SOLTEC HEALTH: COMPANY PROFILE

SOLTEC HEALTH

Why Soltec Health?

SOLTEC HEALTH (https://soltechealth.com/) has developed a safe, non-invasive, drug-free system, which can greatly expand the already growing field of neuromodulation. With our new technology, it is now possible to influence a region of the central nervous system, the brainstem, which includes the autonomic nervous system (ANS). Earlier neuromodulation devices could not impact the control circuitry of the ANS, which directly affects chronic stress and poor sleep. Stress is the common risk factor for 75–90% of all diseases, including the diseases which cause the foremost morbidity and mortality[1]. Poor sleep increases the likelihood of experiencing greater stress and illness.

SOLTEC technology has been shown to positively impact peripheral neuropathy, in addition to improving sleep and reducing stress. The effects that this new neuromodulation technology has had on sleep improvement (increase in deep sleep and Non-REM sleep quality) and sensory restoration in patients with peripheral neuropathy, strongly suggest, that it not only activates, but also regenerates the respective neural structures. This is consistent with the accepted phenomenon termed neuroplasticity, the ability of the nervous system to dynamically adapt and grow new circuitry.

The Genesis of Soltec Health

Unlike occasional stress, which is a normal response to a challenging situation, chronic stress should be viewed and treated as a primary pathology. Chronic stress often results in severe medical conditions such as hypertension, cardiac ischemia and failure, obesity, hyperglycemia and diabetes, insomnia, anxiety, depression, pain, inflammation, infections, nausea and diarrhea, and even gout. The phrase, “Stress Kills,” or rather, “Chronic Stress Kills,” is quite true. The process is gradual, which is why the correlation between chronic stress and severe illness is not commonly appreciated by the general public.

Chronic stress and poor sleep are intertwined. Chronic stress leads to problems falling and staying asleep and poor sleep quality. Such sleep problems also predispose one to greater stress, thereby producing a vicious cycle.

Our founder, Dan Cohen MD, a Board-Certified neurologist, spent ten years pioneering the field of automated sleep diagnostics. It is well documented in the medical literature that people lose deep sleep (aka Delta or Slow Wave Sleep) as we age. Even by our mid to late-forties, we have lost 60 to 70% of our Delta sleep[2]. This a big problem, as Delta sleep is responsible for 70% of our growth hormone secretion[3], cellular repair and regeneration[4], and removal of β-amyloid plaque from neurons (associated with Alzheimer’s Disease)[5], as well as hormonal and immune system regulation and enhancement[6]. Reduced Delta sleep leads to lack of sleep inertia (inadequate sleep persistence), daytime fatigue, low energy, less resiliency, and therefore, greater stress. Generally, as we age, we face greater stress, less restorative sleep, and an increased prevalence of disease.

Although our original mission was to develop a safe, non-invasive means of reducing stress, we learned through our studies that the mechanism of action required to reduce stress was also applicable to improving sleep, especially, the regeneration of Delta sleep. Both stress and sleep are controlled by the Parasympathetic division of the ANS, which we have learned how to influence. The terms, chronic stress and poor sleep represent consumer applications, exempt from regulatory oversight. The related medical terms, anxiety disorders and insomnia, represent medical opportunities, and require FDA clearance prior to market entry.

Although the initial interest of our Company was in stress and sleep problems, we have independently found evidence, in limited human trials, that our approach can mitigate peripheral neuropathy—a diagnosis with generally poor outcomes and few treatment alternatives (Company White Paper available upon request]. This suggests possible benefits for diseases involving demyelination (such as multiple sclerosis). Further study is warranted in both cases.

SOLTEC Technology

The SOLTEC System is a closed-loop, machine-learning-capable, non-invasive system designed to activate and regenerate many regions of the nervous system. The pivotal system component is a Magnetic Conditioner, a distinctive device that applies specific, low-frequency, magnetic waveforms, to targeted regions of the nervous system to achieve the desired results. For certain applications, real-time physiological feedback is provided through a proprietary wearable wrist device that monitors four parameters, including heart rate variability (HRV), motion, blood oxygen saturation, and snoring sounds. This data informs the Magnetic Conditioner, enabling adjustments to produce desired physiological changes. The entire SOLTEC System operates through a user-friendly app, with patient data securely stored in an encrypted, cloud-based database for clinical research and continual algorithm refinement (data anonymized to protect personal information).

