



OTCQB:VYCO

## **Corporate Presentation**

2023

## Safe Harbor Statement



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## Who We Are



- Vycor Medical is dedicated to providing the medical community with innovative and superior **surgical** and **therapeutic solutions**.
- We have a portfolio of **FDA cleared** medical solutions that are changing and improving lives every day.
- We operate two business units: **Vycor Medical** and **NovaVision**, both of which adopt a minimally or non-invasive approach.



## Our Two Product Lines



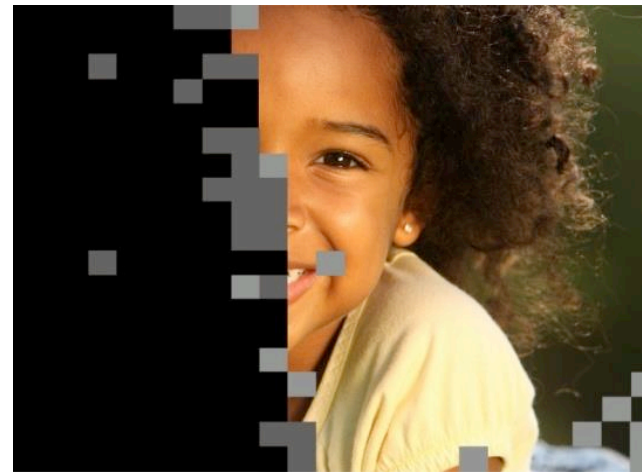
### ViewSite™

Lead product ViewSite™ Brain Access System (VBAS) is a revolutionary neurosurgical device used to retract and gain access to a target within the brain e.g. tumor, other pathologies and other matters such as bullets or shrapnel fragments



### NovaVision®

NovaVision has the most comprehensive, commercially available and clinically supported family of complementary therapies that diagnose (VIDIT) and both **restore** (Visual Restoration Therapy® "VRT") and **compensate** (NeuroEyeCoach™) for vision disorders as a result of stroke or brain damage. VRT is the **only FDA-cleared therapy** for the restoration of this type of vision loss



## ViewSite Brain Access System



*"It is the ideal system for providing deep brain access through a smaller incision."*

*-Neurosurgeon Quote*



# The Future Standard of Care



- Less brain tissue damage
- Less invasive: requires smaller opening
- Better access
- Better visibility
- Self-contained working channel
- Reduced operating and recovery time



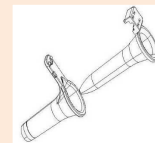
**Allows for use in procedures previously considered inoperable, saving lives**

## Old Blade/Ribbon Retractor Technology



**VS.**

## VBAS Next Generation Technology



**VBAS is a Step Change Improvement. Incumbent Technology Hasn't Changed in Over 50 Years**

## Market and Clinical Need for VBAS



- Since the introduction of the first operative microscope 50+ years ago, microsurgery (and more recently endoscopic surgery) has become an indispensable technique in neurosurgery
- In any surgical procedure adequate visualization of the operative field is critical
- The standard of care has hitherto been so-called ribbon/blade retractors used to create and maintain visual corridor to access targets within the brain (Greenberg, Leyla and Budde Halo retractor systems)
- The brain like other sensitive tissue is subject to injury from retraction – most evident BUT NOT LIMITED TO approaches to deep-seated intracranial lesions

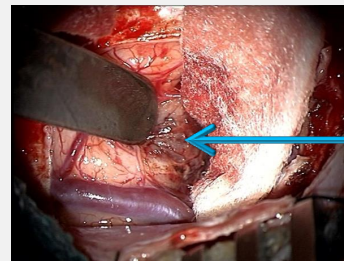
**There was and remains a compelling need for VBAS**

## How VBAS Addresses the Market's Clinical Needs



### Superior Shape

- The VBAS tubular shape disperses retraction forces over a greater surface area and has no edges where pressure build up is most common
- Blunt tip allows for progressive dilation that permits the splitting of white matter rather than its transection
- Lower risk of Ischemic complications and results in faster wound healing and shorter patient recovery period
- Surgeon feedback also points to shorter OR time as no target shift issues through pulling, less consumables needed and greater ease of use



