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Brainsway Ltd.: Market Trends Drive Revenue Growth. An Opportunity for Increased Value based on the scenario of the Successful Execution of the New Business Model

Primary exchange: TASE

Symbol: TASE: BRIN

Sector: Healthcare

Sub-sector: Medical Devices

Stock target price: NIS 27.0

Data As of August 3rd, 2017

(Source: TASE website):

Closing price: NIS 17.8

Market cap: NIS 262.7 million

# of shares: 14.7 million

Stock performance (YTD): -0.1%

Daily-trading-vol. (12 months): NIS 860.3K

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Company overview

Brainsway Ltd. is an Israeli medical device company focused on the development and commercialization of an H-coil helmet device for Deep Transcranial Magnetic Stimulation (dTMS). dTMS enables non-invasive activation of deep brain structures that can cover a broad range of brain disorders. The company has FDA market approval for Major Depressive Disorder, and wide reimbursement coverage for this indication, as well as over sixty clinical studies in leading institutions worldwide for other neuro-psychiatric disorders. The company has recently received positive results in Obsessive Compulsive Disorder (OCD) patients, and will also apply for market approval in the US for this indication. Approximately 15,000 patients were treated to date with Brainsway's device, and the use of Brainsway's platform in treating additional indications is pending.

Highlights

- The company targets multi-billion dollar markets, in which physicians and patients are searching for alternative therputics to medication and surgery.
- The company has FDA market approval for Major Depressive Disorder (MDD), and reimbursement coverage for this indication.
- Brainsway holds CE (European Conformity) mark for 12 indications.
- The company reported positive final results in Obsessive Compulsive Disorder (OCD) patients, and is preparing to submit an application for market approval in the US.
- The company has three pivotal multi centre trials underway with the goal of obtaining clearance for treating bipolar depression, post-traumatic stress disorder (PTSD), and smoking cessation. In total, the company has over sixty clinical studies worldwide with additional indications pending.
- Positive clinical trial results for neurological indications (rather than neuro- psychiatric ones), including stroke would be considered a major breakthrough for this technology.
- Brainsway develops an in-house multi-channel stimulator that enables synchronized activation of different brain regions to improve clinical efficacy.
- A new business model is based on the leasing of systems to secure long-term revenues (we assume it will be a 90% of all future systems sales).
- **We believe, Brainsway's current strategy is supported by several significant market trends: (1) The growing demand for drug alternatives such as non-invasive and minimaly invasive treatments; (2) the company offers a cost-benefit treatment and lowers the economic burden on patients; (3) it offers a win-win business model for psychiatrists.**
- **We estimate the company's equity value at $111.6 million (NIS 397.3 million); target price of NIS 27.0 per share (ranging between NIS 26.0-28.1).**

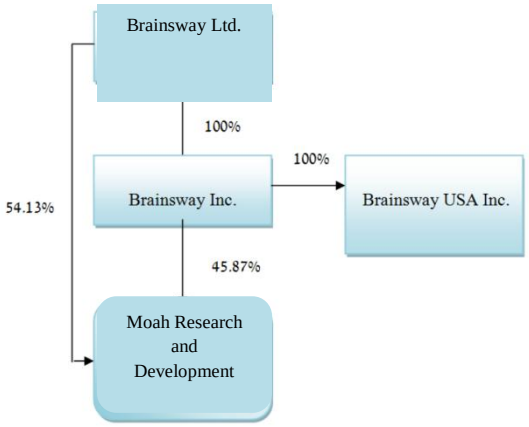
Parameters	2016A	2017E	2018E	2019E	2020E
# of installed systems	160	220	332	444	571
Revenues (thousands $)	11,524	16,311	21,726	28,694	36,207
Operating profit (thousands $)	-2,069	257	3,325	7,526	11,658
EPS ($)	-0.17	-0.03	0.18	0.46	0.74

Stock overview YTD (Source: TASE website)

Executive Summary

Investment Thesis

Brainsway Ltd. ("the Company" and/or "Brainsway", including related companies when applicable) is a publicly-traded Israeli medical device company. The company was established in 2003, and went public on the Tel-Aviv Stock Exchange in January 2007. Brainsway Ltd. wholly owns a US subsidiary, Brainsway Inc.that wholly ownes Brainsway USA Inc. Together these companies cover all US operations. Brainsway Inc. also holds 45.87% in another subsidiary "Moah Research and Development", with the additional 54.13% owned by Brainsway Ltd.



Source: Brainsway

Brainsway develops and provides advanced technological solutions for the treatment of a variety of brain disorders. Brainsway's flagship technology is Deep TMS (dTMS), or Deep Transcranial Magnetic Stimulation. Brainsway's products are based on patents filed by the U.S. National Institutes of Health (NIH), and by the company. The company holds an exclusive license from the NIH for Deep TMS technology patents.

Brainsway's Deep TMS is FDA approved for treating depressive episodes in adult patients suffering from Major Depressive Disorder, who have previously failed to achieve sufficient improvement from anti-depressant medications. The company runs clinical research programs with leading scientists worldwide, collaborating with prominent institutions and researchers in clinical trials covering various neuropsychiatric and neurological disorders.
If successful in its efforts to provide treatment for neurological disorders, such as Parkinson's disease, stroke rehabilitation and chronic pain, Brainsway will become a truly 'game changing' company.

The company has recently changed its sales strategy and is now focusing on promoting the lease of its systems rather than selling them to psychiatrists. We consider this relatively new strategy as a faster way to become a leading company in the growing brain disorders domain. Successful execution of this strategy will lead the company to a steady and growing stream of revenues from installed systems.

Brainsway's growth and current strategy are in line with several major trends, that are expected to accelerate them:

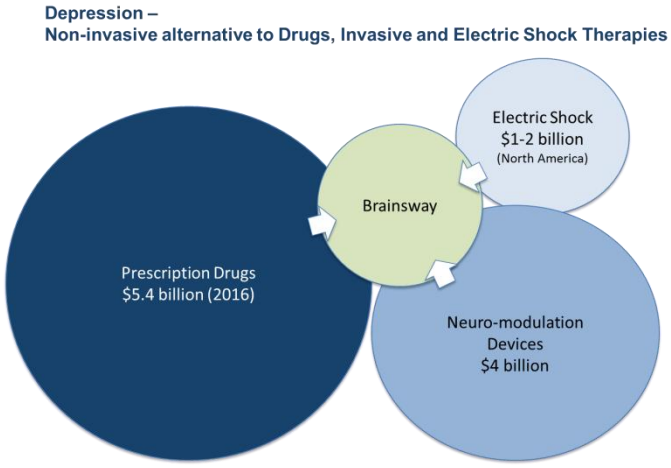
- **Alternatives to drugs -** key forces driving a trend to reduce the use of drugs and explore alternative therapies include:
    - The efficacy of drugs in many brain related indications (psychiatric, neurological) are very low, with effectiveness often below 50%.
    - Compliance of patients is low due to side effects, price and other psychological reasons
    - Side effects- drugs have significant, accumulative, side effects
    - High costs to the healthcare system

- **The rise of non-invasive and minimally invasive treatments**. New treatments using advanced technologies are quickly replacing surgical procedures due to better medical outcomes and lower costs to health care providers.

- Brainsway's strategy also offers a cost-benefit treatment and **lowers the economic burden on patients.** Insured patients in the US pay between $70-200/month out-of-pocket on drugs for treating depression. The higher costs are for newer, branded, drugs with less side effects or, cocktails of medications. Brainsway's treatment requires 20 to 30 sessions to achieve therapeutic benefits to patients, with total treatments cost ranging between $5,000 and $10,000. Albeit, 95% of the cost is reimbursed by insurance companies in the US (out of pocket expenses are limited to $500).

- A significant benefit of Brainsway's strategy is that it offers a**n attractive business model for psychiatrists.** Brainsway's lease and pay-per-use business models are an attractive and lucrative business opportunity for clinics and psychiatric professionals. The cost of each treatment performed is $200-$300 out of which the psychiatrist pays $70 to Brainsway, thus, instead of writing a prescription for a drug, the psychiatrist can direct patients to a non-invasive treatment and gain additional revenues.

Overall, Brainsway offers a safe, relatively efficient and cost-effective alternative treatment for a $5.4 billion market.



Source: Frost & Sullivan

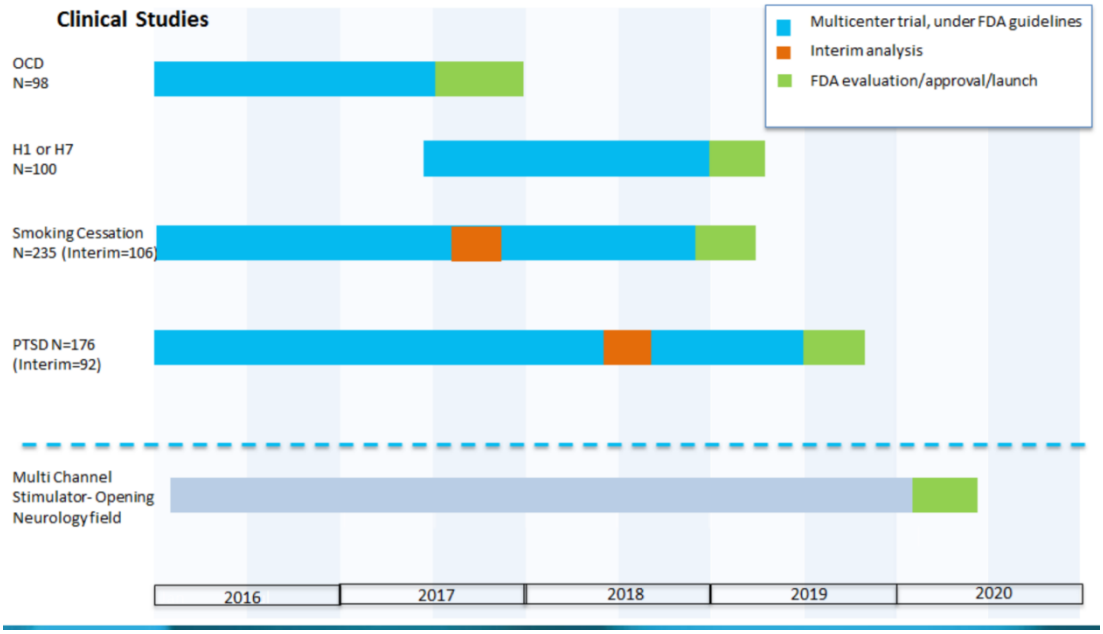
Brainsway is deeply involved and takes full responsibility for each stage in the value chain, including product development, design and system assembly. The company also sells directly, and provide post-sales service and system maintenance. These occur independent of the local distributors in most cases. All of these activities are conducted in parallel with clinical development. In summary, the company should employ the most efficient practices to ensure synchronization of the entire value chain puzzle. A major risk for Brainsway is disruption to certain areas of their activities.

We believe the company will succeed from its business model, leasing more systems, engaging with more clinics and hospitals in the US, as well as other locations. However, Brainsway's management is facing multiple challenges such as; growing working capital requirements, managing a B2C sales force across several geographies, raising awareness and increasing adoption rates for an innovative treatment not yet being used "first line", and maintaining high standards in customer service and clinical development.

We see the company as a good investment, as the move to the lease model is expected to be reflected in its revenues for the second quarter of 2018. In the long term, the company has a significant development pipeline, which will also contribute to additional sales in other areas such as OCD and Neurology.

Pipeline Summary

Brainsway is currently advancing multiple clinical programs:



Source: Brainsway

Upside scenarios	Downside scenarios
Brainsway has a strong R&D pipeline that can generate more products in several domains - huge potential.	The company has changed to a 'leasing' business model. This strategic move will require capital raising - further pressure on the company.
Brainsway has an appealing business model engaging psychiatrists to use the company's system .	Brainsway faced several management changes in recent years, along with new strategies and business models. This has aroused uncertainty among investors. If major changes occur, they may hamper Brainsway's strategy and investors' confidence.
If the company will meet sales forecasts it will generate a predictive, steady stream, of cash flow that has high value to growth companies.	The company is responsible for all aspects of operations – from clinical development to direct sales and post-sale services. This requires strong C-level leadership and capable middle management to make sure targets are met and best practices are implemented.

Upcoming Potential Catalysts

Program	Event	Significance	Timeline
Obsessive Compulsive Disorder (OCD)	Market approval in the US for OCD	High	**Q1 2018**
Smoking cessation	Final results of large multicenter trial	Medium	**Q1 2019**
Post-Traumatic Stress Disorder (PTSD)	Final results of large multicenter trial	High	**Q2 2019**
Bipolar Depression	Final results of large multicenter trial	Medium	**2020**
H7/H1 for Major Depressive Disorder (MDD)	Final results of multicenter trial	Medium	**Q3 2018**
Neurologic Disorders (Stroke rehabilitation and Chronic pain)	Initiation of multicenter trial	High	**Q1 2018**

Source: Frost & Sullivan analysis

Valuation Methodology

R&D company valuations are challenging due to non-cash valuation and a long time to market in the majority of cases. The methods typically used for company valuations, such as Asset Valuation ort the Multiplies Method, are incompatible for valuing R&D intensive businesses. In such corporations, the current business status cannot be analysed through the capital on the balance sheet, and in most cases cannot be compared to similar companies due to their uniqueness both technologically and financially.

As part of the accepted method used in financial valuations – Discounted Cash Flow (DCF), there are several modifications to an R&D company's valuation. In general, a DCF valuation comprises three primary methods:

- **Real Options** - designated for pre-clinical and early-stage clinical programs/companies where the assessment is binary during the initial phases, and based upon scientific-regulatory assessment only (binomial model with certain adjustments).
- **Pipeline assessment** - used for programs/companies prior to the market stage. The company's value is based on the total discounted cash flow, plus unallocated costs, and an assessment of the future technological basis. The latter is established based on the company's capability to “produce” new clinical and pre-clinical projects and their feed rate potential.
- **DCF valuation** - similar to companies outside life sciences, i.e. those with products that have a positive cash flow from operations.

Brainsway is a medial device company with significant value in its clinical pipeline. Furthermore, the company already has revenues and products on the market. Thus, we evaluate the company based on DCF valuation, whilst also considering potential future products.

Valuation Summary

Brainsway enters into lease contracts with its customers in one of two ways; leasing or purchasing. There are two leasing structures and a single structure for purchasers.

- Rental fees plus per-use billing - "minimal use": The system is leased for an annual fee of $28,000 and an additional fee of $70 per treatment performed using the system.
- Rental fees including unlimited use – "unlimited use": The system is leased for a fixed annual fee of $52,000 for the first year and $72,000 for subsequent years. A typical contract is signed for a period of 3-4 years.
- Purchase option.

We evaluate the company`s operations until 2024, when their main patent expires. Nonetheless, we take into account the company's potential in our terminal value valuation (see below). We assume the company will reach the following numbers of installed systems:

Parameter	2016A	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Total systems	**160**	**220**	**332**	**444**	**571**	**715**	**879**	**1,066**	**1,279**
YoY%			*51%*	*34%*	*29%*	*25%*	*23%*	*21%*	*20%*

We also assume, based on our clinical evaluation that the company will receive FDA approval for the OCD indication during 2018, and begin selling helmets by 2019. These helmets will be add-ons to previously installed systems and can also add to the original system's potential in other locations given the dual-use for both depression and OCD. These helmets may also serve other neurological indications in the future. We assume 5% of future installed systems and 15% of future installed systems from 2021 will add to the company`s revenues. In the table below we present our forecast analysis for the years 2017-2024:

Years	2014A	2015A	2016A	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Revenues	**3,380**	**6,800**	**11,524**	**16,311**	**21,726**	**28,694**	**36,207**	**46,705**	**57,063**	**68,969**	**82,652**
YoY%				42%	33%	32%	26%	29%	22%	21%	20%
Total cost of revenues	656	1,466	2,427	2,670	2,937	3,230	3,553	3,909	4,300	4,730	5,202
Gross profit	**2,724**	**5,334**	**9,097**	**13,642**	**18,790**	**25,463**	**32,654**	**42,796**	**52,764**	**64,239**	**77,450**
% of revenues	*81%*	*78%*	*79%*	*84%*	*86%*	*89%*	*90%*	*92%*	*92%*	*93%*	*94%*
R&D Expenses	6,438	4,103	3,792	4,644	5,108	5,619	6,181	6,799	7,479	8,227	9,050
% of revenues	*190%*	*60%*	*33%*	*28%*	*24%*	*20%*	*17%*	*15%*	*13%*	*12%*	*11%*
Other Payments				652	869	1,148	1,629	2,102	2,568	3,104	3,719
Marketing Expenses	1,896	3,281	5,180	5,744	6,738	7,933	9,364	11,080	13,129	15,575	18,494
% of revenues	*56%*	*48%*	*45%*	*35%*	*31%*	*28%*	*26%*	*24%*	*23%*	*23%*	*22%*
General and Administrative	1,667	2,455	2,194	2,344	2,749	3,237	3,821	4,522	5,358	6,356	7,547
% of revenues	*49%*	*36%*	*19%*	*14%*	*13%*	*11%*	*11%*	*10%*	*9%*	*9%*	*9%*
Operating Profit (Loss)	**-7,277**	**-4,505**	**-2,069**	**257**	**3,325**	**7,526**	**11,658**	**18,293**	**24,229**	**30,977**	**38,639**
% of revenues	*-215%*	*-66%*	*-18%*	*2%*	*15%*	*26%*	*32%*	*39%*	*42%*	*45%*	*47%*

As of March 31, 2017, the Company has non-operational assets (cash) of approximately $7.8 million with no loans, besides liabilites from R&D funding ($5.3 million) calculated based on the company's projected revenues, to which we reffered as part of our analysis. The company`s burn rate is approximately $3 million per quarter. Accordingly, the company will have to raise capital in the next 3-4 quarters.

Below are the equity valuation elements:

Parameters	(in thousands $)
Enterprise Value (EV)	103,754
Cash and non-cash equivalences	7,808
Equity Value	111,562

We estimate the equity value of the company at $111.6 million (NIS 397.3 million).

Sensitivity Analysis

In the table below we present Brainsway's target price in relation to the capitalization rate. We set a range of 0.5% change from our CAPM model (as presented in Appendix B) as the stock range.

Sensitivity analysis - Capitalization rate and growth rate vs. target price

Cap. rate / Growth rate	1.50%	2.0%	2.50%
18.0%	28.7	29.3	29.9
18.5%	27.6	**28.1**	28.6
19.0%	26.5	**27.0**	27.5
19.5%	25.5	**26.0**	26.4
20.0%	24.6	25.0	25.4

We estimate the target price in the range of NIS 26.0 - NIS 28.1, with a mean of NIS 27.0

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Company Activity and Strategy

Brainsway is an Israeli medical device company that develops and commercializes advanced technology for the treatment of a variety of brain disorders. Brainsway's Deep Transcranial Magnetic Stimulation (TMS) technology is a non-invasive neurostimulation technology utilizing magnetic pulses which pass through the scalp unimpeded to aid in the stimulation of neurons in the brain tissue underneath. Generally speaking, Brainsway products are used to treat neuro-psychiatric indications.

Brainsway's technology is part of a growing trend in brain disorder treatment based on minimally or non-invasive therapeutics that result in less systemic side effects, and require no hospitalization or anesthesia. One of Brainsway's key differentiators compared with other non-invasive neurostimulation technologies is its ability to penetrate deep brain regions rather than use acute superficial stimulation. Frost & Sullivan awarded Brainsway for its technology already in 2012 in the frame of Frost & Sullivan reward acknowledgment.

Brainsway was established in 2003, based on patents filed by the U.S. National Institutes of Health (NIH) and the company for Deep TMS. The company holds an exclusive license from the NIH for the patent and for the technology. Brainsway's H-coil helmet is its patented asset, which provides the device with its uniqueness. A variety of H-coils and helmets are utilized to treat a range of psychiatric and neurological conditions. In addition, Brainsway is developing a multi-channel stimulator as an integral part of its products that will exert novel treatment protocols not possible today for a variety of brain disorders.

