“Direct Delivery of Medications from the Upper Nasal Cavity into the Brain”

A new technology developed by SipNose LTD., generates an aerosol spray that spreads medication in the upper nasal cavity, and from there directly into the brain.

Company’s Core Team (from right to left) Dr. Liron Hadar, Dr. Iris Shichor, Daniel Shahaf and Lia Kaufman | Photography: Zeev Stern

By Yuval Ben Moshe

The brain, the most important organ in our body, is protected from penetration of un wanted substances by a barrier known as the Blood Brain Barrier (BBB). This barrier serves us well in most of the cases,. however, when there is a need to deliver a medication to the brain, this barrier constitutes an actual problem (in fact, approx. 98% of all medications cannot penetrate into the brain via the blood circulation).

“In cases where the need to overcome this barrier is a must, the common solutions are invasive such as canulated shunts into the brain or delivery of drugs directly into the spinal cord. These are complex solutions which necessitate inpatient care”, explains Dr. Iris Shichor, CEO and co-founder at SipNose.

“SipNose is an Israeli startup, established approx. 8 years ago, focused on finding a suitable solution for delivery of drugs directly into the brain in a non-invasive manner. The Company’s core team consists leaders in the drug delivery and engineering fields. Dr. Iris Shichor – CEO and co-founder, Daniel Shahaf – R&D Director and co-founder, Dr. Liron Hadar – VP Product Development and Regulation and Lia Kaufman – Operations and Production Manager.

Despite the small team, SipNose is constituted of goal-oriented professionals, who are motivated by their vision of advancing the field of drug delivery into the brain, and finding new solutions for un-met need medical problems.

“The world’s population is growing older, life expectancy is steadily increasing, but the human brain is unable to keep up. Therefore, we see many more people with various types of dementia, including Alzheimer’s disease, as well as other injuries to the nervous system, stroke, epilepsy, Parkinson’s disease, etc. That is in addition to brain cancer which cannot be resolved because drugs are poorly delivered into the brain. If it was possible to deliver chemotherapy or even bio-medications into the brain there was at least a chance of treatment and recovery”, emphasizes Dr. Shichor.

Dr. Shichor explains that approx. 20 years ago a natural bypass of the BBB was discovered , , through the olfactory epithelium located at the upper area of the nasal cavity. The researcher who found this gap, Prof. William Frey,has investigated this area for many years and was the first to suggest that this breach may be utilized in drug delivery and in fact allow bypassing the BBB.

“This discovery has led to a search for a technology that will enable drug delivery into the upper area of the nasal cavity and from there into the brain by utilizing natural processes. And so, a new field of drug delivery, from the nose to the brain, was conceived (the direct Nose-to-Brain delivery)”.

It is a great discovery, isn’t it?

“Over the years it was discovered that this challenge is not simple at all, as the nose’s natural role is to filter and remove substances and invaders. The structure of the nose is complex and in fact makes drug delivery into its upper area quite difficult in practice”, so clarifies Dr. Shichor.

Since this discovery, several companies worldwide have attempted to take on this challenge, however, without a significant success. Devices developed so far by the various contender companies suffer from low efficacylimitted dose of the delivered drug, a difficulty in adjusting the drug formulation and at times, also required a highly skilled user.

So, what is new in SipNose’s technology?

“SipNose presents a breakthrough in this area, with a technological capability of highly effective drug delivery to the upper nasal cavity. SipNose has developed a patent protected novel device to deliver liquid and powdered drug formulations through the nose. Among the various liquid drugs with which SipNose has demonstrated its feasibility were formulations in different viscosities (including oils and cannabis formulations), proteins and even cells”.

Tell us about the technology

“The SipNose’s technology is based on compressed air and a proprietary spraying mechanism that generates a

unique aerosol spray pattern of the drug delivered to the upper nasal cavity.

