

Alzheimer's: A String of Unsuccessful Stories

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ALZHEIMER'S: A STRING OF UNSUCCESSFUL STORIES

Pfizer, Inc.—one of the largest pharmaceutical companies—took the healthcare industry by surprise during the first week of 2018, with its decision to end its neuroscience discovery and early development efforts. This unexpected move was followed by its repeated failure of drugs in clinical trials. Alzheimer's disease and Parkinson's disease comprised an integral part of Pfizer's neuroscience division. Alzheimer's disease is a major cause of dementia which affected around 47 million people globally in 2016, according to the World Alzheimer Report (2016). Owing to growing prevalence of this condition, companies are increasingly investing in R&D for Alzheimer's treatment. However, Pfizer and Merck's attempt did not bear fruit. Officials at Pfizer announced re-allocation of resources from neuroscience division to other divisions, in which the company has a strong pipeline and scientific experience. Pfizer in collaboration with Johnson & Johnson was working on the development of Bapineuzumab, a human monoclonal antibody for Alzheimer's disease, which failed in Phase 3 trials in 2012. According to the data published in BMC in 2016, the phase 3 trials showed no significant difference between co-primary endpoints of the real drug and its placebo and Bapineuzumab showed no effect on amyloid load or cerebrospinal fluid phosphorylated tau. The decision of quitting R&D of Alzheimer's and other neurological disorders must have been hard for Pfizer, considering the potential this market holds.

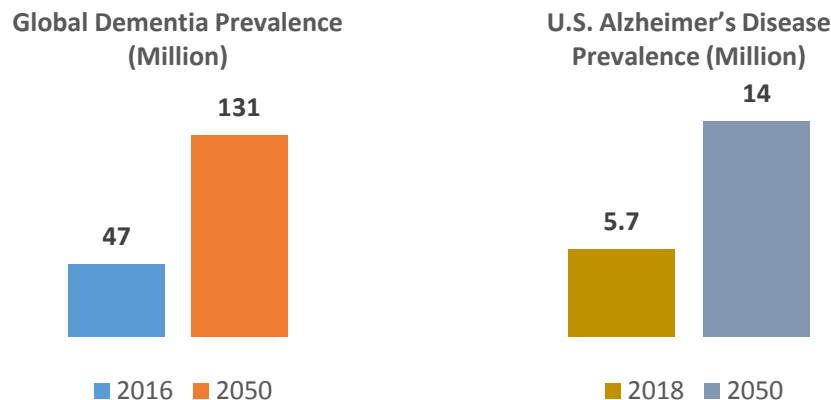
Market Opportunity

The worldwide cost of dementia is expected to cross US\$ 1 trillion mark by 2018 end

Alzheimer's accounts for an estimated 60% to 80% of all of dementia cases, according to 2018 Alzheimer's Facts and Figures published by Alzheimer's Association. Moreover, according to the World Alzheimer Report 2016, around 47 million people were living with dementia worldwide in 2016, and this is expected to increase three-fold to reach 131 million by 2050. U.S., the largest healthcare market, suffers from maximum loss by this disease. According to the data published by Alzheimer's Association 2018, around 5.7 million people in the U.S. are living with Alzheimer's disease, the number for which is estimated to increase to 14 million by 2050.

<https://www.coherentmarketinsights.com/market-insight/alzheimers-drugs-market-1373>

Fig 1. Dementia and Alzheimer's Disease Prevalence

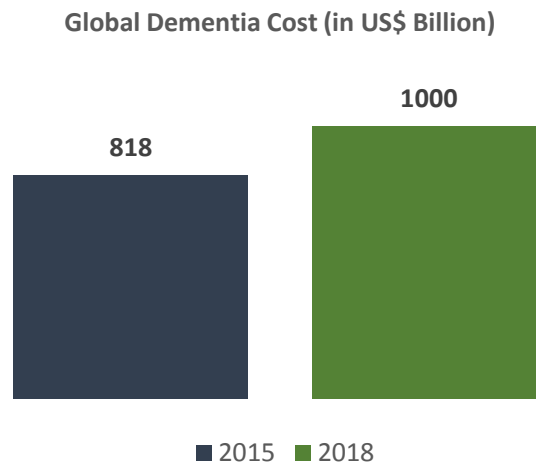


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Source: World Alzheimer Report 2016, Alzheimer's Association