Brainsway's target markets include clinics and medical centers that treat populations with multiple Neuro-Psychiatric indications. The company has received marketing approval from the FDA for Major Depressive Disorder (MDD) in adult patients that failed to achieve satisfactory improvement from medication treatment,[1] with broad reimbursement coverage for this indication in the US. Additionally, the company holds a European certification mark for 12 indications (including- Alzheimer's, Parkinson's, Stroke, Addictions, ADHD and more). All in all, the company is involved in over 60 clinical trials across the globe that include 28 clinical indications. To date, over 15,000 patients have been treated with Brainsway's device.
In June 2017, Brainsway received positive final results from a multicenter study of patients with Obsessive Compulsive Disorder (OCD), and is preparing to submit an application for market approval in the US for this indication. The study of OCD patients was the first of its kind, showing that deep magnetic stimulation may bring promising clinical outcomes for what has long been considered a hard-to-treat disease. Therefore, it represents a new era in brain disorder treatment that is applied not only to classic psychiatric conditions but to addictive disorders as well. In this regard, positive results for indications in neurology, such as post-stroke rehabilitation, will be considered a true breakthrough for treatment with a non-invasive medical device, positioning Brainsway as a key player in the field.

Source: Brainsway

[1] FDA 510(k) No. K122288

Market, Standard of Care and Unmet Needs

Brainsway's buisness is a part of the neuromodulation industry. It targets clinics and medical centres that can offer deep TMS as a therapeutic option for multiple indications. Each indication exposes the company to another application segment of the neuromodulation market that derives from the number of patients, as well as the existing competition, be it drugs or other technologies used to treat that specific indication. In the following section we refer to the neuromodulation device industry whereas in the 'product' section we refer to several markets, each comprising a potential additional indication from which Brainsway can yield a share of the market.

Background

Deep Transcranial Magnetic Stimulation (dTMS) is a non-invasive neuromodulation technology. Neurostimulators are medical devices that utilize electrical or magnetic pulses to aid in the stimulation of neurons, thereby regulating the physiological activity of body organs. This technology has long been explored, well before Silvanus Thompson in 1910, who used magnetic fields to stimulate neurons. TMS modulates the brain's electrical environment by using magnetic fields, which pass through the scalp and skull unimpeded. The magnetic field strength produced by TMS is comparable to an MRI device in the order of 1.5-3 Tesla (which is considered to be safely used in human brains), except that it focuses on a limited area of the cortex (the outer layer of the brain just below the skull), and it uses transient pulses (typical pulse width is less than a millisecond). [2]

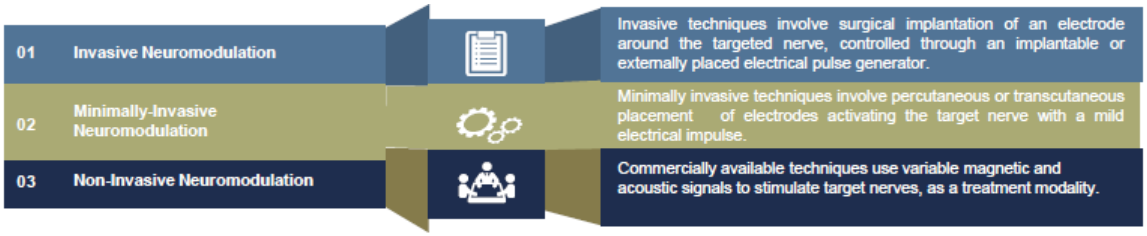
Advances with imaging methods such as MRI and fMRI, allows associating particular disorders and symptoms with specific brain areas,[3] and targeting them with techniques such as deep brain stimulation (DBS) or transcranial magnetic stimulation (TMS). FDA clearance of the first TMS device for the treatment of major depression was provided in 2008 to US-based Neuronetics, and in 2013 to Brainsway's Deep TMS.

Brainsway's Deep TMS technology was developed by Abraham Zangen and Yiftach Roth, commencing in 2000, within the framework of their research with the NIH. The promising results for treating depression with dTMS has led the U.S. Food & Drug Administration to license the use of deep TMS technology as an antidepressant therapy, and paved the way for other psychiatric and neurological indications in the approval pipeline. Studies indicate potential for treating symptoms of Parkinson's disease, Nuropathic pain, Stroke rehabilitation, Smoking Cessation, OCD, PTSD and other pending indications. For further information see appendix C.

Types of Neuromodulation Technologies

There are three types of neuromodulation technologies currently available consisting of invasive, minimally invasive and non-invasive systems. Invasive technologies are more established and prevalent, consisting of electrodes inserted into tissues; however noninvasive technologies such as magnetic stimulation are gaining significance as reliable methods of nerve stimulation.

[2] P.G Janicak, Neuropsychiatr Dis Treat. (2015) 11: 1549–1560
[3] Mayberg HS, The Hastings Center report, (2014) Spec No, S31–36



Neuromodulation: Innervation Methods & Clinical Applications, Global, 2016

Type	Innervation Method	Applications (Commercial & R&D)
Invasive	Spinal Cord Stimulation	Low Back Pain, Failed Back Syndrome, Angina Pectoris, Causalgia, Peripheral Neuropathy
	Deep Brain Stimulation	Parkinson's Disease, Dystonia, Essential Tremor, Epilepsy, Psychiatric Disorders, Epilepsy
	Vagal Nerve Stimulation	Epilepsy, Psychiatric Disorders, Heart Failure, Arrhythmia, Hypertension, Obesity
	Phrenic Nerve Stimulation	Heart Failure, Arrhythmia, Obstructive Sleep Apnea
Minimally Invasive	Tibial Nerve Stimulation	Interstitial Cystitis, Urinary Incontinence, Fecal Incontinence
Non-Invasive	Transcranial Magnetic Stimulation	Headache, Parkinson's Disease, Stroke, Psychiatric Disorders, Traumatic Brain Injury, Obesity, Tinnitus
	Random Noise Stimulation	Tinnitus
	Pulsed Ultrasound Stimulation	Parkinson's Disease, Stroke, Psychiatric Disorders, Traumatic Brain Injury, Depression, Alzheimer's Disease, Coma

Source: Frost & Sullivan [4]

Several modes of invasive electrical stimulation currently dominate the market: Deep Brain Stimulation (DBS), which stimulates deep brain tissues, and is prescribed to end-users for indications that include depression, advanced Parkinson's disorder, dystonia, essential tremor, and refractory epilepsy; Vagus Nerve Stimulation (VNS) therapy, which stimulates the vagus nerve to treat both epilepsy and depression; Sacral nerve stimulation, which is used primarily for treating incontinence; and Spinal Cord Stimulation (SCS) to manage chronic pain and other pain related disorders. There is currently wide commercial adoption of these aforementioned methods.

Among non-invasive methods, TMS therapy is commercially available today for treating depression in the US, whereas other indications are still under examination. Similar technologies in development may offer an alternative across the continuum of care, such as the use of a low-intensity and low frequency ultrasound (LIFU),[5] transcranial laser therapy,[6] and infrared therapy.

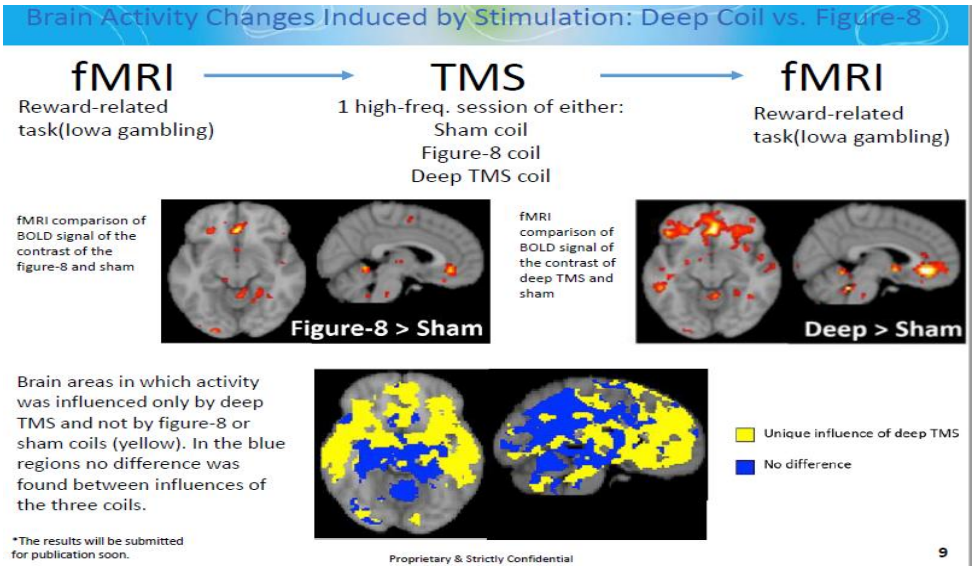
Although the non-invasive approaches provide outstanding utility, invasive techniques remain non-replaceable as the resolution of brain signals received from non-invasive techniques are mediocre, with spatial resolution in the range of 5-10 mm in comparison with 0.5-1 mm for invasive methods such as Intracortical Neuron Recording (INR) and ECoG (ElectroCorticography). Nevertheless, in terms of neuroplasticity, larger spatial volume may be beneficial as clinically observed, resulting in greater remission effect. To date, TMS is likely the non-invasive brain stimulation intervention with the strongest evidence in terms of efficacy in psychiatric disorders, as documented by randomized controlled trials (RCTs) and meta-analyses.[7] In a manner similar to electric shock, which is still considered the most effective treatment for psychiatric disorders, both TMS and ECT stimulate brain regions with larger spatial resolution. Moreover, both are believed to function similarly by stimulating the prefrontal cortex to rebalance areas in the brain responsible for mood regulation. [8]

Currently, the efficacy of TMS is being further investigated in use for other psychiatric and neurological disorders, with preliminary and some advanced, encouraging results emerging in various fields. All in all, the tolerability and safety

[4] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016
[5] Basic and Clinical Neuroscience (2016) 7(3), 187-194
[6] Hacke W et al., Stroke (2014); 45(11):3187-93
[7] Tarique Perera, Brain Stimulation (2016) 9, 336–346
[8] George MS. Arch Gen Psychiatry. (2010) 67(5), 507-16

profiles of TMS are advantageous, with the technique being non-invasive, generally well-accepted and devoid of systemic side-effects. The use and extension of superficial TMS in psychiatric disorders other than depression may be limited by the power of penetration (2-3 cm on average), which allows mostly targeting the gray cortical matter up to the junction with white matter.[9] However, deep TMS (dTMS) can lead to a noninvasive stimulation of a deeper area of the brain, up to 4 cm of depth depending on the configuration of the specific H-coil being used,[10] compared with the classic figure-of-eight coils. This increased stimulation depth is achieved due to the multiple windings in multiple planes inside the H-coil helmet. The magnetic fields of these multiple windings improve the depth of penetration of the electromagnetic field without the need for increased electric intensity. Moreover, the H-coils' configuration includes elements which are mostly tangential to the skull, thus enabling better electromagnetic field penetration. Finally, the H-coils stimulate larger areas, i.e. ~17 cm^3 of the brain tissue with the H1, compared with the ~3 cm^3 of conventional figure-8 coils, when both are operating at 120% of motor threshold (MT). This volume difference can affect extensive neuronal pathways, including deeper cortical regions and fibers targeting subcortical regions, finally eliminating the need for imaging and neuronavigation and making the treatment less costly and more tolerable.[11]

A large multisite randomized controlled trial (RCT) involving 212 patients for up to 16 weeks of acute and maintenance phases suggested that dTMS monotherapy was significantly more effective than sham dTMS in reducing depression scores on the Hamilton Depression Rating Scale, with a 0.76 effect size, and in improving response (38.4% *vs* 21.4%) and remission rates (32.6% *vs* 14.6%).[12] The technique has also shown some positive results in the treatment of psychiatric disorders, such as bipolar depression,[13] obsessive compulsive disorder,[14] PTSD,[15] cognitive and negative symptoms in schizophrenia [16] and neurologic disorders, like Parkinson's disease,[17] stroke rehabilitation,[18] and chronic pain.[19]



Source: Brainsway

[9] B. Benatti et al. Evidence-based Psychiatric Care review (2016), 2, 77-8
[10] Roth Y et al. Neuromethods. (2014) 89, 57–65.
[11] A. Tendler et al. Expert Review of Medical Devices (2016) 13, 10, 987-1000
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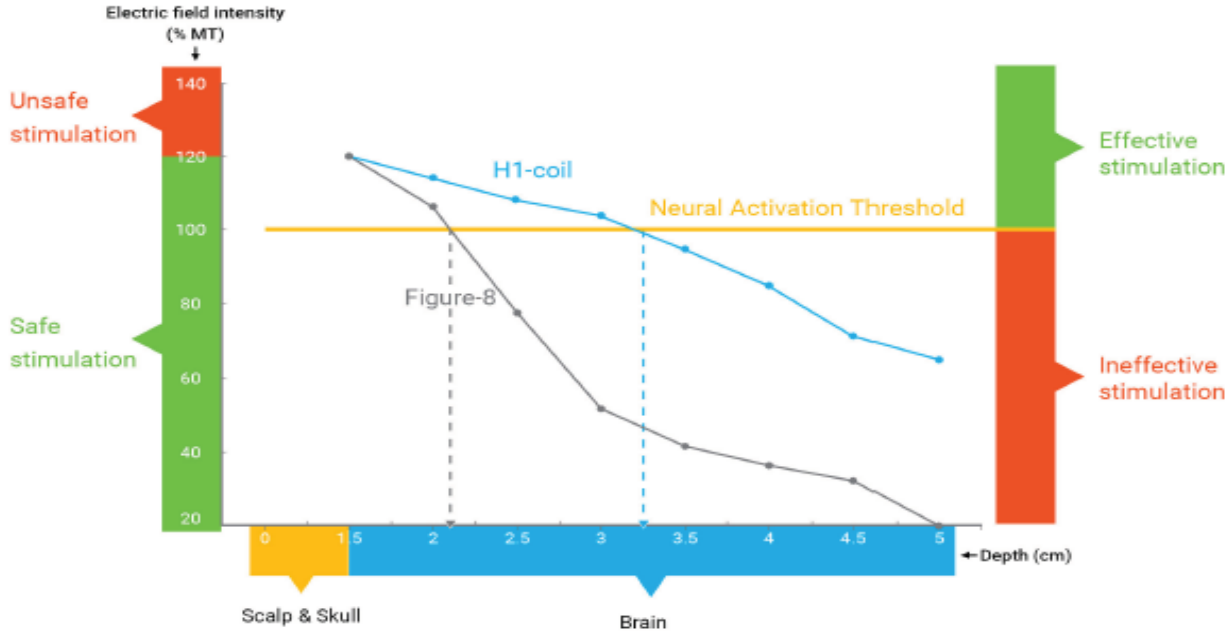
[14] Modirrousta M, et al. Depress Anxiety (2015) 32:445-50
[15] Karsen EF, et al. Brain stimul (2014) 7:151-7
[16] Levkovitz Y, et al. Int J Neuropsychoph (2011), 14:991-6
[17] Cohen OS, et al. Clin Neurol Neurosurg 2015;140:73-8.
[18] Chieffo et al. Arch Phys Med Rehabil (2014) 95:1141-1147
[19] Onesti E et al. Eur J Pain (2013) 17:1347-1356

Other TMS coils might achieve their claims of depth penetration at the cost of stronger activation of superficial regions, which may be intolerable by the patient. Brainsway's unique and proprietary H-Coil structure offers a good compromise between depth and focality with less sensitivity to coil orientation, allowing deeper electric field penetration at safe and tolerable stimulation levels. The produced, directed electromagnetic fields can induce excitation or inhibition of neurons deep inside the brain by controlling the operating frequency. Moreover, the device includes several different types of coils, designed to target various parts of the brain, with a process tailored for each disorder. These proprietary coils optimize the utilization of the energy and allow for deep, noninvasive stimulation of the brain, 2.5 times deeper than Standard TMS. Deeper prefrontal cortex structures have significantly more neuron connections with other reward system sites compared with superficial structures, thus allowing for better treatment results.



Source: [20] Decay profiles of the electric fields produced by the H1-coil and figure-8 coil. The maximal depth of effective penetration can be read off the graph at the points of intersection of the decay curves with the threshold for neuronal activation.

Market Overview

Brainsway is a player in the market for Neuromodulation devices, which are medical devices that use electrical or magnetic pulses to stimulate neurons and consequently modulate a body organ's physiological activity. The principle behind this technology has long been explored, but very few companies have developed this concept for commercialization until a decade ago. The neurostimodulation industry is rapidly progressing and is primed for future growth. An increase in medical device innovations by new entrants, primarily minimally or non-invasive for the treatment of psycho-neurological disorders, has gained significance in a market once ruled by pharmaceutical companies.

[20] Rosenberg O, et al. Depress Anxiety (2010) 27:465-9

The neuromodulation market is dominated by invasive technologies such as Deep Brain Stimulation (DBS), Spinal Cord Stimulation (SCS), Vagus Nerve Stimulation (VGS) and Sacral Nerve Stimulation. There is a wide commercial adoption of these technologies for various indications, including: Chronic Pain, Urinary and Fecal Incontinence (UFI), Refractory Epilepsy, Parkinson's, Essential Tremor and Dystonia and Major Depression Disease (MDD), the indication for which Brainsway holds marketing approval since 2013.

On the other hand, a high degree of invasiveness, high costs, surgical risks and other complications have resulted in end-users adopting non-invasive therapies as a therapeutic option, with the most commonly used being magnetic stimulation. Over the past recent years, magnetic stimulation has gained significance among end-users such as clinicians and patients as a reliable non-invasive method of nerve stimulation. In 2008, the FDA approved NeuroStar Transcranial Magnetic Stimulation (TMS) Therapy developed by Neuronetics for use in adults suffering from treatment-resistant depression, and Brainsway received approval for deep TMS technology in 2013. Other companies, such as Magstim and MagVenture, have entered the market with TMS devices since then. The therapy is provided with prescription and enables patients to undergo treatments at their convenience, at a physician's office or a mental health center with no need of anesthesia. More than 1,200 TMS devices are estimated to be available on the market globally, with more than 15,000 patients being treated only with Brainsway's devices.

The neuromodulation market is consolidated in nature with major players that develop invasive technologies such as Medtronic (U.S.), St. Jude's Medical (U.S.), Cyberonics (U.S.), and Boston Scientific Corporation (BSC) (U.S.) having a significant market share. Medtronic leads the market, whereas Cyberonics witnessed the highest CAGR in the market over the past 5 years.[21] Other competitors include Nevro Corporation (U.S.), DePuy Synthes (Johnson & Johnson) (U.S.), Neuropace, Inc. (U.S.), Aleva Neurotherapeutics (Switzerland), Beijing Pins Medical (China).

On the non-invasive side, TMS therapy is commercially available today, primarily for treating depression and incontinence, whereas marketing approval for other indications has not yet been clinically validated. Neuronetics (US) and Kitalpha Med (Germany) are notable companies that commercialize such devices for therapeutic usage. Neuronetics was reported to have 600 systems installed and to have treated over 25,000 patients.[22] The Neurostar device was approved *de novo* in 2008, and has been subject to further developments with the latest 510(k) approval in 2014. Key players that provide TMS technology include: Magventure (Denmark), Nextsim (Finland), Magstim (US), Axilum Robotics (France), MAG & More (Germany), Neurosoft (Russia), Remed (Korea), eNeura Therapeutics (US), Neurosigma, Inc. (U.S.), Dr Langer Medical (Germany). Additional novel noninvasive technologies are being researched, while others have been commercialized. Examples include Tal Medical's use of Low Field Magnetic Stimulation (LFMS) to treat Depression, SynSonix's pulsed ultrasound for the treatment of Parkinson's disease and epilepsy, transcranial laser therapy for stroke,[23] and infrared therapy for pain. All these may offer alternatives for clinicians across the continuum of care.

Most technology innovations take place in the US, followed by Europe, and Israel at companies such as Briansway for deep TMS, BrainsGate Ltd. for treating stroke, and BioControl Medical for treating heart failure. Technologies developed in Israel are primarily aimed at both the US and European markets. Though little technology-related activity has been carried out in regions such as Japan, China, Korea, and South America, there is much potential for existing companies to expand into these regions through their offerings.

