Case Analysis

AbbVie: compressing costs, expanding the pipeline

Andrea Ferrante
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Background

HISTORY

AbbVie is a research-based biopharmaceutical company originating from a strategic separation within Abbott Laboratories. In 2011 Abbott announced that it would separate into two publicly traded companies. The one maintaining the original name would focus on diversified medical products, including medical devices and tests. The new company would be named AbbVie and would specialize in research-based pharmaceuticals. The separation was effective on January 1st, 2013.

Although AbbVie history is recent, it cannot be separated from the history of the mother company, Abbott. Abbott is a Chicago-based company leader in pharmaceuticals and health care products. It was founded in 1888 by Dr. Wallace C. Abbott under the name of Abbott Alkaloid Company. Dr Abbott had only graduated from the University of Michigan three years earlier, and was a practicing physician and owner of a drug store. Using the active part of a medicinal plant, known as the "alkaloid", he formed tiny pills called "Dosimetric granules". These granules provided more accurate and effective dosing for his patients than any other administration method available at the time. The company's first year sales came to a total of US $2000.

As the demand for these granules increased, so did Abbott Alkaloidal Company, and one of the world's most broad-based healthcare companies was born. By 1910, there were over 700 new products in the Abbott catalogue. The company had expanded too, with branches in New York, San Francisco, Seattle and Toronto, as well as a European agency in London and business in India. To reflect the company's growing research orientation and move into synthetic compounds, the name was changed to Abbott Laboratories in 1915. During World War I, Abbott's antiseptic agent, chlorazene, was used to clean wounds on the battlefields. In 1921, Dr. Abbott died and Dr. Alfred Stephen Burdick was named president of the company. Eight years later Abbott was listed on the Chicago Stock Exchange – the offering was 20,000 shares for $32 each. It was during the 1920s when the development of Butyn, a butyl alcohol-based anesthetic, marked the beginning of Abbott's long, productive and groundbreaking involvement in the field of anesthesia. By 1930, the anesthetic Nembutal was introduced – this went on to become Abbott's best-known and longest-lived products. In 1936, Pentothal, another anesthetic agent, was introduced. Fifty years later its developers, Abbott scientists Drs. Ernest Volwiler and Donalee Tabern, were named to the U.S. Inventors Hall of Fame for their discovery of the compound. The company is among the pioneers of the I.V. business, supplying hospitals with bulk intravenous solutions.

Abbott celebrated its 50th anniversary in 1938 with the dedication of a new, state-of-the-art research center in North Chicago. In 1941, the US Government enlisted Abbott as one of five pioneers to develop a large-scale production of the new anti-infective penicillin. One of Abbott's first of many epilepsy treatments was introduced in the year of 1945 and was called Tridione.

In 1946, Abbott became the first pharmaceutical company to have a special laboratory for radiopharmaceuticals – a move that led to the creation of the world's leading immunodiagnostics business. Radiocaps, capsules containing an accurately controlled, invisibile and un-weighable film of radioiodine that simplifies the diagnosis and treatment of thyroid disorders, was introduced in 1953. During the 1960s, Abbott entered the Japanese market through a joint venture with Dainippon Pharmaceutical Co., Ltd, to manufacture radiopharmaceuticals. In 1963, the company had created the Triosorb diagnostic test kit. This test kit no longer required a patient to swallow a radioactive substance. Instead, it allowed for a blood sample to be inoculated with a radioactive form of thyroid hormone. Ausria, a radioimmunoassay test to detect serum hepatitis, was launched in 1972 and marked the beginning of Abbott's immunodiagnostics business. A year later, the Abbott Diagnostics Division was formed to bring together the company's diagnostic products and services. In 1977, TAP Pharmaceuticals was formed as a joint venture between Abbott and Japan's Takeda Chemical Industries.

