

AN EVALUATION OF INNOVATION WITHIN A POST-ACQUISITION
LIFE SCIENCE ORGANIZATION: TEXT AND CASE STUDY

by

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ABSTRACT

The pharmaceutical industry is rooted in the ability to research, develop, market, and distribute safe and effect drugs that meet the need of patients. In many cases pharmaceutical companies attempt to accelerate their drug development efforts by acquiring other companies for their pipeline; however, there may be missed opportunities to protect, foster, and metabolize a core asset throughout the acquisition process: innovation.

The following capstone, presented as a single case study, focuses on innovation retention and protection through the lens of an acquired organization. While plenty of research has been conducted to prescribe how companies can become more innovative, this capstone explores practical methods for protecting existing innovative assets while reviewing challenges and opportunities through an organizational dynamics lens. The overall goal of this paper is to establish a suggest framework for protecting innovation in order to maximize organizational effectiveness.

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CHAPTER 1

This capstone examines how an organization protects and promotes innovation following an acquisition within the life sciences industry. This analysis—presented as a case study—will focus on the acquired organization’s methods for sustaining innovation. Particular attention will be paid to the changes in the organizational environment from the pre- to the post-acquisition while studying methodologies that did and did not work. The overall goal is to provide future “acquirees” with a roadmap for sustaining an innovative culture by collecting various examples from the acquired organization in this case and by assessing the available literature.

Introduction

In keeping with the life sciences theme I'd like to illustrate the causal relationships between acquirer and "acquiree" by presenting as metaphors the concepts of pharmacodynamics and pharmacokinetics—terms that are typically assigned to research laboratories and clinical settings. These are disciplines that study the relational effects of the drug product on the consumer (pharmacodynamics; herein PD) and of the consumer on the drug product (pharmacokinetics; herein PK). In other words, how does A impact B and how does B impact A. Most non-scientists might not find this field of study to be particularly interesting; however, as a student of Organizational Dynamics I have begun to consider how PK/PD can be useful in examining organizations' working harmoniously.

In fact it has become most interesting to me to offer a case study of the organization that has been at the epicenter of my Organization Dynamics learnings. Avid Radiopharmaceuticals (herein Avid) has historically been a small, start-up organization that has focused on developing innovative diagnostics products for molecular imaging of neurodegenerative diseases, namely Alzheimer's disease (herein AD). In its ten-year existence Avid has made tremendous strides in augmenting AD clinical research with the hopes of supporting the development of safe and effective therapies. Yet this case study offers more than a history of Avid's innovation because in the fifth year of Avid's

existence it was acquired by Eli Lilly & Co. (herein Lilly), a large pharmaceutical organization and the producers of blockbuster drugs such as Cialis®, Cymbalta®, Prozac®, and Zyprexa®.

Throughout this capstone we will examine the dichotomy of Avid pre-acquisition and post-acquisition while considering how innovation is/was protected as Avid's paramount asset. The goal is to collect methodologies, which may then be more generally applicable, for protecting and spreading innovation from Avid's perspective and to gather details for which practices did—or did not—work.

This is, however, not a capstone designed to criticize process-heavy bureaucratic organizations nor will we praise innovation-centric “startups.” In some cases we will discover that Lilly demonstrates some dynamic characteristics that Avid will eventually emulate. Nonetheless, while the bureaucratic model might suggest that size and creativity are inversely proportional (Navaretti et al, 2013), we are experiencing a rebirth of organizations of all types that are willing to learn from each other in order to optimize the ecosystem that can continue to face new and old challenges alike. The new model is characterized by or derives from the ability to reflect, exchange, and apply new learnings. It is rooted in an organization's commitment and ability to innovate. To make something new, or better.

Background of Alzheimer's Disease and Context

While the following paper will not focus on the scientific details of AD, it feels appropriate to spend some time providing a non-scientific summary of the disease itself. I am not, by any means, a scientist. My role within Avid is an operations/project manager, and I personally believe that this summary will help provide the necessary context to better understand how continuity of innovation is helping to find a cure faster.

AD was attributed to Alois Alzheimer following his 1907 published account of a 51-year-old patient named Auguste D (Alzheimer, 1907). Auguste D had suffered from various health conditions ranging from hallucinations, memory impairment, aggressive behavior, and disorientation. Following her death, Alzheimer performed a postmortem histological analysis—via autopsy—of Auguste's brain and found unusually dense bundles of amyloid- β (A β) and accumulated tau protein (Allsop, 2000; Ittner & Götz, 2011). Thus the presence of accumulated A β and tau proteins have since become the two hallmark neuropathological indicators for diagnosing AD (Allsop, 2000).

The problem that the medical community faced in 1907 was determining the presence of these two hallmark indicators *in vivo*. While scientists and researchers were able to study various therapeutics and effects of treatment, they were not able to unequivocally determine if a patient's ailments were caused by chronic alcoholism, psychosis, dementia, or AD (Arieti, 1946; Bresler, 1912;

Osnato, 1923). While research was still conducted, the inability to determine the presence or absence of A β and tau proteins hindered the scientific communities' ability to conduct controlled studies to include patients that fit the AD criteria (Jorm et al, 1991; Cohene et al, 2005). The community was left with collecting uncontrolled case studies for decades.

This method of data collection continued for almost a century until 2004 when the first radioactive amyloid tracer, Pittsburgh Compound-B (PiB), was successfully used to determine the presence of A β *in vivo*. When the brain was imaged using positron emission tomography (PET) cameras and PiB, researchers were able to demonstrate “marked retention of PIB” in regions of the brain known to contain amyloid deposits (Klunk et al, 2004). Although PiB was the first ligand that offered hope for researchers, it had a very limited half-life—roughly 20 minutes—and almost no chance of being used widely through clinical research due to a complex manufacturing process (Furst & Kerchner, 2012).

Avid—as we will review in Chapter 3 of this capstone—, previously a non-innovation- focused organization, was able to leverage this existing technology into an innovative imaging agent that could change the dynamics of AD research. Thus we will present Avid's experiences as part of a case study. We will investigate how Avid developed into an innovative organization that could transform AD drug development and how it worked to protect its ability to innovate following an acquisition.

Limitations of Research

This evaluation of innovation will consider a multitude of perspectives from various peer-reviewed journals, books, periodicals, and presentations; however, not all perspectives can be shared within a limited analysis. Additionally, the evaluation will include data collected from two organizations within the life sciences industry—Avid and Lilly. Although this organization has experienced a transition from pre- to post-acquisition, it does not necessarily embody the actions, performance, thoughts, and opinions of every pharmaceutical company following an acquisition. This, after all, is the spirit of a single-case study.

For instance, consider that many organizations are acquired for rights to their pipeline and not for the staff responsible for creating such a pipeline. That is, head count is often a casualty in acquisitions. The organization reviewed in this analysis did not lose head count. When compared to organizations who did lose head count, one might expect a vastly different set of results from interviews.

Additionally, the case study and subsequent analysis use historic and current events. Considering the nature of drug development and the sensitivities of intellectual property we will refrain from discussing any data that are not in the public domain.

Personal Note: Why I Am Writing About This

Since this capstone project has absorbed a considerable amount of personal time, I wanted to ensure it would be applicable to my career and to the careers of others. During my second semester in the Organizational Dynamics program I received sage advice from a trusted professor who shared that a capstone should be an aggregation of my learning with the goal of having a specific expertise by the end of the program. That professor was Ravi Chaturvedi, a former VP at Proctor and Gamble, a brilliant, quiet, and humble business mind. This advice has resonated with me throughout the program. I've found myself most interested in organizational behavior and understanding how corporate culture is developed and ultimately sustained or changed.

Developing ideas for the capstone suddenly started to crystalize once I was introduced to Gary Hamel's *The Future of Management* and Robert Quinn's *Becoming a Master Manager* (Hamel, 2007; Quinn, 2010). Both books were assigned reading materials from Janet Greco's Perspectives on Organizational Dynamics course that I attended during the spring 2015 semester. I derived value from Hamel's perspective about management innovation and how to transform organizations (Hamel, 2007). When paired with Quinn's viewpoint on applicable management techniques—namely reserving time for creative thinking and innovation—I was certain I would have a complete capstone rich with application.

Additionally, researching Hamel and Quinn lead to uncovering Schumpeter's Models of Economic Growth, a thesis that suggests new products

and continual improvements of existing products would ultimately lead to growth and development (Schumpeter, 1912). Schumpeter's theories, first published in 1912, focus on the role of entrepreneurs and their ability to demonstrate innovation's centralized role in growth.

The end goal is application in my current and future roles. At the start of this capstone I have been working through the process of the acquisition and making myself familiar with the challenges that an acquired company experiences. In terms of future roles, Lilly will likely continue to acquire smaller organizations or in-license drugs. By understanding the benefits of innovation as an acquirable asset, I will be primed to support our company through exceptional transformation.

Audience

My target audience has a relatively wide range. I believe the research compiled within this capstone could provide benefit to a multitude of pharmaceutical stakeholders, namely acquirers and "acquirees." This capstone will result in concrete examples of what worked and what did not work in one typical case. As such, this capstone might be considered a useful guide to post-acquisition innovation excellence. Furthermore, for organizations that routinely invest in external entities, the materials collected within this paper can help exploit innovativeness for the next acquisition(s). After all, if an organization is

being acquired for its innovative staff/culture/product, it makes sense for the acquiring organization's leadership to foster and metabolize the innovation that the buyer is paying to acquire.

Additionally, leading successful change doesn't need to be restricted to the pharmaceutical industry. Although not covered within this capstone, industries ranging from education, technology, and government might benefit from the analysis. If a highly regulated industry can find ways to optimize their processes, one might suspect that a lesser regulated organization can emulate these enhancements.

Capstone Outline

The remaining chapters have been organized as follows: Chapter 2 will examine, via the literature, the concept of innovation: what is it, why is it valued in drug development, how does leadership impact innovation, and why is innovation ultimately needed in AD research? The purpose is to demonstrate that innovation is a highly desired trait and that Avid fits certain defined criteria. Chapter 2 will also discuss the value of studying innovation through the framework of a single-case study.

Chapter 3 will dive into the case study to help peel back the layers of innovation's role in a dynamic ecosystem. The case study format closely emulates the style utilized by Thomas DeLong in his *Professional Services: Text*

and Cases casebook (DeLong, 2003). This format described the organizations past then present in order to maximize context as the case unfolds. The case study is framed to provide a comparison of Lilly and Avid—how they are different, how are they similar, and how could they co-exist following an acquisition. This Chapter will study the experiences collected from both Lilly and Avid's perspectives, thus presenting a unique look at how innovation was protected as an asset through a Lilly lens and an Avid lens. We will also study what threatens/threatened innovation and what techniques were used to ensure the success of the acquisition. In short, Chapter 3 will provide the "case" in this case study.

In contrast to the aforementioned "case," Chapter 4 will provide the "study." Although there will be some limitations to the scope, the goal is to observe how Lilly and Avid employees visualize the prevalence and utilization (or lack thereof?) of their organizations' asset of innovation. We will evaluate how innovation was protected and the lessons learned from my experiences. Chapter 4 will also provide a number of complementary organizational dynamics lenses that were used to better understand the post-acquisition interactions between Avid and Lilly.

Last, Chapter 5 will provide a conclusion by reviewing personal reflections on what was learned throughout the capstone process.

CHAPTER 2

On Saturday August 22nd, 2015, Frank rolled out of bed, changed into his running clothes, laced up his shoes and headed out for his morning run. Frank is a man of habit. His route hasn't changed in the 30 years that he's been living in his home but that day was different. While running through town he became lost. He stopped, panicked, and remembered he had been running with his phone (he had been using it for music during his run). Frank called his wife and had somehow forgotten her name. Frank continued to panic, as did his wife when she picked him up in their car several minutes later. By the time she had arrived, he had managed to remember where he was and his wife's name. Frank chalked this occurrence up to "forgetfulness." The problem was that this wasn't the first time this scenario occurred. These situations had become more frequent over the summer of 2015.

