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# **Corporate Profile**

# Medical Device Innovator with Two FDA-Cleared Product Lines

#### **Vycor Overview**

## **About Vycor Medical**

Vycor Medical provides minimal or non-invasive neurosurgical and neurotherapeutic solutions.

Technologies have been validated by numerous independent practitioners and published clinical studies.

IP portfolio of 46 patents and 11 pending.

Public company with management as controlling shareholders (61%)

#### **Two Divisions**

Vycor Medical – ViewSite™ Brain Access System (VBAS™): a minimally invasive neurosurgical device designed to improve access to brain lesions while reducing tissue damage and enhancing patient outcomes. The VBAS system has been approved and used in over 300 hospitals in the US and in numerous countries internationally. VBAS is protected by 46 issued and 11 pending patents and has been validated through over 40 peer-reviewed studies. These studies demonstrate that use of VBAS results in: less brain tissue damage; less invasive procedure; improved access and better visibility; and reduced operating and recovery time.

**NovaVision – NovaVision Visual Restoration Therapy**® **(VRT)**: Only commercialized FDA-cleared therapy for restoration of vision loss as the result of stroke or brain damage. **NeuroEyeCoach®:** enables dramatic improvements in patients' ability to detect objects in the visual field by training them to make better eye movements with improvement in over 80% of patients. (FDA registered). Clinically supported by a 296-patient study (the largest to date in the neuro visual space).

High gross margin both divisions: 80%+

Sizeable addressable markets

#### **Opportunity Overview**

Vycor Management who are also the majority shareholder believe its current market valuation undervalues the Company and its opportunities and as such has retained Maxim Group LLC to assist Vycor in its strategy to grow the Company through strategic acquisitions and with efforts to position itself for a potential uplisting to a US exchange. Management believes there are several possible transactions that could make sense and allow it to achieve its objectives:

#### **Medical Devices Merger Partner**

The Vycor division operates in an attractive market where its high margin, niche disposable medical devices are viewed as a "must have" for neurosurgeon users for certain procedures. This gives Vycor tremendous reach and strength in distribution (in the US and internationally) and a quality cachet for products neurosurgeons can trust. These specialist medical device markets require greater critical mass and so the Company is seeking opportunities to bulk up through transaction opportunities with private or public companies where the partners could utilize their mutual manufacturing, distribution/sales and regulatory infrastructure to grow the merged entity.

Vycor Medical is an OTCQB company that went public through an S1 registration and as such is NASDAQ/NYSE eligible with the correct transaction and funding structure.

## **NovaVision Opportunity**

NovaVision has a meaningful market opportunity and is well suited to capitalize on the global trend towards digital health. Vycor has invested in product and therapy development and clinical data, and the products and therapies have a proven market need among patients and clinicians. The therapy programs still require substantial development to allow them to successfully address the market potential, so the company is seeking a partner with the market reach and capability to leverage the product platform and fulfill NovaVision's potential. Management also believes there could be a lucrative low-risk exploitation of its technologies in non-healthcare markets. The Company is open to a very broad range of transaction alternatives.

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# **Vycor Medical Division - ViewSite Brain Access System (VBAS)**

Retractor damage is most acute and evident during approaches to deep-seated intracranial lesions, during which the surrounding white matter comprising the surgical corridor is vulnerable to retractor-induced damage, however retraction injury to brain tissue is a possibility whenever retraction is required. VBAS addresses this issue.

The ViewSite™ Surgical Access System (VBAS™) is a suite of clear cylindrical minimally invasive disposable devices that are clinically supported and shown to allow for speedier, safer and more economical brain surgeries, and a quicker patient discharge. VBAS is designed to optimize neurosurgical site access, reduce patient risk, accelerate recovery and add tangible value to the neurosurgical community.

VBAS has an extensive body of over 40 peer-reviewed clinical studies covering over 500 patients and 12 other clinical papers demonstrating the key advantages to surgeons and hospitals:

#### **Less Invasive Procedure/Shorter OR time**

Given the retractor's tubular elliptical shape, a large amount of white matter does not have to be resected since the retractor gently splits as it is advanced into white matter without further damage or transection. Clinical studies point to shorter OR times.

