



Shareholder Update Teleconference January 31, 2019

Transcript has been edited for clarity and readability

Jared Bauer: Welcome everyone. This is Jared Bauer, Interim CEO of ProLung. We are excited to have you on this call. One point of our seven-point strategy is increased transparency with our shareholders, and we're grateful to those who have joined us this afternoon. The idea for more frequent conference calls came from comments that we received at and after our annual meeting. We hope it works out well. One of the limitations of this call is the ability for you to ask questions. We want to answer questions and encourage you to send them to acr@prolunginc.com. We will monitor that email address and answer those questions that we receive.

The agenda today covers six items:

1. Review information covered at the annual meeting in December for those who were unable to attend.
2. Give an update on business since our meeting in December.
3. Give the preliminary results of our validation study, PL-208. Many of you have waited years for this and we have those results for you.
4. Put the past behind us and focus on our future as a company.
5. Outline our plan to move the company forward and to accomplish several possible objectives. Those objectives include a potential exit, becoming the gold standard in lung cancer co-diagnostics, further research, international distribution of the device, the 510k de novo domestic commercialization, improvement of care for cancer patients, and a return on investment for our large investor base.
6. Finally, we will be asking and discussing at the end of this call, and a couple of times during, for your support in helping us to raise the next one million dollars to help us move forward simultaneously on each of these parts.

Let's start with a review of the annual meeting. We gave an accurate foundation of understanding of the company's current position. We went into detail regarding our current product, the status of the PL-208 study, our relationships with potential partners, and our search for additional board members. A couple of takeaways deserve repeating:

First, many incorrectly believed breaking the blind potentially meant the same thing as FDA approval, I want to be very clear today that it is only one step in a long process towards FDA approval. A related item is that beyond the PL-208 study the FDA has requested, at minimum, a new study to be done showing repeatability in patients with pulmonary nodules.

Next, we discussed completion of the proxy solicitation, cutting costs, reduction of payroll, and reorganizations on reporting within the company. ProLung is no longer a top down company. We have focused on collaboration and transparency internally. We



also outlined that many of our former consultants are now willing to return and assist the company, and we are developing those relationships. We also mentioned the FDA Pre-Submission process. Michael Garff and Dr. Rex Yung will be discussing that in a few moments.

Continuing with progress since our annual meeting, there is a gap in financial reporting in publicly reporting companies that occurs between the financial report that we submit in the fall and the financial report that we submit for the end of year/fourth quarter in early spring. To increase transparency, we now disclose the company's current financial status. Here are a few high-level points. We now spend as much per quarter as the company did per month in 2017. We reduced our annual spend by 4.2 Million dollars, 15 percent of which was salary reductions. In other words, we've cut 3.7 Million dollars in non-payroll spending off of the spend in 2017. We now spend on average \$169,000 monthly, which works out to be \$508,000 per quarter, or about \$2 million per year. If you would like more specifics, we would be happy to discuss them further at another time.

We've also made substantial progress in our product research. In fall of last year we began to do bench testing based on the FDA's request for a repeatability study. We have now concluded and analyzed the results of that round of bench studies. While this is not the right medium for a full dive, I will state that we uncovered issues in the PL-208 protocol, the most significant of which is the high level of inter-operator variability. We will discuss this further when we disclose the PL-208 results. Since our annual meeting we have also received additional information from both the Fresh group on their updated device, as well as our partner in China, ProLung Wuxi. I want to discuss those two items briefly now. First, our partner in China is on the verge of completing their 450-patient study; it will conclude in the next couple of months. According to our partner, that 450-patient study has been getting results which are far above the results that we anticipated getting in the PL-208 and are far above what would be required for an FDA approval. Further, we have now validated that the Chinese study utilized a clinical research organization (CRO), and that CRO works to validate that data to U.S., European, and Chinese standards. That's what CRO's do. They also have mitigated some of the issues that we have identified through methodology improvements. For example, their technicians are incredibly well trained. We believe this has been one of the reasons that their results thus far have been stronger than those from PL-208. I should also disclose that as of this morning we have received a contract from our Chinese partner that will allow us to utilize their results as part of a Pre-Submission with the FDA. We also received updates from the Fresh group on the technology that they were developing. And while I cannot disclose the details of what the Fresh group has done, I can disclose that we are in active negotiations with them. In fact, we have moved past verbal negotiations, and now we're working on the details of a licensing contract for their new and improved system. One of the key takeaways of their new technology is their focus on a reduction of noise by providing additional user feedback that allows the user to be more precise in how they take the measurements using the ProLung device. We're very optimistic about the progress of both groups, and how we might bring those items together to create a solid path for ProLung in the future.