Unfortunately this isn't a rare occurrence. Frank is one of an estimated 5.3 million Americans are living with the memory-robbing disease (Alzheimer's Association, 2015). The Alzheimer's Association has deemed AD to be an epidemic stemming from the large aging baby-boomer generation. In fact, the projected number of American's living with AD in 2050 will skyrocket to 13.8 million, barring the development of medical breakthroughs (Alzheimer's Association, 2015).

Yet finding a cure, or even slowing the progression, of AD has been a challenge facing the medical community since 1907 when Alois Alzheimer first

reported his account of Auguste D (Alzheimer, 1907). One report, published in 2014, has suggested that there is an extremely high attrition rate among clinical trials focused on finding a disease-modifying agent. To be precise, the failure rate was 99.6%, although it should be noted that the 0.4% successful trials only help treat the symptoms of AD, not the underlying pathology (Cummings, Morstorf, & Zhong, 2014; Becker, Greig, & Giacobini, 2008). This failure rate is statistically higher than studies focusing on cancer and all other therapeutic areas, 95% and 90%, respectively (Kola, 2004). In other words, from a historical perspective, it has been easier to cure or slow cancer than AD (Kola, 2004).

Despite these clinical failures, the medical community and the pharmaceutical industry have been relentless with their continued efforts for finding disease-modifying interventions. Industry leaders recognized that a cure, in many ways, represents the Holy Grail (Holtzman et al., 2012). In terms of purely enterprise success, a cure, or a means of slowing the progression of the disease, could fetch \$15-20B in annual revenues (Holtzman et al, 2012).

These trends and consequent potential forced the AD research community to consider changing their approach for conducting drug development research. Industry leaders have embraced these challenges citing that the pressures of R&D can often serve as a catalyst for introducing new innovations into the discovery process itself (Kola, 2008). These innovations hold the promise to “deliver the greatest opportunity and leverage for bringing important efficiencies to big pharma R&D” (Kola, 2008).

By the end of 2009 pharmaceutical organizations were hemorrhaging cash on expensive AD clinical trials that hadn't yielded a quality product. In fact analysts have projected the costs of these studies ranged from \$1.7B – \$5B (Mullin, 2014; Herper, 2013). The AD research community recognized the need to change their drug development methods and began looking for creative ways to design trials that optimized their likelihood for success.

It was around this time in 2009 that Lilly began looking for innovative solutions to help improve AD trial outcomes. This is when they found a potential partner to help them revise their approach for conducting AD trials. What is it that Avid was able to do to help an expansively large company like Lilly? To better understand let us first review the nature of innovation. What is it and why does it matter?

What is Innovation?

Since there is such perceived interchangeability in the use of the terms “creativity” and “innovation,” it feels imperative to add clarification of the definitions used herein. Some researchers and theorists define creativity according to the characteristics of the *person* whereas others will focus on the *process* (Amabile, 1988). One definition, specifically focused on the *person*, suggests using the term creativity to “refer to the constellation of personality and intellectual traits shown by individuals who, when given a measure of free rein,

spend significant amounts of time engaged in the creative process” (Findlay and Lumsden, 1988). Meanwhile, *process-centric* definitions suggests that “creativity is the emergences in action of a novel relational product, growing out of the uniqueness of the individual on the one hand, and the materials, events, people or circumstances of his life on the other” (Rogers, 1954).

As an extension, many definitions of innovation explicitly include the ideas of creativity's being successfully executed by a larger group. Within an organizational and management perspective, Drucker suggests that innovation is the “purposeful and organized search for changes” (Drucker, 1985) while other thought leaders define it as “any idea, practice, or material artifact perceived to be new by the relevant unit of adoption” (Zaltman, Duncan, & Holbeck, 1973). Kanter adds that innovation is the “process of bringing any new, problem-solving idea into use” and adds that “innovation is the generation, acceptance, and implementation of new ideas, processes, products, or services” (Kanter, 1984).

Additionally Joseph Alois Schumpeter, an economist in the first half of the twentieth century, pointed to the role of innovation and entrepreneurship in economic growth. Schumpeter initially acknowledged that innovation started with “new combinations” and an entrepreneur’s ability to carry out the combination to the marketplace (Schumpeter, 1912; Schumpeter, 1934). Thus, he acknowledged the need for creativity and focus to drive innovative in the marketplace as a means of spurring economic growth.

As a clarifying point, there is a distinct difference between *innovation* and *invention*. Invention refers to the creation of a product or the creation of a new process while innovation focuses on the improvement or significant contribution to an existing product, service, or process (Grasty, 2012). Additionally, the concept of diffusion can be described as the spreading of innovation. (Grasty, 2012).

Characteristics of Innovation

In his *Theory of Economic Development* Schumpeter defines the characteristics of an innovation (refer to Figure 1). Accordingly a change can be categorized as innovation per se by meeting one or more of the following criteria:

Figure 1: Schumpeter's Characteristics of Innovation (Schumpeter, 1934)

- 1 •The launch of a new product or a new species of an existing product;
- 2 •Application of new methods of production or sales of a product that is not yet proven in industry;
- 3 •Opening of a new market that has not been represented in industry;
- 4 •Acquisition of new sources of raw materials or semi-finished goods;
- 5 •New industry structure such as the creation/destruction of a monopoly position

Based on Schumpeter's theory it appears as though Avid fits at least the first three criteria outlined, thus laying claim to a bona fide innovative organization in the Schumpeterian models. Refer to Table 1 below.

Table 1: Schumpeter's Characteristics of Innovation and Avid

Schumpeter's Criteria	Avid's Alignment with Schumpeterian Model	Yes / No
The launch of a new product or a new species of an existing product	Avid has successfully launched at least one product that was widely regarded as the first of its kind	

Schumpeter's Criteria	Avid's Alignment with Schumpeterian Model	Yes / No
<p>Application of new methods of production or sales of a product that is not yet proven in industry</p>	<p>Avid has managed to innovate for both the production of AV45 and the sales of AV45.</p> <p>From a production side, Avid was able to modify the manufacturing process to use ¹⁸F-labeled ligands to ensure a longer shelf life.</p> <p>From a sales perspective, Avid and Lilly coupled AV45 with future therapeutics. This will require that AV45 is used to determine the effectiveness of future therapies, thus ensuring sales</p>	
<p>Opening of a new market that has not been represented in industry</p>	<p>Up until 4 years ago radiotracers were almost entirely used to the US and EU marketplace; however, in order to pave the way for future therapies, Avid has developed new manufacturing facilities in emerging markets</p>	

Schumpeter's Criteria	Avid's Alignment with Schumpeterian Model	Yes / No
Acquisition of new sources of raw materials or semi-finished goods	Avid's history or projected future does not seem to fit this criterion	
New industry structure such as the creation/destruction of a monopoly position	Avid operates in a competitive environment. Therefore Avid does not fit this criterion	

Another factor to consider is that innovation is a continuous process. This is widely true in most industries (consider what a car or computer looked like thirty years ago) and is especially true in the life sciences industry. Kline and Rosenberg help illustrate that a single innovation is often the result of a lengthy process involving many interrelated parts, or departments (Kline & Rosenberg, 1986). They share that:

“it is a serious mistake to treat an innovation as if it were a well-defined, homogenous thing that could be identified as entering the economy at a

precise date – or becoming available at a precise point in time... The fact is that most important innovations go through drastic changes in their lifetimes – changes that may, and often do, totally transform their economic significance. The subsequent improvements in an invention after its first introduction may be vastly more important, economically, than the initial availability of the invention in its original form” (Kline and Rosenberg, 1986)

Like Schumpeter, Kline and Rosenberg recognize that innovations are often built on previous innovations or inventions and that continually attaining innovation is a journey of collective achievement. Kline and Rosenberg’s Theory seemingly suggests the need to apply a systems perspective rather than to focus solely on separable innovations or individual creativity.

Defining Innovation for Our Case Study

For purposes of this case study we will adopt a combined definition of Kanterian, Schumpeterian, and Kline/Rosenberg’s innovation (Kanter, 1984; Kline and Rosenberg, 1986; Schumpeter, 1912; Schumpeter, 1934). Kanter’s definition offers an intriguing element that the other definitions seemingly miss: implementation. Kanter’s innovation is fundamentally different in the sense that it includes focus and direction. Without focus and direction, creative concepts can manifest themselves in a variety of ways. Schumpeterian innovation also considers innovation’s economic impact. Considering the for-profit nature of

pharmaceuticals, it feel important to add this element—focus and direction to profit—to our proposed definition. Last, Kline and Rosenberg’s systems perspective is pervasive in Avid’s style of innovation. Avid, much like other pharmaceutical organizations, has built a sub-industry based on a collection of previously discovered technologies.

Thus, the combined meaning moving forward advocates that innovation is “the systematic generation, acceptance, and implementation of new ideas, processes, products, or services with the intent to drive economic growth in the marketplace” (Kanter, 1984; Kline and Rosenberg, 1986; Schumpeter, 1912; Schumpeter, 1934). Now that a definition has been established for an innovative organization we can explore why innovation matters in the realm of drug development.

The Value of Innovation in Drug Development

The need for innovation in the work place is hardly a novel concept. There is something inherently human about the inclination to think about new and better ways of doing things and trying them out in practice (Lawrence & Nohria, 2002). This is especially natural in a capitalist economy. Reflecting on the impact innovation has had on life sciences, consider a world without vaccines, anesthesia, HIV/AIDS treatments, and modern medical imaging techniques. These products and procedures have been important medical contributions over

the past century in the sense that they have improved quality of life; however, from an economics perspective these innovation have provided an enormous contribution to economic growth (Hanush, 2007), reflecting the composite definition of innovation offered above.

The pharmaceutical industry is considered a highly research-intensive field and is at the “far end of the continuum of industry sectors in terms of innovation being a dominant feature of the generic business model rather than an afterthought” (Coombs & Metcalfe, 2002). Pharmaceutical organizations, both large and small, are considerably volatile, uncertain, and risky. These characteristics are, in fact, rooted in the drug development process itself since drug development is a high-risk/high-reward venture. Development timelines tend to be lengthy, require large amounts of capital to coordinate, and despite the great amount of effort to predict the clinical trial outcomes, there are often failures that send clinicians back to the drawing board (Coombs & Metcalfe, 2002).

The pharmaceutical industry has been in a state of flux for the past two decades, partly due to problems surrounding failures in research productivity. Innovative research is critical to pharma since it provides companies with the ability to continually create new revenue streams (often through Schumpeterian innovation), remain commercially relevant, and “reinvest” into corporate research and development (Schumpeter, 1912). Yet, in order to achieve these goals small and large pharma organizations are required to roll out new products every year (Horrobin, 2000).

What has become particularly intimidating are the sky-rocketing costs for producing a new drug. Based on the assumptions by Forbes, the cost of each new drug will cost roughly \$5B, which is mostly due to funding the 95% of drugs that fail in clinical trials due to safety or efficacy (Herper, 2013). Although this number seems exceptionally high, this still doesn't account for the cost created by the new drug development landscape that has waved goodbye the one-sized-fits-all drugs and has accepted the need to design tailored therapeutics (Kalia, 2013), a notion that suggests that drugs are now designed with the end users' unique characteristics in mind.