Further refinement of the technology has allowed SOLTEC HEALTH to personalize the frequency of interest to further enhance the benefits for improving sleep and reducing stress. This refinement was necessary, as it was determined that subjects with a history of more severe stress (those with Generalized Anxiety Disorder – GAD, and PTSD) were functioning at a level of the ANS closer to the sympathetic range (fight or flight mode) versus the parasympathetic range (rest and rejuvenate). Both manual and automated mechanisms were developed to personalize the frequencies used for reducing states associated with stress and further enhancing sleep induction and Delta sleep in those with poor sleep. We plan to perform clinical studies and seek FDA clearance to market this technology for insomnia, GAD and PTSD.

The Soltec system comprises several integrated components: 1. The Z•GEN Magnetic Conditioner, which generates magnetic waves. 2. The Z•TRACK Analyst, which is a biological tracker that transmits instructions to the magnetic conditioner in real-time to adjust the frequencies and sends information to the application. 3. The SOLTEC•Z App, which communicates with the Z•TRACK Analyst to optimize a person's sleep and to receive and display user data. A centralized database that compiles anonymized data from users on a voluntary basis, which serves as a resource for ongoing research, development, and system optimization. The system is fully debugged and deliverable. The Company began fulfilling initial sales during the second half of 2023.

Evidence of Efficacy

Small sleep study

In 2018 we commissioned a very small, four person, 60-minute, morning nap study to evaluate the effectiveness of low-frequency magnetic stimulation on sleep. Subjects should not fall asleep during a morning nap after sleeping all night. Subjects showed long trains of normal-appearing, slow-rolling eye movements (SREM), during the end of Wake, throughout Stage 1 sleep, and into Stage 2 sleep. SREMs, a key biomarker, are typically only present in the later part of Stage 1 – light sleep. Increased SREMs illustrate an enhanced normal sleep response, as demonstrated by electroencephalogram (EEG) recordings. Delta sleep was also induced in 3 of the 4 subjects. This is unusual since Delta Sleep rarely occurs during morning naps.

Of interest, the same frequencies that produce deeper Delta sleep also produce the deepest levels of stress reduction. This should not be surprising, as greater activity of the Parasympathetic division of the ANS is associated with all of the benefits of deep relaxation. Superficially, the ANS is akin to a seesaw. When the Parasympathetic division (rest and rejuvenate) is high, the Sympathetic division (fight or flight) is low – when one division is activated, the other is inhibited.

Larger sleep study from customer data

We recently performed an analysis of the sleep of 67 subjects' sleep data, as contained within our database (customer data). Here is a summary:

Methodology:

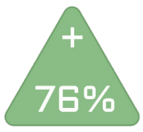
The data in this study was derived from sixty-seven subjects, who used the SOLTEC System for on average, 116 nights (7,772 recordings). All users wore the Z•TRACK Analyst, which measured heart rate, movement, blood oxygen saturation and snoring sounds. Heart rate variability (HRV) was analyzed in all subjects, resulting in both time and frequency-based metrics. All data was stored in an encrypted, cloud-based database.

The data collected during the last 30 nights of recordings (Gold area) were compared to the data collected during the first 30 nights (Blue area) to determine any changes in Sleep Time, Time spent in Delta sleep, Time spent in REM sleep, and Non-REM sleep quality (NREM). Non-REM sleep quality reflects the depth of Light and Delta sleep quantitatively. This evaluation allows for a more granular assessment of the depth of Non-REM

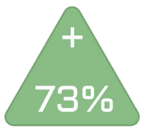
Results:

Statistically significant results related to Sleep Time (p = .011), Delta sleep (p = .02), and extreme significance related to non-REM quality (NREM) (p = .0000022) were achieved. Non-REM quality signifies the depth of both Light and Delta sleep.