As its centennial approached, Abbott reached a few more product milestones during the early 1980s. Firstly, the TDx therapeutic drug monitoring system was introduced, followed by the US approval of a new epilepsy treatment, Depakote (divalproex sodium). Then, in 1985, Abbott launched the world's first HIV antibody assay. In 1996, one of the first protease inhibitor drugs indicated in combination with other antiretroviral agents for the treatment of HIV was launched. This drug is called Norvir (ritonavir). By the end of the 90s, Abbott had entered into the hematology testing market following the acquisition of Sequoia-Turner Corp. It had also acquired MediSense, Inc., marking the company's entrance into glucose monitoring for people with diabetes, and Perclose, a leading vascular closure devices company, marking the company's

entry into vascular care. Also, a next-generation diagnostic system, ARCHITECT, had been launched.

Throughout the 2000s, there were many more significant product approvals and acquisitions. Kaletra (lopinavir/ritonavir), a next-generation treatment used in combination with other antiiretovirol agents for HIV, was approved in 2000, **followed by the approval of Humira (adalimumab) in 2002**. Humira is a treatment for moderate to severe rheumatoid arthritis, the first of six disease indications it has received en route to becoming Abbott's most successful product ever (**now produced and distributed by AbbVie**). Abbott acquired the pharmaceutical business of BASF, including the global operations of Knoll Pharmaceuticals, expanding the company's global scope and biotech capabilities. Vysis, Inc., a leading genomic disease management company, was acquired the same year to strengthen Abbott's position in the molecular diagnostics market. The Vysis UroVysion molecular test to monitor for recurrent bladder cancer was approved. In 2003, Abbott acquired JOMED's coronary and peripheral intervention business lines, and entered the healthy-living nutrition category with ZonePerfect Nutritional Co.

Abbott Diabetes Care was created in 2004 with the acquisition of TheraSense Inc., a leading blood glucose monitoring business. The diagnostics portfolio was expanded with the addition of i-STAT Corp., a maker of point-of-care diagnostic technologies and EAS Inc., a leader in performance nutrition products, was also acquired. In 2006, Abbott acquired Guidant, a leader in coronary and vascular products, and Kos Pharmaceuticals, a speciality pharma company with a significant lipid management portfolio. In 2009, Ibis Biosciences was acquired,

as was Advanced Medical Optics, Visiogen and Evalve. To focus on its growing position in emerging markets, Abbott created the Established Pharmaceuticals Division in 2010.

Finally, in 2011, Abbott announced it was to separate into two leading healthcare companies by the end of 2012. On January 1, 2013, AbbVie became an independent, publicly traded company as a result of the distribution by Abbott Laboratories (Abbott) of 100 percent of the outstanding common stock of AbbVie to Abbott's shareholders. Each Abbott shareholder of record as of the close of business on December 12, 2012, received one share of AbbVie common stock for each Abbott common share held as of the record date. AbbVie was incorporated in Delaware on April 10, 2012 and is comprised of Abbott's former research-based pharmaceuticals business. AbbVie's common stock began trading ''regular-way'' under the ticker symbol ''ABBV'' on the New York Stock Exchange on January 2, 2013.

In two years, AbbVie has already expanded research pipeline, terminated clinical trial and gained FDA approval for 3 new compounds. AbbVie has expanded its manufacturing facilities in Ireland, Singapore, and as of March 4th 2015 has announced the acquisition of Pharmacyclics, the producer of Imbruvica, a drug indicated for the treatment of blood cancers. AbbVie has already collected a significant number of awards and recognition both for the company products as well as organizational culture and work ethics. AbbVie production focuses on health issues pertaining immunology (including rheumatology, dermatology, lupus, Crohn's disease), kidney disease, liver disease (specifically chronic HCV infection), neuroscience (Alzheimer's, Parkinson's, Multiple sclerosis), oncology and women's health (endometriosis and uterine fibroids).

ORGANIZATIONAL STRUCTURE AND CULTURE

AbbVie is a large and complex company, operating in 15 primary research and manufacturing facilities around the world (mainly US and Europe), with about 100 subsidiaries for distribution and limited R&D across the globe, and selling their products in more than 170 countries. AbbVie's corporate offices are located at 1 North Waukegan Road, North Chicago, Illinois 60064-6400. AbbVie's principal manufacturing plants are in the following locations: United States: Abbott Park, Illinois (leased property); Barceloneta, Puerto Rico; Jayuya, Puerto Rico; North Chicago, Illinois; Worcester, Massachusetts. Outside the United States, AbbVie owns manufacturing plants in Campoverde di Aprilia, Italy; Cork, Ireland; Ludwigshafen, Germany; Sligo, Ireland, and a recently acquired facility in Singapore. In addition to the above, AbbVie has other manufacturing facilities in the United States and worldwide. AbbVie also has four United States research and development facilities located at: Abbott Park, Illinois; North Chicago, Illinois; Redwood City, California; and Worcester, Massachusetts. Outside the United States, AbbVie's principal research and development facilities are located in Shanghai, China and Ludwigshafen, Germany.