Theoretically, developing new drugs will never go away as long as there are unmet needs in the medical community and the industry remains lucrative; however, the projected costs for developing one successful drug need to be addressed. The ballooning cost of development is putting a new focus on how companies can develop drugs faster and cheaper. An infusion of innovative products or process improvements might be just what the doctor ordered for an industry faced with looming financial concerns (Herper, 2013)

Part of the industry has responded to financial pressures by attempting to streamline their processes solely by focusing on external investments. In such cases large pharma absorbs start-up companies that are on the fringe. This is commonly done in order to acquire an early stage compound that market research determined could yield enough revenue to keep their heads above

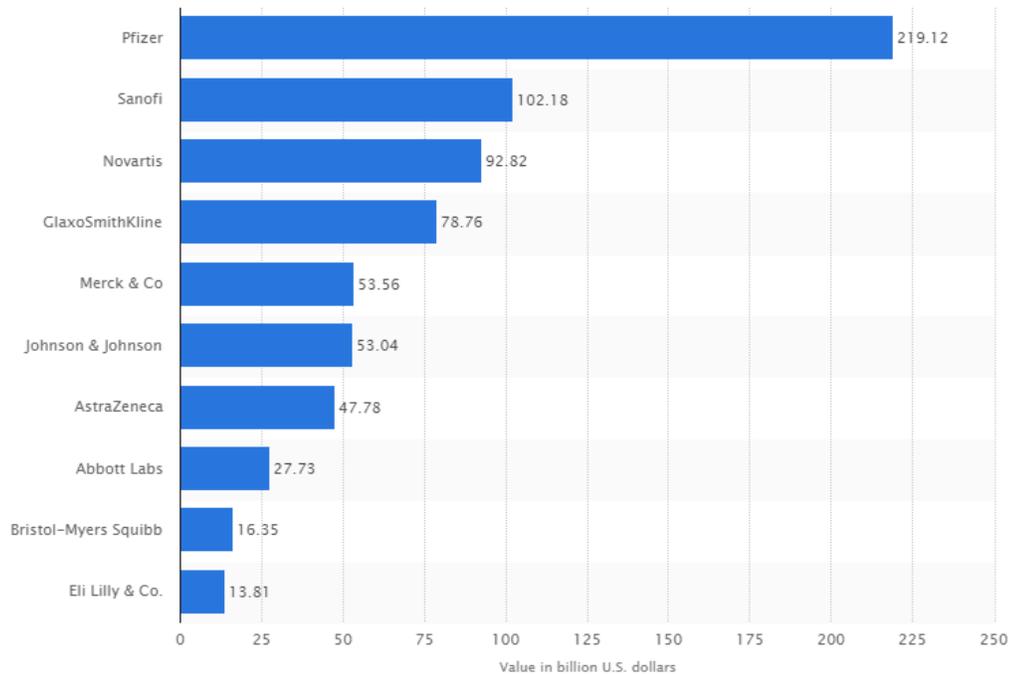
water (Horrobin, 2000). The problem with this model is three-fold as described in Figure 2 below.

Figure 2: Potential Problems with Acquisitions

- 1 • The originators of the acquired drug are often not retained post-acquisition;
- 2 • Despite the acquiree's best effort, it is nearly impossible to harvest all knowledge specific to the acquired product(s) and;
- 3 • Even if an employee is retained post-acquisition, the new corporate environments—and their bureaucratic processes—can adversely impact an employees' ability to perform in the same way.

Interestingly, when compared to their Big Pharma colleagues, Lilly has historically shied away from acquiring companies to bolster their pipeline (Truss, 2014). Instead Lilly has relied on a more traditional, self-funding technique. Figure 3 provides an illustration of the monetary value of acquisitions across Big Pharma companiesⁱ (Truss, 2014)

Figure 3: Value of Acquisition by Top Pharma Companies (1994-2014) (Truss, 2014)



Note: while there are plenty of case studies worth being written about one large pharma company acquiring another large pharma company (e.g. Pfizer purchasing Wyeth), this analysis review will focus on the numerous occasions where a large pharma company acquires a smaller, privately held company.

A case can be made that R&D in big pharmaceutical organizations are experiencing a paradigm shift and the ripple effect can be problematic for an industry rooted in finding new therapies and diagnostics tools. As pharma continues to acquire and merge in favor of streamlining development processes, the corporations become bigger and as a result, more bureaucratic (DiMasi, Grabowski, & Vernon, 1995; Califf, 2006). In many cases innovation and free-

thinking are replaced by standards, checklists, and work instructions that dictate what can and cannot be done. At times it becomes evident that processes have become a surrogate for creativity (Califf, 2006).

In an ever evolving marketplace it has become critical to think beyond today's balance sheet as the sole criterion for organizational and R&D decisions and consider how establishing a qualitatively distinct balance sheet—an environment and culture that welcomes thought-provoking research—could shift the way big pharma thinks. Consider the evolution of non-pharmaceutical companies who welcomed these paradigm shifts—W.L. Gore & Associates, Google, and Whole Foods (Hamel, 2007). These are organizations who fundamentally adopted novel approaches in 'how' to do their organizational and business work and have since succeeded with defining innovation in their respective industries.

Pharma is awaiting their next revolution and it's only a matter of when, or who, that will bring us into the new drug development ecosystem (Greiner, 1998). In theory drug developers look to their leadership for direction, and possibly permission, for how to act, think, and produce.

Why is Innovation Needed in the AD Research Community?

The National Institutes of Health (NIH) and National Institute on Aging (NIA) supported a retrospective analysis to determine why so many AD drugs fail in clinical trials. Their report, published in 2008, identified a series of factors that shed some light on the pattern of failed trials (Becker, Greig, & Giacobini, 2008). While the report called out several control issues relative to blinding/unblinding studies (effectively controlling placebo and active treatment) and investigator/publication bias, they also cited key problems relative to the “population selection” for many of these clinical trials. The NIH suggested that many clinical studies have been enrolling patients that may not have AD pathology (Becker, Greig, & Giacobini, 2008).

“Population selection,” or selection criteria, is an important point that we ought to link back to Chapter 1. As noted, a patient only has AD if there is evidence of accumulated A β . So what happens when a drug that has been designed to “flush out” accumulated A β is studied in a clinical trial that has been enrolled with fifty-percent of subjects with AD pathology and fifty-percent without AD pathology (Doody, 2014; Sullivan, 2014; Karran & Hardy, 2014)? The data effectively become diluted to the point that an efficacy claim cannot be made. Thus, a drug that might have done its job in the right population is destined to be shelved or retested. Or is it?

This was the conundrum facing AD drug developers through the early 2000s. Many companies, including Lilly, believed that they had developed effective “amyloid modulation” mostly through passive vaccinations or amyloid

immunotherapy (Salomone et al., 2012). As part of the case study in Chapter 3 we will discuss how Lilly overcame this challenge by thinking differently. For now, let's unpack leadership's role in creating an innovative ecosystem that would set themselves up for long-term success in the AD marketplace.

Leadership and Innovation

A worldwide survey of top-level executives shows that over 70% of executives acknowledge that innovation is an important short-term growth driver; however, the same survey indicated that 65% of executives are disappointed in their companies' ability to innovate despite investing in workshops, motivational speakers, and consultants. These surveyed executives shared that processes slowed down the speed of innovation in their organizations while reporting that their staff seemed disengaged, dull, and subdued (Soken and Barnes, 2014).

It has been implied that it isn't enough for executives to have the right mentality regarding the need to innovate—leaders need to create a culture where employees feel like they are contributing to a common goal (Soken and Barnes, 2014). Leadership must have the correct mindset and put the right practices in place. This involves having executives who are future oriented enough to trade off investments in maximizing a firm's present technology in order to create new generations of technology. This also means that management must create an

environment that empowers people and encourages experimentations with new unproven ideas (Tellis, Prabhu, & Chandy, 2009).

It isn't enough to schedule workshops, motivational speakers, and consultants. These processes, in many ways, are analogous to distributing a memo that reads, "Be more inventive!" The key is to holistically develop an innovative culture that sets time apart for staff to work on pet projects, new ideas, or brainstorming activities (Quinn, 2010). These notions will be unpacked later when we discuss leadership's role in promoting an innovative workplace.

Leaders often misrepresent themselves to their staff. Staff might infer that their leadership is aloof, thus shattering any opportunity to build key relationships with staff. Clarifying purpose, taking risks, measuring/rewarding innovation, and busting boundaries are all necessary qualities seen in leadership of organizations that excel with regards to innovative practices (Quinn, 1987).

True leadership is a core ingredient to building an innovative culture. Instead of seeing one's role as a manager in charge of resourcing and controlling, a quality leader would recognize that an organization comprises unique human beings with varying skills and interests. True leadership is able to engage people at a different level of interaction, build meaningful relationships, and establish a common set of goals and values (Soken and Barnes, 2014).

Executives may not understand the value of an innovative culture for countless reasons. Perhaps they cannot see past "their finance-focused mindsets" (Fischer, 2011) or maybe they don't see a need to risk revisiting a

process, product, or service that can be reconstructed into something better. In many ways the ability to innovate starts with the leadership's prioritizing it over short-term gains.

So what role does leadership play in preserving or inventing an innovative spirit within their organization? One might argue that quality leadership is the premier catalyst to launch an innovative culture within their own organization. In his guide *Becoming a Master Manager*, Quinn shares his viewpoint on applicable management techniques and suggests reserving time for creative thinking and innovation (Quinn, 2010). Quinn shares that leadership must help protect and reward the process. These values must be ingrained in the organizational culture to demonstrate that strong, top-down leadership authorize, encourage, and support innovative activities throughout the organization (Fischer, 2011).

Leadership's Role in Promoting an Innovative Workplace

Leadership also have the opportunities to develop right-sized policies to fit their organization's needs. Consider the reserved innovation policy at Google. Within Google's corporate headquarters it is expected that 20% of an employee's time would be dedicated to working on pet projects, exploring new opportunities, or cross-pollinating ideas with different groups. For one day a week, each Google employee dives into focused free-thinking with leadership's expectation

that it ultimately contributes to a “change engine” (Gersch, 2013). This policy, albeit counter-intuitive to many, is designed to help improve employee morale while supporting Google’s core values to create innovative products, tools, and experiences.

This notion isn’t entirely unique to Google. Consider W.L. Gore, a fluoropolymer manufacturing company, who also protected 10% of an employee’s time to work on projects that would otherwise be off budget and/or out of scope (Hamel, 2007). W.L. Gore also exhibited a distinctive management practice that focused on eliminating unnecessary hierarchy and reinforcing the notion that anyone can innovate when given the proper opportunities (Hamel, 2007).

Other examples include IDEO and their “set designer” role, who enriches their organization by maximizing space to promote better and more organic communication among their teams (Kelly & Littman, 2008), or the Virgin Group, who decided that their corporate policy with respect to vacation schedules should be non-existent (Branson, 2015). In other words, Virgin employees are trusted by their management to work when they need to, vacation when they are able, and not worry about punching the clock. This policy—or non-policy—demonstrates the trust that Virgin leadership has in their staff.

Fostering an innovative culture starts with leadership. Leadership, in many ways, promotes and supports a corporate culture that permeates an innovative spirit in all facets of the working model. If leadership understands the

value of innovation, it is important to instill these values whenever possible. Recognize that innovation is like a fire—it has to be fed, poked, and prodded occasionally to ensure it's still burning hot. Communicating the desire to create early and often remains an urgent need. This focus on fostering an innovative culture represented one of Avid's core competencies.

Avid's long-term President could effectively feed, poke, and prod his drug development team by preaching the need to be “paranoid” that somebody else will catch up and develop a competitive product better, faster, and cheaper.ⁱⁱ At Avid remaining “paranoid” becomes a core competency in many ways. Among other groups in the organization, project management were challenged by this notion to find ways to cut timelines without cutting corners and clinical developers to seek strategic partnerships and examine new opportunities. Scientists were encouraged to cross-pollinate with each other and to seek outside expertise. Even senior management was challenged to find ways to set the company up for short and long term success.