Discoloration of tissue near the retractor tip



## How VBAS Addresses the Market's Clinical Needs

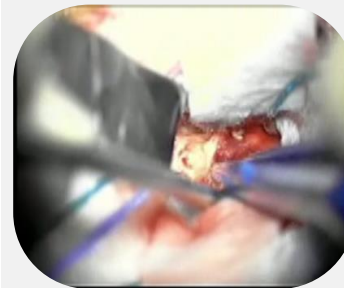


### Superior Field of View

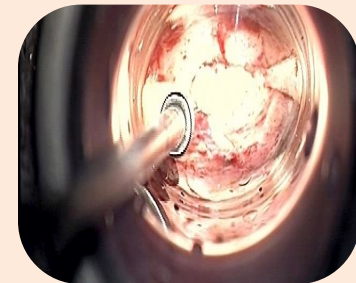
- Made of polished transparent polycarbonate
- Significantly increases the surgeons vision through clear walls
- Allows for continual monitoring of surrounding tissue and structures during insertion and surgery
- Coated in biocompatible non-reflective ink does not suffer from reflection issues experienced with other retractors

### Surgical Field of View

Standard Retractor



VBAS



## How VBAS Addresses the Market's Clinical Needs



### Improved Working Channel

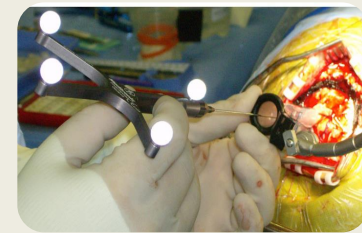
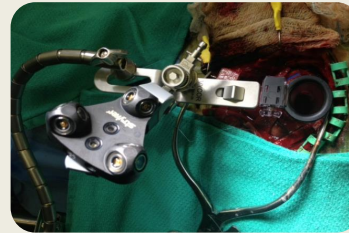
- Elliptical shape provides a widened working channel in one access, gives the surgeon greater working room allowing for bimanual surgical maneuvering
- The contained working channel provides protection of peripheral anatomy from inadvertent instrumental or thermal damage
- Provides an air instead of CSF medium that provides better intra-operative visualization

## How VBAS Addresses the Market's Clinical Needs



### Compatible with Neuronavigation

- The tip of the VBAS introducer literally becomes the “pointer” on the neuro-navigation system, allowing for real time monitoring of its position
- Clip of the recently launched VBAS AC locks in place the most commonly used neuro-navigation pointers



## VBAS Saves Lives




### Previously Inoperable...Now Operable

*"Her case would have been inoperable via a traditional surgery, because she was taking Avastin®, which delays surgical wound healing.*

*"The VBAS' minimally invasive nature enabled the surgeon to gain access to the target through only a 3cm incision.*

*"The patient was discharged uneventfully and there were no issues regarding her wound."*

– Daniel Prevedello, MD, Director of the Minimally Invasive Cranial Surgery Program, Ohio State University  THE OHIO STATE UNIVERSITY  
WEXNER MEDICAL CENTER



### Bullet fragment removal

*"We would not have attempted this without this technology. It's very exciting"*

– Narayan Sundaresan, MD, Chief Neurosurgeon at Lincoln Medical Center, NY, and Professor at Mount Sinai Hospital, NYC



## Benefits Evidenced Through Extensive Clinical Data



- Build up of clinical evidence to support the VBAS advantages has been a key management objective
- VBAS has now been the subject of 29 peer reviewed studies and 12 other clinical papers
- Studies now conclusively point to reduced white matter damage and better patient outcomes, shorter post-operative hospital stay adding to neurosurgeon comments of reduced OR time

**Strong Body of Clinical Data Supporting VBAS Superiority**

# ICH New Exciting Opportunity



## Intraparenchymal hemorrhage evacuation using the Vycor retractor system

Lydia Kautzani, Tyler Sparks, Scott Rahimi

### INTRODUCTION

- Minimal invasive craniotomies for the surgical management of intracerebral hemorrhage (ICH) have been developed
- Some of the current equipment used for evacuation of hematomas in a minimally invasive way are often cost prohibitive
- In an effort to improve outcomes for patients with ICH in rural settings we have developed a novel and affordable technique using the Vycor retractor system.