Of the 67 subjects:

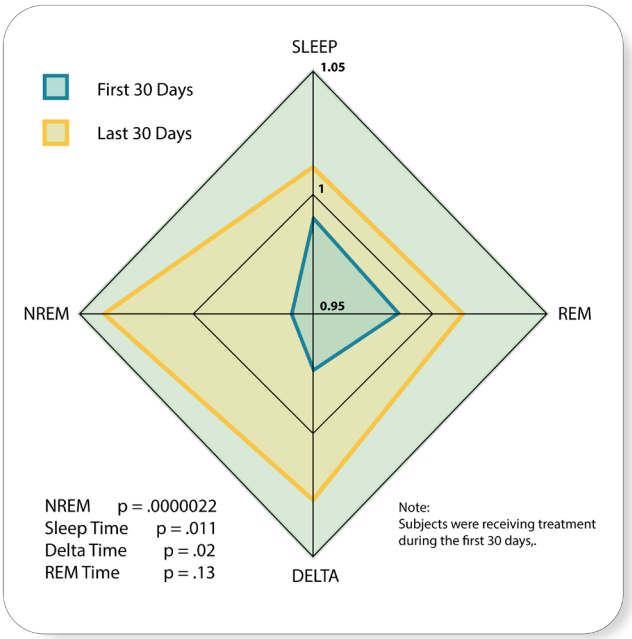


76% Subjects with initial Delta levels below 75 minutes (average of 55 minutes) improved, on average by 15%, demonstrating that those that were more Delta deficient improved to a greater extent.



73% Responded positively regarding Non-REM quality.

69% Responded with improved Delta sleep, and Sleep Time.



The 37 subjects with initial Delta levels below 75 averaged 7.5 minutes of improvement in Delta sleep compared to an improvement of 0.4 minutes for the 30 subjects with initial Delta levels equal to or above 75 minutes.

Conclusions:

1. The SOLTEC System can improve Delta Sleep and Sleep Time using specific extremely low frequency magnetic waves timed with normally occurring Light and Delta sleep – Real Time Sleep Stage Enhancement.

2. Non-REM quality is an early sensitive indicator of improved sleep, as it includes the deepening of Light sleep, which often comprises half of the sleep session.

3. No negative side effects were reported by the subjects.

4. It's important to note that sleep was measured by objective measures, not self-reported recollection (which could be influenced by a placebo effect).

5. Subjects did not receive the benefits of customized (personalized) frequencies for sleep induction and Delta sleep protocols, which had not yet been released. In early testing, this new feature further improves the results.

Intellectual Property

SOLTEC's patent portfolio was developed with Dan Preston, President and CEO of ClaroVia Holdings along with the services of Taft Law, acting as IP counsel. Mr. Preston is a named inventor on 156 patents and applications pending in diverse technology spaces. Notably, one of Mr. Preston's enterprises ranks as the second-highest recipient of U.S. patents for autonomous driving vehicles, trailing only behind Google.

In 2018, a U.S. patent was successfully granted for an earlier iteration of SOLTEC's technology, and subsequent continuation applications stemming from this patent have been diligently pursued and several have been issued (patent numbers: 9,949,004; 8,668,045; 7,918,308; 11,478,604). A comprehensive application for the SOLTEC System is patent pending in multiple countries, encompassing 140 pages of disclosure material and 166 formulas. According to Mr. Preston, patents are expected to be approved in multiple countries in Q1 and Q2 of this year. Many of SOLTEC's algorithms will be maintained as trade secrets.

Funding and Exit Strategies

The company has identified approximately 50 companies that are currently active participants in markets related to stress and anxiety, sleep and insomnia, diabetes and peripheral neuropathy, and fitness. Therefore, they represent potential future strategic partners and acquirers. Management anticipates this could position SOLTEC for an exit as soon as 2025. Alternatively, if public market conditions improve, the company may become a good candidate for an IPO exit after anticipated FDA clearance. On the whole, management believes a strategic takeout by a multinational drug, medical device, or integrated pharmaceutical company would be optimal, so as to maximize cost-effective marketing and distribution.