On a final point, leadership also has the opportunity to encourage risk taking. Innovation is inherently risky and getting the most from a collection of innovation enterprises is more about managing risk than eliminating it (de Jong, Marston, Roth, & van Biljon, 2013). Business magnate Elon Musk helped illustrate the value of risk taking and failure by saying “failure *is* an option here [at Tesla Motors]. If things are not failing, you are not innovating enough” (D'Onfro,

2013). Adding to Mr. Musk's thoughts, early 20th-century architect Daniel Burnham famously shares:

“Make no little plans; they have no magic to stir men's blood and probably themselves will not be realized. Make big plans; aim high in hope and work, remembering that a noble, logical diagram once recorded will not die, but long after we are gone be a living thing, asserting itself with ever-growing insistence. Remember that our sons and our grandsons are going to do things that would stagger us. Let your watchword be order and your beacon beauty” (Daniel Burnham, 1907)

Translation: playing it safe won't yield tremendous results and risks are a necessary evil. Out-of-the-box thinking ought to be encouraged. Ideologies such as “this is how we've always done it here,” hold no water in a cutting edge organization.

The Value of a Single Case

Up until now we have determined what innovation is and why it is a desired asset in important in drug development and AD research. We have also spent time discussing leadership's role in the process. At this juncture we need to develop an understanding of the value of case study research, as this will be the primary delivery of the documented learnings in Chapter 3.

The essence of case study research is to capture the complexity of a single case, namely a case that holds a special interest to the audience. A case study itself is the “study of the particularity and complexity of a single case” (Stake, 1995) and allows the researcher to investigate activity under the nuanced circumstances. There is power in studying a single-case regardless of our ability to replicate the same design or circumstance. We are interested in the uniqueness of each study, and yet we are drawn to understanding commonality so we might learn from others (Stake, 1995)

While multiple reporting formats exist for case studies, this capstone will adopt the classic linear-analytic single-case study approach (Yin, 2013). In the realm of AD research a case could easily be written about an individual, a project, a drug, or a company; however, this case study will dive into the relationships between two very different companies with respect to innovation. Over the course of the past six years I have had opportunities to observe both Lilly and Avid from a singular employee/contractor lens, yet this capstone offers me the unique opportunity to evaluate both organizations—pre- and post-acquisition—through an Organization Dynamics (OD) lens.

CHAPTER 3

Throughout Chapter 3 we will attempt to understand two drastically different companies that share a similar vision. Lilly, a market leader, has an impressive history and track record of developing high-end products while still identifying themselves as a family company (Madison, 1989). Avid, a “pull yourself up by your own bootstrap” company, had a comparatively short presence in the marketplace; however, Avid had a valued asset that could reshape AD development. How could this marriage work? It might make sense to start at the beginning of amyloid tracers and a small start-up company in Philadelphia.

Avid: From the Lab to Acquisition Candidate

Prior to any involvement with potential pharmaceutical suitors arriving in 2009 and 2010, Avid, a spin-off of the research laboratories at the University of Pennsylvania, had recognized the clinical utility of PiB and began adapting the manufacturing techniques with the goal of producing an amyloid biomarker that could be used on a large scale (Klunk et al, 2004). Starting in the year they were founded, 2005, Avid had re-formulated the tracer using fludeoxyglucose (herein ^{18}F), a common isotope used for PET imaging, to help increase the half-

life of the newfound tracer (Jacobson & Chen, 2010). This was, in essence, a Schumpeterian innovation. In 2009 researchers (led by Avid) concluded that:

“Treatments are being developed for Alzheimer's disease that are designed to prevent the accumulation of cerebral plaques and tangles or to disaggregate them once they are present. A noninvasive method of determining the regional cerebral patterns of these lesions would not only assist in early diagnosis of Alzheimer's disease but also facilitate monitoring of the efficacy of such treatments” (Choi, 2009).

Avid had recognized that by utilizing a biomarker it could determine the presence or absence of amyloid. Moreover, at the start of the organization Avid also believed that measuring amyloid burden longitudinally could offer researchers a tool to measure the change in burden over time.

This seemingly simple concept, when paired with cutting edge imaging and manufacturing technology, showed the potential of revolutionizing the methods used in modern AD research. Much as with any other drug product, Avid needed to test its biomarker—clinically titled ^{18}F -AV45—before gaining the necessary approvals to offer the product commercially. The process of conducting clinical studies and providing the necessary safety and efficacy evidence to regulators tends to be a lengthy process while costing several millions of dollars.

Following the aforementioned publication of the pre-clinical evidence (Choi, 2009), pharmaceutical industry leaders began pursuing Avid as a clinical partner with the intention of including amyloid imaging in their inclusion and exclusion criteria within their clinical drug development processes.

How Had Pre-Acquisition Avid Been Innovative?

From a Schumpeterian perspective Avid demonstrated a keen ability to leverage existing technology and create a new product to serve an existing need. This, of course, was not enough. As we defined innovation in Chapter 2, Avid's leadership needed to find a way to "implement these new ideas and processes with the intent to drive economic growth in the marketplace" (Kanter, 1984; Kline and Rosenberg, 1986; Schumpeter, 1912; Schumpeter, 1934). The major challenges that Avid was faced with were 1.) capital investment and 2.) defining the regulations. Each of these unique challenges required an innovative approach, especially considering radiopharmaceuticals were relatively unknown venture. Let's review examples of how Avid was able to overcome these obstacles on their road to success.

Capital Investment

Much like other start-up organizations, Avid needed a cash infusion to properly scale their business. At the time Dr. Daniel Skovronsky, the Scientific Director of High Throughput Screening and Drug Discovery at the Center for Neurodegenerative Disease Research at the University of Pennsylvania, had recognized the potential benefit of amyloid imaging in AD research and saw a unique opportunity to launch into the marketplace. Dr. Skovronsky also recognized that an academic lab was a great incubator for this research but could become rate limiting when trying to scale.ⁱⁱⁱ

A common path taken by young entrepreneurs in the life sciences industry is to seek venture capitalist investment, but there are trade-offs to consider. By accepting a cash infusion to rent buildings, buy equipment, hire staff, and pay for regulatory fees, Dr. Skovronsky knew he would need to relinquish some level of control.^{iv} After all, venture capitalists will look to squeeze every cent out of a business transaction. So what were the alternatives?

Instead of seeking venture capitalist funds, Dr. Skovronsky, while still employed at the University of Pennsylvania, was determined to finance his newfound business while maintaining maximum control. He took two approaches: negotiate an exclusive licensing agreement with the University and apply for lucrative NIH funding.

First, Dr. Skovronsky had recognized that the University had historically been a fertile breeding ground for breakthrough technologies and that they had used this to their advantage (Farrell, 2008). Simply put, the University of

Pennsylvania (among many esteemed universities) has found a way to turn research into revenue. He was able to leverage key relationships internally to negotiate an exclusive license agreement with the school that would enable him to use the amyloid biomarker technologies. While the specific terms remain confidential, Dr. Skovronsky was given exclusive access to the technology and a small start-up “kicker” with the understanding that the University of Pennsylvania would have the rights to a percentage of the commercial sales in perpetuity.

Second, the newly formed Avid had applied for NIH funding to continue to development of their research. To Avid’s surprise they were rewarded with two NIH funds to help continue their unique research. Once the funds were secured, Avid was able to officially start its fully independent venture.

In 2008 Avid had successfully developed AV1, an amyloid tracer that demonstrated good imaging characteristics (contrast, retention, wash-out, etc.) and proved to be viable for research purposes. Avid also knew that they had other compounds, namely AV45, in their pipeline that might prove to have better imaging characteristics and could be more easily scaled from a manufacturing perspective. Avid decided to bet on itself. They opted to sell AV1 to Bayer AG, a German-based pharmaceutical organization that believed AV1 would complement their imaging portfolio. By selling to Bayer they became cash flush and reinvested in their own development pipeline. This allowed Avid to hire subject matter expert consultants to help develop its next big thing, AV45. This was clearly a risk since Bayer was primed to be “first in class,” a notion that

suggests greater-than-fair market share on average (Cha & Yu, 2008). Yet, Avid had positioned itself to succeed by re-writing the path to a New Drug Application (herein NDA).

Defining the Regulations

The problem Avid faced was that radiopharmaceuticals, especially in AD, barely had documented regulations. Most radiotracers had been designed for cancer imaging and didn't necessarily follow the same regulatory approval processes. Instead of seeing this as a problem, Avid saw this as a solution. As Dennis Gabor once said, "the best way to predict the future is to invent it" (Gabor, 1968).

Avid saw itself in an advantageous circumstance. While Bayer might have a drug in Phase II testing, Avid recognized that Big Pharma had big processes that required big time investments. Avid flipped the script and saw an opportunity to invent the new process for developing a radiopharmaceutical. Instead of taking a traditional method of completing studies phase-by-phase (refer to Figure 4: Traditional Clinical Trial Phases), they effectively accelerated their whole program by conducting several studies in parallel, a notion that was innovative for biomarker research (refer to Figure 5: Accelerated Clinical Trial Phases).

Figure 4: Traditional Clinical Trial Phases



During the development of AV45, Avid included both healthy controls and AD subjects in the Phase I process. This allowed the medical team to understand how the drug would work in the desired population months—or maybe years—earlier than in a traditional Phase I study design. They also blended Phases II and III together to create a hybrid Phase II/III that allowed them to start their Phase III studies faster.

Figure 5: Accelerated Clinical Trial Phases



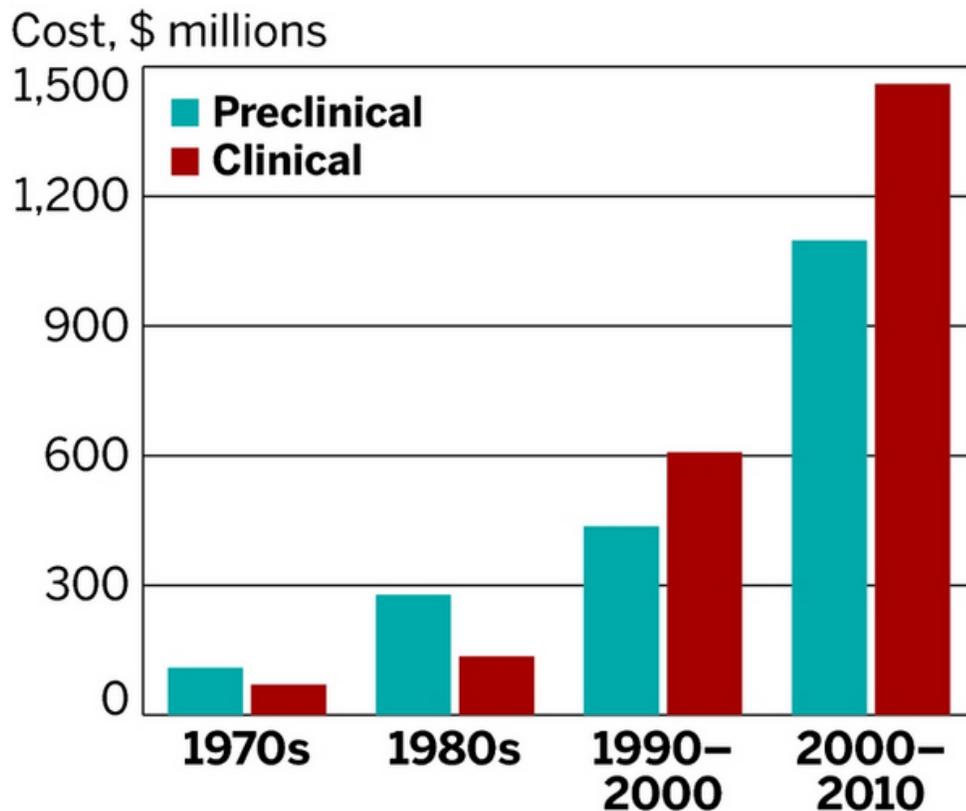
Of course this was not planned in a box. Avid, using the funds from the Bayer sale, was able to hire regulatory experts to help influence the FDA and other regulators to approve their drug development plan^v. As fate would have it, Avid was able to finish its NDA-enabling Phase III study in 2008, a full two years faster than Bayer was able to complete their Phase III study in 2010. Although the costs cannot be made available in this text, it is clear that Avid would have exclusive access to the market with a solid two-year head start.