### OBJECTIVES

- We developed a new operative technique for ICH evacuation using the Vycor retractor system.
- This is a simple technique that may be used with basic neurosurgical equipment available at most hospitals at minimal cost.
- This method will allow any rural and regional hospital with limited resources to provide minimally invasive evacuation of ICH without investing in expensive and complex equipment.

### METHODS

- Patients that meet the inclusion criteria undergo general anesthesia and are placed on a donut head rest. Mayfield frame is not necessary. Frameless Stealth navigation was occasionally used to localize the intraparenchymal hemorrhage.
- A small linear incision is marked over the region of the bleed. A small craniotomy is performed. The dura is coagulated using bipolar cautery. The dura is opened in a cruciate manner a corticectomy is performed.
- Subsequently a 17mm large Vycor retractor is placed in the hematoma. The clot is evacuated using suction and bipolar cautery.
- Hemostasis is achieved, the dura is reapproximated and the small bone flap is replaced.

### RESULTS

- Fifteen consecutive patients were completed using the Vycor retractor system. Five were female and ten were males with a mean age of presentation of 68 years of age. The mean operative time was 58 minutes.
- The median Glasgow Coma Scale (GCS) score at presentation was 11±2.14 (range, 8-14). The median hematoma volume as identified on head CT scan on admission was 52.4 ±20.2 mL (110-33 mL) while the median hematoma volume after surgery was 6.77±7.50mL.
- The degree of hematoma evacuation was >95% in five patients, between 90-95% in five patients, 85-90% in one patient, 80-85% in two patients, 75-80% in one patient and 35.7% in one patient. The degree of evacuation of the hematoma was statistically significant (p<0.001).
- The average length of stay in the neuro ICU was 4.8 days and the average length of hospital days was 9.6.

### CONCLUSIONS

- Using the Vycor retractor system in combination with Stealth navigation we were able to develop a simple technique for removal of an intracerebral hematoma.
- With this technique we reached statistical significance for the reduction of intracerebral hematoma volume.

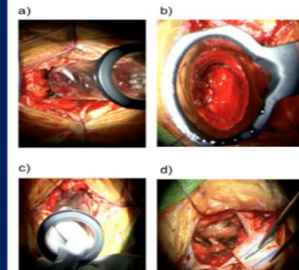
In this project, we have shown that by using the Vycor retractor system we had a significant intracerebral hematoma volume reduction. This is a novel, simple and affordable technique for the management of patients with intracerebral hemorrhage in rural hospitals.



Table 1: Inclusion and Exclusion criteria of study

| Inclusion Criteria   | Exclusion Criteria  |
|--|---|
| Age of patient between 18-80 years old   | Vascular malformation on CT angiogram of the head, hemorrhagic conversion of ischemic stroke, ICH due to tumor or trauma              |
| Non-contrast head CT scan showing spontaneous supratentorial ICH the volume of which was between 30-60cc | Non-contrast head CT scan demonstrates expanding hemorrhage and/or acute sign on CT angiogram of the head                             |
| Performing surgery within 24 hours of ictus  | Infratentorial ICH  |
| GCS on arrival between 5-14 and NIHSS greater than 6   | Intraventricular hemorrhage involving more than 50% of ventricular system, or requiring treatment as a result of mass effect or shift |
| Prehospital mRS 2 or less  | Mitomycin or thalamic hemorrhage  |
| Systolic blood pressure less than 180mmHg sustained  | Patient on long-term anticoagulation or anti-platelets that cannot be reversed  |
| Non-contrast head CT with Stealth protocol   |   |