The worldwide cost of dementia was estimated to be US\$ 818 billion in 2015 and expected to reach US\$ 1,000 billion (i.e. US\$ 1 trillion) by 2018, according to the World Alzheimer Report of 2016. Keeping things in perspective, the estimated worldwide cost of dementia for 2018 is almost equivalent to the global pharmaceutical market size; higher than the current market value of the highest valued global company Apple Inc. (as of May 27, 2018); and over twice the total revenue (2017) of the top 10 pharmaceutical companies globally.

Fig 2. Global Dementia Cost



Source: World Alzheimer Report 2016

Current Treatment Method

Out of 5 available drugs three were blockbuster drugs before the entry of generics

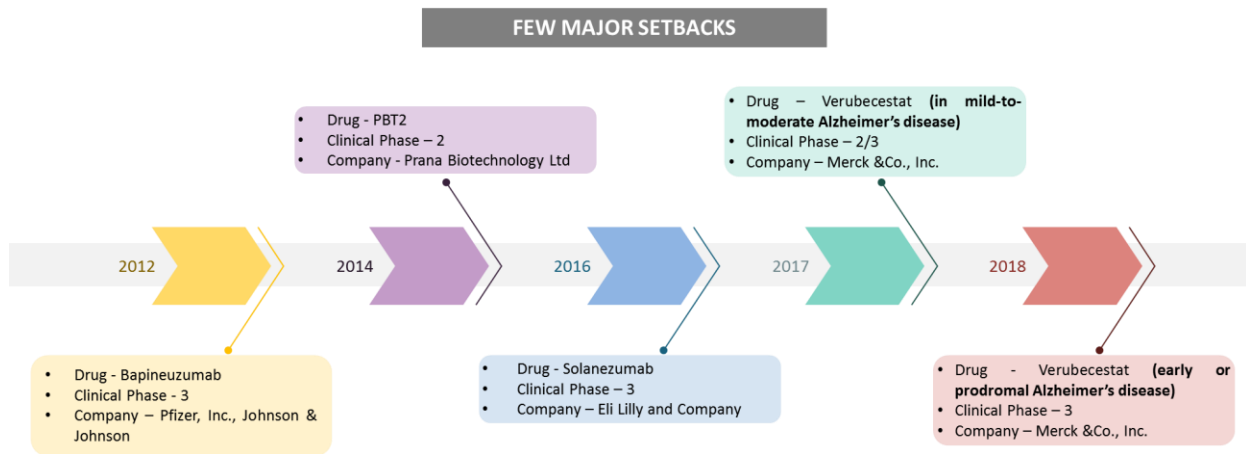
One way to verify this immense opportunity is assessing the performance of already approved drugs for the treatment of Alzheimer's disease. Currently, 5 drugs namely, donepezil (Aricept), Galantamine (Razadyne), Memantine (Namenda), Rivastigmine (Exelon), and Memantine + Donepezil (Namzaric) are approved for the disease, four of which have already lost their patents. Furthermore, three of these five drugs (Aricept, Namenda, and Exelon) were blockbuster drugs (i.e. US\$ 1 billion revenue a year). Namzaric was approved in 2014 and generated revenue of US\$ 11.2 million in 2015 and US\$ 57.5 million in 2016, exhibiting 413.4% year-on-year growth. Aricept, manufactured by Eisai Co. Ltd., is so far the most preferred drug for the treatment of Alzheimer's disease. The drug generated maximum revenue of US\$ 3.4 billion in 2010, and sustained its position as a blockbuster drug during 2004-2010, until the entry of generics in 2010.