Despite the promise shown by neuromodulation devices, the concept of resolving a disorder or disease using a neurostimulator device has been only partially embraced. A few issues concerning the adoption of these technologies exist in the US, primarily due to regulatory and reimbursement matters, coupled with the need to establish extensive clinical data. Marketing capability is also a major factor entrusted with creating awareness among the clinician

[21] https://www.researchandmarkets.com/research/rlbmh8/global
[22] Neuronetics website
[23] Philip V. Peplow, Neural Regen Res. (2015) 10(8): 1186–1190

community on upcoming technologies. Even if regulatory approval milestones are successfully achieved, companies still need to maintain a long-lasting relationship with the Center for Medicare/Medicaid Services (CMS) in the US, and create awareness regarding the effectiveness of their therapy, in order to boost device sales and usage among end-users.

A "Non-Depressed" Market

The total neuromodulation market size is estimated to reach $6.2 billion in 2020 at a CAGR of 11.2%. Dominated by invasive solutions provided by four large US companies, it is experiencing strong growth. Other participants, such as Nevro Corp, have the potential, sooner or later, to become major participants. A high-market growth rate is expected in three key areas of neurostimulation: deep brain, spinal cord and sacral nerve stimulations. This could be attributed to a "lag phase" in commercialization of drug-related therapies from research till reimbursement, and the failure of drugs in clinical trials, which have created a huge demand among customers to search for alternative means of therapy.

Neuromodulation: Market Profile, Global, 2016

Measurement Name	Measurement	Trend
Market Stage (Nascent, Growth, Mature)	Growth	
Market Revenue (Top 4 Competitors, 2015)	~$3 Billion	
Market Concentration	Consolidated	
Major Participants (80%+ Market Share)	Medtronic, St. Jude Medical, Boston Scientific, Cyberonics	
Other Participants	Cogentix Medical, Nevro Corporation, ImThera Medical, Autonomic Technologies, EnteroMedics	

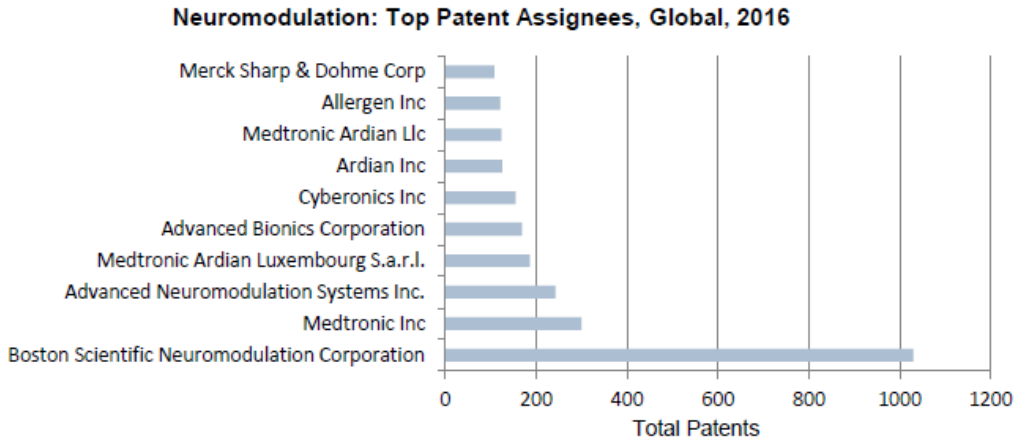
Neuromodulation: Key Drivers & Challenges, Global, 2016

Source:Frost & Sullivan.[24] Yellow indicates sustained trend over the last few years, green indicates increase in trend

Threat of new entrants affects the pipelines of Original Equipment Manufacturer (OEMs). For instance, Medtronic strategically acquired Advanced Uro Solutions for Nuro Percutaneous Tibial Nerve Stimulation system in 2015. Such acquisitions enable OEMs to improve sales, while responding to pricing pressures worldwide.

Intensive IP (intellectual property) creation activities are taking place worldwide, having exponentially increase over the past decade, with over 70% of patents filed in the US. Yet, neuromodulation therapies (mostly invasive ones such as dbs, scs, and spgs) are considered last-resort options for patients that have failedto respond to medications. Although Invasive therapies are widely reimbursed worldwide, they are still a long way from becoming a mainstream treatment.

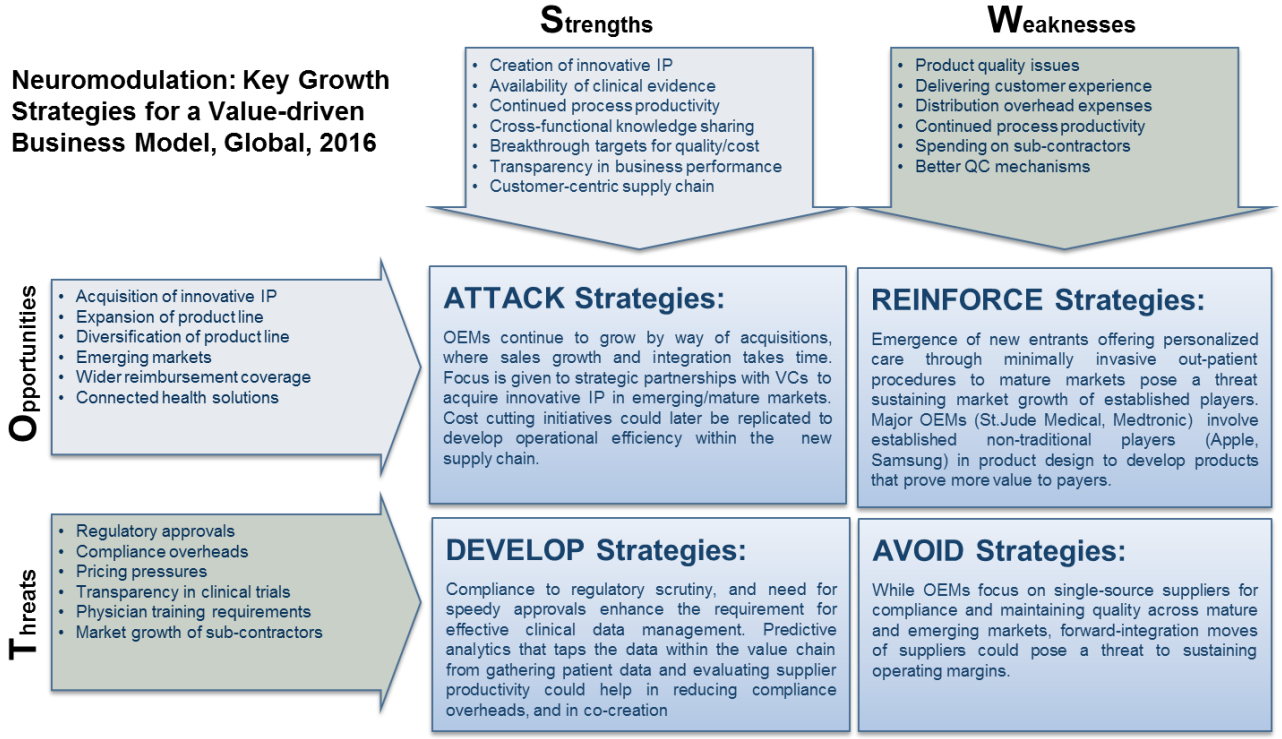
[24] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016



Source: Frost & Sullivan[25]

The non-invasive nature of therapy is gaining precedence over other forms of therapy, providing hope to patients suffering, for instance, from treatment-resistant depression. Noninvasive treatment of diseases, such as major depression, which are currently addressed using invasive DBS and VNS therapies, improves depth of market penetration. Nevertheless, while non-invasive stimulation has the high capability to penetrate markets for a range of applications, the current adoption rate of these therapies is low. To date, only several products have been approved by the FDA and CE for limited applications such as depression.

Chronic Pain is identified as the largest application segment of the neuromodulation market. Urinary and Fecal Incontinence (UFI) is the second leading segment in this market. Refractory epilepsy is the third, and Parkinson's disease holds the fourth highest share. These four segments are followed by Gastroparesis, Essential Tremor and Dystonia, respectively.[26]

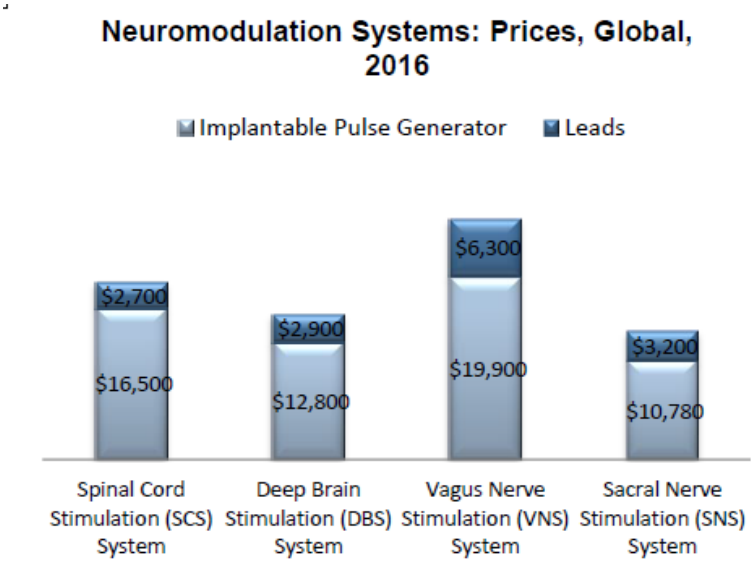


Source: Frost & Sullivan [25]

[25] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016
[26] http://www.prnewswire.com/news-releases/global-neuromodulation-market-by-application-technology-region-and-company-and-forecast-to-2021---research-and-markets-300452153.html

Drivers & Restraints

- High cost of treatment is restraining growth of the neuromodulation market. Prices of neuromodulation devices are in the range of thousands of dollars, with invasive implantable devices (consisting of lead-nerve cuff electrodes and a pulse generators) being the most expensive. Treatments with TMS technologies involve multiple sessions (at approximately $200-300 per session), with no less than 20 to 30 sessions required to provide therapeutic benefits to patients. Thus, the total cost is on average $5,000-$10,000, still less when compared with VNS Therapy that costs approximately $25,000 for both device and implantation. In the US, the benchmark for a cost-effective treatment is based on whether the cost of a QALY (quality-adjusted life-year) comes in at less than $50,000. For TMS, one QALY costs $36,000, which makes it cost-effective.[27] Development of Brainsway's new multi-channel stimulator might be of particular interest in reducing the overall time duration of treatment and subsequently its cost.
- Consumers that are insured pay approximately $70/month out-of-pocket on drugs for treating depression, or at the most a couple of hundred dollars monthly for newer branded drugs with lower side effects or, cocktails of medications. Prices for these drugs are considerably lower than for medical devices. Thus, among other reasons, neuromodulation therapies are considered second line, or last-resort options for patients, and only after medications have failed; otherwise these therapies cannot be covered by insurance companies.



Source: Frost & Sullivan.[28] Prices for invasive technologies comprising the pulse generator that stimulates the nerve and lead (the metallic component that cuffs the nerve)

- Negative social perception inhibits noninvasive technology from becoming a mainstream treatment. Electroshock therapy, for instance, which is still considered to be the most effective method for treatment of depression and other psychiatric disorders,[29] continues to be the most stigmatized treatment available in psychiatry, a fact that hinders people from pursuing it.[30]
- Noninvasive technologies enable patients to receive therapy at a physician's office or medical center. There is no need for hospitalization or anesthesia and there are negligible side effects. Complex surgical intervention, e.g., drilling into the skull for deep brain stimulation, is not required, as in the case of invasive technologies. Moreover,

[27] Raeburn P, Cost Repetitive TMS, Med Page (2016)
[28] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016
[29] Dukakis KTLS. Shock: the healing power of electroconvulsive therapy; 1 edition: Avery, New York (2006)
[30] Payne NA, Prudic J, J Psychiatr Pract (2009)15(5):346–368

there is a clear benefit for noninvasive technologies, if clinically proven, to become an alternative to drugs rather than a second line of therapy or last resort, as in the case of invasive therapies.

- Reimbursement issues and third party insurance coverage from Medicare, Mediclaim or other private companies for neurostimulation therapies present critical challenges. CPT (Current Procedural Terminology) codes are listed in the US, particularly for TMS treatment of major depression. 90% of the U.S. population carries health insurance plans that cover TMS treatment, for patients who fail to benefit from at least one prior antidepressant in the current episode. Several studies,[31] found that approximately 50% of patients treated fall into this category.

CPT Code	Description
0310T	Motor function mapping using non-invasive navigated transcranial magnetic stimulation (nTMS) for therapeutic treatment planning, upper and lower extremity
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management

CPT® is a registered trademark of the American Medical Association

Source: United HealthCare Services, Inc. [32]

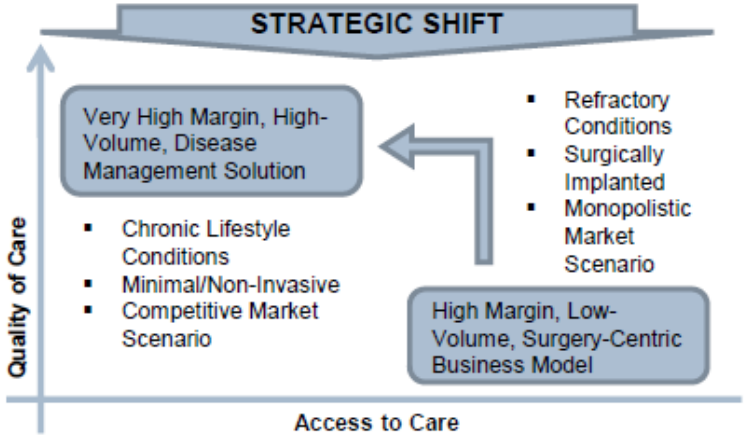
Each indication requires a listed CPT code, even if the same medical device is used for different indications. Challenges within the reimbursement fold include: Unlisted CPT codes, unsatisfactory demand for well-established clinical trial publications from the Center for Medicare/Mediclaim Services (CMS), a low HEDIS (Healthcare Effectiveness Data and Information Set) ranking that is a registered trademark of the National Committee for Quality Assurance (NCQA), and third party insurance payers.

- Insufficient clinical evidence is available on the therapeutic effect of the technology (small sample size, lack of a validated sham comparison in randomized controlled studies, and variable uses of outcome measures).[29] According to The Clinical TMS Society Consensus Review there have been only three large, multisite, randomized sham-controlled trials that included an aggregate sample of 703 adult patients with major depressive disorder (MDD).[33] In 2013, private US insurance companies such as UnitedHealthcare, Aetna, and Cigna stated that the role of TMS in the treatment of depression and other disorders had not been clearly established.[34] Only in 2015 and 2016 did these companies start to cover Brainsway's deep TMS treatment for depression, giving a boost for other indications to come.

Market Trends and Future Markets

A strategic shift is occurring as consumers move from invasive to non-invasive technologies , with companies developing therapies for lifestyle chronic diseases, and not only acute disorders. Accordingly, the clinical applications of neuromodulators are expanding to treat lifestyle disorders such as obesity, low back pain, hypertension and headache, which hold commercial attractiveness upon availability of clinical evidence. Findings clearly suggest that there is a shift toward minimally-invasive and connected health technologies that enable patients to receive therapy at the convenience of a physician's office or at home.

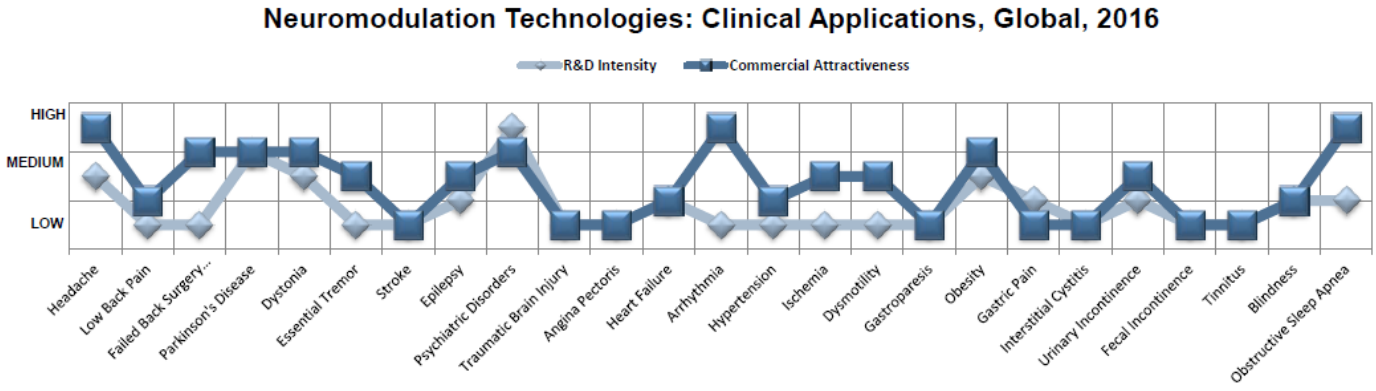
[31] Rush et al. (2006) American Journal of Psychiatry
[32] Transcranial Magnetic Stimulation, Copyright 2017 United HealthCare Services, Inc
[33] Tarique Perera, Brain Stimulation 9 (2016) 336–346
[34] Transcranial Magnetic Stimulation. Copyright 2013 United HealthCare Services, Inc. http://www.webcitation.org/6Ln87XaDU



Source: Frost & Sullivan[35]

The neuromodulation market can be seen as a tradeoff between quality of care and access of care. Quality of care refers to the level at which a treatment is considered safe, effective, durable, sustainable, provides fast recovery, and the degree of side effects. Access of care refers to cost of therapy, level of reimbursement, availability of therapy, trained physicians and the ability of a patient to pay for the treatment. A strategic shift is taking place in the neuromodulation market, from one that is dominated by a few companies with high margins, to a market with very high margins, with new players and new products focused on solutions for managing chronic lifestyle disorders such as diabetes, obesity and hypertension. The cost of treatment is still not low, but patients are ready to pay for clinically proven alternatives to drugs, or for non-invasive or minimally-invasive therapies that target a range of disorders offering a meaningful value proposition for improved quality of life in the long-term. Patients show increasing interest in adopting a disease management solution rather than paying for a one-time high-cost surgical implantation, a trend that plays in favor of non-invasive therapies.

The following chart reflects the market demand for non-invasive methods and therapies for lifestyle disorders.



Source: Frost & Sullivan[35]

- Clinical trials focusing on psychiatric disorders such as Tourette syndrome, obsessive compulsive disorder, depression, schizophrenia, Huntington's disease, Alzheimer's, anorexia nervosa and bipolar disorders are leveled high, which is also seen to be a segment of high commercial attractiveness.

[35] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016

- There is significant demand for research on cardiovascular disorders by existing participants in the market, which include Medtronic and Boston Scientific that are investing significant resources on generating sufficient clinical evidence for conditions, such as arrhythmia, ischemia and heart failure.
- With only one approved product in the market for obesity, clinical trials of therapies for obesity have increased over the past five years. Adverse effects associated with drug intake have pushed obese patients to consider neuromodulation as a treatment option.
- Applying magnetic stimulation in treating debilitating neurological disorders may pave the way for using the technology in further applications.
- Major OEMs (including St.Jude Medical and Medtronic) strategically involve established non-traditional players (such as Apple and Samsung) in product design to develop products that provide more value to payers. The Invisible Trial System launched by St. Jude Medical in 2015 that uses Apple's programming interface and Bluetooth SIG‟s wireless technology, is an example.