Figure 1: Vycor retractor system used for the evacuation of ICH



a) Vycor retractor placed in the clot  
 b) Clot as seen through the Vycor retractor system  
 c) Stealth probe can be used to localize hematoma  
 d) Clot evacuated and Vycor retractor removed from cavity

## Validated Technology



### Approved for Use in 200+ US Hospitals

- Significant body of clinical papers and studies evidence VBAS' clinical superiority and improved patient outcomes
- International presence with regulatory approvals in key international markets
- Technology protected by 31 granted and 11 pending patents in the US and internationally



## Virtual Company: Reduces Cost



- Vycor operates a “virtual outsourced” business model to focus its resources on product development and direct targeted marketing to physicians and hospitals
- **Manufacturing:** outsourced to qualified sub-contract manufacturer
- **US sales:** outsourced to 20 distributors with av. 4-5 reps each who are experts in the neurosurgical device space, have local presence and are in the OR daily
- **International sales and marketing:** outsourced to leading distributors in each country/region focused on neurosurgical devices



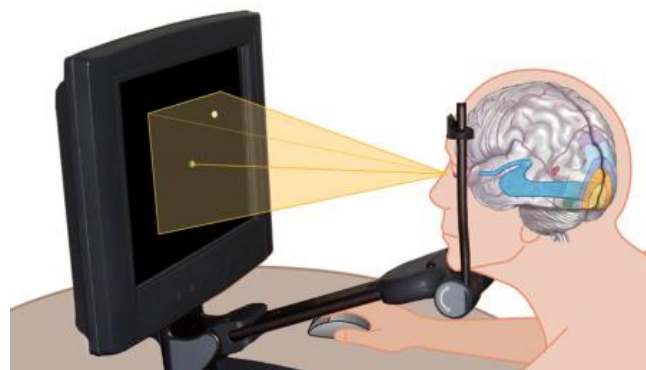
**Virtual Business Model Enables Vycor to Leverage Both Its and Its Outsourcing Partner Resources to Maximize Efficiency & Reduce Cost**



# NovaVision



## NovaVision's Suite of Complementary Therapies Addresses Patients with Vision Disorders Resulting from Stroke or Brain Injury



During each therapy session, you fixate your eyes on a central point displayed on the computer screen. You press a button every time you see a light target appear.

 NovaVision®

**“We do not need a new brain, but innovative methods of treatment to overcome the functional consequences of brain injury”**

*- Prof. Josef Zihl, Ph.D., Professor of Neuropsychology  
University of Munich*

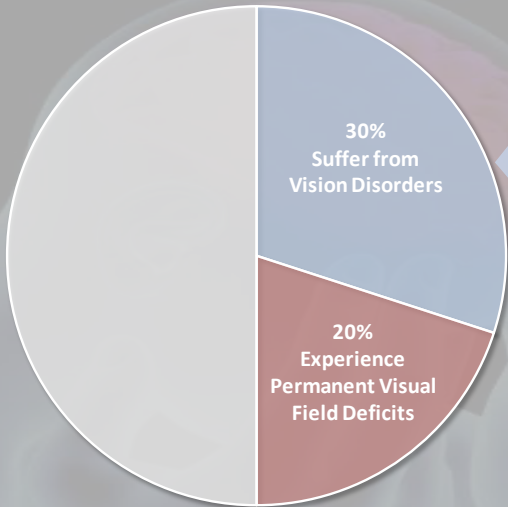
**“VRT makes a world of difference. Every day I feel like I see a little better. This would not be possible without NovaVision. This is second time NovaVision saved my eye sight when no-one else would help. Your program is a life saver I can smile again.”**

*- Annette. MI. VRT and NeuroEyeCoach patient*

# Multi-Billion Dollar Market Opportunity



## 8 Million Stroke Survivors in the U.S.<sup>1</sup>

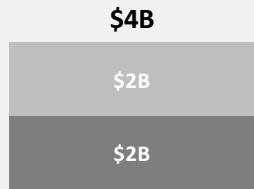


Vision loss from stroke and traumatic brain injury (TBI) has been a big unaddressed issue, each year, **600,000 new people** suffer from vision disorders due to stroke or TBI.