We also have created a six-month strategic plan and budget. The goal of the six-month strategic plan is to lay out our initial steps as the company moves forward, as well as a very specific budget around that. I will disclose on this call that that budget calls for a 24 percent increase above our now reduced monthly spend, which would be used entirely to hire additional staff to further validate and improve our hardware and software. We also hope to use this staff to better understand how and why the ProLung system works, as well increase our research and understanding of how and why our system works. We have also been working with a strategic partner who has worked with ProLung in the past. This is a large organization with a great deal of expertise both in Medtech and within the marketplace. They have many international relationships, and we believe that reengaging with this particular partner, who I can't disclose on this call today, will allow us to be more successful in the future. We also have potential engagements that we hope to disclose here within the next few weeks with others who recognize that the opportunity is broader than our initial focus of early detection of lung cancer and are interested in joining us to continue the research and bring a product to the marketplace.

We also continue to work with some from the former “Enlarge and Enhance” group, sometimes known as the Eror group, and others in an effort to reconstitute the board. Our goal was to have an announcement ready for today, but we were unable to announce today due to the company policy mandated process of verifying the history of potential board members by performing a background check. We anticipate making some announcements there very soon.

We have completed the restructuring of the \$3M debenture that was raised in the spring of 2018 and the new terms of that, which has been signed by almost all members of that group, have extended the due date to March 31, 2022, the new terms also reduced the strike price to \$5.20. We also unilaterally made changes to the warrants that had been issued on the previous \$8M offering. We extended those through that same time period of March 31, 2022, and we lowered the strike price on those to \$5.20. The feedback from these changes has been overwhelmingly positive and we're grateful for everyone's support in making that happen.

We continue to work with the Division of Securities. And to clarify, this is the Utah Division of Securities, not the SEC. I want to make sure everyone understands the difference there. While that issue has not yet been settled, I am able to disclose that private discussions with them would have us believe that Prolung will be okay in this investigation. They have stated multiple times, and have said it's okay to state publicly, that they do not have a desire to hurt shareholders with that investigation. We expect the outcome of that to be known soon. We actually expected the outcome of that to be known closely after the annual meeting, but there were some additional documents that were brought forward by an unknown party, and those documents required an extension of their investigation.



So final piece of business, we've laid out a strategic plan. We now have excellent data from the Chinese study. We have a version 2 of our device that allows us to have to be more sensitive, more specific, and more accurate in our readings moving forward. That's going to require additional development, and part of the strategic plan is to put together a team that can continue iterating on these improvements. But we're starting to have a solid path for ProLung to move forward on. And as you're about to hear, while the PL-208 results are not perfect, PL-208 did show one thing and it showed it clearly, and that is that the ProLung device works. We believe that the combination of these three things is enough for us to justify in a very big way. In fact, we actually feel like it's more than a justification; we feel like at this point we now have a responsibility to double down, to dedicate additional time and additional effort to making ProLung a success in a very specific path. We believe that a million dollars, which we're now working to raise, will get us to midsummer at which point we will have time to fully re-engage with partners, put together the long-term strategic plan, and bring in higher level board of director members that will help us raise the funds needed to take us through to commercialization.