On the consumer side, SOLTEC will be proactively pursuing strategic partnerships with established consumer product companies, specifically focusing on those engaged in the production and retail sales of wearable monitors featuring heart rate variability capabilities. A strategic collaboration aims to empower these companies to enhance their product offerings by incorporating a therapeutic option that none of them presently offer. Leveraging our magnetic generator technology, these wearable devices can operate it in real-time to facilitate sleep improvement and stress reduction versus simply monitoring these conditions.

In addition to forging partnerships, SOLTEC intends to maintain a direct presence in the consumer market by continuing to offer and sell our system. This dual approach broadens our market reach and enables us to accumulate valuable data and iteratively refine our technology.

Key Takeaways

- Market opportunities and unmet needs – SOLTEC's solution for treating nervous system conditions offers multi-billion-dollar annual revenue opportunities across diseases, including peripheral neuropathy, PTSD, anxiety, and insomnia.

- Novel, disruptive, and proprietary (IP protected) solution that delivers therapy that is markedly more effective and convenient (i.e. self-administered) for the patient and healthcare system.

- Early validated efficacy and safety in volunteer studies have demonstrated the dramatic advantage of SOLTEC's neurotechnology compared to current methods.

- Multiple valuation creation strategies and exit pathways.

Convertible Note Offering

SOLTEC has raised $12.4 million in equity financing, including $2.1 million invested by founders Dan Cohen and Ellen Cohen, along with $900 thousand invested by board members and management. Additionally, the Company closed on $2.1 million of convertible debt during 2023.

The Company is offering Convertible Notes with the following terms, which are detailed more fully in Term Sheet available upon request:

- Maximum issuance of $2.5 million. There is no minimum deal size.
- Minimum investment equals $100,000 and is only available to accredited investors.
- Securities to be offered: Unsecured Convertible Notes.
- 10% annual simple interest.
- No payment of principal or interest due other than on an Event of Default.
- Notes mature March 31, 2027.
- 20% warrant coverage on the first $1,250,000 of investment proceeds.
- Automatic conversion upon completion of the Company's Next Financing which raises minimum equity capital of $2.5 million at lessor of (a) 80% of the offering price per share of Next Financing, or (b) $11.00.
- Maturity conversion price per share of $9.00.
- Optional conversion into shares of common stock prior to completion of Next Financing or the Maturity Date at a price per share of $11.00. Pre-money valuation at the optional conversion price is approximately $84.6 million.
- The offering is being made through a Note Purchase Agreement which will include extensive risk disclosures.

Uses of Proceeds

- Clinical research, particularly related to medical, as opposed to consumer applications,
- Regulatory and legal Support,
- Limited Product Development extending the technology's applications,
- Affiliate/B2B Sales for Consumer Applications, /Application and Clinical Idea Pipeline generation,
- Asian partner development, with particular focus on Japan and Korea,
- Inventory, Product Launch and General Corporate

Trends and Sources

Against the backdrop of a global surge in anxiety, insomnia, and mental health disorders, partly catalyzed by the COVID-19 pandemic, there is a growing public awareness of the need for self-care interventions. SOLTEC's scientific, engineering, and clinical advancements are positioned to address these societal and medical trends.

By offering low-cost solutions beyond traditional hospital and clinical settings, SOLTEC is poised to meet the increasing demand for interventions that empower individuals to promote health, prevent disease, and cope with illness, with or without direct healthcare worker support. SOLTEC's therapeutics can be quickly and easily self-administered in a home or office setting.