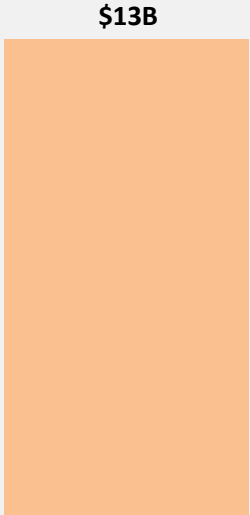
Every 40 seconds someone has a stroke

<sup>1</sup>) Company estimate derived from published data

## US/Europe & Global Market Opportunity<sup>1</sup>



US & Europe



Global

<sup>1</sup>) Company estimate derived from published data

## An Important Therapy for Daily Life



*"My vision began coming back after the first month of therapy...I passed my driving test, can read normally, and enjoy driving my boat on the lake...my life is back to normal." – Stroke survivor and VRT patient*



*Pre-VRT*



*Post-VRT*

**The Impact on Daily Lives Can Be Dramatic, Enabling a Person to Be Home Alone, Cross the Road Unaided, Shop, Read & Even Drive**

## ... And it Works



### Clinically Demonstrated to Restore and Make the Most of Remaining Vision

- **VRT:** 15 years of research, 20 clinical studies including a 302 patient study in which notable improvements were seen in over 70% of the patients. Prescription-based, bespoke “at home” therapy — **Not an App**
- **NeuroEyeCoach:** based on empirical evidence gained from several decades of research and 14 studies on a total of 591 patients
- 2020 definitive study by Universities of Aberdeen and Miami with 300 patients largest of its kind and a game-changer

### Patient Success Stories

- Substantial body of testimonials from enthusiastic patients whose lives were changed
- Carol Urban, a former patient, interviews aired on 200+ US radio stations

*“I can't put a value on what I have gained with NeuroEyeCoach, I can just say thank you with all that I am.”*

*- Luree- Virginia, U.S.*

*“VRT makes a world of difference. Every day I feel like I see a little better. This would not be possible without NovaVision.*

*This is second time NovaVision saved my eye sight when no-one else would help. Your program is a life saver I can smile again.”*

*- Annette, a VRT and NeuroEyeCoach patient*

# NovaVision Therapies: From Clinic to Home



Continual supervision and support from clinic to home

**for Rehab Clinics/Centers**  
testing and treatment



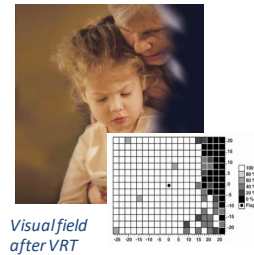
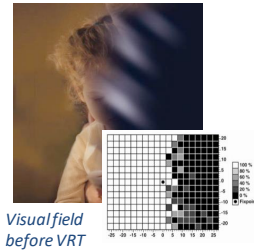
## Visual Diagnostics (VIDIT)

Testing of the central visual field to identify visual processing disorders



## NeuroEyeCoach

Training of faster and more efficient eye movements to automate compensation strategies



**for Patients**  
in their home



## NeuroEyeCoach

Training can be started in clinic and completed at home, or entirely performed at home



## Vision Restoration Therapy (VRT)

improved vision through intense light stimulation, individual adjustment and progress monitoring

## NovaVision Today



### For patients:

Most comprehensive, commercially available and clinically-supported line of complementary therapies:

**Visual Restoration Therapy® (VRT):** the only FDA-cleared therapy for the restoration of vision loss as the result of stroke or brain damage