Key Trends and Financial Environment for the Neuromodulators Industry

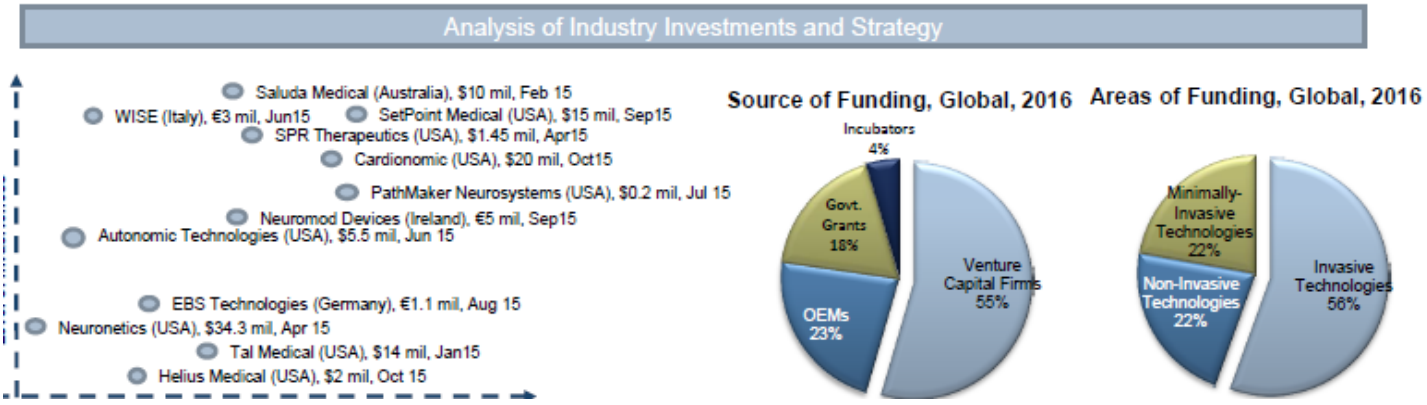
There has been an increase in cross-selling agreements with pharmaceutical companies, as can be seen in the following table that summarizes this activity for 2015.

OEMs	Partners	Year	Partnership	Strategic Intent
Medtronic	Samsung	Dec-15	Product Development	To develop connected health solutions that enable doctors, patients to use Android smartphones and tablets to manage therapies for chronic pain, movement disorders, incontinence and other conditions.
Greatbatch	NEA, Cleveland Clinic, Cardionomic	Oct-15	Strategic Investment (Series-A)	Continue clinical trials on neuromodulator to treat acute decompensated heart failure (ADHF).
Boston Scientific	Covedien Ventures, GlaxoSmithKline, SetPoint Medical	Sep-15	Strategic Investment (Series-C)	Advance clinical studies on neuromodulator to treat rheumatoid arthritis and Crohn's disease
Johnson & Johnson	CVRx, BBT Fund, SightLine Partners	Jul-13	Strategic Investment	Drive strategic investment via Johnson & Johnson Development Corporation (JJDC) for furthering clinical trials and expansion of CVRx products
St. Jude Medical	NeuroTherm		Acquisition	Diversify product portfolio for market expansion
Boston Scientific	Brainlab AG	Apr-15	Sales Agreement	Bundled distribution of Brainlab DBS surgical planning portfolio with Vercise DBS System in Europe, Israel, Australia, Latin America and Asia Pacific
Sky Medical Technology	Domtar	Aug-15	Sales Agreement	Complementary resources for clinical trials, and to further market access to enter UK and Norway markets by tapping the existing channel of Domtar, which is catering to urinary incontinence markets with Attends and INDAS portfolio of products
Cyberonics	Sorin Group	Oct-15	Merger	Technology and market access to gain market share in Europe and Japan; with products for heart failure, sleep apnea
Legend Holdings	Axonics Modulation Technologies, Edmond de Rothschild Partners, NeoMed Management, The Alfred E.Mann Foundation	Dec-15	Strategic Investment (Series-B)	To conduct multi-center clinical studies in Overactive Bladder in Europe and North America
Medtronic	Fountain Healthcare Partners, Mainstay Medical	May-14	Strategic Investment (Europe IPO)	To drive commercialization of products in Europe and FDA approval
Greatbatch	Lake Region Medical	Aug-15	Acquisition	To expand contract research capabilities in the neuromodulation sector
A&B Company Limited	Helius Medical	Oct-15	Strategic Agreement	To develop (own IP) and commercialize (sales transactions) Helius Portable Neuromodulation Stimulator indicated for treating chronic neurological symptoms of traumatic brain injury in China, Hong Kong, Macao, Taiwan, and Singapore.

Source: Frost & Sullivan[36]

In addition, consolidation trends attract prospective investments within the global industry. For instance, in April 2015, GE Ventures joined a Series-F investment round in Neuronetics, a company pioneering non-invasive transcranial magnetic stimulation therapy for patients with major depressive disorder, a treatment similar to that offered by Brainsway. We believe that entry of minimal/non-invasive technologies with strong IP, regulatory approvals (CE/TGA) and strong clinical data for chronic lifestyle disorders would drive further consolidation within the market through acquisitions by OEMs, providing exits for VC/PE firms.

[36] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016



Source: Frost & Sullivan[37]

OEMs race against VC/PE firms to invest in neuromodulation technologies.

- While OEMs continue to gain ground in establishing safety/efficacy of existing products in mature markets through clinical trials, their VC divisions continue to invest early in technologies that enable the creation of new products/services for existing markets, while reducing costs of acquisitions of such technologies once commercialized. A case-in-point is Covidien Ventures' (Medtronic) investment in Entellus Medical (Aug 2011, $35 mil), Nevro Corporation (Mar 2013, $48 mil), and SetPoint Medical (Aug 2013, $30.6 mil).

- Market expansion activities of OEMs have been largely restricted to acquisitions, where the addition of new products has enabled organizations to both scale customer base for their clinically proven therapies worldwide. However, such strategic acquisitions have been driven by synergies in leveraging the low-cost and established supplier relationships of acquired firms, rather than the value of the firm's intellectual portfolio.

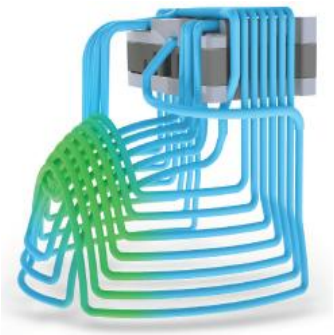
  With positive scenarios on reimbursement, traditional OEMs enter the neuromodulation market by investing in companies that have been widely recognized for safety and efficacy in patients. An example is GE's 2015 investment in Neuronetics, a company pioneering non-invasive transcranial magnetic stimulation therapy for patients with Major Depressive Disorder, a treatment similar to that offered by Brainsway. Consequently, Neuronetics are considered a competitor for Brainsway and their technology.

[37] Frost & Sullivan report, Neuromodulation Technologies – Strategic Perspective, February 2016

Company's Products

Brainsway is a medical device company focused on the development and commercialization of a helmet-device for deep Transcranial Magnetic Stimulation (dTMS). The H-coil helmet is the product and the real asset of the company, widely and globally protected by the company's patents. Brainsway's target markets include clinics and medical centers that treat populations with multiple Neuro-Psychiatric indications. Different H-coils are utilized to study and treat a variety of psychiatric and neurological conditions with identifiable brain targets. For each indication, a specific H-coil helmet is tailored according to the stimulation area of the brain and intended protocol of treatment. Moreover, Brainsway is currently developing a multi-channel stimulator that will serve as an integral part of its product, enabling treatment protocols that are not possible with commercially available off-the-shelf stimulators provided with the helmets as commercially available today, given as a part of the product. Brainsway's simulator will allow the treatment of the most complicated brain disorders through a combined synchronized differential activation of different brain regions in parallel.

Currently, the technology has FDA clearance for depression and European clearance for additional disorders. The H1-coil is the most tested coil.[38] In the US, dTMS using the H1-coil is FDA cleared for treating unipolar major depression in patients that have failed to respond to medication. In Europe, dTMS using the H1-coil is cleared for the treatment of unipolar depression, bipolar depression, negative symptoms of schizophrenia, and post-traumatic stress disorder (PTSD), while several other H-coil versions designed to target other brain networks are cleared for the treatment of Alzheimer's disease, chronic pain, smoking cessation, obsessive compulsive disorder (OCD), autism, Parkinson's disease, stroke rehabilitation, and multiple sclerosis (MS). Additional coils with significant clinical evidence and ongoing multi-site clinical trials are the H4 for patients with addictions and the H7 for patients with OCD and PTSD.



The Deep TMS H1-Coil

Source: Brainsway

Brainsway's deep TMS is a platform technology, and its feasibility to treat patients suffering from Major Depressive Disorder (MDD) is only the first indication for exemplifying a new form of treatment of brain disorders with additional indications pending. The company has succeeded in commercializing its H1-coil helmet-device to treat MDD in the US market, and intends to replicate its sales and grow into other key markets for the treatment of other indications. Throughout the years, the company has gained significant clinical experience, conducting large multi-center trials for various indications, and is fully engaged and capable of advancing its clinical studies. It has a sales and marketing office based in the US that generates 90% if its revenue.

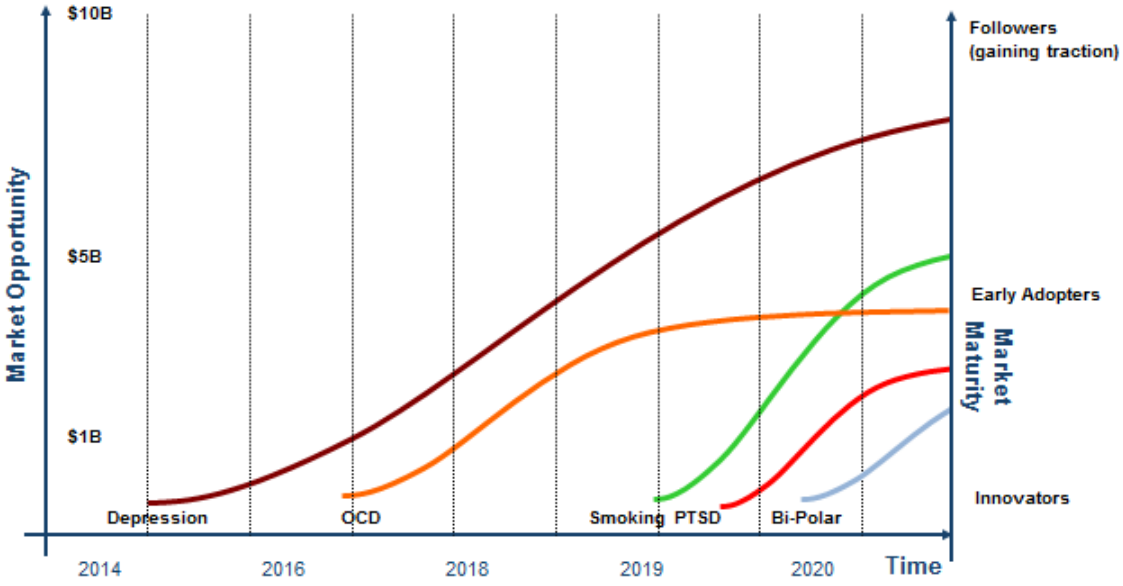
The system developed by Brainsway is intended for the treatment of brain disorders in the fields of psychiatry, neurology and addiction. It is non-invasive, does not necessitate anesthesia, and has no known systemic side effects. Adverse effects associated with this therapeutic approach involve a number of localized problems at the site of the coil placement. The most common problem includes application site discomfort or pain.

[38] A. Tendler et al. Expert Review of Medical Devices (2016) 13:10, 987-1000

Deep TMS practice protocols are similar to the ones that are used with conventional TMS. A deep TMS treatment session lasts approximately 20 minutes, whereas superficial TMS sessions range from 37-55 minutes in length. A typical deep TMS treatment protocol lasts 4-6 weeks with 3-5 sessions per week. Following these sessions, patients can continue with their normal daily routines.

On June 2017, Brainsway received positive final results in Obsessive Compulsive Disorder (OCD) patients; the company intends to submit an application for market approval in the US for this indication. Trials were conducted with an H7-coil helmet, with a coil specifically tailored to OCD that targets the anterior cingulate cortex (ACC) rather than the left dorsolateral prefrontal cortex (DLPFC), as with H1 coil in depression. Additionally, Brainsway has three pivotal multi-center trials underway with the goal of obtaining clearance for treating bipolar depression, post-traumatic stress disorder (PTSD), and smoking addiction. Altogether, it is conducting over 60 clinical studies worldwide. Additionally, during 2017 a multicenter trial is set to compare the efficacy of the two Brainsway deep TMS coils H7-coil to H1-coil in subjects with Major Depression Disorder (MDD).

Brainsway Platform– Roadmap Analysis

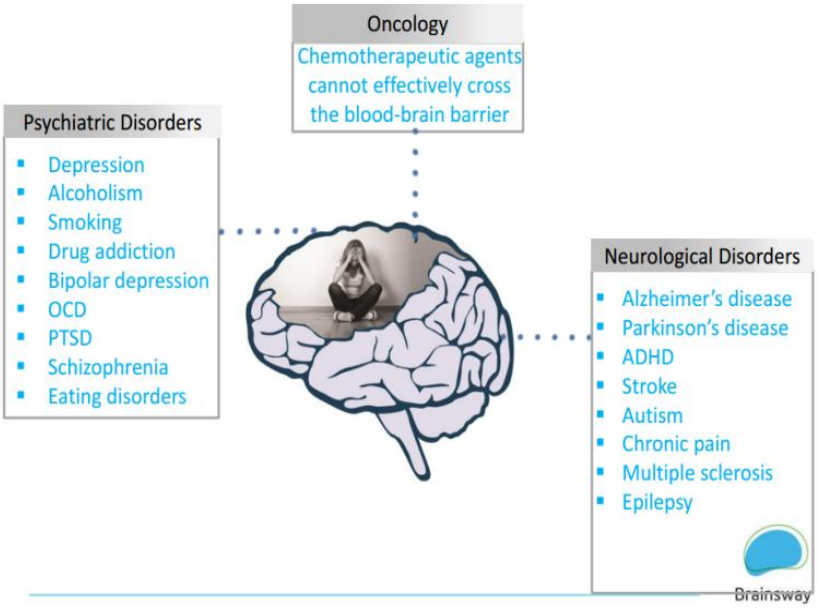


Source: Frost & Sullivan

Brainsway's technology is primarily based on discoveries and patents filed by the US National Institutes of Health (NIH) and by the company for deep TMS, and holds an exclusive license from the NIH for the patent and for the technology. Additionally, the company holds a license from the US Public Health Service (PHS) to develop, produce, utilize, import and sell any product or treatment that is based on these patents. Its technology is further covered globally by seven family patents that include the coils for the magnetic stimulation, the system and methods, and the use of TMS to modulate the permeability of the Blood-Brain Barrier. Some of its first patents filed in 2000 have already expired, some are still on examination, and some are issued with expiration dates from 2021-2029.

The company's pipeline consists of multiple indications involving: psychiatric disorders such as MDD, Bipolar Depression, OCD, PTSD, Schizophrenia, ADHD, Tourette, eating disorders; neurological disorders such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, neuropathic pain, stroke rehabilitation, autism & asperger's, epilepsy, migraine, tinnitus, and blepharospasm; oncological disorders such as blood-brain barrier opening for drug delivery; addiction disorders such as smoking, drug, alcoholism, and gambling. Each indication represents a product by itself, requiring the technological adaptations to adjust a helmet-coil and a protocol specifically per indication, followed by a set of clinical trials, regulatory, market and reimbursement approvals. The time lag between a patent filing date and a

registration date of the corresponding approval for a class II medical device such as Brainsway's by the European regulation authorities is, for instance, six years on average. [39]

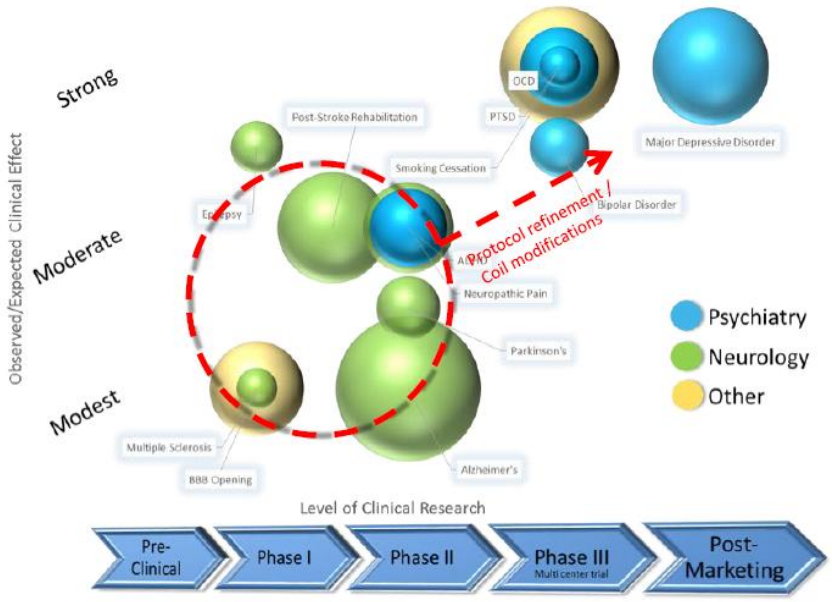


Source: Brainsway

A convincing form of "sham" TMS that matches the discomfort and noise of TMS, to test for placebo effects in conscious individuals is a challenging task. A 2011 review found that only 13.5% of 96 randomized control studies of TMS to the dorsolateral prefrontal cortex had reported blinding success.[40] According to the clinical TMS society consensus review, only three large, multisite, randomized sham-controlled trials in major depressive disorder (MDD) were conducted, including the two trials that led to FDA clearance for Neuronetics[41] and Brainsway.[42] All three trials were consistent in their evidence, establishing a statistically significant and clinically relevant benefit with TMS therapy compared to the sham condition. Brainsway's trial used an active sham method that fully blinded patients, treaters and raters.[43] The Brainsway's H-coil TMS system contains a sham coil placed inside the same helmet that generates an "active" sham that gives a sensation of a real treatment. The sham coil mimics the sound and scalp sensations induced by the active coil without having any stimulating activity.

Brainsway anticipates its timeline progress and clinical effect, according to the following chart. We believe that clinical success with neurological indications would be considered a true clinical breakthrough, and will have a major impact on Brainsway's market value. Positive, neurological clinical trial results are not anticipated before 2019-20, if at all.

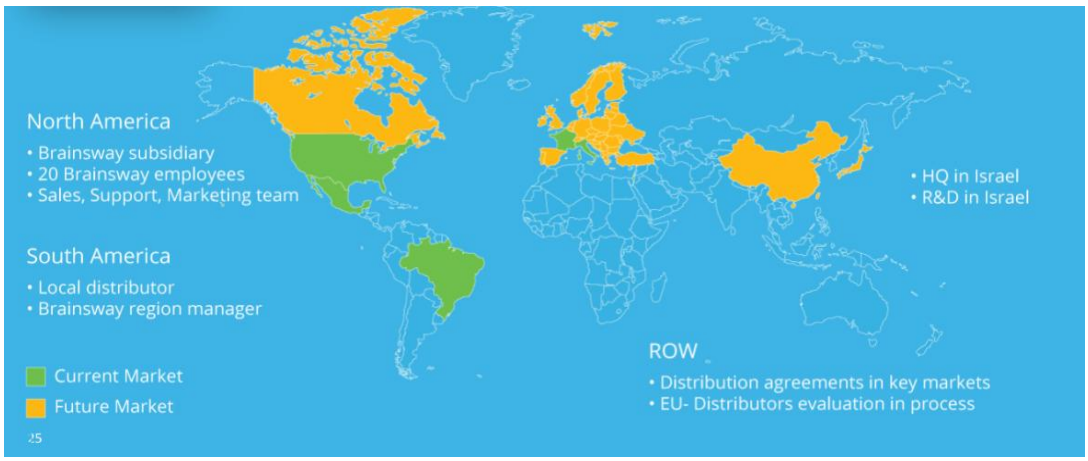
[39] Current Directions in Biomedical Engineering (2016) 2(1): 599–602
[40] Broadbent, HJ et al. World Journal of Biological Psychiatry (2011) 12 (4): 240–8
[41] O'Reardon, JP. Et al., Biol Psychiatry (2007) 62, pp. 1208-1216
[42] Y. Levkovitz et al., World Psychiatry(2015) 14 , pp. 64-73
[43] Perera T et al., Brain Stimulation (2016) 9, 336–346



Source: Brainsway. Estimation of Clinical Pipeline

In the US, from a regulatory point of view, Brainsway is classified as a class II medical device company, and received an FDA 510(k) clearance for Major Depressive Disorder (MDD). In Europe, the company holds the European certificate mark for 12 indications including MDD, Bipolar depression, Schizophrenia, Post-Traumatic Stress Disorder (PTSD), Alzheimer's, Parkinson's, Chronic pain, Stroke, Smoking addiction, Multiple Sclerosis (MS) and Obsessive Compulsive Disorder (OCD). In Israel, the company has an approval from the ministry of health for MDD, Bipolar depression, Schizophrenia, Post-Traumatic Stress Disorder (PTSD), Parkinson's, Neuropathic Pain, Smoking addiction, Alzheimer's and Obsessive Compulsive Disorder (OCD). The company also holds regulatory approvals for several indications in Canada, Brazil, Peru, Australia and Mexico.