AbbVie employed approximately 25,000 people as of January 31, 2014. The vertical span of the executive organizational chart starts with the CEO Richard Gonzalez. He served as Abbott's Executive Vice President, Pharmaceutical Products Group from 2010 to 2012, and was responsible for Abbott's worldwide pharmaceutical business, including commercial operations, research and development, and manufacturing. He has also served as President for Abbott Ventures Inc., Abbott's medical technology investment arm, from 2009 to 2011. Mr. Gonzalez joined Abbott in 1977 and held various management positions before briefly retiring in 2007,

including Abbott's President and Chief Operating Officer; President, Chief Operating Officer of Abbott's Medical Products Group; Senior Vice President and President of Abbott's former Hospital Products Division (now Hospira, Inc.); Vice President and President of Abbott's Health Systems Division; and Divisional Vice President and General Manager for Abbott's Diagnostics Operations in the United States and Canada.

The board of directors overseeing the company is formed by nine professionals (Robert Alpern, Roxanne Austin, William Burnside, Edward Liddy, Edward Rapp, Roy Roberts, Glenn Tilton and Frederick Waddell). Reporting to him are the CFO, William Chase (who, in turn, oversees the responsible officer for tax reporting, Krista Fiedler); the Business Development, External Affairs and General Counsel, Laura Schumacher; the responsible for Commercial Operation, Carlos Alban; the CSO, John Leonard, (to whom the R&D and second CSO Michael Severino responds); the director of Human Resources Tim Richmond (who oversees Talent Acquisition Laura Smith; Talent Proposition Melissa Aufmann and Talent management Angela Lane); the director of Operations Azita Saleki-Gerhardt; the responsible for Ethics and regulation Ronald Robison and the responsible for Strategic Initiative Glenn Warner. The CFO has an implied authority over other department heads, although he is reported at the same level as the others. The organizational structure then develops in a matrix-like fashion, since every project developed by a project manager will be cross-supervised by several departments (such as operation, regulation, ethics, and so on) through the pertinent sub-departments (such as chemical pharmacy, pharmaceutical logistics, animal model handling, licensing, pharmacoeconomics, and so on). This very brief description of the organizational chart is not considering the R&D activities performed abroad (Ireland, Italy, Germany) and the management of the multitude of

subsidiaries responsible for local distribution and some limited R&D. The organizational chart is shown in the Appendix.

The executive officers of AbbVie are elected annually by the board of directors. All other officers are elected by the board or appointed by the Chairman of the Board. All officers are either elected at the first meeting of the board of directors held after the annual stockholder meeting or appointed by the Chairman of the Board after that board meeting. Each officer holds office until a successor has been duly elected or appointed and qualified or until the officer's death, resignation, or removal.

The culture of AbbVie is channeled through their values:

- Pioneering: leading-edge science. AbbVie sets its sights on pioneering solutions that advance healthcare.
- Achieving: customer-focused outcomes and world-class execution. AbbVie strives to achieve results for those served by the company by setting our own high standards.
- Caring: making a difference in people's lives. AbbVie shares deep passion for work and caring for the people who use AbbVie products.
- Enduring: AbbVie states to be proud of a 125-year heritage (referring to Abbott's history). They build on their strong, enduring heritage and continue to invest in the future to address health needs where they are greatest.

AbbVie states that each of their employees "brings their own unique ideas, approaches and life experiences to AbbVie. This type of diversity creates an eclectic workplace". AbbVie encourages employees to challenge ideas, take risks and create novel solutions to better meet

patient needs. By fostering creativity and rewarding innovation, AbbVie seeks development of new discoveries.