Amyloid Imaging and Its Impact in the Industry

The discovery of AV45 was recognized as a standard when the NIH and NIA confirmed that amyloid imaging was a useful diagnostic tool when used

appropriately (McKhann et al, 2011). Industry leaders started seeing the potential of AV45 as a means of tracking the efficacy of amyloid modulators (i.e. comparing baseline and follow-up imaging to determine a change in amyloid burden) and optimizing their protocol selection criteria. Leaders also acknowledged that AV45 could be used as a means of determining which patients would respond to therapy in large, expensive Phase III studies. AV45 could also be used to “kill” ineffective therapies being tested in Phase I and Phase II trials years before the Phase III studies are even conceptualized. Considering the cost to develop a new drug has exploded to \$1.7B – \$5B (of which nearly 60% is done in the clinical phase—see Figure 6) the inclusion of amyloid imaging helped identify therapeutics that were worth the investment (Mullin, 2014, Herper, 2013).

Figure 6: The Cost of Developing a New Drug



The cost of developing a new drug has skyrocketed since the 1970s. Source: Tufts Center for the Study of Drug Development.

By the beginning of 2010 the development of neuroimaging biomarkers had begun to change the landscape for how clinical trials would be conducted and ultimately (hopefully) how new AD medicines are brought to market (Risacher & Saykin, 2013). Several pharmaceutical organizations recognized that innovative A β biomarkers were primed to change the way drugs progress through their development lifecycle (Castellani and Perry, 2012; Wolfe, 2012). Big Pharma companies like Pfizer Inc (Pfizer), Merck & Co (Merck), and Lilly had begun to “kick the tires” of Avid’s product. As a result they worked with Avid to

include AV45 in their trials. For these trials AV45 was used as an exploratory endpoint, which suggested that the pharmaceutical company's protocols would use AV45 in a subset of subjects enrolled in their study to determine if the tracer was a sufficient surrogate biomarker to help determine efficacy.

Avid leadership started to take notice of these trends, and although their intention was to remain independent they also saw how a strategic partnership could benefit Avid, a partnering company, patients, treating physicians, and AD advocates alike.

Lilly: A Recent History

For just shy of 140 years Lilly has cemented themselves as an industry leader in several therapeutic areas. While many drug historians might point to Lilly's proud history of developing diabetic and insulin products, the Big Pharma organization boasts a wide array of products that includes cardiovascular, depression, oncology, osteoporosis, ED, and pain. As surprising as it might be Lilly has established themselves as a leader in AD research and development for the past thirty years (Madison, 1989).

Over the past ten years Lilly had begun funneling more research and development funding into their AD franchises. They believed they had some game-changing products in their pipeline, including a late phase product called

semagacestat and an early phase product referred to as solanezumab, nicknames Sema and Sola, respectively.

By 2008 Lilly, among other pharmaceutical organizations, had started a professional relationship with Avid. They were using AV45 in a subset of subjects in their latest Sema and Sola Phase III protocols. The theory was to compare a subject's earliest AV45 scan with a future AV45 scan to see if Sema and/or Sola could "wash-out" the amyloid plaques. In other words, AV45 wasn't used to its fullest extent as a selection criteria tool, it was only used to measure change.

The Phase III Sema study kicked off in September 2008 and by mid-2010 Lilly would receive disappointing results from a mid-study interim analysis that showed Sema had performed worse than placebo (Karran, Mercken, & De Strooper, 2011). The Phase III Sola studies would experience a similar fate in August 2010 when an early data read out suggested Sola did not meet their primary endpoints (Kambhampthy & Smith-Parker, 2012). This was a crushing blow for a company that needed a win and was primed to be first in class. Then again, drug development is not for the faint of heart (Mochly-Rosen & Grimes, 2014).

During a post-mortem Lilly had diligently combed through their data to help see where mistakes were made. As scientific experts Lilly began asking themselves difficult questions. Was the science erroneous? Were there problems with the delivery method? As they poured over the data they

recognized that a small element of the data had some promise. Well after the studies were deemed to be cancelled, Lilly assessed each of the subjects that had been imaged with AV45 at the beginning of the study, rough ~200 in total. What they saw changed the course of their research.

Of the ~200 subjects that were imaged with AV45, only 70% actually had the pockets of accumulated amyloid plaque in their brains. The remaining 30% had no evidence of amyloid. Further analyses concluded that the 70% of subjects that actually had AD pathology were actually responding to treatment, a treatment that was specifically designed to wash out amyloid. Lilly immediately began drawing up a new protocol with the hopes of proving that Sola has been effective. Their next Sola Phase III protocol would include amyloid imaging as selection criteria, a study that would be the first of its kind.

The Acquisition

By mid-2010, Avid was nearing the completion of their pivotal Phase III study that would enable their New Drug Application (NDA) with the FDA. Coincidentally the positive results from Avid's study were first published on August 27th, 2010, just ten days after Lilly discovered the fate of Sema. The results from Avid's study quickly became news in the AD research community and Avid was

suddenly an acquisition target. Among the most prominent were Merck, Pfizer, and Lilly.

Fortunately for Avid it was independent and was able to select the best strategic partner based on portfolio, relationship, and position in the market. All companies spent several weeks on-site at Avid combing through financial records, INDs, clinical files, Trial Master Files (TMFs), and SOPs to access value, risk, and potential. Avid also had its fair share of demands. They wanted to keep their team in tact in Philadelphia, they wanted to remain independent and follow their SOPs, and they wanted a partnership, not a traditional acquisition.

In the end, Avid chose not to sell to companies in the Philadelphia region, such as Merck. Instead Avid agreed to terms with Lilly, a Midwest-based organization located in Indianapolis, Indiana that sold Dr. Skovronsky and other on the “family feel” and the willingness to keep Avid at an arm’s distance. The driver for the decision, in large part, was Lilly’s willingness to acquire Avid and keep it independent. On November 8, 2010, prior to Avid's receiving FDA approval for AV45, Lilly acquired Avid for \$800M to help bolster its AD diagnostic portfolio (Carroll, 2010).

The Challenge: Remaining Innovative Post-Acquisition

At the time of the acquisition Lilly and Avid were companies on very different ends of a cultural spectrum—refer to Table 2: Avid and Lilly Corporate Comparison. At the beginning of the acquisition there was some level of anxiety among Avid employees primarily because expectations were unclear. Most hadn't been involved in an acquisition before and were unsure what the next steps would be. Leadership had given some assurances about their jobs and had encouraged them to continue to focus on the work at hand as if “nothing has happened.”

Table 2: Avid and Lilly: Corporate Comparison

	Avid	Lilly
Location	Philadelphia PA	Indianapolis IN
Size	75 employees, all domestic	41,000 employees 55 countries
Ownership	Private	Publicly Held (NYSE)
Products	Amyvid®	Numerous (30+ currently)
Culture	Young, vibrant, independent, unrestricted	Collaborative, process-focused, family oriented

	Avid	Lilly
Employee Experiences	Average employment last 3-4 years	Average employee projects to retire from Lilly after 23.5 years of service
Issues Facing the Organization	Developing new compounds and support therapeutic trials	Drug pricing and gaining 2-3 drug approvals per year

Over time Avid began to see Lilly adding processes where processes hadn't existed before. New systems were implemented and training sessions were scheduled. Quality groups were on site for weeks to help establish more robust guidelines to help protect against audits. Lilly was clearly trying to protect their asset by ensuring Avid was compliant and functioning under Lilly standards; however, these processes, systems, and guidance were threatening to hamper Avid's best quality: the ability to innovate under an independent setting. What was Avid able to do to help protect its innovative qualities while promoting the same qualities throughout Lilly?

Avid and Lilly's Organizational Development Challenge

By 2012 the United States Food and Drug Administration (FDA) had approved Amyvid®, the brand name associated with AV45, as the first amyloid imaging tracer available on a commercial scale (Garber, 2012). While Amyvid® was groundbreaking, the community realized that amyloid burden is not consistently associated with disease severity or duration, only with the existence of amyloid plaques. In fact, it is a patient's *tau protein burden* that generally correlates with symptom severity and progression (Devous et al 2014).

Following the acquisition, new research has suggested that the presence of A β was important to determine disease but the rate of accumulating tau proteins was key to understanding the overall progression of the memory-robbing disease. Researchers have recently illustrated this by saying “A β and tau serve as respective triggers and bullets for AD pathogenesis” (Nisbet et al, 2015). In lay terms, Amyvid® remained an important tool for determining AD pathology but imaging tau proteins would be a more sensitive measurement of disease progression. Amyloid imaging would help detect the presence of disease at earlier stages but tau protein imaging would be more sensitive in determining progression (or lack thereof) longitudinally. This led Avid and Lilly to pursue opportunities to develop a tau protein biomarker to complement Amyvid® and by mid-2013, Lilly and Avid made two concurrent changes.

First, Lilly appointed Dr. Skovronsky as their Senior Vice President of Product & Clinical Development within their Tailored Therapeutics division. In this role, Dr. Skovronsky was asked to redesign processes to make Lilly more

efficient while ensuring high-throughput. While still serving on Avid's Board of Directors, he would be tasked with driving change in therapeutic areas beyond AD. Lilly had recognized his ability to drive organizational excellence on a smaller model and wanted to leverage this experience to influence leadership within Lilly.

The second change was more concrete. In an effort to shore up its lead in AD biomarkers and diagnostics, Lilly acquired an imaging agent from Siemens (Steenhuysen, 2013). This agent was specifically designed to image a patient's tau protein in vivo, using a technology similar to that of Amyvid®. Lilly and Avid leaders collaborated on the decision to acquire the new imaging agent and agreed that Avid would be tasked with developing the imaging agent. Following the acquisition, Avid retooled the manufacturing process and labeled its new asset ^{18}F -AV1451 (herein AV1451).

There is, however, a critical difference in the environment where Avid had developed Amyvid® versus that in which AV1451 would be developed. In 2010, when Avid was acquired by Lilly to "complement the drug maker's development of new treatments for Alzheimer's disease" (Loftus, 2010), Avid had completed most of their Phase I, II, and III development work; however, AV1451 would start in Phase I and would be developed alongside Lilly.

Avid's leadership and staff had experienced the need to protect their innovative culture following their acquisition. Experiences from the early stages

of the acquisition demonstrated the importance of identifying barriers, illustrating a need for balance, and ultimately demonstrating value through reciprocity.

Now that it was tasked with developing a new imaging tracer with Lilly, Avid was primed to enter a new phase of its corporate relationship.

How might this change with the acquisition of a new asset? Could they reuse the same strategy to exemplify the independence suggested in their “wholly owned subsidiary of Eli Lilly & Co” title? Or would Avid need to find new approaches to protecting its innovative culture?

CHAPTER 4

As of the beginning of 2016 AV1451 has been studied in Phase I and Phase II clinical studies and has recently moved into recruiting their Phase III studies (Devous et al, 2015). The intention had been for Avid to independently develop a tracer that would be sensitive to imaging tau proteins to help the medical community follow tau accumulation longitudinally to better determine which therapeutics were having the highest effect on a patient's "tauopathy" (James, 2015). The operative words in the preceding sentence were "independently develop." This would quickly change.

Throughout the early development of AV1451 Avid had started seeing some positive data that caught the attention of Lilly's AD Platform team. As a result Lilly and Avid's leadership decided to co-develop AV1451 within Lilly's AD therapeutics studies. In lay terms, Lilly began adding AV1451 imaging into studies like Sola. In theory Sola would benefit from adding AV1451 by demonstrating the slowing or reduction of tau protein burden over time. Additionally, AV1451 would benefit from Sola since the Sola trials were expansive and offered access to new patients who could benefit from tau protein imaging.

This shift proved to be another means of innovating AD medicines. In this case Lilly had begun adding AV1451 into its therapeutic studies. This methodology—the idea of using two experimental drugs simultaneously—would require multiple, study-specific teams at Lilly to work closely with Avid.