The following figure indicates Brainsway's target markets. The company's technology is primarily aimed at the US, where 90% of Brainsway's current sales activity are taking place, Brazil, Japan, as well as in European markets, where its dTMS technology has CE approval for multiple indications. Although little technology-related activity has been carried out in regions such as China and Korea, these are markets with high potential for the company to expand.



Source: Brainsway

Clinical Data

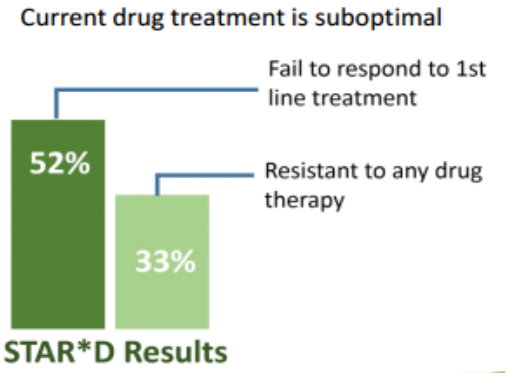
In the following section, we will elaborate on the most advanced indications that Brainsway treats, including Major Depressive Disorder (MDD), Obsessive Compulsive Disorder (OCD) and neurological indications such as Stroke Rehabilitation and Chronic Pain.

Major Depressive Disorder (MDD)

Major depressive disorder is one of the most prevalent pathologies of our time, ranked as the second leading cause of disability, according to World Health Organization (WHO),[44] affecting nearly 15 million American adults each year. [45] MDD is a psychiatric syndrome, a mood disorder, which causes a persistent feeling of sadness and loss of interest. The effects of depression are related to all aspects of life, from relationships and work, to basic daily routines. The physical source of depression lies in neural structures within the human brain. Various abnormalities in the electrical functionality of the limbic system, which comprises brain networks controlling our emotions and drives, lead to major depressive disorder.

Depression has been associated with reduced expression of brain-derived neurotrophic factor (BDNF) in the hippocampus.[46] Additionally, it has been shown that actual reduction of the BDNF protein in specific brain sites can induce depressive-like behaviors or affect neurogenesis in vivo, specifically in the dentate gyrus, but not the CA3.[47]

Major depression is often difficult to diagnose accurately, and there is no laboratory test to diagnose major depression.[48] Diagnosis is based on an individual's reported experiences and a mental status examination. It is estimated that about half of the individuals in the US who experience a major depressive episode annually are not diagnosed correctly. Of those who are identified and receive treatment (e.g., psychotherapy, medications, or various combinations of these therapies), only about 50% benefit.[49] This problem is highlighted by the results of several studies including the National Institute of Mental Health (NIMH)-sponsored Sequenced Treatment Alternatives to Relieve Depression (STAR*D) large study that included 4,040 participants.[50] Despite the availability of psychotherapy and over four classes and 30 distinct pharmacological agents, a large portion (32–52%) of the MDD population is still considered treatment resistant. Additionally, there is a high prevalence of behavioral health comorbidities which complicate treatment of care and further increase the cost.

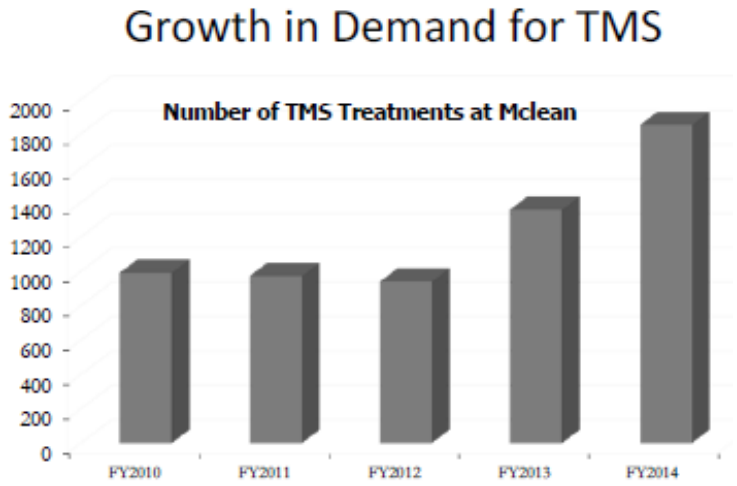


Source: Brainsway

[44] Ferrari AJ, et al. findings from the global burden of disease study 2010, Plos Medicine (2013) 10(11)
[45] Kessler RC, et al., Archives of General Psychiatry (2005) 62(6):617-627
[46] Smith MA, J Neurosci (1995) 15: 1768–1777
[47] Taliaz, D, Molecular Psychiatry (2010) 15, 80–92
[48] Janicak, P G, Neuropsychiatr Dis Treat. (2015) 11: 1549–1560
[49] Kessler RC, et al. The epidemiology of major depressive disorder (2003) 289(23):3095–3105
[50] Rush AJ, et al. STAR*D report. Am J Psychiatry (2006) 163(11):1905–1917

Electroconvulsive Therapy (ECT), formerly known as electroshock therapy, which has been available for over 75 years, is still considered to be the most effective method of treatment.[51] About 100,000 patients annually receive ECT in the United States.[52] Yet, the procedure is associated with side effects and continues to be the most stigmatized treatment available in psychiatry, a fact that hinders people from pursuing it. Clinically it is considered to be the 'last resort' and is used only for severely drug-resistant patients.[53]

Nonetheless, advances in the field of psychiatry exponentially increased the physician's toolbox. New classes of pharmacological drugs were developed, electroconvulsive therapy (ECT) protocols were optimized,[54] and focal brain stimulation techniques were invented.[55] Transcranial magnetic stimulation is a neuromodulation technique increasingly used to partly fill this therapeutic void. This increase is exemplified in recent years due to a growth in demand for TMS in psychiatric clinics and other treatment centers, such as McLean Hospital, the Psychiatric affiliate of Harvard Medical School, as well as a positive scenario on reimbursement for TMS treatment for MDD patients who had failed intake of medications.



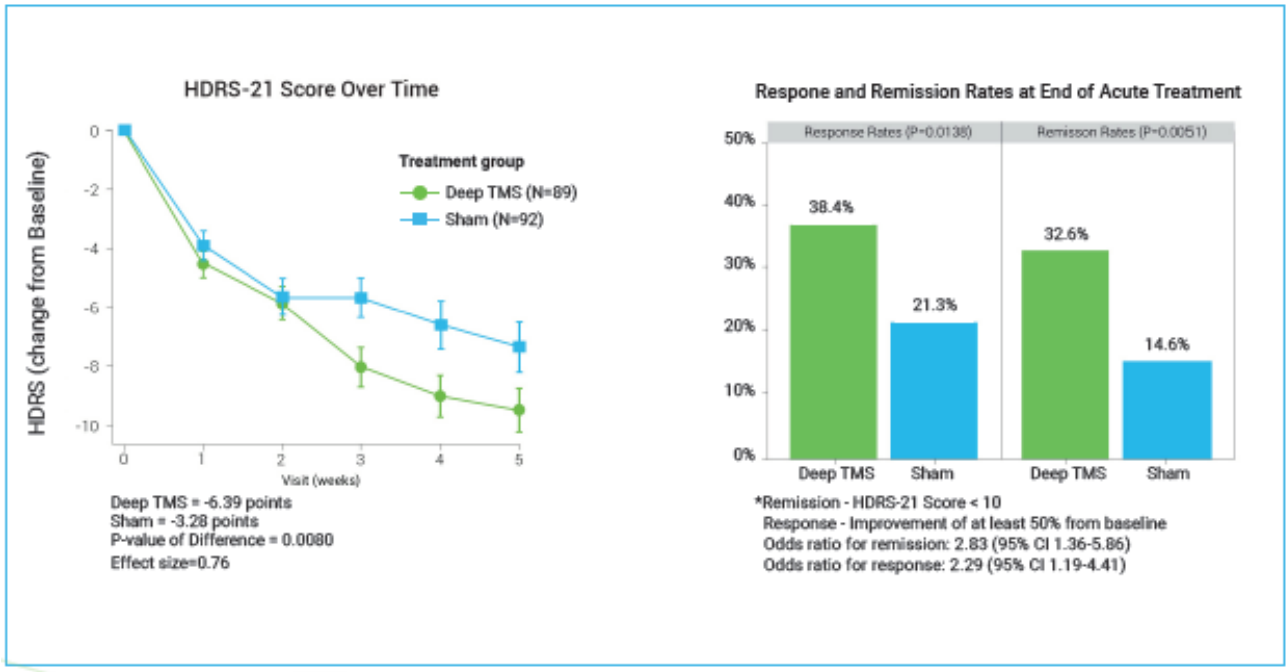
Source: The American Psychiatric Nurses Association [56]

Brainsway's H1-coil that is used for the treatment of MDD was designed to induce activation of left and right lateral and medial prefrontal cortex structures, with a preference to the left hemisphere.[57] The H1-coil is the most tested coil, available in numerous dTMS centers. There is early data suggesting that higher numbers of pulses may be helpful for patients with psychotic depression or schizoaffective disorder depressive phase as well as patients who failed ECT.

The company received FDA clearance in 2013 for treating depressive episodes in adult patients suffering from MDD, who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode. The true test of efficacy is the patient response in adequately powered randomized clinical trials. Remission is considered the preferred endpoint for treatment of major depression, as it is associated with the best prognosis for recovery.[58] A double-blind sham-controlled trial was performed in the Brainsway pivotal trial sampling 212 patients. The acute treatment phase was 5 sessions per week for 4 weeks, followed by a continuation phase of twice-weekly treatment for an additional 12 weeks. Stimulation parameters were 120% MT, 18 Hz frequency, train duration of 2 s,

[51] Dukakis KTLS. Shock: the healing power of electroconvulsive therapy;1 edition: Avery, New York (2006)
[52] Sadock BJ, et al. Brain Stimulation Methods, 10th ed. Lippincott Williams & Wilkins (2007) Chapter 36.37
[53] Lisanby SH, N Engl J Med.(2007) 1939-1945;357 (19)
[54] Payne NA, et al. J Psychiatr Pract (2009)15(5):346–368
[55] George MS, et al., Chinese Medical Journal; Free China Ed.(2002);65(8):349–360.
[56] APNA (The American Psychiatric Nurses Association) 29th Annual Conference, Session 4033: (2015)
[57] A. Tendler et al., Expert Review of Medical Devices (2016) 13:10, 987-1000
[58] Trivedi MH, et al. Int Clin Psychopharmacol (2009) 24:133-8

inter-train interval of 20 s and 55 trains per session, leading to a total of 1980 pulses over 20 min. The primary endpoint was the change score on the HAMD21 at week 5, which favored the active versus sham procedure (i.e. 6.39 point improvement active versus 3.11 points sham, $p < 0.001$). At week 5, the response rates were 38.4% for deep TMS versus 21.4% for the sham treatment ($p = 0.014$). Remission rates were 32.6% for TMS versus 14.6% for the sham treatment ($p < 0.01$). At week 16, the response rates were 44.3% for TMS versus 25.6% for the sham treatment ($p < 0.01$). Remission rates were 31.8% for deep TMS versus 22.2% for the sham treatment ($p = 0.15$).[59]



Source: Brainsway

Going deeper into the neurological effect obtained from TMS treatment, findings from animal models based on rats with inherent depressive-like behaviors, exhibiting lower levels of brain-derived neurotrophic factor (BDNF) in specific brain regions, support responsiveness to electroconvulsive treatment with stimulation parameters similar to those used in TMS for major depression in human patients.[60] Additionally, it was found that high-frequency stimulation during rTMS induces a profound, long-lasting effect on neuroplasticity markers (BDNF and GluR1) which may underlie the clinical benefits of this treatment in neuroplasticity-related disorders.[61]

An on going trial to compare the efficacy of the H7-coil to H1-coil dTMS in subjects with Major Depression Disorder

A multicenter double blind randomized controlled trial is on going during 2017, aiming to compare the efficacy of the H7-Coil to H1-Coil deep Transcranial Magnetic Stimulation (dTMS) in subjects with Major Depression Disorder (MDD). H1 coil is the FDA cleared coil for major depressive disorder (MDD), whereas H7 coil is the coil used in the trial for OCD which recently yielded positive results. It is also currently in use as part of the PTSD trial. The study's hypothesis is that certain MDD patients will benefit from a treatment with the H1 coil, while certain patients will benefit more from treatment with the H7 coil. Both coils can treat the MDD brain structures related to deficiencies in the brain's 'reward system' network. Moreover, the study will include EEG measurements in order to find specific EEG-based neuromarkers that can predict the response to each of the two treatments. One of the main objectives of the trial is to

[59] Levkovitz Y, et al., World Psychiatry (2015) 14:64–73
[60] H. Moshe et al. ,Brain Stimul. (2016) 9(2):243-50.
[61] Roman Gersner,The Journal of Neuroscience (2011) 31(20):7521–7526

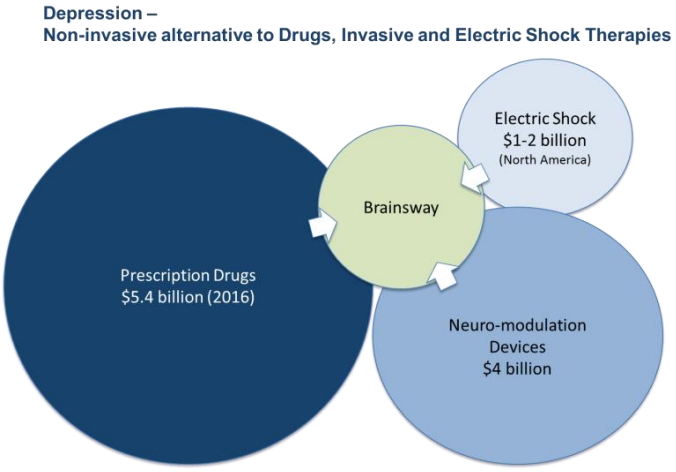
provide physicians with a simple set of EEG tests that will enable them to assign the MDD patient, with a high degree of certainty, either the H1-Coil treatment or that with the H7 coil, and accordingly increase treatment effectiveness.

Market for Treatment of Depression

Major depressive disorder (MDD) is a commonly occurring disorder, which affected approximately 216 million people (3% of the world's population) in 2015.[62] In the OECD countries the prevalence of depression stands at 4.5% of the population, and in the last decade (2005-2015), the rate of depression has increased by 18.4%. One in 6 adults in the US suffers from a major depressive disorder episode during his or her lifetime, and in any given year there are 15 million Americans who suffer from a major depressive episode.[63] A total of 4.8 million people in the US are considered Treatment-resistant Depression (TRD) patients, and this number stands at 17 million worldwide.[64]

According to the company, 1.5 million Americans are treated in solo practice, 1.2 million in group practice, 1.8 million in University hospitals, and 0.04 million in community hospitals. In 2016, 37,518 certified American psychiatrists were reported to be active in the field.[65] There are approximately 21,000 Psychiatric clinics across the US.

Subject to clinical acceptance and effectiveness, the potential market share of Brainsway's dTMS for treating MDD can be calculated as the sum of certain percentages of three alternative therapies: drugs, invasive neurostimulation technologies, and electric shock (ECT).



Source: Frost & Sullivan

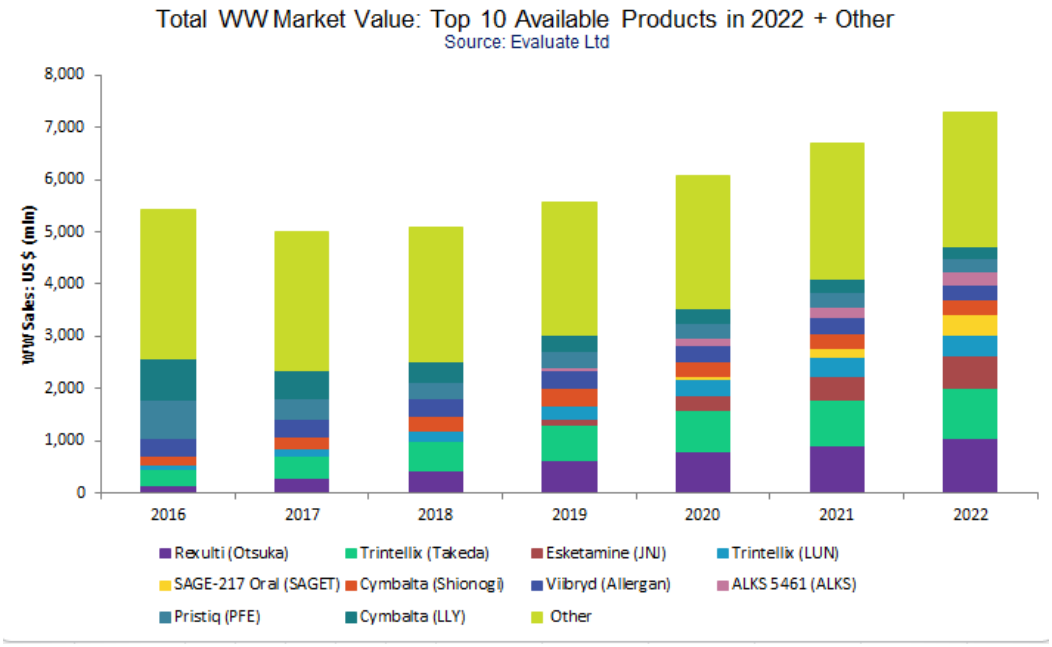
Approximately $64 billion was spent on prescription medications for the treatment of various brain disorders in 2014 (company). Of this amount, the market for depression medications in the US totaled $5.411 billion in 2016 and is forecast to reach $7.282 billion in 2022, as shown in the following table:

	2016	2017	2018	2019	2020	2021	2022
Rexulti (Otsuka)	162	283	443	622	791	917	1,042
Trintellix (Takeda)	295	434	539	671	785	871	956
Esketamine (JNJ)				129	283	452	620

[62] *Lancet*. (2016) **388** (10053): 1545–1602
[63] Brainsway 2016 financial report
[64] https://www.pharmorx.com/about
[65] The American Board of Psychiatry and Neurology, 2016. https://www.abpn.com/wp-content/uploads/2016/08/ABPN-Total-and-Active-Certifications.pdf)

Trintellix (LUN)	76	132	202	257	314	363	403
SAGE-217 Oral (SAGET)					54	168	400
Cymbalta (Shionogi)	176	222	282	334	282	282	282
Viibryd (Allergan)	342	333	336	339	311	314	278
ALKS 5461 (ALKS)			8	60	143	202	264
Pristiq (PFE)	732	418	317	296	285	267	251
Cymbalta (LLY)	783	527	403	333	286	250	218
Other	2,845	2,647	2,560	2,521	2,548	2,597	2,568
Total	5,411	4,996	5,090	5,561	6,083	6,683	7,282

Source: Evaluate pharma



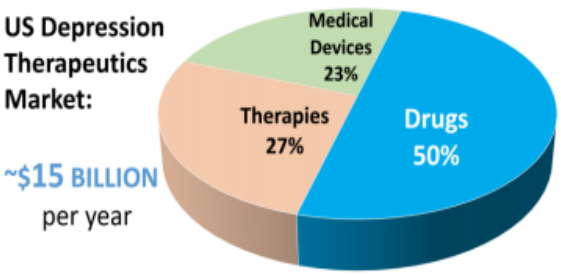
Source: Evaluate pharma

The cost ($) per patient annually is ranked as follows:

	2016
Effexor XR (PFE)	7,247
Trintellix (Takeda)	4,912
Cymbalta (LLY)	3,589
Venlafaxine XR (TEVA)	2,804
Pristiq (PFE)	2,585
Lexapro (Allergan)	2,210

Source: Evaluate pharma

In total, the US depression therapeutics market is estimated at $15 billion annually (company).