The SipNose technology is capable of delivery of relatively large quantities of drug to the brain, directly, without causing damage or pain, with high efficacy that is expressed as an effective uptake of the drug in the target organ – the olfactory epithelium located at the upper area of the nasal cavity. The use of the device does not require a particular professional skill and allows a daily home therapy, if needed”.

The SipNose devices are currently under clinical trials in combination with several drugs in areas of epilepsy, dementia, Parkinson’s disease and regeneration of the optic nerve. A pediatric treatment phase was recently completed successfully under a clinical trial at Schneider Hospital. The trial has proved the efficacy of SipNose in calming children prior to undergoing a medical procedure in the Emergency Care Units (Sedation and anti-anxiety treatment).

In what area of therapy which requires drug delivery to the brain can the SipNose technology already assist?

“The SipNose technology may assist in the field of psychiatry where the need for drugs delivery to the brain is obvious. This is a field where no significant breakthrough has occurred for many years now. SipNose has selected the area of eating disorders as the first psychiatric area to be addressed. Eating disorders in general and Binge Eating Disorder (BED) in particular constitute conditions where no proper solution is available for a vast population. Eating disorders are recognized as psychiatric diseases by the American Psychiatric Association. The new message SipNose brings to this field is a short term and acute therapy, aimed to reduce the familiar unwanted drug side effects”.

So how does it work in practice?

“The product allows a fast and effective treatment at the moment of need to prevent the formation of the binge while it occurs. By delivering the drug through the nose by using SipNose technology a direct delivery of the drug to the brain is achieved, which is the key factor in the success of this therapy. At present there is no competing product which allows treatment on need base at such cases”.

Is there already proven evidence in the field?

“SipNose has successfully completed a phase I trial in human beings and will soon start a phase II study in a population suffering from binge eating disorder. Our goal is to change the manner of treatment to the vast population by offering a focused drug therapy on a need basis and so, eventually reduce the level of morbidity and improve the quality of life of people suffering from eating disorders and obesity”.

The approval procedure of such a product is along and expensive process, are you set for such a process?

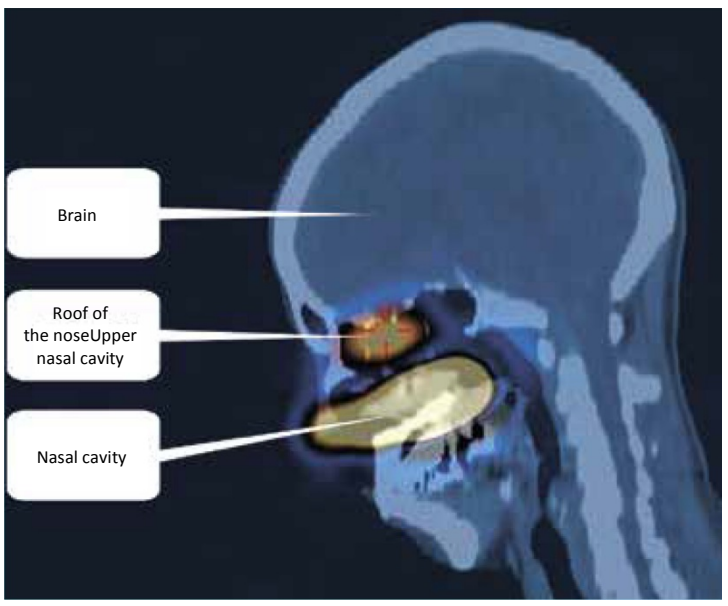
“SipNose is going for a fund raising round which its goal is advancing the psychiatric project. Raising this capital will fund the upcoming steps leading to the approval of the product by the FDA and its commercialization”.

Where do you see yourself in 5 years’ time?

“As a pioneer in its field, SipNose aspires to reach the market with its significant products already in development, and assist the various pharmaceutical companies with effective drug delivery to the brain by employing commercial collaborations, which is impossible at the present,”.

www.sipnose.com

SipNose’s drug delivery device for drugs administration via the nasal cavity | Photgraphy: curtesy of SipNose



From CT head imaging: a trial with the SipNose device