### **Reduction of Venous Pressure/Faster Patient Recovery**

The tubular shape of the VBAS disperses retraction forces over a greater surface area than conventional blade retractors, which lowers the risk of ischemic complications resulting in fast wound healing and short patient recovery period.

#### **Superior Field of View**

Made of polished transparent polycarbonate, the VBAS significantly increases a surgeon's field of vision through a clear, visible and stable channel, allowing for continual monitoring of surrounding tissue and structures during insertion and surgery.

#### **Improved Working Channel**

The elliptical shape of the VBAS device provides a widened working channel in one axis to give the surgeon greater working room, while keeping the other axis smaller to minimize invasiveness.

#### **More Accurate Target Access**

Traditional retractor technology does not integrate well with IGS navigation systems. VBAS facilitates IGS use and the newly launched VBAS AC model locks the IGS pointer in place to allow vertical/horizontal alignment and single-handed navigation.

#### **Avoiding Target Shift**

Standard retractors pull on the brain's soft tissue. This pulling may cause the target area to shift. There is no target shift with VBAS as its elliptical shape distributes uniform pressure to the surrounding brain areas.

VBAS has been predominantly used for deep tumor access, however there is a growing trend towards surgical intervention in ICH cases for which tubular retraction is well suited for access and drainage; this provides a much larger and exciting potential growth end market.

Vycor Medical is ISO 13485:2016 and MDSAP certified, and VBAS has FDA 510(k) clearance, a Health Canada Medical License, and CE Marking for Europe (Class III), as well as regulatory approvals in a number of other international markets. The US is the Company's largest market (approx. 70% sales), and VBAS has been approved and used in over 300 hospitals nationwide. The Company's other largest markets are Canada, Japan and the UK and international provides a significant area of opportunity for growth.

The Vycor division maximizes efficiency by sub-contracting manufacturing to US-based manufacturers and distributing through independent specialist distributors in the US and internationally.

Vycor has 46 issued patents and 11 pending patents covering the product range, including some exciting indevelopment products.

## **NovaVision**

Every forty seconds someone has a stroke in the United States and there are approximately 8 million stroke survivors in the United States alone. Up to 30% of these experience a resultant vision disorder, up to 20% permanently. NovaVision's products are focused on Compensation and Restoration, with digitally-delivered product offerings tailored to physicians, clinics and centers as well as direct to patients. Vision Restoration Therapy® (VRT®) is provided by NovaVision in a therapy suite with its NeuroEyeCoach® compensation therapy.

#### VRT:

- The only commercially available FDA-cleared therapy designed to restore vision loss due to neurological brain damage.
- Therapy is done at home on the patient's own computer and on their own schedule.
- Improvement does not depend on how long ago their vision loss occurred.
- VRT is performed twice daily, six days a week for approximately six months.

## NeuroEyeCoach:

To perform normal daily tasks, such as finding an object at home or on a supermarket shelf, effective eye movement is required. These normal eye movements are often affected after brain injury, which is what NeuroEyeCoach was created to address. Its efficacy has been evidenced in a 296 peer-reviewed patient study (largest ever conducted on eye movement training) conducted by University of Aberdeen and University of Miami Miller School of Medicine, published in *Cortex*. This showed that patients who undertook NeuroEyeCoach:

- Achieved major improvements in a short period of time.
- Experienced meaningful improvement in visual search performance (87% of patients) resulting in improvements in navigation skills and object finding.
- Increased the efficiency of a patient's eye movement and re-trains the patients' ability to make the most of their remaining vision; 80% had made less errors leading to real improvements in daily living

The program has been designed to be intuitive and user-friendly and not to be overly demanding; can be quickly completed in 2-4 weeks in comfort of their own home on patient's own computer or supervised in a rehabilitation environment.

#### **NovaVision Opportunity:**

NovaVision's therapies and programs are well suited to capitalize on the global trend by health providers to promote digital health – whereby patients commence therapy in the clinic and continue it digitally-monitored at home, reducing cost.

NovaVision estimates the theoretical US market opportunity to be significant - only real "competition" is lack of awareness and broad physician acceptance. However, the therapies still require significant development to allow them to successfully address the market potential.

There is also a potential to move into non-healthcare markets, where the NeuroEyeCoach technology can provide variants for markets such as sports, aviation, gaming and security markets among others.