Evaluation of AbbVie's performance and environment

ABBVIE'S STRENGTHS

AbbVie possesses a number of competitive advantages that distinguish the company from its competitors, including:

Portfolio of leading products. AbbVie has a strong portfolio of products led by its market leading biologic, Humira. Humira is approved for seven indications in the United States and nine in the European Union, and is also in development for a number of additional indications. AbbVie has leading market positions in several treatment areas including rheumatoid arthritis, psoriasis, Crohn's disease, HIV, cystic fibrosis complications, low testosterone, and thyroid disease. These treatment areas have significant growth potential driven by a number of factors, including increasing prevalence and diagnosis, demographics, and market penetration. AbbVie's products demonstrate strong clinical performance for the patient and economic value for the payor.

Broad pipeline of small molecule drugs and biologics targeting areas of unmet medical need. Building and advancing AbbVie's existing product pipeline is a key driver to future growth. For example, AbbVie's investigational interferon-free HCV treatment, which has been recently approved by FDA (Viekira), has the potential to shorten and simplify treatment and

increase cure rates. In addition, other Phase III programs (the final phase of clinical trials) include: daclizumab for multiple sclerosis; a levodopa-carbidopa intestinal gel (LCIG) in the United States for advanced Parkinson's disease; elagolix for endometriosis; elotuzumab for multiple myeloma; and several new Humira indications. AbbVie's pipeline also includes 10 compounds or new indications in mid-stage trials, including several that are expected to advance to Phase III within the next 18 months.

Worldwide commercial infrastructure and opportunity for continued geographic penetration and expansion. AbbVie's products are sold in more than 170 countries. AbbVie has strong and extensive sales, marketing, and distribution organizations around the world to support its products. In 2013, AbbVie had sales of approximately $7.7 billion outside of the United States, including sales to emerging markets of approximately $2.4 billion, or 14 percent, of sales. Continued penetration of Humira and other products will help drive growth in markets worldwide.

Strong cash flow. In 2013, AbbVie generated approximately $6.2 billion in operating cash flow and spent approximately $0.4 billion on capital expenditures. AbbVie anticipates that its business will continue to generate stable cash flow going forward, which would allow the company to continue to invest in its pipeline and return cash to stockholders in the form of dividends.

Experienced management team with track record of successful performance. AbbVie's management team has a strong track record of performance and execution, including the CEO Richard A. Gonzalez; the CFO, William J. Chase; the General Counsel and Corporate Secretary, Laura J. Schumacher; and the Chief Human Resources Officer, Timothy J. Richmond.

ABBVIE'S ENVIROMENT AND CHALLENGES

The business segment in which AbbVie operates, pharmaceutical products, is characterized by a turbulent environment. The challenges that AbbVie, and any other pharmaceutical company of comparable size and complexity experience are numerous and they relate in general to the following aspects of business operation: reserarch and development activities, intellectual property protection and regulatory exclusivity, sales, marketing and distribution capabilities, competition, regulation of discovery and clinical development (for different markets and countries); regulation of commercialization, distribution and manufacturing (for different markets and countries); human resources management and information technology management. In what follows, the three main factors posing risks to AbbVie performance at the present time or immediate future are discussed. In the next paragraph, recommendations will be suggested in response to these factors.

Competition: AbbVie needs to face a highly competitive market. AbbVie competes with other research-based pharmaceuticals and biotechnology companies that discover, manufacture, market, and sell proprietary pharmaceutical products and biologics. For example, Humira competes with a number of products that are approved for a number of disease states and AbbVie's virology products compete with protease inhibitors and other anti-HIV treatments. The search for technological innovations in pharmaceutical products is a significant aspect of competition. **The introduction of new products by competitors** and changes in medical practices and procedures can result in product obsolescence. **Price is also a competitive factor**, and this aspect will be particularly addressed in our recommendations. In addition, the

substitution of generic pharmaceutical products for branded pharmaceutical products creates competitive pressures on AbbVie's products that do not have patent protection.