I want to be specific here. We have very clear goals for what this financial raise is going to be spent on and what it's going to accomplish, and we can absolutely provide documentation on both of those items to anyone who's interested. I also want to state there's been a certain amount of criticism to towards the board that can be summed by the statement, "Why don't you put your money where your mouth is." So, I want to state publicly that the \$150,000 of that 1 million dollar raise has been raised internally at ProLung. These are members of the board who see that there's a great opportunity here and are joining the company in the effort to raise that million dollars. The docs are ready; this is something that we're working on now, and we need help.

Now I want to turn the time over to Michael Garff for Chief Operations Officer and Dr. Rex Yung our Chief Scientific Officer. We're going to reveal the results directly from the PL-208 study.

I want to be clear on a couple of items. First of all, we're going to reveal the PL-208 study in a great amount of detail. We don't expect everyone to understand this. One of the criticisms that we've received is that we use a lot of jargon. We've done our best to remove as much of that jargon as we possibly can, but we want to make it absolutely clear that any shareholders who have questions about this can get in touch with us for clarification. We want this to be as transparent and as open as possible. We're happy to sit with you and discuss it and help you understand everything that has occurred. This is something that many shareholders have waited years for. It's a big moment in ProLung's history. We're going to go through how the study was conducted, who was involved, and then what the results were in great detail. Here is Michael Garff, our Chief Operations Officer.

Michael Garff: Hello. As Jared mentioned, my name is Michael Garff and I'm the Chief Operating Officer of ProLung. Today I'm going to present the PL-208 study results, and talk to you more about the study. The PL-208 study is a validation study of the ProLung



Test™ that was conducted throughout the US at 15 premier cancer hospitals. We recruited centers such as Stanford, Beth Israel (which is an affiliate of Harvard), Mayo Clinic, M.D. Anderson, UCLA, and others. Throughout this process, and especially as we approach the end of this process, we have surrounded ourselves, and relied on and collaborated, with top experts in the fields of statistics, clinical studies, and regulatory affairs. These experts include former directors of the FDA Division of Biostatistics, Director of the 510k Premarket Notification staff, director of the Center for Devices and Radiological Health of the FDA, chief of statistics of the National Institute of Health, the former chief of staff for the FDA, as well as faculty members from the University of Utah, BYU, UC-Irvine, and other expert companies and individuals in statistical models, predictive analytics, machine learning, good clinical practice, and FDA submissions. I'll give you two examples of the caliber of expert consultants that we are that we are currently working with.

The first is our lead algorithm development statistician. He's a faculty member of computer science, the Institute of genomics and bioinformatics, statistics, biomedical engineering, machine learning, and mathematical computational and systems biology. He also has expertise in over 60 publications, including papers in cell-based biomarker diagnostics, biomedical informatics, and predictive models for cancer detection. The second consultant I'd like to highlight is our lead FDA statistician. He has over 20 years of successful FDA consultant experience, and 20 years as an FDA senior manager. While at the FDA, he was the director of the division of statistics, and he authored and co-authored several of the FDA guidance documents. He has expert understanding of the types of clinical studies and analyses necessary for FDA submissions. These experts are two of an impressive blend of consultants that have real world, deep, first-hand experience in obtaining study results and shepherding companies like us through the FDA process.

I'm now going to talk a little bit about the ProLung PL-208 study design. The purpose of this study was to demonstrate the accuracy or efficacy of the ProLung test by comparing our results to the actual patients' diagnoses. We did this by enrolling patients with suspicious lung nodules. They received the ProLung test and were subsequently followed until they received a tissue biopsy or a follow up CT showing radiological stability. The study had two phases: the first phase is a stabilization phase, which is two hundred patients set aside to train and optimize a predictive algorithm; the second phase is the validation phase. In this phase, the trained algorithm is applied to the patients and its performance is evaluated. In this study, we had 174 patients in the validation phase.