The timing of these events coincided with my progression through the MSOD program. Throughout the course of this co-development, I had the unique opportunity to proactively apply my MSOD education to better understand the interactions between the two companies. In short, Avid had become my laboratory that provided rich, real-world learning experiences.

This chapter is dedicated to understanding Avid's post-acquisition organizational behaviors. First, to better understand how innovation was protected at Avid, we will spend time reviewing methodologies that did and did not work. Second, we will look through a number of complementary organizational dynamics lenses to better understand the post-acquisition interactions between Avid and Lilly. The complementary organizational dynamics lenses will be presented in a vignette-like arrangement. The goal by the end of this Chapter is to examine the effects each organization had on each other while providing a roadmap for sustaining innovation in an evolving workplace.

How Innovation Was Protected at Avid – Introduction

From the very start of the co-development it was clear Avid wouldn't carry on with "business as usual." There was clearly a need to connect systems and allow Lilly access to Avid's intellectual property. While these elements were

essential to Lilly, Avid was also trying to protect its culture. Avid recognized that successful innovation is not created through good fortune and magic—it is a product of a properly aligned strategy, a supportive culture, talent, an understanding leadership core, and risk-taking (Soken and Barnes, 2014).

A balance must be maintained: bureaucracy must be held in check and the rush to develop drug for the marketplace should not undermine the cross-functional collaboration, continuous learning cycles, and clear decision pathways that help enable innovation (de Jong, Marston, Roth, & van Biljon, 2013)

This was an opportunity for Avid to reassess their role and pivot. At various stages following the acquisition, Avid attempted to protect its innovative culture by 1.) identifying the real or perceived barriers of innovation, 2.) illustrating a need for balance, and 3.) demonstrating value through reciprocity.

Identifying the Real or Perceived Barriers of Innovation

Before Avid could learn to protect its innovative culture they first needed to understand what threatened it. Immediately following the acquisition it was clear that Lilly's well-defined structure—processes, SOPs, and systems—could hinder Avid's approach; however, the structure itself wasn't necessarily designed to stifle innovation or creativity. For large companies like Lilly, the structure was needed to organize and mobilize large team in a consistent, standardized way (Soken and Barnes, 2014).

The problem that many large companies face regarding agility occurs when structure implicitly or explicitly reinforces the status quo (Soken and Barnes, 2014). In other words, some employees—mostly associate level—might have felt encouraged to stay within the defined boundaries—if not, they could expect to be realigned with the status quo or pushed out completely (Soken and Barnes, 2014).

This process-driven structure lends itself to a demonstrated lack of flexibility and openness to new opportunities. At Lilly, it is typically expected to have a complete analysis rife with statistics, pricing models, task force charters and timelines before alternatives would be considered. Alternatively smaller, innovative organizations could thrive in the “now.”^{vi} A common metaphor used with Avid’s office space was “flying a plane while building it,” a notion that demonstrates their willingness to try new, maybe risky, opportunities without suffering from “analysis paralysis.”

From a marketplace perspective Avid prides themselves on making the best decisions with the end customer in mind. Avid employees are encouraged to think “is this right for the customer?” before thinking “is this right for the company?” or “is this best for my department?” (Gault, 1994) While Lilly makes every effort to manufacture high-end drugs with the consumer in mind, the relative operative structure is the complete opposite of an organization in touch with the customer. Staff are inclined to think “is this best for my department?” before considering “is this right for the company?” (Gault, 1994)

For Avid, understanding the barriers of innovation was both an initial and iterative process. It was also apparent that “big companies do not easily reinvent themselves as leading innovators as they have too many fixed routines and cultural factors can get in the way” (de Jong, Marston, Roth, & van Biljon, 2013).

Lilly was modeled to be a scalable, global organization. In order to scale, clearly defined processes and standards needed to be implemented. Avid didn't require the same rigorous processes to be impactful. From a leadership perspective, however, Lilly's senior management proved to be open to input and suggestions from Avid's core teams. On several occasions Avid's perspectives were considered and ultimately used to change part of Lilly's processes. This became an interesting learning experience. While Avid initially perceived Lilly to be a barrier to its own success, it was becoming clearer that Avid was considered a partner who could influence Lilly.

The barriers were often perceived barriers. Avid's staff had managed to tell themselves a story about Lilly that was exaggerated. Lilly had established themselves as a learning company and proved willing to listen and apply change when it was appropriate. From Avid's middle-management's perspective, this was a game-changer and presented opportunities to strike a balance in drug development practices. Avid had the opportunity to co-exist but would need to find ways to bend-and-not-break.

Illustrating a Need for Balance

A proper balance needs to be maintained in order to fully realize the benefits of a partnership (de Jong, Marston, Roth, & van Biljon, 2013). The bureaucratic practices—SOPs, Best Practices, Clinical Planning Documents—that were being pushed onto Avid from Lilly had value but had to be kept in check, otherwise the processes could adversely impact Avid’s historically successful methodologies. Simultaneously Avid needed to understand that it had a new stakeholder to consider and rushing through projects might potentially undermine the “cross-functional collaboration, continuous learning cycles, and clear decision pathways that help enable innovation” (de Jong, Marston, Roth, & van Biljon, 2013).

In my experience working across both organizations, there was one exemplary instance that illustrated a time when it was appropriate to seek a balanced approach that would satisfy both groups. At the point of acquisition Lilly’s Quality Management Team spent time at Avid to review work instructions, SOPs, and guidelines to get a better sense for the processes that were employed at Avid. The initial internal audit report was returned several weeks later and recommended a total overhaul of processes at Avid. Avid’s Quality Assurance Team, consisting of only two employees, was faced with the daunting task to establish new processes that they didn’t fully understand. Lilly had recommended various systems and tools that could be made available to help organize Avid and theoretically make it more compliant with Lilly standards.

The problem, as Avid saw it, was that new processes would suffocate its ability to produce in the same time frame that they had produced in the past. Avid's Quality Assurance Team added that increased processes would set Avid up for failure. From their perspective increased processes could result in more errors because teams might not realize what rules they were breaking.

By seeking balance between the leadership in both organizations, the end result was "right-sizing" Avid's procedures to align with the spirit of the Lilly standards while giving Avid the flexibility to work within the confines of the procedures. This was managed by leveraging the political network from both sides of the organization. In the aforementioned SOP example, Avid's senior management was able to effectively negotiate with Lilly's Operations team to explain the need to "right-size" SOPs to fit Avid's culture. These negotiations ultimately led to balancing Lilly's expectations with Avid's capabilities.

Relationship development and management became a critical part of Lilly and Avid's mutual success (Johanson & Vahlne, 2003). By demonstrating mutual respect and demonstrating a willingness to learn from each other, Lilly was able to see how processes could hinder Avid. Meanwhile, Avid understood the importance of satisfying a newfound stakeholder as part of a post-acquisition integration process (Birkinshaw, et al, 2000), thus leading us to concept of reciprocity.

Demonstrating Value Through Reciprocity

As has been explained above, Lilly acquired Avid to tap into its deep domain knowledge and to leverage their existing pipeline and manufacturing network to support Lilly's ongoing and future clinical trials. This is the value that Avid was able to bring to the table. Yet, at the beginning of the relationship Avid sensed its expertise was being marginalized by a Lilly team that was accustomed to following their own processes.

Avid felt that it had something to offer Lilly as they had their "finger on the pulse" of a budding imaging biomarker sub-industry. From Avid's perspective Lilly could come across as bureaucratic and seemingly comfortable conducting research using their tried-and-true methods. While Lilly was process driven, Avid perceived that Lilly was periodically preoccupied with their own view of the world (Gault, 1994). Who is to say that Avid is right and Lilly is wrong? Herein lies a linchpin to maximizing post-acquisition organization success—reciprocity (Oliver, 1990).

Reciprocity emphasizes the need for cooperation and collaboration over domination, power, and control (Oliver, 1990). By demonstrating a willingness to adopt a new perspective and evaluate a different paradigm through a new lens, collaborating organizations can theoretically "see the whole elephant" (Saxe, et al, 1963).

While Avid had a knack for innovating and accelerating its drug development, they still needed support with scaling their network, standardizing

processes, and developing a more appropriate infrastructure to support their forecasted clinical and commercial demand. This is where Lilly thrived.

Alternatively parts of Lilly found themselves working by procedures and not necessarily thinking outside the box for new approaches. This is where Avid thrived.

The Lilly “family”^{vii} appreciates the notion of reciprocity. Their teams preferred transparency and a sense that they didn’t need to guess what their teammates were working on. Lilly employees, while more machine-like (Morgan, 2006) in approach, eventually demonstrated a willingness to teach their process while learning from the expertise of others (Morgan, 2006). In other words, they didn’t intentionally pose a threat to Avid’s innovation—they were merely trying to learn and scale.

Avid didn’t need to follow Lilly’s “cultural rules“ but to demonstrate a certain level of respect for their rules. Lilly possessed a rich history and their employees genuinely believed that they were standing on the shoulders of giants. While Avid and Lilly’s work ethic, history, culture, and ambitions are different, both organizations believe they are doing it the right way.

Making a concerted effort to understand each other’s strengths and weaknesses helped provide various strategic options for managing innovation and productivity; however, this effort needed to be balanced, honest, and actionable. Reciprocity can be a primary catalyst to tap into a wide range of collaborative relationships with the intention to access knowledge, skills, and

resources that cannot be produced successfully alone (Powell, 1998). The key challenge in pharma (and other innovation-intensive fields) is to develop organizational routines for learning that are robust, flexible, and durable (Powell, 1998).

How Innovation was Protected at Avid - Conclusion

Through the use of identifying real or perceived barriers, finding balance, and demonstrating reciprocity, Avid was able to change their perspective. Avid found that the best way to protect its innovativeness was to demonstrate their successes and overall impact to a learning company. Fortunately, Lilly proved to be a learning company that wanted to be flexible with Avid's core competencies. Lilly saw the overall benefit and opted to integrate Avid's best practices if doing so made both companies more dynamic.

There were several organizational dynamics factors that were used throughout this process: developing and leveraging political network, and "seeing the whole elephant;" however, there are many other examples for how my Organizational Dynamics education helped me understand the the post-acquisition interactions between Avid and Lilly.

Evaluating Post-Acquisition Life Through Complementary Organizational Dynamics Lenses

The aforementioned section focused on how Avid protected its innovative culture by identifying barriers, finding balance, and the value of reciprocity; however, there are other key organizational dynamic principles that help us understand the post-acquisition interactions between Avid and Lilly. Concepts such as transition and change management, storytelling, organizational lenses, evolution, revolution, episodic change, organizational metaphors, and leadership all played a pivotal role in the pre-to-post-acquisition phases. While many of these principles or tools were modestly applied during this process, they provided rich learning experiences that we can learn from. In the following section I will unpack these concepts from my personal experiences and review these against Avid's drug development experiences in a post-acquisition world.

Transition and Change Management

Despite Avid's staff's being supportive of the acquisition, there were still concerns about their jobs and how an acquisition could change their career trajectories. Would the Philadelphia office close? What jobs were now expendable since Lilly has a robust pool of resource? Should we start looking for housing in Indianapolis?

On top of these concerns Avid was going through growing pains of its own and it was proving difficult to motivate a staff to perform at a high level. In the case of Avid, its leadership was faced with the challenge of managing a team

during an elongated Neutral Zone, a term that refers to a stage where people affected by change are confused, uncertain, or impatient (Bridges, 2003).

During this elongated Neutral Zone period (Bridges, 2003), Lilly had begun implementing some new processes to align Avid with their model of running projects. At that point several legacy employees dug their heels into the ground and stuck with the process that they felt comfortable using. While it never appeared obvious that Avid team members were maliciously acting out, Avid and Lilly's leadership missed an opportunity to acknowledge the legacy employees' loss openly (Bridges, 2003). They had a chance to sympathize with their various changes and offer some praise for their efforts with adopting new processes (Bridges, 2003).