Competition for AbbVie's biologic products is affected by the approval of follow-on biologics, also known as ''biosimilars.'' Biologics have added major therapeutic options for the treatment of many diseases, including some for which therapies were unavailable or inadequate. The advent of biologics has also raised complex regulatory issues and significant pharmacoeconomic concerns because the cost of developing and producing biologic therapies is typically dramatically higher than for conventional (small molecule) medications, and because many expensive biologic medications are used for ongoing treatment of chronic diseases, such as rheumatoid arthritis or inflammatory bowel disease, or for the treatment of previously untreatable cancer. Significant investments in biologics infrastructure and manufacturing are necessary to produce biologic products, as are significant investments in marketing, distribution, and sales organization activities.

The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an **abbreviated licensure pathway** for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. The Affordable Care Act, therefore, facilitates AbbVie's competitors as they apply for licensure of drugs with a pharmacodynamics, pharmacokinetics and activity comparable to those ascribed to Abbvie's biologics, first and foremost Humira. If competitors are able to obtain marketing approval for biosimilars referencing AbbVie's biologic products, **AbbVie's products may become subject**

to competition from such drugs that can be produced at lowers costs and therefore priced lower on the market.

Patenting and licensure. AbbVie relies on patent, trademark and other intellectual property protection in the discovery, development, manufacturing, and sale of its products. In particular, patent protection is, in the aggregate, important in AbbVie's marketing of pharmaceutical products in the United States and most major markets outside of the United States. Patents covering AbbVie products normally provide market exclusivity, which is important for the profitability of many of AbbVie's products. As patents for certain of its products expire, **AbbVie will or could face competition from lower priced generic products**. The expiration or loss of patent protection for a product typically is followed promptly by substitutes that may significantly reduce sales for that product in a short amount of time. If AbbVie's competitive position is compromised because of generics or otherwise, it could have a material adverse effect on AbbVie's business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs. Any such proposals that are enacted into law could worsen the effect of generic competition. The United States patent for Humira, which is AbbVie's largest selling product and had worldwide sales of approximately $10.7 billion in 2013, is expected to expire in December 2016, and the equivalent European Union patent is expected to expire in the majority of European Union countries in April 2018. **Patent expiration will obviously have important effects on AbbVie's performance.** Therefore it is imperative for AbbVie to adopt and implement a strategy in the remaining two years (four years in Europe) to limit the consequences of Humira patent expiration, and recommendation will be made with respect to this instance in the following

paragraph. Finally, AbbVie's major products could lose patent protection earlier than expected, upon third parties or government authorities initiative, which could adversely affect AbbVie's future revenues and operating income.

Cost-containment efforts and pricing pressures. Governments and private organizations are increasingly subject to cost-containment efforts. To the extent these cost containment efforts are not offset by greater demand, increased patient access to health care, or other factors, AbbVie's future revenues and operating income will be reduced. In the United States, the European Union and other countries, AbbVie's business has experienced downward pressure on product pricing, and this pressure could increase in the future. In the United States, practices of managed care groups and institutional and governmental purchasers and United States federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act, contribute to pricing pressures. Recently enacted changes to the health care system in the United States and the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries could result in additional pricing pressures. In numerous major markets worldwide, the government plays a significant role in funding health care services and determining the pricing and reimbursement of pharmaceutical products. Consequently, in those markets, AbbVie is subject to government decision-making and budgetary actions with respect to its products. In particular, many European countries have ongoing government mandated price reductions for many pharmaceutical products, and AbbVie anticipates continuing pricing pressures in Europe. Differences between countries in pricing

regulations could lead to third party cross-border trading in AbbVie's products that results in a reduction in future revenues.

Recommendations

The brief analysis presented in the previous paragraph has highlighted instances of AbbVie's business environment posing risks to the company performance at the present time and in the immediate future. The following recommendations are proposed in order to address these risks and allowing AbbVie to maintain its position as one of the leading pharmaceutical companies worldwide. One common trait of these recommendations is the increased efficiency of AbbVie production, mainly by compressing expenses, since there is the likelihood that future revenues and operating income will decrease.

Prioritizing and expanding the pipeline. With the threat posed by the increasing number of competitors in the field of biologic, AbbVie ought to bring to market products that demonstrate strong clinical performance for patients and economic value for payors. The company's pipeline should include both small molecules, cheaper to produce, and targeted biologic therapies, and a mix of new compounds and new indications. Currently, the company has several compounds or indications in Phase II or III development individually and under collaboration or license agreements.