After we completed study recruitment, we pursued a Pre-Submission process with the FDA to get their input and buy-in on our proposed statistical analysis. In the first pre-sub, the FDA suggested that we change the endpoint of our study from relative risk to positive predictive value (PPV) and negative predictive value (NPV). After making those changes and we approached the FDA again for a second round of the pre-submission process where we further discussed the statistics. This second pre-sub meeting was conducted recently on January 8, 2019, and after the conclusion of the meeting



ProLung, along with its statistical and regulatory consultants, determined that we had received sufficient feedback to justify breaking the blind of the study.

We then made all the preparations required to break the study blind. That included locking the ProLung prediction algorithm. This algorithm utilizes the ProLung measurements combined with the patients' age and was developed using the 200-patient training phase subjects. We then took that locked algorithm and applied it to the 174-patient validation set of patients. In that set of patients that we obtained the following results: a sensitivity of 68%, a specificity of 49%, positive predictive value of 70%, negative predictive value of 47%, and an overall accuracy of 61%. I'm now going to turn the time over to Dr. Yung. He's our chief scientific officer, and a practicing pulmonologist and principal investigator in our study. He's going to explain further what these results mean from a clinician's perspective and also to our company as shareholders.

Dr. Rex Yung: Good afternoon everyone who is on the call. This is Rex Yung. I've been listening attentively, and of course I've been observing attentively the whole process over the last couple of years. So first, I think Mike has done a very good job in summarizing the step-by-step development and clinical trial, and who all were involved in an advisory capacity. As Jared has mentioned, I think a quick review of terminology is warranted, just to make sure everyone is starting off at the same point. Sensitivity is the proportion of patients with cancer that are correctly identified as such. So if there's 100 cancers, how good is my test at detecting them? In our case it's 68 out of 100. Specificity is the proportion of patients without cancer that are correctly identified as such. In other words, of all patients without the disease condition, how many did your test identify. In this case the specificity is 49 percent. Sensitivity is different from positive predictive value, or PPV, which is the probability that subjects with a positive test result truly have cancer. That's different from sensitivity of picking it up. And in this case, it's 70%. And a negative predictive value is the probability that subjects with a negative test result truly do not have cancer. In this case it's the NPV of 47. Now these are metrics are especially important for the clinicians, and how we use these numbers depends a bit on variability. Some tests I've done described the sensitivity, other people want to know PPV. Regardless, we need to discuss how these performance results might be received by clinicians.

The sensitivity and the positive predictive value, both of which are around 70 percent are not homeruns, but they do suggest the signal of a test that can be used to risk stratify the probability of a malignancy in patients with pulmonary nodules. That's our primary intention for use: the first non-invasive bioconductance marker for the lung. An important point is that, we never tell our clients -doctors or patients- that oh you don't need to do a biopsy. This is intended as a co-diagnostic tool so that clinicians can say, "You know, my patient Joe, you should really go for biopsy even though it's invasive and has risks." What most clinicians would prefer is of course a higher number; we always want more accuracy. When we're talking about a PPV of 70%, it is not irrelevant, but it is not 90% or 80%.