Source: Brainsway

The economic burden of MDD however, is higher. Depression is among the most burdensome disorders worldwide, giving rise to considerable effects of daily living for extended periods of time. In the US, it is a leading cause of disability for people aged 15-44, resulting in almost 400 million disability days per year, substantially more than most other physical and mental conditions. The incremental economic burden of individuals with MDD was $173.2 billion in 2005 and increased by 21.5% to **$210.5 billion** in 2010. The composition of these costs remained stable, with approximately 45% attributable to direct costs, 5% to suicide-related costs, and 50% to workplace costs. Only 38% of the total costs were due to MDD itself as opposed to comorbid conditions.[66]. The cost impact of ineffective treatment of comorbid behavioral health conditions has been attributed to an estimated $350 billion spent annually on unnecessary medical and surgical services.

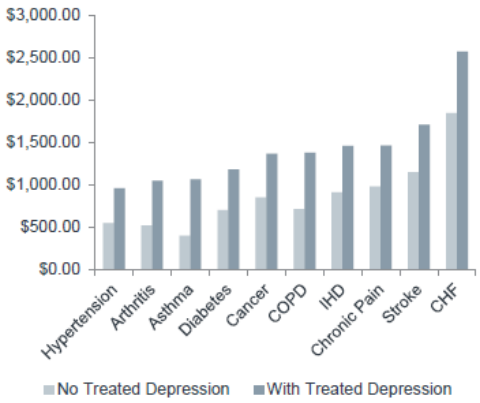
Expected Comorbid Depression Prevalence[1]

2005-2006

Chronic Medical Condition	Comorbid Depression Prevalence
Hypertension	23%
Arthritis	25%
Asthma	45%
Diabetes	25%
Cancer	30%
COPD[2]	30%
IHD[3]	35%
Chronic Pain	50%
Stroke	40%
CHF[4]	35%

Health Care Costs for Patients with Comorbid Depression[1]

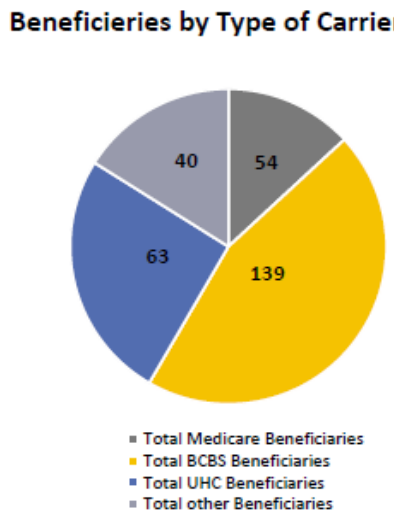
Per Member Per Month
2005-2006



Source: [67]

The cost effectiveness of TMS treatment has leveraged consensus for the acceptance of TMS for the treatment of depression among more and more insurance companies and other third party players. Currently, 47 Insurance Companies are covering Brainsway's dTMS in the US for depression, including 100% of Medicare beneficiaries, which is equivalent to ~90% of the US population (296 million covered lives). The coverage is based on listed CPT (Current Procedural Terminology) codes, particularly for TMS treatment of major depression.

[66] Greenberg PE et al., Economic Burden of Adults with Major Depressive Disorder_J Psychiatry_2015
[67] The Advisory Board Company Document, Evaluating Reimbursement Models for Integrated Behavioral Health Programs, 2014



Source:Brainsway

The actual market for Brainsway's technology will eventually include 52% of the annual MDD prevalence treatment seekers.

US adult population (22-65)	160 million
12-month MDD prevalence	10.5 million (6.6%)[1]
Treatment seekers	5.5 million (51.7%)[2]
Treatment seekers covered by insurance	5.2 million (estimated 95%)
Treatment seekers eligible for reimbursement (3-4 treatment failures)	2 million[3]
Number of treatments covered by insurance	20-36

1 | Kessler RC, Berglund P, Demler O, et al.; National Comorbidity Survey Replication. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). JAMA. 2003;289(23):3095-3105.
2 | Wang PS, Lane M, Olfson M, et al. Twelve-month use of mental health services in the United States: results from the National Comorbidity Survey Replication. Arch Gen Psychiatry. 2005;62(6):629-40.
3 | Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905-17.

Source: Brainsway. US Major Depression Market Size

Competitive analysis for the use of stimulation devices for the treatment of Major Depressive Disorder

Among the available brain stimulation technologies, ECT is still considered to be the most effective method, with an over 70% remission rate.[68] Its use, however, is limited by several disadvantages, including the lack of access in many areas, adverse cognitive effects, substantial relapse rates after a successful acute treatment course, and a negative public image.

Generally, during a course of ECT, which encompasses 6-12 treatments at a rate of 2-3 per week, the patient cannot work or drive. Hospitalization for ECT costs range between $10,000 to $20,000.[69] Moreover, it is usually reserved for the most severely ill patients encountered in clinical practice.

Deep Brain Stimulation (DBS) has also been shown to alleviate depressive symptoms in drug-resistant MDD patients.[70] However, DBS has major drawbacks, as it involves a complex surgical intervention (i.e., drilling into the skull with the

[68] Dukakis KTLS. Shock: the healing power of electroconvulsive therapy; 1 edition: Avery, New York (2006)
[69] Raeburn P, Cost Repetitive TMS, Med Page (2016)
[70] A. tendler et al., Expert Review of Medical Devices (2016) 13:10, 987-1000

risk of infection), requires replacing the subcutaneous battery periodically, and carries a higher overall cost,[71] in the range of $15,000.

Another option presently cleared by the US Food and Drug Administration (FDA) for the treatment of depression is Vagus Nerve Stimulation (VNS). Although available since 2005, to date VNS is not widely utilized for treatment of depression. This is in part because of the need for a surgical procedure to implant the device and the need for prolonged exposure over months to achieve optimal results.[72] Furthermore, in the US, most insurance companies do not reimburse for this process, and eligible patients usually need to pay out of pocket, with the cost typically exceeding $25,000.

In contrast, TMS, which has been clinically available since 2008 by Neuronetics, and by Brainsway since 2014, is a noninvasive procedure for the treatment of an acute major depressive episode. No systemic adverse effects are known and it is usually better tolerated than medications or other therapeutic neuromodulation approaches. [73] Each treatment session lasts approximately 20 minutes, whereas a typical treatment protocol lasts 4-6 weeks with 3-5 sessions per week. After each session, patients can follow through their normal daily routine. In addition, relative to VNS and ECT, the cost of an acute treatment course in the US is lower (typically in the $5,000–$12,000 range). 90% of the US population carries health insurance plans that cover TMS treatment, for patients who fail to benefit from at least one prior antidepressant in the current episode. Fees may vary between States, and even within a State, based on locality. Private payers are usually reimbursed between $250-450 per session, but may even be refunded up to $600. Private payment rates vary between clinics with the majority of clinics charging in the range of $300-500 per session. Yet, in the US, approximately 100,000 patients are treated with ECT annually, while only about 30,000 are treated using TMS.

Obsessive Compulsive Disorder (OCD)

Obsessive Compulsive Disorder (OCD) is a chronic psychiatric disease characterized by a pattern of obsessive thoughts and compulsive repetitive behaviors, which has a significantly destructive effect on patients' day-to-day functioning. The condition is associated with tics, anxiety disorder, and an increased risk of suicide.[74]

OCD is a difficult condition to treat. Although 50% to 60% of patients respond to a first line of treatment, which typically includes Selective Serotonin Reuptake Inhibitor (SSRI) medicines and/or psychological intervention, approximately one-third of the patients experience only partial improvement, and roughly 20% do not respond to conventional treatment strategies. The duration of the treatment is usually indefinite, since relapse occurs in 80% to 90% of patients upon full discontinuation. [75]

Approximately 36.3% of lifetime OCD patients are seeking treatment,[76] which is equivalent to 820 thousand patients from the 2.24 million patients in the US with 12 month prevalence OCD. Of those, approximately 50% are considered treatment resistant, and are considered as the potential market for Brainsway's dTMS treatment for OCD.

[71] McIntosh E, et al. Movement Disordersv (2016) 31:1173–1182.
[72] Rado J. et al., J Psychosoc Nurs Mental Health Serv. (2007) 45(7):43–51
[73] Janicak PG, Neuropsychiatr Dis Treat. (2015) 11: 1549–1560
[74] Diagnostic and statistical manual of mental disorders, 5 ed., Washington: American Psychiatric Publishing. (2013) 237–242
[75] Brainsway data
[76] Mayerovitch, JI. Comprehensive Psychiatry(2003) 44, Issue 2, 162-168

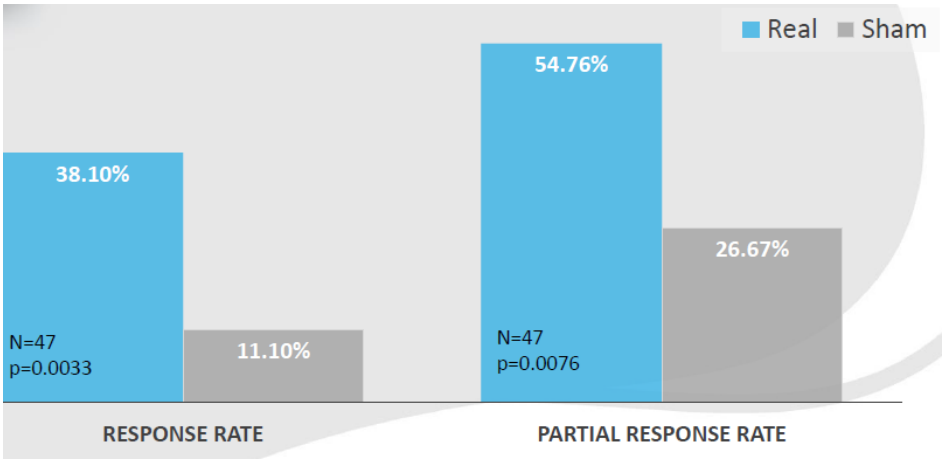
US adult population (>18)	224 million
12-month prevalence	2.24 million (1%)[1]
Treatment seekers	820K (36.6%)[2]
Treatment-resistant treatment seekers	410K (estimated 50%)[3-5]

1| Kessler RC, Berglund P, Demler O, et al.; National Comorbidity Survey Replication. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). JAMA. 2003;289(23):3095-3105.
2| Mayerovitch JI, du Fort GG, Kakuma R, et al. Treatment seeking for obsessive-compulsive disorder: role of obsessive-compulsive disorder symptoms and comorbid psychiatric diagnoses. Compr Psychiatry. 2003 Mar-Apr;44(2):162-8.
3| Greist JH. The comparative effectiveness of treatments for obsessive-compulsive disorder. Bull Menninger Clin. 1998;62(4, suppl 1A):A65–A81.
4| Marks I. Behaviour therapy for obsessive-compulsive disorder: a decade of progress. Can J Psychiatry. 1997;42:1021–1027.
5| Ballenger JC. Current treatments of the anxiety disorders in adults. Biol Psychiatry. 1999;46: 1579–1594.

Source: Brainsway

In June 2017, Brainsway received positive final results from a double-blind placebo controlled, multicenter study in Obsessive Compulsive Disorder (OCD) patients. The company is near to submitting an application for market approval in the US for this indication. The study, which included 94 OCD patients, who previously failed to sufficiently respond to pharmacological or psychological treatment, was the first of its kind to demonstrate that focused magnetic stimulation may bring promising clinical outcomes for what has long been considered a hard-to-treat disease. Therefore, it represents a new era in brain disorder treatment that is applied not only to classic psychiatric conditions but to addictive disorders as well.

The treatment protocol was conducted with Brainsway's H7-coil dTMS system that was developed for the stimulation of the anterior cingulate cortex region in the brain. The results showed that after six weeks of treatment, there was a statistically significant improvement in the YBOCS score (Yale–Brown Obsessive Compulsive Scale, the gold standard measure of OCD symptom severity) for the active treatment group when compared to sham (p=0.0157). The improved clinical effect on YBOCS scores was maintained in the active group one month after treatment completion, and the improvement was more pronounced than that achieved in the sham group (p=0.0459).



Source: Brainsway. Results of the OCD trial. 38.1% of patients in the active group achieved a response as defined in the protocol, compared with just 11.1% in the sham group (p=0.0033). Furthermore, 54.8% of patients in the active group achieved a partial response as defined in the protocol, versus just 26.7% in the sham group (p=0.0076).

Other indications

Currently, there are three indications in advanced random, double blind, sham-controlled, multi-sites clinical trials, including: Smoking cessation which includes 235 participants and is expected to be completed by 2019; Post-Traumatic Stress Disorder (PTSD) which includes 166 participants and is expected to be completed by 2019; and Bipolar Depression which includes 236 patients and expected to is be completed by 2020. These are psychiatric and addiction-related syndromes, in which positive results will bring dTMS technology one step further on the way to becoming an acceptable treatment method in hard to treat psychiatric diseases. Although the company is focused on these indications, other indications that have shown promise at early stages of investigation. Some are neurological indications such as post-stroke rehabilitation, Parkinson's disease and chronic neuropathic pain. Positive results in large pivotal studies for these indications, will turn the company into a key player in neuromodulation devices .

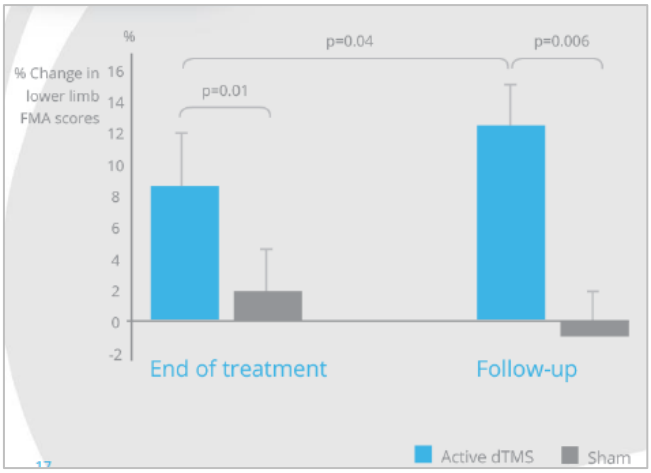
The expanding adoption of TMS into neuroscience research is reflected by the striking increase in scientific PubMed publications when searching for transcranial magnetic stimulation: from 67 in 1990 to 1,488 in 2000 to 8,699 in 2012.[77] Currently, the efficacy of TMS as a therapeutic tool in neurologic contexts has yet to be confirmed, but only for diagnostic purposes, such as with the Nexstim eXimia Navigated Brain System TMS device, which has FDA approval for presurgical motor and language mapping. Nevertheless, a growing body of experimental work suggests that the clinical applicability of TMS in neurology, both as a diagnostic instrument and as a means of inducing changes in neural processing to achieve therapeutic gains, may be further expanded. Available evidence of efficacy to date is limited to proof-of-principle studies and often to only acute effects. Larger and better-controlled clinical trials that address the durability of the potential benefits are needed to explore the therapeutic potential of TMS.

Post- Stroke Rehabilitation

Stroke is the leading cause of adult disability. Less than 40% of stroke survivors completely recover, despite intensive acute care and rehabilitation training. The use of TMS for therapeutic purposes or as part of a neuro-rehabilitation strategy for stroke recovery is relatively new, with the first clinical trials having commenced in 2001.[78] Application of cortical stimulation in stroke is aimed at either correcting maladaptive brain plasticity induced by the cerebrovascular accident or enhancing adaptive brain plasticity during rehabilitation. The chronic phase is commonly starts six months after stroke onset, and is characterized by a marked slowing in the rate of naturally occurring functional recovery.

A pilot study of Briansway that included 10 subjects was conducted to examine deep repetitive transcranial magnetic stimulation with H10-coil on lower limb motor function in chronic stroke.[79] A significant improvement following rTMS treatment was shown in lower limb motor function. This effect persisted over time (follow-up) and was significantly greater than that observed with sham stimulation. These data demonstrated that three weeks of high-frequency deep repetitive TMS (rTMS) could induce long-term improvements in lower limb functions in the chronic post-stroke period, lasting at least one month after the end of the treatment. These findings are in line with several controlled studies applying rTMS, all confirming the value of this approach in the chronic phase of stroke recovery.[80]

[77] Eldaief, MC.,Neurol Clin Pract (2013) 3(6): 519–526
[78] Hummel FC, et al. Brain Stimul (2008) 1:370–82
[79] Chieffo, R., Arch Phys Med Rehabil (2014) 95, 6, 1141–1147
[80] Lefaucheur JP, Clin Neurophysiol (2014) 125(11), 2150-206



Source: Brainsway. The Fugl-Meyer Assessment (FMA) of motor recovery after stroke to evaluate and measure recovery in post-stroke patients.[81]

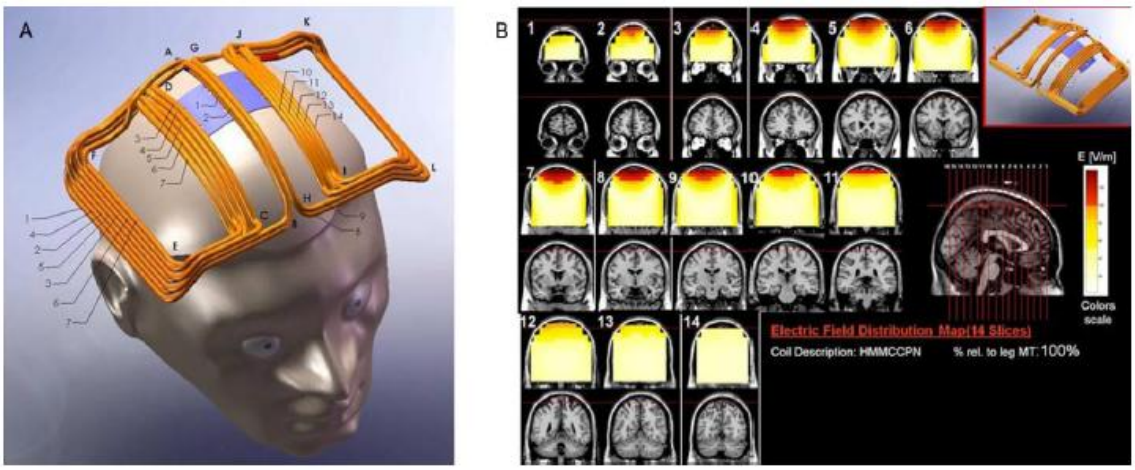
Neuropatic Pain

Neuropathic pain is a major public health problem because of its prevalence (affecting up to 6–7% of the general population,[82] and because of the limited efficacy of current therapies, only 30–40% of patients declare they receive satisfactory (>50%) relief from their chronic pain through pharmacological treatment. [83]

Several studies have shown that cortical stimulation with TMS in the treatment of chronic neuropathic pain targeting the motor (precentral) cortex may be beneficial; promise was observed in decreasing chronic pain in patients with neuropathic pain (resulting from peripheral nerve, spinal cord, or central sensory pathway injury), fibromyalgia, and complex regional pain syndrome.[84] Ongoing studies are aimed at better defining the target of stimulation, the parameters for stimulation, and the patient characteristics that predict response. However, effect sizes in patients who do respond to TMS can be substantial, and duration of benefit can be clinically significant. [85]

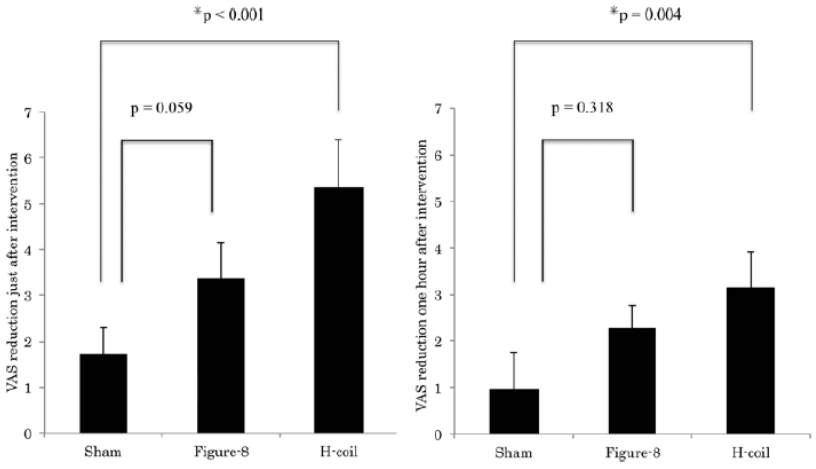
Brainsway's H-coil deep rTMS stimulation was applied over the motor cortical lower-limb to relieve pain in 25 drug-resistant patients with diabetic neuropathy by inducing motor cortex plasticity and activating descending inhibitory pain control systems. The data supported a reduction in chronic drug-resistant distal diabetic neuropathic pain for at least 3 weeks by activating deeper cortical areas which are difficult to target when using a standard coil, without inducing adverse events. [86]

[81] Chieffo, R., Arch Phys Med Rehabil (2014) 95, 6, 1141–1147
[82] Torrance N, et al., J Pain (2006) 7, 281–9
[83] Attal N, et al. Eur J Neurol (2006) 13:1153–69.
[84] Hallett M. Neuron (2007) 55, 187–199
[85] Mark C. et al., Neurol Clin Pract. (2013) 3(6), 519–526.
[86] E. Onesti, Eur J Pain (2013) 17, 1347–1356



Source: [87]. A) A sketch showing the H-coil used in the study. B) Colored field maps for the H-coil indicating the electrical field absolute magnitude in each pixel, for 14 coronal slices 1 cm apart.