Abbvie should prioritize development of those compounds with the lowest cost of production and targeting the largest patient population, or with potential multiple indications. With this regard, decisions should be made by management in accordance with a task force of individuals from the various sub-departments (chemical pharmacy, pharmaceutical logistics, animal model handling, licensing, pharmacoeconomics) who have direct supervision on the developmental and production phases.

Additionally, AbbVie ought to make adjustments as necessary to increase the value of its product portfolio. AbbVie will achieve this objective in a variety of ways depending on product and circumstances by, for example, identifying supply chain efficiencies, pursuing additional indications, and optimizing residual value as products reach the end of exclusivity. By adopting a similar approach, AbbVie will be able to maintain a strong operating margin on existing products.

Finally, AbbVie should increase collaborations with smaller companies, possibly from developing countries, for both R&D as well as manufacturing. A similar approach would help reach the goal of expanding the product portfolio, yet containing production costs. For instance, AbbVie might decide to collaborate with companies whose research and development efforts focus on infrequent or rare conditions, to grow in market segments and in geographical regions where the competition is weaker. AbbVie has begun to use this recommendation, as evidenced by the recent acquisition of Pharmacyclics, a small company focused on the development of antineoplastic compounds. Once AbbVie identifies companies with R&D potentials, decision will have to be made with respect to the nature of the collaboration (consortium, partnership,

joint venture, acquisition). Also outsourcing product manufacturing in countries with cheaper labor can increase efficiency. However, similar decision will require an effort from AbbVie management to ensure that the subsidiary company will comply with all the U.S. policies regarding production of pharmaceuticals (as they might be more stringent than those adopted in foreign countries), and with the local labor legislation.

Expanding Humira sales and managing patent expiration. Humira sales have had and still have a great impact on Abbott and AbbVie revenues. However, as mentioned above, AbbVie patent will expire in December of 2016. Until then, AbbVie should exploit Humira sales in two ways. First, AbbVie should expand the number of patients using Humira for the approved applications. Worldwide use of biologics as Humira in applicable populations continues to be low, ranging from mid-single digit percentages in moderate to severe plaque psoriasis to the ~25% for conditions such as moderate to severe rheumatoid arthritis and moderate to severe Crohn's disease. Thus, there is significant room for increasing clinically appropriate use across all of Humira's therapeutic areas, particularly in international markets, including Brazil, China, India, Mexico, Russia, and Turkey. Second, AbbVie should expand the Humira patient base by applying for regulatory approval of new indications for Humira, treating other rheumatologic conditions. Achieving the second outcome will require allocation of funds to obtain approval from FDA and European equivalent Health authorities of the new Humira applications, therefore a cost/benefit analysis is required in order to assess the upper limit of the investment budgeted to this aim.

Because HUMIRA is a biologic and biologics cannot be readily substituted, it is uncertain what impact the loss of patent protection would have on the sales of Humira. However, at the beginning of December 2014, the Indian company Cadila launched in India the first biosimilar version of Humira for a fifth of the price. Cadila expects to launch the medicine in the United States in 2019. Thus, AbbVie should plan on shifting profit margins from Humira to the newly patented compounds in the next 18 months, and drop Humira price to make it comparable to the one of equivalent products that AbbVie's competitor will be releasing after patent expiration.

Summary

AbbVie is a leading pharmaceutical company, delivering innovative pharmaceutical, nutritional, diagnostic and medical products all around the world. Although AbbVie has stability, resources, and expertise rooted in a 125-year history, the pharmaceutical business environment is dynamic and turbulent, and requires scalability, adaptability, and robustness. At the present time, the greatest challenges for AbbVie are compressing production costs to increase efficiency, expanding and prioritizing product pipeline to keep ahead of the competition, and plan the future of Humira, as new biosimilars are facing the market. Implementation of the proposed recommendations, together with other interventions that tackle issues not discussed here, are expected to help AbbVie maintain its leadership position.

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Appendix: Organizational Chart