market. Michael Garff will return to his position as COO where he will prioritize FDA approval.

I am excited to join the ProLung team. Moving forward, the management and executive team will be characterized by deep medical technology industry-specific expertise. The new team is prepared to enhance ProLung’s research and development function, improve regulatory compliance, and achieve FDA approval. In order to do so, the Company is announcing reductions in non-essential staff as part of the reorganization to focus on ProLung’s core technology. The Company has also hired an outside accounting firm to perform its accounting and prepare SEC filings, which will ensure transparency in its accounting practices moving forward.

- Jared Bauer, Interim CEO
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Your Board and management team are committed to full transparency and look forward to making demonstrable steps that will mend the relationship between the Company and its shareholders. The team is eager to create an effective diagnostic product that can make a difference for lung cancer patients, and provide a better opportunity to earn a financial reward for its shareholders while doing so.

- Robert Raybould, Vice Chair of the Board of Directors

The Company is also announcing the following changes:

- In order to assist the Company with cost-cutting, Mark Anderson resigned as CFO. ProLung will outsource its accounting and finance needs going forward to save shareholder money. Mr. Anderson will continue to add value as a member of the Board. We wish Mr. Anderson continued success and commend him for his efforts at ProLung.
- Andy Robertson, currently Chief Marketing Officers, will become VP of Business Development. Mr. Robertson will pay particular attention to increasing partnerships, improving relationships with distribution partners, reimbursement, and utilizing ProLung's CE mark.

Corporate Strategy

In a letter to shareholders attached to this press release, Mr. Bauer has expressed in a comprehensive manner the reasons he accepted the position of interim CEO, his assessment of the past management problems experienced by the Company, the challenges confronting the Company, and his plan for the future success of the Company. Mr. Bauer believes this will require a paradigm shift towards prioritizing the product and maintaining its unique value. Your Board has outlined a new **Seven-Point Strategy** that defines how this can be achieved:

1. *Full Transparency.* The ProLung team is committed to full transparency. This includes celebrating successes together with its investors as well as addressing setbacks in a timely manner. Starting today, the Company will also renew its regular updates via email, and will meet with shareholders as often as possible for a public company.
 2. *Focus on the Core Team.* The Company looks forward to re-organizing and re-deploying its internal talent to focus on regulatory affairs, science and technology, with the driving goal of supporting ProLung's FDA De Novo submission. This requires ensuring that the right people with the right skills are in the right positions to navigate the ProLung Test along the path toward FDA approval and marketplace penetration.
 3. *Technology Focus on ProLung Test Performance.* Technological performance will ultimately determine ProLung's success. Therefore, technological progress dictates ProLung's future. Improving our internal technology processes requires collaborating with the right experts, including statisticians to optimize our predictive algorithm, FDA experts to fine-tune our De Novo submission, regulatory and quality experts to ensure that we are compliant with regulations, and engineers that can characterize the ProLung System and patient database as well as address end of life and patient data privacy regulations.
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4. *Leveraging our Clinical Partnerships.* The Company will regularly engage with key Primary Investigators (lead researchers for clinical trials) to determine the publication strategy for PL-208, commercial strategies, and next steps on an ongoing basis. Our current partners include MD Anderson in Houston, Medical University of South Carolina in Charleston, Henry Ford Hospital in Detroit, and Loyola in Chicago. Where applicable, we will engage with additional medical experts.
5. *Cultivate our Strategic Partnerships.* The Company intends to both nurture its strategic relationships as well as identify additional potential partners. Our goals include: (1) a potential strategic partner exit, (2) utilizing existing go-to-market teams that will deliver more rapid and less costly revenue, and (3) licensing our product to improve the performance of the ProLung Test, or to increase the size of the lung cancer product offering.
6. *Gain Reimbursement for ProLung Test.* As reimbursement drives doctors' purchasing behavior in the United States, the Company intends to leverage its growing base of evidence for codes. We must invest in this process now, as it requires published evidence of our clinical validation study, as well as the product efficacy in the marketplace, in order to support an explosive go-to-market strategy and generate revenue.
7. *Maximize and Protect our Financial Capital.* Our goal is to ensure that our capital spending, and shareholders' investment, is cost-effective and provides the Company with maximum flexibility. We will better allocate our remaining capital by focusing on our essential business objectives rather than the residual structure left by the former CEO. This will likely include fundraising, so ProLung will have time and resources to make the best possible choices for the product and the flexibility to return the highest possible value to shareholders.

We are confident that adhering to these strategic principles and strengthening its executive team with industry-specific experience will reinvigorate ProLung's ability to make great strides in lung cancer diagnostics, improve lung cancer patient outcomes, and provide a better path to return value to its shareholders.

- Scott Nixon, Director

Sincerely yours,

THE BOARD OF DIRECTORS OF PROLUNG, INC.