Additional results, compatible with the findings in the previous study, further proved that H-coil stimulation in the lower limb region of the primary motor cortex could provide significant short-term pain relief. The clinical effects of deep rTMS with an H-coil and rTMS using a figure-8 coil were assessed in 18 patients with failed–back surgery syndrome (FBSS), subacute combined degeneration (SCD), spinal cord injury (SCI), and central poststroke pain (CPSP); exhibiting pain relief immediately and 1 hour after stimulation. The pain relief due to H-coil stimulation, rather than figure-8 coil stimulation, was significantly better than sham. [88]



Source: [88]The mean Visual Analog Scale (VAS) reduction in the short term (primary outcome)

Pipeline Competition

Current existing treatments for Psychiatric, Neurological and addictive disorders may pose competition to the indication based treatment method developed by Brainsway. Nevertheless, in this section we will discuss direct competitors of the company that offer TMS therapy as well.

The main competitors of Brainsway in the US and indeed globally are Neuronetics (US), Magstim (UK), MagVenture (Denmark) and Neurosoft (Russia). These companies are selling devices based on superficial TMS, whereas Brainsway's exclusive technology offers deep TMS. The treatments offered by the competitors are given mainly to treat

[87] E. Onesti1, Eur J Pain (2013) 17, 1347–1356
[88] Shimizu,T., J Neurosurg (2017), 3

Depression, and receive insurance coverage in the US based on the same listed CPT (Current Procedural Terminology) codes as Brainsway. The competition is therefore in the depth of technology, price and quality of service.

Practically speaking, the advantages of dTMS mainly relate to the time of treatment. dTMS treatments are 20 minutes in duration, with the system running continuously all day. In comparison, conventional figure-8 coil TMS lasts 37.5 min, and requires navigation to target the intended area of the brain area, which misses the target in 27–32% of patients.[89] Although there have not been any head-to-head studies comparing between dTMS to figure-8 coil, there are two published case series from credible sources demonstrating better clinical outcomes for patients treated with dTMS.[90] The variable costs are relatively nominal and include systems in the range of $65,000 to $100,000.[91]

At present about 90% of all dTMS treatment in the US is for Treatment Resistant depression (TRD). However, competing TMS devices such as those of Neuronetics may treat patients for off label conditions, depending on the assessing physician's responsibility to fit the protocol and treatment area to the relevant disorder. Brainsway's H-coil is fixed in a helmet with less degrees of freedom, and therefore is primarily suited to the intended labeled indication.

In the table below, we explore and detail the competitive landscape for dTMS:

TMS and Brain Stimulation Systems			
Company	**Device(s)**	**Comment**	**Source**
Ant Neuro	**eego mini-series powerMAG-ANT visor2 XT**	Founded in 1997 as a spin-off company from the University of Twente, Netherlands *ANT Neuro* focused on developing software for source analysis (asa) of EEG and MEG data. After a few years they pivoted towards complete solutions for recording and analysing neurophysiological signals in neurological, psychological and physiological research, as well as in other related clinical applications. *ANT Neuro*'s products are used in many internationally renowned laboratories.	Ant Neuro (Listed in the Nexstim Prospectus 2014, as a competitor in the TMS area)
Axilum Robotics	**TMS-Robot**	Transcranial Magnetic Stimulation (TMS) was Axilum Robotics' initial projects. TMS applies highly intense magnetic impulses to areas of the cortex through a coil placed upon the head. One's cognitive and neurophysiological mechanisms can be studied. The robot's potential applications for auditory hallucinations and major forms of depression are currently being investigated. Axilum Robotics TMS-Robot is the 1st robot specifically designed to automate transcranial magnetic stimulation (TMS and rTMS).	Axilum Robotics
Brain Science Tools (The Netherlands)	Neural Navigation Software	The company sells Neural Navigation software which incorporates MRI data with TMS responses for brain function mapping. The tracking uses a weak magnetic field and head sensor. The product is CE marked, compact, transportable system and purportedly sells at a reasonable price point.	Brain Science Tools
Rio Grande Neurosciences (US)		*Carvel Neurotech*'s TMS network in the investigational stage using "multiple magnetic coils placed directly on the scalp…to steer the magnetic field toward the specific network of brain regions associated with a particular disorder". The company was acquired by RioGrand Neurosciences in October 2015.	
Cortical implants		Method of stimulating the brain through implants placed directly on the cortex through invasive surgery. Unfortunately this difficult method of delivery is unavoidable as when deep brain stimulation is needed only magnetic fields can stimulate the cortex.	

[89] A. tendler et al., Expert Review of Medical Devices (2016) 13, 987-1000
[90] Viner L, et al., Comparison of TMS outcomes : Brainsway and Neurostar. Brain Stimulation. (2016) 9(5), e5–e6.
[91] Ontario Health Technology Assessment Series (2016) Vol. 16: No. 6, 1–51

Deymed Diagnostic (Czech Republic)	**DuoMAG MP**	The DuoMAG MP is a versatile mono-phasic stimulator capable of high-power stimulation for clinical diagnostics and research use. A large selection of coils are available, including designs for specific applications. Intensity and stimulation controls are included on all deymed coils.	Deymed Diagnostic
Dr. Langer Medical	**DuoMAG MP** **DuoMAG XT** **DuoMAG-Dual**	The DuoMAG MP is a multipurpose, mono-phasic and high-power stimulator for clinical diagnostics and research. An assortment of coils are available, including for specific applications. Intensity and stimulation controls accompany all deymed coils.	Dr. Langer Medical
eNeura Therapeutics (US)	**Spring TMS**	*eNeura's* Spring TMS utilises single-pulse TMS to prevent migraines with aura pain. The handheld device sits over the back of the head. It is not suitable for stroke. It was approved in 2015 de novo.	eNeura Therapeutics
Kejijan (Xuzhou Kejian Hi-Tech)	**Transcranial magnetic stimulator**	Increase regional cerebral blood flow, improve microcirculation; Activate the cerebral endogenous neuro-protection mechanism, and protect the nerve cell; Lower the exitotoxicity damage to nerve cells; Stabilize cerebral neurocyte membrane potential, inhibit depolarization wave; Suppress the cerebral infectious reaction, absorb the oedema and alleviate the acute intracranial hypertension; Ameliorate the disturbances of heart autonomic nerve of the cerebral apoplexy patients. Indications - Stages of cerebral infarction, convalescence stage of cerebral hemorrhage, wakening of the cerebral trauma patients, convalescence stage of cerebral trauma, prevention of apoplexy, insufficiency of cerebral blood-supply(insufficiency of blood-supply of vertebral artery caused by cervical syndrome), hemicrania, insomnia, recognition functional impairment, senile dementia, depressive disorder etc..	Kejian
Mag & More (Germany)	**PowerMap**	Based in Germany, *Mag&More* produces high-quality TMS PowerMap systems using infrared sensors to position the figure of eight magnetic coil in a reproductive manner, with precision and alignment to MRI scan data via a head tracking device (see website). The system utlizes an algorithm to plan treatment and can draw diagnoses by linking with EMG (muscle). The products are CE certified, seemingly without prior clinical studies. The range features a variety of system configurations for different users with the navigated feature being the flagship.	Mag & More
MagStim (US)	**INSIGHT** **Neurosign**	Magstim's Rapid^2 Therapy System is an FDA-cleared, non-invasive device for Major Depressive Disorder (MDD) that are resistant to conventional treatment.	MagStim
MagVenture (Denmark)	**MagVita**	The *MagVita* system gained CE clearance in 2011 and was 510(k) cleared in July 2015 for drug resistant major depressive disorder. In 2010, the *MagPro* diagnostic system was 510(k) approved for stimulating peripheral nerves; futher applications are being investigated. MagVenture also sells a range of TMS equipment.	MagVenture
NeuroConn (Germany)	**Several**	Sells a variety of CE approved brain stimulating products and services with three clinics (two in Holland, one in Germany) including direct non-magnetic electrical transcranial brain stimulation via electrode pads affixed to the patient's scalp.	NeuroCare
Neuronetics (US)	**NeuroStar**	According to their official website, *Neuronetics* boasts 600 installed systems which have treated more than 25,000 patients. Their *Neurostar* product has been approved since its inception in 2008 and has has undergone several developments, expecially since the latest 510(k) approval in 2014. As the coil is freely positioned over a patient's head, it might be applicable to stroke therapy. The system has a "Coil Positioning System" which "assures repeatable and accurate depression treatment" using a disposable head tracking laser device and an algorithm that selects the optimal location. Such systems can be used to map motor functions. The SenStar device attached to the coil reduces scalp "tingling". It could be potentially used for multiple applications. Neuronetics is a private US company. It also has a series of clinical academic studies running, for example in schizophrenia. The company is private and sales are undisclosed.	Neuronetics

Neurosoft	**NEURO-MS NEURO-MS Paired**	A Transcranial Magnetic Stimulator with a strong monophasic stimulus and extraordinarily low interference.	NeuroSoft
NeuroStar Advanced Therapy	**NeuroStar TMS Therapy System**	*Neuronetics*, Inc. is the global market leader for therapeutic applications of MRI strength pulsed magnetic field for central nervous disorders. The FDA approved *NeuroStar TMS Therapy System* has set a new standard in neuromodulation.	NeuroStar Advanced Therapy
Nexstim	**NBS System (Navigated Brain Therapy System)**	Over 130 units placed and FDA 510(k) approval in 2009 for motor mapping. Added speech mapping functionality on 510(k) in 2011. NBS uses MRI scan data though sophisticated software. Has a disposable head mounted tracking sensor (introduced late 2014 to replace a reusable tracking device). Claims highly precise navigation.	Nexstim Inc.
Remed (Korea)	**TAMAS Transcranial magnetic stimulator**	TMS utilizes a rapidly changing magnetic field to stimulate neurons in the brain by way of intensely focused MRI strength magnetic pulses which galvanize specific regions of the brain responsible for mood regulation. It is indicated for the treatment of neuropsychiatric disorders and rehabilitation purposes.	Remed
Robotics/exoskeletons (Ekso Bionics, Rewalk, Rex Bionics)		There remains no conclusive evidence that peripheral nerve stimulation using exoskeletons improves rehabilitation results any more than traditional rehabilitative techniques.	
Rogue Research (US)	**TMS Diagnostic systems**	The company offers various research systems including the Brainsight TMS diagnostic system known for connecting data generated from EMG and MRI scans by employing complex mapping and visualisation programs. At present, over 400 Brainsight units are purportedly in use across the globe. The product is for research use and does not appear to be FDA registered or CE marked.	Rogue Research
	ECT	ECT is usually used to treat severe, treatment-resistant depression, but may also be diagnosed for other mental disorders such as bipolar disorder or schizophrenia. It is also effective in life-threatening circumstances such as; when a patient is not responding to his/her environement (e.g., catatonia), is suicidal, or is malnourished due to severe depression. ECT can reduce the chances of relapse when patients undergo follow-up treatment. Two major advantages that ECT has over medications are that it begins to work rather immediately, often within a week, with older patients responding especially fast.	National Institutes of Mental Health

Source: companies websites

Financial Analysis

Brainsway is an Israeli medical device company whose shares were incorporated and began to be traded on the Tel Aviv Stock Exchange in 2006. The company develops, markets and sells non-invasive medical systems for treating various common brain disorders. The company has 77 employees as of 31 March 2017.

The technology is based on a helmet that contains a uniquely structured electromagnetic coil connected to a rapidly changing electrical current, creating an electric field by which different regions of the brain can be affected by nerve stimulation or suppression. The system has FDA approval for MDD treatment, as well as CE approval and Israeli Ministry of Health approval for 13 indications.

As of this report's publishing, the company's focus is on promoting treatment for two indications: Major Depressive and obsessive-compulsive disorders (MDD and OCD). In addition, the Company has additional treatments in development .

In 2016 the company changed its sales strategy from selling systems to promoting long-term lease contracts. Brainsway offers two lease contract options and a selling option:

Rental fees plus per-per-use billing - "minimal use": The system is leased for an annual fee of $28,000 and an additional fee of $70 per treatment performed by the system,.

Rental fees that include unlimited use – "unlimited use": The system is leased for a fixed annual fee of $52,000 for the first year and $72,000 for subsequent years. A typical contract is signed for a period of 3-4 years.

Selling option – The system is sold for 195k, where maintenance is 15k from the second year.

Company's business model from a customer perspective

Customer's perspective	Risk Share Model (RSM)	Lease	Buy
Payments	Minimum commitment per year minimal to cover procedure volume	3-4 years Annual fix fee	One time purchase-
Procedures /Sessions	Pay per use	Unlimited	Unlimited
Service	Included	Unlimited	Included only for 1st year

Source: Brainsway

The company`s backlog, i.e. commitments from clients, is $15 million as of March 31, 2017.

P&L Analysis

Company`s revenues increased by 70% in 2016 to $11.5 million in comparison to $6.8 million in 2015, due to rental and sales of new systems. For Q1 2017, revenues were $2.2 million in comparison to $2.5 million in Q1 2016. The decline is explained by the shift in Brainsway's strategy to promote rentals over sales of systems. i.e. Gross profit in 2015 and 2016 is similar (78%, 79% respectively) as is that for Q1 2017 (79% gross profit).

The company`s R&D expenses were $3.4 million in 2016 and $4.1 million in 2015. As of Q1 2017 Brainsway R&D expenses were $1.2 million, similar to Q1 2016, representing an annual expenditure of approximately $4.2 - $4.8 million, an increase due to the completion of patient recruitment in the OCD trial. Marketing expenses were $5.2 million in 2016, an increase of $1.9 million from 2015. This increase is due to operational activity in the US including recruitment of sales people. This increase is also reflected in the Q1 2017 results at $1.4 million, higher than Q1 2016 results by $400k. General and administrative (G&A) expenses were $2.2 million in 2016, a decrease from 2015 ($2.45 million). At Q1 2017, G&A expenses were $0.6 million in compare to $1.1 million in Q1 2016. These changes are mainly due to forfeiture of stocks options. Operational loss was $2.1 million in 2016 and $1.5 million in Q1 2017 ($1.2 million in Q1 2016).

Balance Sheet and Operational Cash Flow Analysis

The company’s cash, as of March 31, 2017, is $7.8 million, and fully funded by its shareholders. The Company's operating assets grew in the last year mainly due to an increase in fixed assets based on the company`s new business model and the transition to rental of the systems recorded in the company's books. Net fixed assets were $7.3 million as of March 31, 2017. The company`s equity as of March 31, 2017 was $8.5 million in comparison to 31 December, 2016 ($10.3 million). A decrease caused mainly due to the company`s burn rate. The company’s operational cash flow needs are $1.7 million for Q1 2017, a decrease from Q1 2016 ($65K) due to the company`s new business model.

Valuation

Business Models

As we described in a previous section, Brainsway enters into lease contracts with its customers in one of two ways, and additionally offers a purchase option:

- **Rental fees plus per-use billing - "minimal use": The system is leased for an annual fee of $28,000 and an additional fee of $70 per treatment performed by the system,.**
- **Rental fees that include unlimited use – "unlimited use": The system is leased for a fixed annual fee of $52,000 for the first year and $72,000 for subsequent years. A typical contract is signed for a period of 3-4 years.**
- **Purchase option**

Following is a summary of key financial inputs we used:

Inputs per 1 system - model 1 (RSM) "minimal use":		**Inputs per 1 system - model 2 (Lease) "Unlimited use":**		**Inputs per 1 system - model 3 "sell":**	
Commitments for new systems	28,000	**Commitments for new systems**	52,000	**Commitments for new systems**	195,000
cost for client - from 2nd year		**cost for client - from 2nd year**	72,000	**cost for client - from 2nd year**	none
Commitment time	3-4 years	**Tender time**	3-4 years	**Tender time**	none
# of patients per day	1.5	**# of patients per day**	N/A	**# of patients per day**	N/A
# of treatments	360	**# of treatments**	N/A	**# of treatments**	N/A
Pay Per Use (PPU) - $	70	**Pay Per Use (PPU) - $**	N/A	**Pay Per Use (PPU) - $**	N/A
Added revenues per 1 system	37,800	**Revenues per 1 system**	N/A	**Revenues per 1 system**	N/A
Maintenance	-	**Maintenance**	-	From 2nd year	15,000

The company expects that sales under models 1 and 2 will be 45%, while model 3, "sell" will represent 10% of the company`s future sales. We embrace this assumption as the company`s strategy and formation of its US-based sales team begin to take shape.

Revenues and number of installed systems

The company`s revenues were $11.5 million in 2016, $6.8 million in 2015 and $3.4 million in 2014. In the table below, based on the company`s financial reports we present the breakdown of leases and sales:

Revenues	2014	2015	2016
Lease	2,708	4,299	5,327
%	80%	63%	46%
Sales	672	2,501	6,197
%	20%	37%	54%
Total revenues	3,380	6,800	11,524

From 2014 to 2016, there is a change in the breakdown of leases and sales to 46% to 54%, respectively. We analyze the number of installed systems, extracting the data from past revenues and breaking them down based upon Brainsway's business model. We assume the company sold 160 systems by 2016. Recall that Neuronetics (US) and Kitalpha Med (Germany) are key industry players offering such devices for therapeutic usage. Neuronetics reported on its website to have 600 systems installed.

We assume Brainsway will reach 220 installed systems by the end of 2017. This projection is based upon; the current progress rate, competitive landscape and the company's current clinical success momentum. Looking forward, from 2018-19 we assume the company will install 50 systems under model 1 (minimal use); 50 systems under model 2 (unlimited use) as it is starting to develop a pipeline of large hospitals. Also the company is estimated to sell one system per month, i.e. 12 systems annually . Revenues are expected to reach $21-$22 million in 2018.

We evaluate the company`s operations until 2024, when its main patent expires, albeit we take into account the company's potential in our terminal value valuation as will be discussed later.