In this case storytelling could have provided Avid's staff with a way of visualizing what the future looks like (Denning, 2011). Especially in instances when a company is traveling through the Neutral Zone, stories allow the presenter to transport an audience into the unknown and paint pictures describing what the future could hold. The idea of visualizing the future helps an audience understand 1.) they are possibly in an undesirable state, 2.) the corporate goal is to reach the end of their transition, 3.) they know about the new beginning, and 4) what opportunities for creativity could look like (Bridges, 2003).

Providing a few easily memorized stories to a group of new employees can help elicit strong connections. These connections build relationships that

eventually lead to trust. After all sharing values enables teams to work together while promoting an environment centered in trust (Denning, 2011).

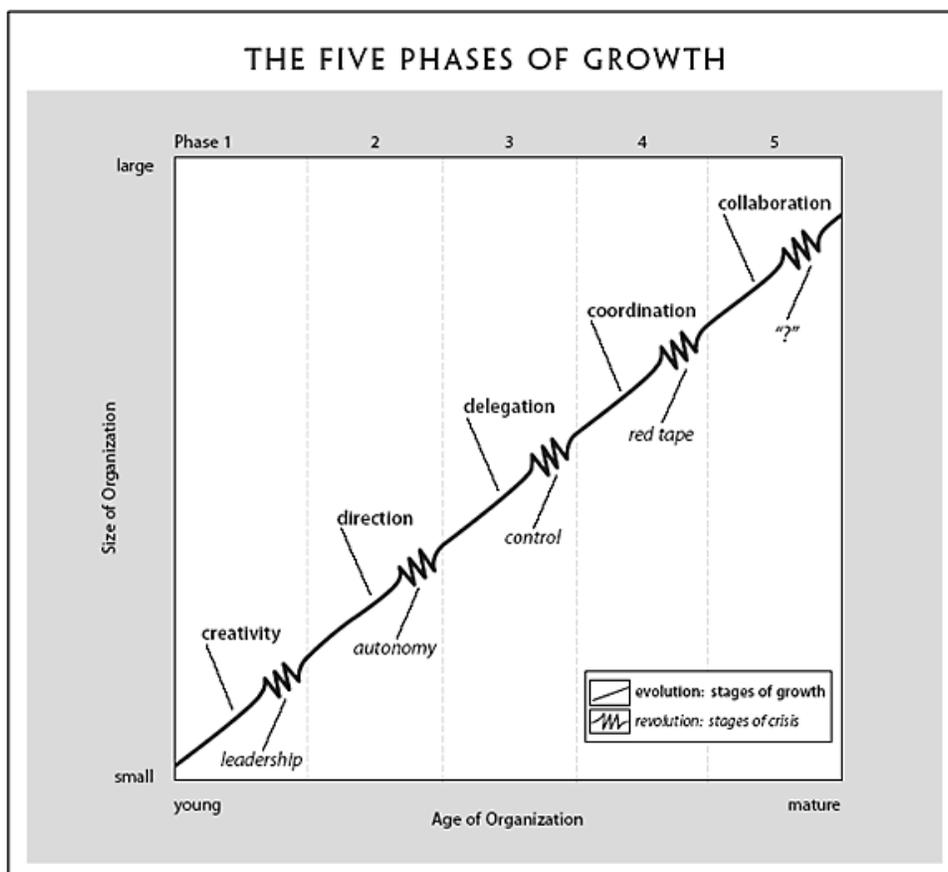
Lilly had an interesting opportunity here. Since Avid brought a unique skill set into the organization, it might have been appropriate for Lilly's teams to interview Avid's experts to determine the best way to perform their unique tasks. Avid's employees could revert to telling illustrative stories about manufacturing the imaging agent or how they organize regulatory filings (Smith, 2012). The idea is that stories provide a timeline that is easily followed, thus allowing the documentation experts at Lilly to "fit" processes that match Avid's core competencies. This way the Avid employees can see that they actually own the process as it is written and they could see their contribution in the transition plans (Smith, 2012; Bridges, 2003).

Evolution, Revolution, and Episodic Change

Throughout the post-acquisition process Avid needed to understand its current corporate maturity and where they were headed. Greiner's Evolution and Revolution model (and to a lesser extent Marshak's gradual change model) helped illustrate Avid's trajectory (Greiner, 1972; Marshak, 2004). Greiner's model demonstrates that over time an organization needs to experience specific stages of growth in order to grow at a given rate. Within his model he aptly accounts for various periods of growth—referred to as evolution—and periods of crisis—referred to as revolution (Greiner, 1998). This model helps illustrate the

need for organizations, management, and individuals to continually reinvent themselves as their needs change. Refer to Figure 6.

Figure 6: Greiner's Evolution and Revolution Model



An interesting element of Greiner's model is that it isn't necessarily time-dependent. Evolution could require years or decades before witnessing Revolution. Instead the model is dependent on the organization's Five Phases of Growth (Greiner, 1998). Avid didn't need to wait decades for their Evolutions and Revolutions to occur; however, I have played witness to the first three evolutionary phases of growth and two revolutions. Avid started evolving through

creativity before experiencing a revolution of *leadership*. The *leadership* revolution was followed by a long period of *direction*. *Direction* lead to the next revolution: *autonomy*. Following *autonomy* is our current stage of *delegation*.

One might argue that the acquisition catapulted Avid into a period of crisis and throughout this period of chaos, Greiner's model has somehow proven to be a source of direction and understanding. By studying the model itself, Avid's leadership can adopt a roadmap for their next steps. If we know the next phase is *control* how might Avid plan to embrace the next revolution? From a communication tool perspective, this model becomes an easy illustration to point to and show that this type of chaos isn't just normal, it's expected!

Starting from mid-2015, each quarterly company meeting features a similar type of illustration. Marshak and Greiner's models of change have become a standard method of explaining our organization's metamorphosis—a simple way to show where we are with respect to our corporate maturity.

Working With Machines and Organisms

From the day Avid was founded it had proven to be lean, especially from a financial perspective. Avid was effectively a laboratory project that showed commercial potential; however, in order to become commercially successful Avid first needed to conduct a series of expensive and time consuming clinical trials. It was mentioned earlier that leadership was able to secure investments through

savvy business arrangement in order to get the dream off the ground. This scrappiness became embedded in the culture.

Over the first several years of Avid's existence it generated lean documentation practices and found short cuts to shave months off their clinical trial timelines. Cross collaboration was the name of the game and despite having departments, there were very few silos. Leadership often spoke of "Industry Paranoia." This mentality ensured that we wouldn't become lazy or complacent—competition was around the corner and we needed to be faster, leaner, and more prepared to make a splash in the marketplace when our time came.

Avid was Organismic but without a long-term partner the goal of producing a commercially viable product was a longshot (Morgan, 2006). Additionally Avid needed to become a learning organization because the landscape of an emerging sub-industry was constantly changing and effectively required constant double-loop feedback (Morgan, 2006). These events led Avid to Lilly.

As it turns out Lilly was really good at designing a stepwise process that nearly anybody with the right exposure could perform identically regardless of site location. In other words, a project manager in Japan would need to follow the identical process to a project manager in Poland. Their staff was trained to reference process procedures and to carry-out these procedures to the best of their ability. Lilly, like most large corporations, was a Machine and in a Tayloristic

way they were dependent on an infrastructure that helped define roles (Morgan, 2006). This was, however, done at the expense of being adaptive.

By the end of the transition most Avid employees started to realize that many Lilly processes made sense once they had worked through them. The reverse was also true. As of today Avid is continuing to find ways to “right size” processes while trying to find new ways to influence Lilly. Fortunately Lilly values Double-Loop feedback at most levels (Morgan, 2006).

Small wholly-owned subsidiaries rarely have a chance at making a dent in the Big Pharma machine. It had become evident that we needed a champion within Lilly to recognize the benefit of “The Avid Way” and to apply it in some instances. Fortunately, through the use of political networks Avid and Lilly have found a way to work collaboratively by playing to its individual strengths.

Conclusions

Throughout the Organizational Dynamics Program I’ve become increasingly inspired to understand innovation and how a corporate environment can act as an incubator to cultivate change in a positive way. I’ve also learned that one framework isn’t enough to truly understand the behaviors of a given organization. In this line of thinking it has occurred to me that leaders must delicately balance politics, power, flexibility, and control in order to maximize output. Furthermore, we must consider how individuals interact with this complex ecosystem.

Whether through Evolution v Revolution, metaphors, developmental Action Logics, or power, there are countless ways to analyze organizations (Greiner, 1998; Morgan, 2006; Torbert, 2004; Quinn, 2010). Although there are endless perspectives to consider it would be fair to say that the perspectives reviewed throughout this program have provided me with tremendous value with regards to diagnosing and course correction. Understanding these concepts is likened to having a road map.

CHAPTER 5

Before concluding this capstone, I would like to summarize my thoughts and advice for individuals at an acquired company. My advice is solely based on my single case experience and is focused on the process of protecting and fostering innovation. Studying a single case has given me valuable perspective for my current role and although each case study is unique, I believe there may be enough parallel so that experiences can be applied to other organizations regardless of industry.

In my experience, the process of being acquired has proven to be a daunting task. At the beginning there were more questions than answers; however, my education has helped me see the corporate world for what it is. Organizations are so wonderfully human and the merging of two organizations can be better understood through an organizational dynamics lens. At the start of an acquisition I firmly believe that if one can “see the whole elephant,” share perspective, and find meaningful connections, that person can change the vector of that organization. I would also warn about the stories you may assign to the acquiring organization.

“Seeing the whole elephant” has become a common theme throughout my time at the University of Pennsylvania and at Avid. This concept derives from an Indian legend of blind men who wanted to study an elephant by feeling it. One man felt the elephant’s trunk and determined that an elephant was like a snake.

Another felt it's leg and resolved an elephant was a pillar. Finally, a third man felt the elephant's ear and believed it was a rough, leathery fan. Of course all three men were right in a certain sense, but they had not comprehended the entirety of the elephant (Meier, 1982).

The parallel to organizations has become clearer to me over time. Throughout the acquisition I found that it was imperative to understand the perspective of everyone impacted by the merging of two teams. For instance, Avid might have felt like its innovative culture was being interrupted while our colleagues at Lilly might have felt threatened by a new technologies that they couldn't fully understand. Another example was related to processes. Lilly needed clearly defined processes since standardization was interwoven with its identity. On the other hand, Avid enjoyed a more relaxed body of standards because it was creating imaging tracers that have never been created before—how could it know what standards or controls were needed?

By “seeing the whole elephant” Avid would be able to understand Lilly's perspective, and vice versa. Different methods and values do not necessarily mean one company is right and the other is wrong; however, it is important to share perspectives and be open to new ways of looking at the world. At the onset of the acquisition some Avid team members had dug in their heels and refused to change. This was one way of trying to protect themselves against change but this stubbornness proved to be ineffective. Alternatively, the members who were most effective openly communicated and shared their

perspective. These individuals recognized that if there was something worth protecting (e.g. innovative characteristics) then they should be vocal and clearly describe their position.

Another core element to finding success through an acquisition is relationship management. Building a network within the acquiring organization had proven to be one of the most important assets to an influencer. Remember that organizations are comprised of humans with various wants and needs. By creating meaningful connections you create opportunities to express your perspective, drive positive change, and become recognized as a contributing team member; however, there are some pitfalls to building these networks. For instance, be cautious not to blindly follow leaders. Understand the goals of your leadership and align yourself with leaders who think beyond a limited scope. Be sure leadership understands your goals and ambitions, otherwise you might find yourself on the wrong career path. I have found it is also important to be true to yourself and offer unique insight when opportunities present themselves.

Last, be cautious of the stories you assign to people, processes, and groups. In the early phases of the acquisition I recall some Avid team members expressing concern about Lilly and their "machine-like processes. I was among the masses who were anxiously entering the Neutral Zone (Bridges, 2003). There were concerns with "fit" and a general sense of negative change on the horizon. These were, of course, stories we told ourselves about Big Pharma acquiring a small company.