Now we all have heard, “hindsight is 20/20.” I think there are multiple learning points from having gone through our very comprehensive study but one of them (and I’m not clear it’s the only one) is the so-called over-fitting. In my first study, when I was the principal investigator at Johns Hopkins, we knew the diagnosis of the patient, whereas the ProLung Test in PL-208 was done before biopsy. In the Hopkin’s study the measurements were in a way adapted to the diagnosis, or the diagnosis is working with the measurements, setting the best algorithm. In retrospect, that’s of course how we came up with a 90/90 sensitivity and specificity. No test is ever 100% accurate, even when we know the end result. As Mike mentioned, we then used this first algorithm to train or to optimize the 200-patient training set of our 420-patient study. Now you have heard 374 patients (200 training plus 174 validation), why not 420? In essence, we enrolled from all the different centers 420 patients, of which 46 were not eligible. For various reasons, e.g., they should not have been enrolled as they didn’t fit the inclusion/exclusion criteria, or they dropped out of the study (they couldn’t be followed up). But that’s actually a pretty good number -barely over 10 percent. Usually we apportion 20 percent of the total enrolled to not go through. In any case, the first Hopkins algorithm was used to test out the first 200 training sets and out of the training set, the algorithm, as Mike has mentioned, is refined or refitted. For now, in essence you can see 200, and then it’s tested openly in the last 174 patients. But even going through the two trainings there’s still a lot of fitting. So, I think overfitting is certainly one of the issues we have to look at, and it would be better if we had, instead of 374, 3000 patients. Better even to have 300,000 patients, and so on and so forth. And with time, all these algorithms will be refined. It’s analogous to the first set of EKG markers. People were saying, “Hmm, I wonder what that squiggle means.” With time it becomes quite codified.

The second point I want to talk about is luck. Even though we talk about being very disciplined in science, I think luck does play a slight role. Unfortunately, our interaction with the FDA in the Pre-Submission process, which is what we’ve really been engaged in the last six months, has at times been bogged down in statistical disagreements. Even though our expert consultant who has had 20 years with FDA, says “Yes, don’t do hazard ratio or risk ratio, everyone else uses sensitivity and specificity.” And yet the FDA statistician on the review board insisted on saying, “You have to use PPV/NPV; I will reject sensitivity/specificity.” It may seem like a trivial, academic argument, but in fact it ended up really hamstringing/enforcing a certain way of adopting the finalized algorithm that we used to test the 174-patient set. As Mike has mentioned there’s a lot of work to do; now that we’ve opened up the blind we’re going to go back and look at all the patients in totality. We will perform sub-group analyses of patients enrolled and their outcomes, which will inform us where our weak points and strong points and, which will help us to develop version 2 in a much more robust way. These analyses might tell us, for example, that in the end maybe we should not look at very small lesions, 4-6mm or even 6-8mm, and this is in fact what’s being done in the real world, which is my perspective as a clinician. Many people know about a PET scan - a sugar scan with radioactivity- it looks for tumors, for instance. And in that case clinicians always say that lesions under one centimeter are too small, and a PET scan will be inadequate. I think with further investigation, we will also be further refining both our role and limitations.



As Jared had mentioned, this is far from the best that we could have achieved. It is, however, the best that we could have achieved based on the data we collected from the study we had designed. Going forward, it is very important to take what we have learned and then to adapt it to a better version two. You had heard about the need - this is again, an FDA mandate- to do a repeatability study, not only in normal volunteer controls without nodules, but also in subjects who have a lung nodule or have cancer. So certainly, we acknowledge that, and we are planning for that. This is also the chance when we can really hone down and make sure the repeatability of a technician, and between technicians, is as optimized as possible. I won't go into more details about hardware limitations that will be improved. Very importantly, we will also be working with the human subject factor because there is a lot of subject variability. These are areas that definitely will be worked on and will be improved, but I think that we can overcome these repeatability issues.

They said there were already some very encouraging data coming out from our Chinese partner licensee, and certainly it's been very impressive, such that they are looking at completing the CFDA, the Chinese FDA study, in calendar year 2019. I think we will be collaborating and helping the process forward. With that, I'm going to turn it back over to Jared to explain the company's future plans.

Jared Bauer: Rex thank you so much for that explanation as well as thank you to Mike. And I want to take 10 seconds and really thank the team: Andy, Mike, Dr. O'Driscoll, Dr. Yung, Carl, Kaai, Cory, our board of director members, and many individual shareholders who have come forward, a few of which we want to thank in particular: Don Patterson, Ron Dunford, the Fresh group, and Ning -who is our Chinese licensee, the head of ProLung Wuxi. There's a lot of people who have come together in a really united way to create a path forward for the company based on what could be seen as disappointing results regarding the PL-208, but which is legitimately a real path forward based on solid data that we're seeing coming from our Chinese licensee.