We assume the company will reach the following installed number of systems:

Parameter	2016	2017	2018	2019	2020	2021	2022	2023	2024
Total systems	160	220	332	444	571	715	879	1,066	1,279
YoY%			*51%*	*34%*	*29%*	*25%*	*23%*	*21%*	*20%*

We furthermore assume, based on our clinical evaluation that the company will receive FDA approval for OCD indication during 2018, and begin selling helmets during 2019. These helmets will be add-ons to already installed systems and can also add to the attractiveness of the systems in new locations given the "dual-use" for both depression and OCD. Moreover, these helmets can function as treatments for other nuerological indications in the future. We assume 5% of future installed systems and 15% of future installed systems from 2021 will add to the company`s revenues.

Cost of revenues and operational expenses

According to the company the total cost of an installed system is approx. $26,000. We assume the same cost structure as in 2015 and 2016 based on the sales of new systems. Thus, with more system sales, gross profit will reach 84% in 2017 compared to 79% in 2016 as a result of increased sales. This expectation is substantiated by the company's good track record and updated business model – from systems sales to a leasing model. However, in order to support this business model, the company formed a sales force in the US and accordingly, marketing and sales expenses are expected to increase. We assume an annual growth rate of 20% in sales and marketing, with an average expenses to revenues ratio of 25%.

R&D expenses will continue to support Brainsway's pipeline with an average expenses to revenues ratio of 16% from 2018 till 2024. In addition, the company has financial obligations, royalties to pay to *Yisum* and grant from the Government of Israel totaling up to $12.4 million from sales in the upcoming years.

General and administrative expenses will grow linearly in relation to growth in revenues. The expense to revenue ration for G&A expenses will remain at an average of 10%.

Other points:

- Tax – the company has an effective tax rate of 7% (and not 23% statutory tax) as it is located in a preferred governmental location. We assume the company will not pay taxes in our model until 2024, although we account for this in our terminal value analysis.
- Working capital needs – The company's updated business model towards leasing will create capital resources affecting the financial structure. We assume, based on the company's financial reports and conversations with executives, ninety inventory days. Accounts payable and accounts receivable also stand at days.
- Capital expenditure – As the company will maintain the installed systems, CapEx will increase in our analysis to $2.5 million, equal to the depreciation in our terminal year.
- Cap. rate – we assume 19% cap. rate based on our CAPM model (see appendix B).

In the table below we present our forcast analysis in the years 2017-2024:

Years	2014A	2015A	2016A	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Revenues	**3,380**	**6,800**	**11,524**	**16,311**	**21,726**	**28,694**	**36,207**	**46,705**	**57,063**	**68,969**	**82,652**
YoY%				42%	33%	32%	26%	29%	22%	21%	20%
Total cost of revenues	656	1,466	2,427	2,670	2,937	3,230	3,553	3,909	4,300	4,730	5,202
Gross profit	**2,724**	**5,334**	**9,097**	**13,642**	**18,790**	**25,463**	**32,654**	**42,796**	**52,764**	**64,239**	**77,450**
% of revenues	*81%*	*78%*	*79%*	*84%*	*86%*	*89%*	*90%*	*92%*	*92%*	*93%*	*94%*
R&D Expenses	6,438	4,103	3,792	4,644	5,108	5,619	6,181	6,799	7,479	8,227	9,050
% of revenues	*190%*	*60%*	*33%*	*28%*	*24%*	*20%*	*17%*	*15%*	*13%*	*12%*	*11%*
Other payments				652	869	1,148	1,629	2,102	2,568	3,104	3,719
Marketing Expenses	1,896	3,281	5,180	5,744	6,738	7,933	9,364	11,080	13,129	15,575	18,494
% of revenues	*56%*	*48%*	*45%*	*35%*	*31%*	*28%*	*26%*	*24%*	*23%*	*23%*	*22%*
General and Administrative Expenses	1,667	2,455	2,194	2,344	2,749	3,237	3,821	4,522	5,358	6,356	7,547
% of revenues	*49%*	*36%*	*19%*	*14%*	*13%*	*11%*	*11%*	*10%*	*9%*	*9%*	*9%*
Operating Profit (Loss)	**-7,277**	**-4,505**	**-2,069**	**257**	**3,325**	**7,526**	**11,658**	**18,293**	**24,229**	**30,977**	**38,639**
% of revenues	*-215%*	*-66%*	*-18%*	*2%*	*15%*	*26%*	*32%*	*39%*	*42%*	*45%*	*47%*

Equity Value

Non-operational assets/Liabilities and unallocated costs

As of 31 March 2017, the Company has non-operational assets (cash) of approximately $7.8 million with no loans, besides liabilites for R&D funding ($5.3 million) calculated based on the company's evaluation for future revenues, which we took into consideration in our analysis. The company`s burn rate is approx. $3 million per quarter. Consequently, the company will need to raise capital in the next 3-4 quarters.

We present below the equity valuation elements:

Parameters	(in thousands $)
Enterprise Value (EV)	103,754
Cash and non-cash equivalences	7,808
Equity Value	111,562

Sensitivity Analysis

In the table below we present Brainsway's target price in relation to the capitalization rate. We set a range of 0.5% change from our CAPM model (as presented in Appendix B) as the stock range.

Sensitivity analysis - Capitalization rate and growth rate vs. target price

Cap. rate / Growth rate	1.50%	2.0%	2.50%
18.0%	28.7	29.3	29.9
18.5%	27.6	**28.1**	28.6
19.0%	26.5	**27.0**	27.5
19.5%	25.5	**26.0**	26.4
20.0%	24.6	25.0	25.4

We estimate the target price to range between NIS 26.0 and NIS 28.1, with a mean of NIS 27.0

Relative Advantages

Investment Thesis and Price Forecast Risks

Medical device companies, particularly those at the research and development stage, are relatively high-risk. Key risks that may affect Brainsway include:

The risk of delay/postponement of marketing regulatory approval decisions

In order for Brainsway to market its products, they require marketing approval from regulatory agencies, such as the FDA (in the US) and EMA (in the EU). Our estimates for time to market are based on the assumption that these products will successfully progress through the regulatory phases. Failure to fulfill the clinical endpoints or regulatory stages will force the Company to conduct additional clinical trials or abandon the development of certain projects. We consider this to be the main risk factor for the company's activity at this stage.

Risks involved in obtaining sources of financing and stock trading

As a relatively small company in its research and development stage (minimal revenue from sales) the company will be required to conduct fundraising prior to becoming profitable, unless early licensing deals are made. Failure to raise funds, or fundraising under conditions that are not beneficial to the company, may affect its worth. In addition, the low level of tradability may deter some investors from buying company stock.

General risks related to similar companies

The value of small companies in the biotech field could, to a relatively high degree, be affected by publications not related directly to their activities. Such publications may be connected to competitors, macro trends in the healthcare sector, political events, and other externalities.

Production/ logistics

As previously discussed, Brainsway covers the entire medical devices value chain in its operations – from clinical development, to design, to system construction, to market entrance, to sales and marketing. Again, in most cases, this occurs without input from distributors. All these milestones are met in parallel to the Company's continuous endeavors to further its clinical development. Thus, the company needs to work precisely and carefully so that all stages of the value chain work both in sync, and in and of themselves. A major risk remains that disruption to one operational stage will hamper the rest of the company's operations.

Brainsway Contact Details & Management

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Management:[92]

Yaacov Michlin

Chief Executive Officer

Mr. Michlin joined Brainsway in 2015 serving as a director on its board providing exceptional guidance. For the past eight years, Mr. Michlin has served as president and CEO of Yissum, the technology transfer company of Israel's Hebrew University in Jerusalem. At Yissum, he facilitated and oversaw numerous corporate transactions and initiatives in partnership with corporations across the globe and funded and served as chairman of few companies including Integra Holdings, a healthcare investment company and Agrinnovation an investment fund focusing on Agriculture and food sciences. Prior to Yissum, Mr. Michlin practiced as a corporate lawyer, advising on major corporate matters including mergers and acquisitions, capital raising and initial public offerings for clients including mainly Teva Pharmaceutical Industries. Mr. Michlin is a lawyer and economist by training, and holds an MBA from the Technion in high-tech company management.

Yiftach Roth, Ph.D

Chief Scientist

As one of Brainsway's founders, Yiftach Roth has served as the company's Research and Development Manager since May 2006, and as a member of the company's Board of Directors since November 2006. From 2003 through 2006, Dr. Roth worked in the Advanced Technology Center of the Chaim Sheba Medical Center at Tel Hashomer as a researcher in the field of Magnetic Resonance Imaging (MRI). Dr. Roth's primary research interests are TMS and Magnetic Resonance Imaging (MRI), and he was one of the two key inventors of Brainsway's patented Deep TMS coil. Dr. Roth holds B.Sc. and M.Sc. degrees in Physics and a Ph.D. in Medical Physics from Tel Aviv University.

Ronen Segal

Chief Technology Officer

Mr. Segal has more than 20 years of top leadership roles in various fields including vast hi-tech management experience in a wide range of leading technological groups. In 2004 he co-founded WiTech Communications Ltd., a

[92] https://www.brainsway.com/management

company providing wireless video solutions for diverse commercial applications, where he served as a Vice President. Prior to this, Ronen served as projects leader for OpTun Inc., where he was responsible for the development of sophisticated fiber-optics communications active switching components. From 1998 to 2000, he worked for the Israeli Navy's development center on a state-of-the-art submarine data communication system. From 1994 to 1998, Mr. Segal served in the Israeli Ministry of Defense's Advanced Technology Unit. He studied at the Jerusalem College of Technology as part of a special academic reserves project in electro-optical Engineering and applied physics.

Hadar Levy
Chief Financial Officer
Mr. Levy has over 15 years of experience in finance and administration. Prior to joining Brainsway, Mr. Levy served as Finance manager in the Latin America Division at Amdocs Ltd., responsible for accounting, financial reporting, treasury, portfolio management and finance support to Mergers & Acquisitions. Prior to Amdocs, Hadar Levy served as Chief Financial Officer & Business Development of Notal Vision, a healthcare company that researches and develops medical technologies for detecting retinal malfunction and deterioration, where he was responsible for all financial functions, and lead financial rounds of equity including M&A activities with strategic partners. Prior to this position, he served as Controller of GE Healthcare Israel. Mr. Levy began his career at Deloitte LLP, holds a BA in Accounting and Economics and an LLM degree from Bar Ilan University and is a Certified Public Accountant.

Amit Ginou
VP Field and Clinical Operations
Amit Ginou manages the Field and Clinical Operations at Brainsway. Prior to this, Amit served as the Clinical Trials Manager at Brainsway, conducting dozens of clinical trials at different phases to explore the efficacy and safety of Brainsway Deep TMS for diverse clinical indications. Amit holds a B.Sc. degree in Neuroscience from Bar-Ilan University, and an MA Law degree from Bar-Ilan University.

Eliran Ron
Vice President, Global Operations
Eliran Ron is Vice President, Global Operations for Brainsway and serves on the company's Management Committee. He is responsible for leading Brainsway's Global Operations, Production, Logistics, Purchasing and Facilities. He joined Brainsway in 2009.Ron is working to drive expansion, efficiency and value creation efforts in a variety of operation roles. He has a record of assessing and diagnosing opportunities to capture value and institute new operational and service delivery models to seize efficiently at scale. His operations management background included creating and executing company plans. Ron studied for a degree in Finance and Accountancy at the Hebrew University of Jerusalem.

Aron Tendler
MD, C.BSM
Chief Medical Officer
Dr. Tendler brings years of experience in the treatment of mental disorders as a psychiatrist. Dr. Tendler graduated in 2002 from State University of New York Downstate Medical School in Brooklyn with Distinction in Research. From 2002-2004, he trained at Tulane University in Internal Medicine and Psychiatry followed by two years at the University of Chicago in General Psychiatry, where he was chief resident of the consultation liaison service and course director for psychosomatic medicine. Dr. Tendler is Board Certified in General Psychiatry, Sleep Medicine and Behavioral Sleep Medicine . In 2006, Dr. Tendler established Advanced Mental Health Care Inc. in Florida, which has since served over

4000 patients in Palm Beach County, Florida. Dr. Tendler began using TMS clinically in 2009 for a variety of psychiatric and neurological conditions, and his clinical research sites participated in the clinical trial that led to Brainsway's FDA clearance. Currently, he has three clinical research sites studying the efficacy of Deep TMS for Bipolar Depression, Smoking Cessation, PTSD and OCD.

Joseph Perekupka
VP Sales Operations, North America
Joseph Perekupka is an award–winning sales and operations executive who designs and implements highly successful strategies and teams that drive revenue and improve market share within medical device and pharmaceutical sectors. Throughout his 20-year career, Mr. Perekupka held leadership positions in variety of companies, including Biotronik Inc., a company specializing in advanced cardiology devices, St. Jude Medical Inc., a cardiovascular manufacturing company, and Forest Laboratories, a company focusing on Manufacturing of Pharmaceutical products. In addition, he held management positions at Bristol-Meyers Squibb, Co. Mr. Perekupka earned a BA in Marketing from Pennsylvania State University and an MBA in Management and Finance from The Gabelli School of Business at Fordham University.

Appendices

Appendix A - Financial Reports

Profit and Loss Statement (in thousands $)

	31.12.2014	31.12.2015	31.12.2016	31.3.2016	31.3.2017
Total Revenues	3,380	6,800	11,524	2,488	2,148
Cost of Revenues	656	1,466	2,427	473	447
Net Profit	2,724	5,334	9,097	2,015	1,701
R&D Expenses	6,438	4,103	3,792	1,044	1,161
Marketing Expenses	1,896	3,281	5,180	1,040	1,436
General and Administrative Expenses	1,667	2,455	2,194	1,103	586
Other Revenues	0	0	0	0	0
Operating Loss (EBITDA)	7,277	4,505	2,069	1,172	1,482
Financial income	3,195	636	186	303	65
Financial expenses	2,463	218	514	197	509
EBIT (Loss before Tax)	6,545	4,087	2,397	1,066	1,926

Balance Sheet (in thousands $)

Current assets	31.12.2014	31.12.2015	31.12.2016	31.3.2017
Cash and cash equivilents	17,201	11,355	9,174	7,221
Short-term deposits	1,075	585	585	587
Net Customers	972	2,009	2,492	2,906
Accounts receivable	510	915	859	942
Total current assets	19,759	14,864	13,110	11,656
Non-current assets				
Long term leasing expenses	30	34	24	27
Net fixed assets	5,868	7,329	6,821	7,287
Intangible assets	25	16	9	8
Total non-current assets	5,923	7,379	6,854	7,322
Total assets	**25,682**	**22,243**	**19,964**	**18,978**
Current liablitities				
Liabilities to suppliers and service providers	1,522	944	810	1,401
Accounts payable	1,180	1,228	1,436	1,321
Revenues in advance	2,650	2,526	1,861	1,966
Liabilities for ST R&D funding	99	198	288	137
Total current liabilities	5,451	4,896	4,395	4,825
Non-current liabilities				
Revenues in advance and other liabilities	218	193	374	291
Liabilites for LT R&D funding	3,817	4,204	4,908	5,326
Liabilities from Investor options	671	55	-	-
Total non-current liabilities	4,706	4,452	5,282	5,617
Total Liabilities	**10,157**	**9,348**	**9,677**	**10,442**
Equity	**15,525**	**12,895**	**10,287**	**8,536**
Total liabilities and equity	**25,682**	**22,243**	**19,964**	**18,978**

Appendix B - Capitalization Rate

Cost of equity capital (ke) represents the return required by investors. The capitalization rate is calculated using the CAPM (Capital Asset Pricing Model). It is based on a long-term 20-year T-bond with a market risk premium, and based on Professor Aswath Damodaran's (NY University) commonly used sample (www.damodaran.com). As of January 1st, 2017, the Israeli market risk is estimated at 6.69%.

A three-year market regression Beta is 1.19, according to a sample of 254 companies representing the US Healthcare products (including medical devices). Brainsway has no loans or any other rate-carrying liabilities, which are considered non-operational liabilities. In order to reach the relative CAPM, we used an unleveraged beta of this sample, which is higher than a leveraged beta, due to high rate of cash versus debt. The implied CAPM is 8.8%.

CAPM model (ke) is estimated as follows:

$ke = rf + \beta(rm-rf) + P$

Brainsway is a small cap company, in which marketability and size premiums need to be considered. Duff and Phelps data research in the years 1963-2012 indicates that a 10.24% premium needs to be added to the CAPM for small cap companies. We therefore estimate the company's CAPM to be 19.0%.

CAPM Model		Value	Source
Long-term (20 years) T-bond	R(f)	2.4%	US Department of the Treasury
Market risk premium	R(m)- R(f)	6.69%	based on Professor Damodaran's sample (1/1/17)
Beta unleveraged	β	0.92	Beta sample of Healthcare products -254 firms Damodaran's sample (1/1/17)
Cost of Capital	ke	8.8%	
Size Premium		10.24%	Duff and Phelps data
CAPM	CAPM	**19.0%**	

Appendix C - Deep TMS background

Deep TMS utilizes the basic principles of TMS but expands them beyond the use of a single focal stimulation source to a summation of several simultaneous operating elements. Deep TMS therapy stimulates the brain based on brief magnetic fields, with pulses administered by passing high currents through an electromagnetic coil that induces an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative to the brain's neuronal pathways, localized axonal depolarizations are produced, thus activating neurons in the targeted brain structure. The electromagnetic pulse is given at a low frequency in the order of 1-10 kHz. Interaction with the human body is caused by the briefly changing magnetic field, and its effect may be neuronal activation.

Many neurological and psychiatric disorders are associated with abnormal neuronal activity patterns in deep brain regions. The exact mechanism behind the origin and transmission of signals to the brain is very difficult to identify, however, these regions can be affected indirectly, through secondary processes involving cortical structures, which are directly activated by TMS and, in turn, affect the deeper structures. It is currently understood that the main mechanism by which the electromagnetic field in transcranial EM stimulation modulates brain function, is neural membrane polarization shift. This shift can, in turn, lead to diverse changes in single-neuron, synaptic, and network activity, which may ultimately be reflected in behavioral and cognitive changes.[93]

[93] Angel V. et al. Brain Stimulation (2012) 5, 435–53

Appendix D – Short Biographies of the Analysts Team

Kobi Hazan is the Lead Analyst at Frost & Sullivan Research & Consulting Ltd., a subsidiary of Frost & Sullivan in Israel. He has over 14 years of experience in capital markets, including research, analysis, investment advisory, and management. Mr. Hazan served as a Fund Manager for provident and mutual funds at Analyst Ltd. and, since 2012, he owns and manages the Amida Israel Fund, a hedge fund specializing in Israeli equities. Kobi holds an Economics and Management degree from The College of Management Academic Studies. He is licensed as an Investment Advisor in Israel.

Dr. Moria Kwiat

Moria joined Frost & Sullivan for the TASE program. A specialist in the field of biotechnology, Moria holds a Ph.D. in Chemistry and nanotechnology, M. Sc. and B. Sc. in Biotechnology from Tel Aviv University. Moria has a broad scientific background in inter-disciplinary fields and over 12 years of conducting original research, with expertise at the interface between Biology and Materials worlds. She has a strong track record of developing biosensors for diagnostics utilizing electrical devices. Moria is the co-author of multiple scientific papers with a vast experience in scientific writing.

Arjunvasan Ambigapathy

Arjunvasan has over a decade of experience at the interface between leading teams, business development and project management. In Frost & Sullivan, he has managed projects delivering end-to-end advisory to global business leaders in tapping the potential of emerging disruptive technologies for business growth. He is also a KPMG-certified lean six sigma expert, and actively contributes to the Project Management Institute (PMI) and All India Medical Devices Association (AIMED) as a professional member. He holds an B.E. in Biomedical Engineering from Anna University, and an MBA in Financial Management from the University of Madras.

Dr. Tiran Rothman is an Analyst and Consultant at Frost & Sullivan Research & Consulting Ltd., a subsidiary of Frost & Sullivan in Israel. He has over 10 years of experience in research and economic analysis of capital and private markets, obtained through positions at a boutique office for economic valuations, as chief economist at the AMPAL group, and as co-founder and analyst at Bioassociate Biotech Consulting. Dr. Rothman also serves as the Economics & Management School Head at Wizo Academic College (Haifa). Tiran holds a PhD in Economics, MBA (finance), and was a visiting scholar at Stern Business School, NYU.

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