**NeuroEyeCoach®:** helps patient compensate for vision disorders as a result of stroke or brain damage



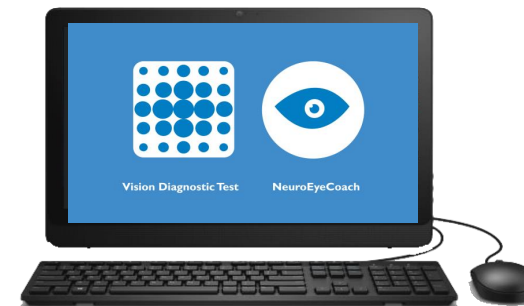
### For Professionals:

#### NovaVision Center Model:

Vision Diagnostic Test (VIDIT): high-resolution 7-minute test to screen for central visual field deficits

NeuroEyeCoach: dedicated visual training program specifically designed to improve scanning and eye movement

**NovaVision Pro Physician Model:** enables physicians to set up patients in their practice and then monitor and consult patients throughout their therapy regime



## NeuroEyeCoach Highly Effective



- The only dedicated visual training program specifically designed to improve scanning and eye movement:
  - Other scanning programs in use at clinics are part of aggregated modular systems
  - Can be completed during patient's stay in clinic or be completed at home under supervision



**before training**  
(small eye shifts, many fixations; longer scanning time)



**after training**  
(larger eye shifts, less fixations, shorter scanning time)

# NeuroEyeCoach Study – A Game Changer



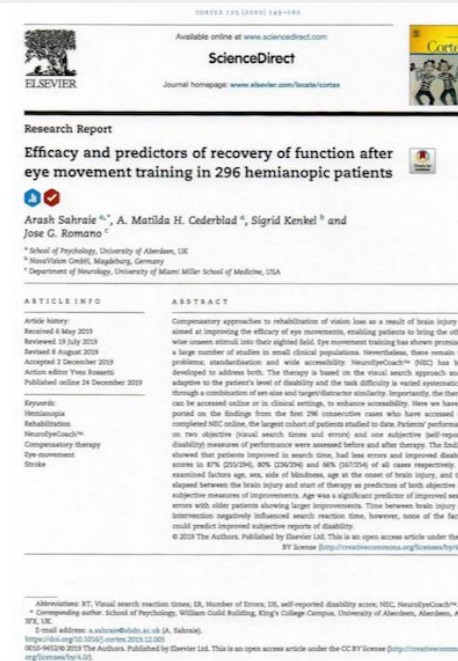
Published in *Cortex*, this is the largest study completed to date in the neuro visual space

- Analysed results of 296 patients who performed NeuroEyeCoach
- Demonstrated dramatic improvement in patients' ability to detect objects in the visual field by training them to make better eye movements
- Improved vision in over 80% of patients
- Improvements were not dependent on age, gender, side of blindness nor time elapsed since brain injury

Study has expanded interest in and attraction to NovaVision's professional products

- Gained wide recognition and will significantly increase acceptance of NovaVision in the professional community

Taken together with an earlier study published in *BioMed Research International*, they conclude the NeuroEyeCoach can be viewed as being the first evidence-based gold standard registered medical device accessible to patients at home or in clinical settings which has a significant impact on patients' abilities to see things quickly with few errors





## NEC Potential in Non-HealthCare Markets



NovaVision believes there is potential to move into non-healthcare markets possibly even through a JV:

- Strong potential for NeuroEyeCoach technology given its strong clinical data
- Potential variants for non-medical use in sports, aviation, gaming and security markets among others
- Medical applications in these sectors remains with NovaVision



Outside of NovaVision's healthcare focus could be a lucrative low-risk exploitation of its technologies

## Key Takeaways



- Two “game changing” product lines
- Devices are FDA-cleared, development risk now off the table
- Address significant markets – NovaVision ~\$4bn in the US/Europe, Vycor \$700m globally
- Limited competition – NovaVision VRT only FDA cleared therapy targeted at vision loss from neurological brain damage such as stroke
- Significant barriers to entry:
  - Robust patent portfolio; 61 granted and 11 pending patents
  - Significant published clinical data supporting technologies
  - Established international footprint
  - Strong new product pipeline
- Management has significant “skin in the game”

# Contact Us



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