

December [REDACTED]

To: Board Members

From: [REDACTED] MD

Since we are approaching the end of the year I thought it was an appropriate time as the Head of the Medical Advisory Board to give my review.

I am extremely concerned about the current path we are on [REDACTED] and would appreciate the opportunity explain why it is essential that we change our focus in order to save our project.

To clarify: we entered a contract [REDACTED] because they assured us we could create a [REDACTED] [REDACTED] has had this project for over eight years and had so much trouble creating a [REDACTED] that I decided to deviate from the original plan just to get moving. It was never my intention to create a [REDACTED] and send it for a 510K. This has taken so long, and technology has advanced so far that now, eight years [REDACTED] dollars later we are so far from the original plan of an innovative [REDACTED] still cannot even compete with current technology.

To send a [REDACTED] for a 510K does not make any sense. Even if [REDACTED] solves all of their technical problems listed below, we would only be left with a [REDACTED] [REDACTED] that is only comparable to current technology at best.

The positive is that we will have a [REDACTED]. The negative is that there is nothing about the technology that has a high threshold to patent. **To further my point, I have reviewed a [REDACTED] that is very similar to ours, built by simply [REDACTED] So the question is: [REDACTED] what will prevent the large companies (ie [REDACTED]) from doing the same thing?**

The answer is nothing, the big companies will and can produce the same [REDACTED] we are attempting to complete [REDACTED] has five [REDACTED] patents that they are not using in our current product. These are all from [REDACTED] [REDACTED] and I designed. I am unsure if they have ever even looked at them.

I have major concerns about our current development trajectory. I have just returned from [REDACTED] [REDACTED] It is clear that large companies [REDACTED] have the development capabilities to create exactly what we are trying to create. Even with a patent we might not be protected from the large conglomerates but it is important to note that our current path makes us extremely vulnerable to this problem. **Furthermore, I am concerned that we are working very hard to create something that is not**

original enough to entice current [REDACTED] to invest and most importantly no interest from [REDACTED] to use it.

I have heard that [REDACTED] continues to have a number of problems in building the [REDACTED]. I can summarize the likely problems and solutions that I have.

[REDACTED]

I believe all of these problems are solvable. However, even if these problems are solved we are only left with [REDACTED]. This is not better than the current [REDACTED] on the market.

This is not what we came to [REDACTED] to create. **Our contract stated that [REDACTED] would create the [REDACTED] and at this time they cannot even complete the [REDACTED] which is not competitive in the current market.**

A few weeks ago, I worked with [REDACTED] who is the original engineer of our [REDACTED] to determine why, in eight years, [REDACTED] was unable to produce an [REDACTED]

Our findings are as follows:

[REDACTED]

[REDACTED]

[REDACTED] currently has five patents that [REDACTED] and I submitted for [REDACTED]. Three potentially might be used in this design.

I hope you can see the benefit of this [REDACTED] and will consider this as we move forward. The biggest problem that I see with our current development trajectory is that we do not have anything truly proprietary and the big companies can most certainly reverse engineer such a product. The large companies out there often do this, even if there are patents protecting the technology.

It was my goal to provide information to help educate everyone in some of the areas where we can improve our own marketability, as well as detail that these developments are possible.

I would welcome an opportunity to discuss these issues which are of grave concern.

Sincerely,

[REDACTED]