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## General Biophysics is Focused on Making Xenon Inhalation Therapy Feasible for Hospitals and Outpatient Centers for Treatment of Alzheimer’s Disease and Other Applications



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**CEOCFO: Dr. Ilyin, according to the General Biophysics site, you specialize in pioneering therapeutic solutions using Xenon gas. Explain what Xenon gas is and how it works in therapeutic situations.** Dr. Ilyin: Xenon gas is a noble gas used in lights, electronics, lasers, and medicine. It has an excellent safety profile and is known for its anesthetic properties, but its potential spans far beyond.

Its multi-target action explains its impact on a variety of biological cascades and disease conditions. We are exploring its therapeutic effects to modulate the immune response in the brain, particularly targeting microglial cells and astrocytes involved in neuroinflammation associated with Alzheimer’s disease and other neurodegenerative diseases. This is our primary application. We are also looking to use Xenon gas for other applications like opioid use disorder and various medical applications related to the brain and neuroprotection.

Xenon gas is expensive, and its delivery to patients through inhalation requires special closed-circuit equipment, accurate dosing, and gas recovery. At General Biophysics, we are developing technologies to make Xenon inhalation therapy feasible at hospitals and outpatient centers.

**CEOCFO: Why is the brain a particularly good target for Xenon gas?** Dr. Ilyin: Xenon gas penetrates the blood-brain barrier and has a history of being used as an anesthetic gas, but it also has a lot of biological effects on the cells in the brain, especially the immune cells. What is interesting is that it also protects neurons from apoptosis, oxidative stress, and more. Therefore, it is effective to be delivered to the brain and has multiple positive effects on brain cells.

**CEOCFO: One of the things you focus on is patient-centric solutions. What does that mean for you?** Dr. Ilyin: We are trying to bring the therapy closer to implementation for patients. We are looking at the difficulties patients might face in accessing this type of therapy and, because of that, we are developing systems that would allow wider availability of the therapy going forward. That is an important part of our overall commercialization strategy because we need to make this therapy accessible.

As I mentioned, Xenon is an expensive gas, so we are working on a recovery system to make the cost of the therapy reasonable as well as feasible in a clinical setting. We are designing this in a way that more hospitals and treatment centers will be able to use our systems with less qualification required for personnel.

The system should be automatic and cost-efficient. This way, we can bring our system to more centers and improve availability for patients.

**CEOCFO: Does the medical community understand the value of Xenon gas, and there just has not been a way to use it, or is it something the medical community has not thought about much?** **Dr. Ilyin:** Xenon gas has been approved in Europe for anesthesia. The biggest barrier to using it widely in surgery is the high cost of the gas compared to other anesthetics. However, Xenon would be considered ideal for anesthesia because of its absence of side effects and its protective effects. Therefore, our focus is on making its application in the biomedical field feasible, considering the high cost of the gas and the barriers to administering it to patients.

Xenon is not unfamiliar to the medical community in terms of its benefits. However, making Xenon therapies feasible has been challenging, and that is what we are focused on as a company.

**CEOCFO: What have you developed so far? Where are you at this point?** **Dr. Ilyin:** On the medical side, we completed our pre-clinical studies for the Alzheimer's disease indication. We are initiating our Phase 1 clinical safety trials and hope to start recruitment in January 2025. The study will be conducted at Brigham and Women's Hospital in Boston, Massachusetts. This is our first clinical study and probably only the second ongoing clinical study in the U.S. for Xenon gas.

**"At General Biophysics, we are developing technologies to make Xenon inhalation therapy feasible at hospitals and outpatient centers." Ilya Ilyin, PhD, MBA**

In terms of equipment and systems to deliver Xenon, we have developed and are commercializing analyzers for measuring Xenon gas concentration. Xenon is a noble gas, and it is very tricky to measure its exact concentration. That is why we developed these analyzers, which can be used in medical practice to measure the concentration of gas administered to patients. We are also exploring commercialization in industrial applications for Xenon gas, as mentioned earlier.

We are also developing a fully automatic inhalation system for delivering Xenon at exact concentrations. We have already built the prototype, and next year we hope to start discussions with the FDA regarding its approval as a medical device. In addition, we are working on a recovery system to reclaim Xenon after patient treatment, which will minimize the cost of gas administration for the treatment.

**CEOCFO: Development is always costly. Are you seeking funding, investment, and partnerships as you continue along?** **Dr. Ilyin:** We currently have several partnerships with academic institutions. We are receiving NIH grants, which have provided great support for our development. I believe that at the end of our Phase 1 clinical trials, we will look for investment and begin raising a Series A round.

**CEOCFO: What have you learned so far that has surprised you?** **Dr. Ilyin:** We unexpectedly learned that Xenon gas is a multi-target drug. Because of that, we position it as a platform technology and therapy. This allows us to explore additional indications, and we are continually surprised by how wide these potential applications and indications could be, where we can expect medical benefits from Xenon.

On the other hand, when we talk to doctors, they often ask how a non-reactive agent like Xenon can have significant biological effects. Our pre-clinical data clearly outlines its mechanism of action and supports the conclusion that Xenon gas effectively modulates immune cells. In our development, we have also worked with preserving blood cells, stem cells, and other types of tissues. We have confirmed that Xenon is a highly effective biological agent, and we expect to uncover many benefits of using it in medical practice.

**CEOCFO: General Biophysics was at MEDevice Boston in September. How do you stand out at a conference where there are so many new ideas?** **Dr. Ilyin:** We were told that we stood out because we presented as a medical device company developing a medical product for specific applications. The majority of exhibitors at the Med Device Boston conference were vendors or service providers for the biomedical community.

We are developing a unique therapy that essentially combines a device and a drug. By doing this, we are creating the necessary technologies critical for translating the therapy to patients. These components are essential to our success.

**CEOCFO: Finally, what might people miss that they should understand about General Biophysics, whether from the medical or investment community? Dr. Ilyin:** One of the key points is that we are, first and foremost, scientifically driven. We did not license this technology; we are developing it ourselves with significant scientific expertise and collaboration with academic partners. Even though noble gas therapy may sound unusual, we believe we have strong biological evidence at the forefront of science showing that these therapies should work. Of course, clinical trials and human data are necessary to prove this and move it through the FDA approval process, but the science behind what we are doing is substantial.

Another aspect of our work is our strong engineering expertise. We are building systems that work reliably. For example, in addition to the mentioned equipment, we developed mouse environmental chambers for our animal studies, ensuring consistent conditions and statistically sound results.