Michael Garff, Mark V. Anderson, Robert W. Raybould, J. Scott Nixon and Jared Bauer

Media Contact:

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About ProLung, Inc.

The mission of ProLung, Inc. (“ProLung” or the “Company”) is to make a difference in time for lung cancer patients. ProLung is the world leader in innovative predictive analytics technology and non-invasive tests for the risk stratification of lung cancer. The Company develops, tests, and commercializes solutions which may shorten the time to diagnosis and expand the therapeutic window for lung cancer patients. ProLung’s predictive analytics platform for lung cancer risk stratification is approved for sale in the European Economic Area and investigational use in the USA.

Important Additional Information

ProLung, its directors and certain of its officers are participants in the solicitation of consent revocations from ProLung’s stockholders in connection with the consent solicitation conducted by Mr. Steven C. Eror and certain other persons acting in concert therewith (the “Consent Solicitation”). On August 27, 2017, Company filed a definitive consent revocation statement and GOLD consent revocation card with the U.S. Securities and Exchange Commission (the “SEC”) in connection with any such solicitation of consent revocations from the Company’s stockholders. **STOCKHOLDERS OF THE COMPANY ARE STRONGLY ENCOURAGED TO READ SUCH CONSENT REVOCATION STATEMENT, ACCOMPANYING GOLD CONSENT REVOCATION CARD AND ALL OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION.** Our definitive consent revocation statement contains information regarding the direct and indirect interest, by securities holdings or otherwise, of the Company’s directors and executive officers in the Company’s securities. In the event that the holdings of the Company’s securities change from the amounts provided in our definitive consent revocation statement, such changes will be set forth in SEC filings on Forms 3, 4 and 5, which can be found through the Company’s website at www.prolunginc.com in the section “Investor Relations” or through the SEC’s website at www.sec.gov. Stockholders will be able to obtain any consent revocation statement, any amendments or supplements to our consent revocation statement and other documents filed by the Company with the SEC at no charge at the SEC’s website at www.sec.gov. Copies will also be available at no charge at the Company’s website at www.prolunginc.com in the section “Investor Relations.”

Forward-Looking Statements

This release may contain forward-looking statements regarding projected business performance, operating results, financial condition and other aspects of the Company, expressed by such language as “expected,” “anticipated,” “projected” and “forecasted.” Please be advised that such statements are estimates only and there is no assurance that the results stated or implied by forward-looking statements will actually be realized by the Company. Forward-looking statements may be based on management assumptions that prove to be wrong. The Company and its business are subject to substantial risks and potential events beyond its control that would cause material differences between predicted results and actual results, including the Company incurring operating losses and experiencing unexpected material adverse events.

Appendix

September 12, 2018

Dear ProLung Shareholders and Colleagues,

I have accepted the position of interim CEO of ProLung, Inc. It is an honor to be given the opportunity to work with each of you and to lead ProLung in its next phase of growth. I am excited by what lies ahead and have already become fully immersed in the Company. I am acutely aware that most of you do not know me. While I look forward to meeting you in person, I want to share why I am excited about ProLung's future and the new initiatives ProLung will be pursuing.

What Excites Me About ProLung

With experience as a hands-on CEO for multiple medtech companies, it is clear that ProLung has a unique opportunity to save lives. I believe that if we are able to make the ProLung device commercially viable and can successfully get through the initial FDA De Novo application, we have a solid market waiting for us.

I have spent the last few weeks closely analyzing the company, its history, its current issues, the way it has allocated its resources, and more. What I have uncovered and observed is deeply disturbing, but also fixable. First, let me preface my findings with facts.

There Are Critical Facts You Need to be Aware of

- In the 13 years that Mr. Eror led ProLung as its CEO, he consistently assembled a Board of Directors WITHOUT specialized medtech / biotech experience. Perhaps more surprising is that his "enlarged and enhanced" proposed Board is also missing expertise in this key area.
 - As a result of the former CEO's misconduct with employees, ProLung has been served with a sexual harassment charge by the Labor Commission of the State of Utah.
 - The ProLung System is built on outdated hardware and software using many key components that are no longer manufactured, supported by the original manufacturers or compliant with basic regulatory guidelines.
 - ProLung does not have, and for many years has not had, the hardware or software development competency to develop and implement critical solutions.
 - Numerous outside consultants have been alienated by our former CEO, Steven Eror, and will not work with us as long as he has any role with ProLung.
 - ProLung does not have reimbursement codes to allow facilities to pay for the ProLung Test, which is critical to successful commercialization.
 - ProLung has not broken the data blind on our pivotal validation study (PL-208) and does not know how the ProLung Test performed. Anyone saying or implying otherwise, is either guessing or not being truthful.
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There Are Challenges We Need to Address Immediately

Traditionally, in pre-revenue and pre-FDA approval med-tech companies, the product receives the internal focus. At ProLung, we see the opposite. While millions of dollars have been spent on building the organization, very few resources have been allocated to product research, development, improvement, or the pursuit of the constantly moving standards required by regulatory authorities. Instead, ProLung spent its money on an ill-advised, ill-timed failed IPO process, non-exclusive consultants, marketing teams (for a product that is not approved for sale), and other support staff that is non-essential and has limited value at this stage.

