Linshom

Every Breath Counts™

Happy New Year Linshom investors, stakeholders and interested parties. Linshom closed out 2019 with some great progress and we are looking forward to an exciting 2020. Your investment has facilitated the achievements detailed below and moved Linshom closer to commercialization of the Linshom Respiratory Monitoring Device (LRMD). Thank you.

Fourth quarter was largely consumed by addressing issues raised by the Food and Drug Administration (FDA) after our submission in the Spring-Summer of 2019. In a few areas the FDA did not feel that we had presented enough data or the FDA did not fully understand what Linshom was saying / claiming in the submission.

On the FDA front we accomplished the following:

- In 4th quarter our team met in person with the FDA to review our submission. Our goals were to i) better understand the FDA's positions, ii) clear up some scientific lack of understanding on the FDA's part, iii) outline our testing plans (to address raised issues) and gain agreement to those plans, and iv) gain agreement on our predicate device. The predicate device is what we are comparing LRMD to. In sum we achieved all four goals and found the FDA team to be most supportive and helpful.
- On January 2nd we submitted our response package to the FDA which included:
    - A modification to the sensor housing such that it can easily and securely snap into a hole in an oxygen mask. This allowed us to submit the mask (which we will OEM source) and sensor together as one unit; a requirement of FDA. Thanks to John Moser and Ronen for the successful work here.
    - Biocompatibility testing on the mask and sensor combination performed by contractor, Nelson Labs.
    - Linshom performance test of RR vs Ventilator
    - Linshom performance test of RR vs. Capnography
    - Linshom performance test of RR vs. Capnography with subject motion
    - Linshom performance test of RR vs. Capnography with supplemental oxygen flow
    - Linshom performance test of tidal volume vs. ventilator at room temperature

    - Linshom performance test of tidal volume vs. ventilator at elevated temperature
    - Linshom performance test of tidal volume vs. ventilator at low temperature
    - Face mask tear and degradation test
    - Human factors and usability test of LRMD with about a dozen health care professionals
- In summary this was a 523-page report of tests run to address the issues raised by the FDA. Great work by Jack Kent who did the heavy lifting on the writing front and Ronen/Doron who did the heavy lifting on the testing front.
- This was done with high efficiency as all was completed for ~$45K and would have cost 5X this if contracted out to third parties. Ronen and Doron found and rented the equipment needed allowing Ronen to complete the engineering testing in house.
- The FDA will respond to us by March 4th and could clear LRMD at that time. However, I predict they will ask for more data in a few of the areas. We will respond and I believe FDA clearance in Qtr. 2, 2020 is realistic.

On the investment side the $1.5M convertible note is subscribed at $550K or 37%. In December Linshom was screened by the Keiretsu Forum Mid-Atlantic and received favorable reviews. Keiretsu is the largest Angel investing group in the US. More detail on Keiretsu can be found here: https://keiretsuforum-midatlantic.com. Linshom will likely participate in one of their road shows in February or March, presenting to Angel investors in New York, Philadelphia / Pittsburgh (by video), and Washington DC.

Fourth quarter also saw successful screenings of Linshom by the Maryland

Momentum Fund (http://momentum.usmd.edu) and the Abell Foundation (https://www.abell.org). These funds require company operational presence in Maryland and Baltimore City respectively. Both funds are doing a deeper dive on Linshom and the markets we plan to commercialize into.
Our investment strategy is to use the convertible note funds for three activities:

- Complete and gain FDA clearance
- Manufacture a small lot of devices for a clinical trial
- Begin a small clinical trial to build the evidence needed for clinical adoption

This will be followed by a $5M series A round of funding that will:

- Complete the trial mentioned above
- Move the sensor from 1 to 2-piece design where the thermistor embedded in the mask (or other form factor like a nasal cannula) is disposable and the thermo-electric cooler (outside of the mask) is reusable.
- Integrate with and display our data on a small monitor (vs. laptop currently).
- Gain follow-on FDA clearance if necessary. This will be a much shorter path as our predicate will be our own device, LRMD.
- Begin commercialization (selling).

On the manufacturing front we have interviewed multiple firms in Boston, Baltimore, Israel and Indianapolis to identify a partner(s) that can industrially engineer the sensor and monitor described above and then move on to full manufacturing. We have a short list of capable candidates and will be doing a

deeper dive this quarter and next.

Quarter 1, 2020 will be focused on completing and gaining FDA clearance and closing out the convertible note round of funding. We will also accelerate our outreach to strategic partners like Medtronic, Massimo, GE, Phillips and others.

Linshom had several discussions with the US Air Force (USAF) as they have an interest in technologies for pilot monitoring, medics, first responders, etc. On December 18th we had a face-to-face meeting with USAF representatives at Wright Patterson AFB in Dayton Ohio. Linshom is now following two different paths regarding the USAF:

- We are in preliminary discussions with several other USAF vendors regarding teaming with them as a subcontractor for response to a USAF request for proposal (RFP). The RFP's focus is pilot monitoring in fighter plane cockpits. Linshom is not capable of fulfilling a primary response to this RFP, but the respiratory rate monitor could provide valuable information for another, larger, company responding (i.e. defense contractor).
- We are also writing an SBIR phase 1 proposal to AFWERX; an open topic solicitation.

Linshom has not changed our strategy or focus on clinical markets with this USAF activity. This is simply an opportunity that may have potential to fund (non-dilutive) some of our forward-looking product development and help the USAF out at the same time.

Should you have investor contacts that are looking for an early stage, de-risked

investment opportunity, please have them contact me. Thank you for your support of Linshom. You can reach me anytime at 443.994.1448 or RHughen@LinshomForLife.com.

Best Regards,
Ric Hughen
CEO