I just wanted to take a quick pause before I continue forward and take a minute to answer a handful of questions we received by email. Typically, I would answer these throughout if we were having a conversation like a shareholder meeting, but we'll do our best to fit these in where we can. The first question is, "How much cash does the company have?" The company right now is in a position to operate for a few more months. We believe that we can get through to the end of April based on the cash that we have or is now committed. There was another question regarding our Chinese partner: "Can you provide some clarification?" The Chinese partner is actually our licensee. We licensed the technology to them many years ago which has proved to be a very good decision that's paying solid dividends for us now. And finally, there was a question: "Under what terms has the first \$150,000, of the total \$1M we are working toward, been raised" That was raised as a debenture under the same terms as the renegotiated debentures: \$5.20 a share, as outlined earlier in the call.



Now I want to just make a couple of overarching statements. The first is that ProLung is in really an incredible position technologically right now, at least in terms of data. While we have technology issues that we have to face, we now have additional clarity around what those concerns are and how they should be addressed. And what we basically see was while there's a handful of issues, and Dr. Yung referenced some of those in his portion, we really see these issues in three areas:

1. There is a substantial amount of noise in the data that we receive. This is caused through really two factors. One is differences in the way the operators are running the tests, as well as locations where those tests are being performed.
2. There are some patients we now know who just simply don't qualify to take the ProLung test for whatever reason. One proposed possibility as to why they may not have the same conductance level as perhaps patients the patient sitting next to them is hydration level.
3. The third factor is the way in which the study was conducted. Had a CRO been involved, and a Pre-Submission process been used, we would have had more of these answers before the study started. And a CRO could have handled more of the details around the study, including some of the training.

If we look though at our partner in China, ProLung Wuxi, they accounted for those issues that we have in our data, both in training and in noise levels. There are methodologies that they utilized that eliminated or controlled those issues, and due to that, and their utilization of a CRO, we believe it's very solid data. When combined with our data showing that the device works, that becomes a really powerful statement for the company.

Additionally, the company now has what I would say is a solid working relationship with the FDA. We've increased the relationship that we have through this pre-submission process. And while there's more work to be done there, we do believe that that relationship will pay dividends in the future. For those of you who are interested, we will be releasing our strategic plan here in the coming days. And as we start to share what that strategic plan is, what our path is to commercialization, what our path is through the FDA, I hope it will be clear that we actually have a really optimistic outlook. I personally have a lot of optimism about it. There have been a lot of questions over the last few months, and I think that it goes without saying that 2018 was a difficult year for the company. But I feel really strongly that the outlook for 2019 is solid. There's a lot of reason for optimism and excitement around the product and around ProLung itself. And a lot of groups who have kind of been circling around the company, some for a short period of time some for many years, are now coming inside and they're joining together to help us succeed. We're excited to have their help; it's been very beneficial thus far and we believe that it will have much more benefit in the coming weeks, months, and potentially years.

So, we move forward. We move forward with a strategic plan. We move forward with lowered expenses and a right sized company. We move forward with better data, a handle on where our issues are, and a path to success. And we'll be working to raise that first million dollars in the coming weeks. We are looking forward to having success



in our raise, reengaging with these larger partners, and doing what we can to make a difference in the way we test for cancer. This idea that ProLung started with is much broader than just lungs, and part of our strategic plan is doing some initial feasibility in some other cancers, to add that to our base of research, and expand our understanding of how and why the device works. We believe that the combination of those things will give ProLung a very solid future. The goal was to keep this to 45 minutes. We're at that 45-minute mark. So, I just want to thank all of you for your time today, thank the team for all of their work, the board of directors for their support, and we're looking forward to working together with each of you with as much transparency as we possibly can in 2019. Thank you again for joining the call.