1. Liu YZ, Wang YX, Jiang CL. Inflammation: The Common Pathway of Stress-Related Diseases. Front Hum Neurosci. 2017 Jun 20;11:316. doi: 10.3389/fnhum.2017.00316. PMID: 28676747; PMCID: PMC5476783.
2. Walker, Matthew, PhD. Why We Sleep, page 96.
3. Van Cauter E, Plat L. Physiology of growth hormone secretion during sleep. J Pediatr. 1996 May;128(5 Pt 2):S32-7. doi: 10.1016/s0022-3476(96)70008-2. PMID: 8627466.
4. Brinkman JE, Tariq MA, Leavitt L, et al. Physiology, Growth Hormone. [Updated 2023 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK482141/
5. Cordone S, Annarumma L, Rossini PM, De Gennaro L. Sleep and β-Amyloid Deposition in Alzheimer Disease: Insights on Mechanisms and Possible Innovative Treatments. Front Pharmacol. 2019 Jun 20;10:695. doi: 10.3389/fphar.2019.00695. PMID: 31281257; PMCID: PMC6595048.
6. Léger D, Debellemaniere E, Rabat A, Bayon V, Benchenane K, Chennaoui M. Slow-wave sleep: From the cell to the clinic. Sleep Med Rev. 2018 Oct;41:113-132. doi: 10.1016/j.smrv.2018.01.008. Epub 2018 Feb 5. PMID: 29490885.

Risk Disclosures

• Incompleteness of information; investor due diligence required. This Company Profile contains selected information about the Company and does not purport to be all-inclusive. The Company materials do not contain all the information that may be required to evaluate an investment in the Company. The delivery of the Company materials does not imply that the information contained herein is correct as of any time after its release date. No reliance should be placed on the information and no representation or warranty, express or implied is made by SOLTEC or any of its respective directors or employees or any other person, nor on any registered broker-dealers associated with this offering, and no liability whatsoever is accepted by any such entity or person, in relation thereto. Further due diligence by each investor is required before making commitment. Potential investors should consult with their professional advisers with respect to legal and financial matters, as well as federal, state, and local tax consequences of an investment in the Company.

• Forward-looking statements: This Company Profile contains financial projections as well as references potential future events, possible outcomes, and projected growth (known as "forward-looking statements" under federal securities law). Readers are cautioned not to assume that the forward-looking statements will prove true. By their nature, forward-looking statements rely upon numerous assumptions, known and unknown risks and uncertainties, contributing to the possibility that the forward-looking statements and projections may miss the mark; this could cause the Company's actual performance and financial results in future periods to differ materially from the forward-looking statements and projections.

• Final terms of any offering will be contained in a subscription agreement. The Company material is indicative, and it should not be construed as a final offering. Such an offering may be made only by the Company through approved offering documents, and any other documents that pertain to the offering (collectively, the "offering documents"). The final terms of any offer will be found only in the offering documents. Offering terms are subject to change or withdrawal without notice.

• High degree of risk: The purchase of SOLTEC securities involves a high degree of risk. You should carefully review the investment risks in the applicable offering documents prior to making an investment. Investors in early-stage companies should be aware that their investment may be impaired, or even rendered worthless, by exposure to numerous risks, including but not limited to (not in rank order of likelihood): risks relating to the US Food and Drug Administration as to timely approval of medical devices (if and when such clearance is sought); patent and trademark risks, including infringement risk and the costs of disputing infringement; failures in protection of intellectual property; unintended side effects; litigation; mistakes in strategy and tactics; shortcomings in management execution; competitive challenges; difficulties in financing; equity dilution; loss of key personnel; incidents of epidemic disease, war, mass violence, and natural or man-made disasters; macro-and micro-economic setbacks; operational difficulties; infrastructure failures; and technological risks.

• Not a public security: restricted liquidity. The potential offering would seek exemption from registration under 17 CFR §230.506(c), as promulgated under the Securities Act (1933) and the JOBS Act (2012). Offerings seeking this exemption must verify the accredited status of each investor and keep archival records of that verification process. There is no assurance that the securities will ever be registered or will trade on an exchange. There are restrictions on the transfer of securities contained in the Operating Agreement, which should be studied with care. Certificates of ownership, whether physical or virtual, will include a legend informing any prospective purchasers or assignees of such restrictions.

Contact Information

Daniel Cohen MD
CEO
Round River Research Corporation
5222 Green Farms Rd
Minneapolis, MN 55436
Email: DCohen@SoltecHealth.com
Mobile: 952-210-4500

Robert Hiben
CFO
Round River Research Corporation
18765 11th Ave N
Plymouth, MN 55447
Email: Bob@SoltecHealth.com
Mobile: 612-220-6840