As noted above, I am absolutely committed to building out a Board of Directors with medtech and biotech experience that can efficiently guide our company forward. In the past few weeks, ProLung has vetted numerous candidates and spent considerable time with five leading candidates for Board or consulting roles. The combined backgrounds of these five former CEOs and functional leaders boast decades of medtech and biotech leadership at the highest levels, specifically in the areas of product development, regulatory submissions, commercialization, mergers and acquisitions and fund raising. Specifically, we have interviewed and are considering the following:

- a candidate with biotech operational experience and pulmonary experience as CEO;
- a scientist with deep cancer diagnostic expertise;
- an National Association of Corporate Directors (NACD) Governance Fellow with pulmonary expertise as a board member, who is well-connected with senior medtech and biotech executives;
- a mechanical engineer with hands-on product development experience for diagnostic and biological detection products; and
- a CEO with extensive medtech operational acumen.

You have my commitment that I will help construct a Board of Directors with these critical skills who can, and will, hold a CEO accountable. You should not accept a Board less qualified (i.e. without medtech experience) or not independent from the CEO.

Focusing on Product Development and Gaining FDA Approval

Beginning today, we will begin an immediate restructuring of ProLung with a direct focus on developing our product, gaining FDA clearance, and building a team with solid product expertise. Changes will include laying off staff that are not essential to where we really are as a company, instead of where we would hope to be some day. We will reorganize the remaining staff with a focus on our core technology. Over the next few months, we will analyze potential changes to our system that will allow us to comply with current regulations and make improvements in our hardware and software.

We will be taking some immediate actions, which we believe will save up to \$1 million annually, including:

- Aligning our staffing with the actual size and phase of the Company, which will lead to an initial annual savings of approximately \$600,000. We expect some offset of that reduction by hiring experts in key areas that will lead to a more sensitive and specific system.
- Implementing corporate policies that require a broader approval for higher level employees, and that will place an immediate freeze on salary increases.
- Shifting from a full-time CFO and accounting department to an outside contractor arrangement.
- Outsourcing marketing, which will also reduce costs but also utilize external expertise on reimbursement codes, pricing and our target market.

Our Seven-Point Strategy for Success

Effective today, all staff will be working from our new Seven-Point Strategy, which is outlined below:

1. *Full Transparency.* The ProLung team is committed to full transparency. This includes celebrating successes together with its investors as well as addressing setbacks in a timely manner. Starting today, the Company will also renew its regular updates via email, and will meet with shareholders as often as possible for a public company.
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7. *Maximize and protect our financial capital.* Our goal is to ensure that our capital spending, and shareholders' investment, is cost-effective and provides the Company with maximum flexibility. We will better allocate our remaining capital by focusing on our essential business objectives rather than the residual structure left by the former CEO. This will likely include fundraising, so ProLung will have time and resources to make the best possible choices for the product and the flexibility to return the highest possible value to shareholders.

As a company we face significant challenges. Many of these challenges seem to be masked by the current proxy fight launched by Steven Error. While I do not intend to make that fight mine, I will make the following statement regarding the previous management based on my extensive review of the organization over the past several weeks.

During my early analysis of ProLung, it became very clear that the previous management team has nearly ZERO knowledge of what it takes to run an early stage med-tech startup, get a product through an FDA 510(k) De Novo application, and manage a pre-revenue company.

For years, the Company had the wrong team, controlled almost entirely by one person, Steven Error. It is evidenced by ProLung's lack of internal knowledge regarding the product, the lack of communication between various departments, software and hardware systems (essential to the product validity) that were outdated a decade ago, out of control spending, very few internal checks and balances, failure to implement or follow policies and procedures, a Board of Directors with less medtech or industry knowledge than was needed, and a general lack of credibility in the marketplace due to the previous leadership's lack of accountability for key development milestones.

ProLung's Path Forward

ProLung is at a crossroads with their current FDA application and preparations to break the blind on the data. Moving forward we will be more systematic, strategic, and intelligent in the decisions we make, in the professionals that we hire, and in our approach with shareholders and investors. ProLung needs a solid team of experts who, when things are difficult, can encourage quick decision making and implement solutions. This will allow us to give the FDA solid answers based on facts and real data moving forward. Let me be clear, having worked with the FDA for many years, as well as regulatory bodies in over 50 countries: data is the ONLY thing that counts.

I cannot predict the future of ProLung, but I can say without hesitation that these changes will greatly increase the likelihood of success for our product, and ultimately a return to our shareholders.

I look forward to getting to know you better as we work together to make ProLung a success.

Sincerely Yours,

Jared Bauer, Interim Chief Executive Officer