Clinical Trials Scenario

Pfizer has officially abandoned this field and Merck & Co., Inc. has no product in pipeline. However, Eli Lilly and Company and Biogen have 5 and 6 products in pipeline, respectively.

The long list of unsuccessful drugs for Alzheimer’s disease is dismaying, however, the rate of failure seems to be uniform across large-, small-, and medium-sized companies. The list includes pharmaceutical giants such as Pfizer, Inc., Merck & Co. Inc., Eli Lilly and Company, and Johnson & Johnson, as well as small- and medium-sized companies such as Axovant Sciences and Prana Biotechnology Ltd. In 2012, Pfizer and Johnson & Johnson ended the phase 3 trial for bapineuzumab as the drug was not able to meet the co-primary endpoints in phase 3. An Australia-based company, Prana Biotechnology Ltd., in 2014, announced that its drug was unable able to meet primary endpoints in Phase 2. In 2016, Eli Lilly and Company dropped plans to seek market approval for Solanezumab, followed by depressive results in Phase 3 trail. In 2017, Merck & Co., Inc. announced plans to halt Phase 2/3 study for Verubecestat, an inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), for mild-to-moderate Alzheimer’s disease, and scrapped the trial for Verubecestat for patients with early or prodromal Alzheimer’s disease in 2018. In 2017, Axovant Sciences Ltd. announced negative results for Intepirdine in Phase 3. The patients treated with the drug did not experience improvement in cognition, according to the company’s press release.

Fig 3. Alzheimer’s Drug Failure in Clinical Trials



Source: Company Website, Company Press Releases, Clinicaltrials.gov

Despite the daunting amount of failures, over 100 drugs currently are present across different phases of clinical trials for Alzheimer’s disease, and majority of the players who have experienced some form of test failure are still in the game. Currently, Eli Lilly’s website shows 5 drugs in pipeline, and Biogen has 6, while Prana Biotechnology Ltd. has 1 product listed on its website, for Alzheimer’s disease. Moreover, new player such as Novartis AG and Amgen Inc. are focusing on strengthening their neuroscience division focused on development of drugs for Alzheimer’s disease. Both these companies, announced expansion of collaboration with Banner Alzheimer’s Institute in November 2017. During the same time, some companies were seen opting out of this therapeutic category. For

instance, Merck & Co. Inc. does not have any product currently in pipeline, and Pfizer has officially announced closure of its division that works on Alzheimer's and Parkinson's disease drug discovery.

Conclusion

“While we are deeply disappointed by these trial results, we also are saddened for the millions of patients and families impacted by Alzheimer's disease. However, we believe that the fight against Alzheimer's and other important areas of unmet need in neurology is too important to be derailed by this setback”

The above statement by the CEO of Axovant Science Ltd., quite accurately describes the current 'Alzheimer's drug development' scenario. Abandoning is no solution for failures in clinical trials. Moreover, this may be an opportune moment for all the stakeholders including biotech and pharmaceutical companies and scientists to look for novel treatment method such as developing a vaccine for Alzheimer's disease. Araclon Biotech, a Spain-based company, is currently working on the development of a vaccine for Alzheimer's disease. In June 2017, the company announced that Spanish Agency of Medicinal Products and Medical Devices has granted approval to start phase II clinical trials for its active immunotherapy (ABvac40) for Alzheimer's disease.

The situation, thus, does not seem to be worrisome owing to the numerous amount of drugs in pipeline for Alzheimer's disease. Most of these are being developed by medium- and small-scale companies. Pharmaceutical giants such as Pfizer, Merck, and Johnson & Johnson have tasted failure in this segment, however, it would be no surprise if they acquire potential drugs under development and re-enter the Alzheimer's drug market through such inorganic strategies.

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