After a short period of time we realized that these stories were generated to make sense of the situation we were in. In fact my experience proved that the story I had told myself was entirely wrong. In general, Lilly had welcomed different perspectives and have worked hard to find ways to encourage Avid's input. This spirit of hospitality helped foster relationships built on trust and understanding.

These concepts from Organizational Dynamics proved to be valuable additions to my management "toolbox." I have found some success in socializing these ideas, models, and theories with leaders and followers alike. My appreciation for organizational understanding is continually rekindled when I look back at my questions/learnings and look forward to the next steps on my journey. Understanding how organizations function—macroscopically and microscopically—continues to fascinate and amaze.

Proposed Next Steps for Continuous Learning

Statistically speaking, many mergers and acquisitions (herein M&A) ultimately fail to add value to companies (Knowledge@Wharton, 2005). In fact, a common documented range for failure is between 50% and 80% (Knowledge@Wharton, 2005). This has not been the case for the acquisition described throughout this paper, and I would consider Lilly's acquisition of Avid to be a success story.

While not covered in this capstone I believe that there are rich opportunities to evaluate the difference between failed and successful M&As through an organizational dynamics lens. While some M&As might fail for various reasons, perhaps due to financial issues, obsolete technology, or poor strategy decisions, there could be other instances of failures that are related to ineffective people management. Even in cases where M&As have been successful, I submit that applying organizational dynamics practices could help provide a smoother transition.

Undoubtedly plenty of research exists that describes why M&As fail. Many analysts consider “clashing corporate cultures as one of the most significant obstacles” to post-acquisition integration (Knowledge@Wharton, 2005), yet I would be most interested in studying the ecosystems where innovation flourishes or flounders. What is the make-up of the leadership in the acquiring organization? What about the leadership in the acquired organization? Are there indicators that could be used to predict success? If so, how could we better prepare acquirers and acquirees to ensure a successful acquisition? These questions, among others, remain on my professional and academic horizon.

Final Thoughts

The past several years have been an enlightening experience that has driven personal change. I've learned from respected colleagues, leaders, and

professors from various walks of life. I've learned about perspective, change, negotiations, leadership, followership, politics, sustainability, storytelling, and countless other organizational dynamic elements that have shifted my way of seeing the world.

The next phase of the journey is the most critical since it consists of continuing to apply my tapestry of knowledge in real-world scenarios. My goal is to ensure that all of my learnings—past, present, and future—are tied into a cohesive story that helps organizations understand how to grow while staying true to their innovative roots.

At the onset of this capstone, Avid was functioning in a supporting role within Lilly's AD unit and appeared tied to the successes or failures based on the outcome of their collective research. If Lilly's pipeline is successful, they would need Avid's support for a very long time. If the pipeline is unsuccessful, all signs show that Avid would be sold to another pharmaceutical company who has a need for their diagnostic imaging agent. This all changed in at the beginning of this year.

In January 2016, after acting as a wholly-owned subsidiary for five years, Avid officially became Lilly. We now share the same tools, benefits, systems, human resources, and data. Avid had proven to be a competent acquisition by Lilly and Lilly had decided that we should be tied together in the long-haul.

The journey doesn't end there. Avid still functions as a cutting edge radiopharmaceutical group in Philadelphia and we are charged with supporting

some of the largest AD trials in the world today. Innovation is what got us here and innovation will keep us on the cutting edge.

Although there are endless perspectives to consider it would be fair to say that the organizational dynamics concepts reviewed throughout this program have provided me with tremendous value with regards to understanding the human components of organizations. Organizations are complex entities with many moving parts. Applying various organizational dynamics lens have helped by providing clarity and guidance. As Quinn said, "Organizations do not exist in a vacuum," so let's continue to study and understand organizations with the goal of making them better (Quinn, 2010, p 254).

REFERENCES

1. Allsop, D. (2000). Introduction to Alzheimer's disease. In *Alzheimer's Disease* (pp. 1-21). Humana Press.
2. Alzheimer, A. (1907) *Über eine eigenartige Erkrankung der Hirnrinde*. *Allg. Zschr. f Psychiatr. Psychisch-Gerichtl. Mediz.* 64, 146–148.
3. Alzheimer's, A. (2015). 2015 Alzheimer's disease facts and figures. *Alzheimer's & dementia: the journal of the Alzheimer's Association*, 11(3), 332.
4. Amabile, T. M. (1988). A model of creativity and innovation in organizations. *Research in organizational behavior*. 10 (1) 123-167
5. ARIETI, S. (1946). Histopathologic changes in cerebral malaria and their relation to psychotic sequels. *Archives of Neurology & Psychiatry*, 56(1), 79-104.
6. Becker, R. E., Greig, N. H., & Giacobini, E. (2008). Why Do So Many Drugs for Alzheimer's Disease Fail in Development? Time for New Methods and New Practices? *Journal of Alzheimer's Disease*, 15(2), 303–325.
7. Birkinshaw, J., Bresman, H., & Håkanson, L. (2000). Managing the post-acquisition integration process: How the human iintegration and task integration processes interact to foster value creation. *Journal of management studies*, 37(3), 395-425.
8. Branson, R. (2015). *The virgin way: How to listen, learn, laugh and lead*. Penguin.
9. Bresler, J. (1912). Progress of Psychiatry in 1911. *The British Journal of Psychiatry*, 58(242), 502-505
10. Bridges, W. (2003). *Managing transitions: Making the most of change*. Cambridge, MA: Da Capo Press.
11. Califf, R. M. (2006). Clinical trials bureaucracy: unintended consequences of well-intentioned policy. *Clinical Trials*, 3(6), 496-502.
12. Carroll, J. (2010). Lilly (\$LLY) snags Avid Radiopharmaceuticals in \$800M buyout deal. *FierceBiotech* <http://www.fiercebiotech.com/story/lilly-snags-avid-radiopharmaceuticals-800-million-buyout-deal/2010-11-08>).
13. Cha, M & Yu, F. (2008) *Pharma's first-to-market advantage*. McKinsey

14. Choi, S. R., Golding, G., Zhuang, Z., Zhang, W., Lim, N., Hefti, F., ... & Kung, H. F. (2009). Preclinical properties of 18F-AV-45: a PET agent for A β plaques in the brain. *Journal of Nuclear Medicine*, 50(11), 1887-1894.
15. Cohene, T., Baecker, R., & Marziali, E. (2005). Designing interactive life story multimedia for a family affected by alzheimer's disease: a case study. *ACM*. (pp. 1300-1303).
16. Coombs, R., & Metcalfe, J. S. (2002). Innovation in pharmaceuticals: perspectives on the co-ordination, combination and creation of capabilities. *Technology Analysis & Strategic Management*, 14(3), 261-271.
17. Cummings, J. L., Morstorf, T., & Zhong, K. (2014). Alzheimer's disease drug-development pipeline: few candidates, frequent failures. *Alzheimer's Research & Therapy*, 6(4), 37.
18. D'Onfro, J. (2013). 11 Elon Musk Quotes That Show His Genius. *Business Insider*. <http://www.businessinsider.com/11-elon-musk-quotes-2013-9>
19. de Jong, M., Marston, N., Roth, E., & van Biljon, P. (2013). The Eight Essentials of innovation performance. *McKinsey Strategy*.
20. DeLong, Thomas J., and Ashish Nanda. *Professional Services: Text and Cases*. New York: McGraw-Hill/Irwin.
21. Denning, S. (2011). *The leader's guide to storytelling: Mastering the art and discipline of business narrative*. San Francisco, Jossey-Bass.
22. Devous, M. D., Joshi, A. D., Navitsky, M. A., Dickson, J., Pontecorvo, M. A., Siderowf, A., & Mintun, M. A. (2014). TEST-RETEST DATA FOR THE TAU PET IMAGING AGENT 18F-AV-1451 (PREVIOUSLY, 18F-T807). *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, 10(4), P901.
23. Devous, M. D., Navitsky, M., Kennedy, I., Joshi, A. D., Lu, M., Pontecorvo, M. J., & Mintun, M. A. (2015). Relationships between cognitive assessments and spatial distribution of neuropathological tau as assessed by 18F AV-1451 PET scanning. *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, 11(7), P881.
24. DiMasi, J. A., Grabowski, H. G., & Vernon, J. (1995). R&D costs, innovative output and firm size in the pharmaceutical industry. *International Journal of the Economics of Business*, 2(2), 201-219.

25. Doody, R. S., Thomas, R. G., Farlow, M., Iwatsubo, T., Vellas, B., Joffe, S., ... & Mohs, R. (2014). Phase 3 trials of solanezumab for mild-to-moderate Alzheimer's disease. *New England Journal of Medicine*, 370(4), 311-321.
26. Drucker, P. (2014). *Innovation and entrepreneurship*. Routledge.
27. Farrell, M. (2008). Universities That Turn Research Into Revenue. *Forbes*. http://www.forbes.com/2008/09/12/google-general-electric-ent-tech-cx_mf_0912universitypatent.html
28. Findlay, C. S., & Lumsden, C. J. (1988). The creative mind: Toward an evolutionary theory of discovery and innovation. *Journal of Social and Biological Structures*, 11(1), 3-55.
29. Fischer, B. (2011). CEOs Say Innovation Is Most Important Factor For Growth. *Forbes* <http://www.forbes.com/sites/billfischer/2011/06/04/ceos-say-innovation-is-most-important-factor-for-growth-voxy-co-nz/#97854372e906>
30. Furst, A. J., & Kerchner, G. A. (2012). From Alois to Amyvid Seeing Alzheimer disease. *Neurology*, 79(16), 1628-1629.
31. Gabor, D. (1968) National Manpower Conference, [Held at the Student Union, Oklahoma State University, Stillwater, Oklahoma, May 17-18, 1968
32. Garber, K. (2012). First FDA-approved beta-amyloid diagnostic hits the market. *Nature biotechnology*, 30(7), 575-575.
33. Gault, R. F. (1994). Large companies, are you listening?. *Management Review*, 83(9), 42.
34. Gersch, K. (2013). Google's Best New Innovation: Rules Around '20% Time'. *Forbes* <http://www.forbes.com/sites/johnkotter/2013/08/21/googles-best-new-innovation-rules-around-20-time/>
35. Grasty, T. (2012). The difference between “invention” and “innovation”. *The Huffington Post*. <http://www.huffingtonpost.com/tom-grasty/technological-inventions-and-innovation>.
36. Greiner, L.E., 1972. Evolution and revolution as organizations grow. *Harvard Business Review*.
37. H. Soken, N. and Kim Barnes, B., 2014. What kills innovation? Your role as a leader in supporting an innovative culture. *Industrial and Commercial Training*, 46(1), pp.7-15.

38. Hamel, G. (2007). *The future of management*. Boston: Harvard Business School Press.
39. Hanush, H, Pyka, A. (2007). *Elgar Companion to Neo-Schumpeterian Economics*. Edward Elagr, Cheltenham, p. 857.
40. Hines, T. S. (2008). *Burnham of Chicago: Architect and planner*. University of Chicago Press.
41. Holtzman, D., Mandelkow, M. E., and Selkoe, D. J. (2012). Alzheimer disease in 2020. *Cold Spring Harb. Perspect. Med.* 2, pii: a011585.
42. Ittner, L. M., & Götz, J. (2011). Amyloid- β and tau—a toxic pas de deux in Alzheimer's disease. *Nature Reviews Neuroscience*, 12(2), 67-72.
43. Jacobson, O., & Chen, X. (2010). PET designated flouride-18 production and chemistry. *Current topics in medicinal chemistry*, 10(11), 1048.
44. James, O. G., Doraiswamy, P. M., & Borges-Neto, S. (2015). PET imaging of tau pathology in Alzheimer's disease and tauopathies. *Frontiers in neurology*, 6.
45. Johanson, J., & Vahlne, J. E. (2003). Business relationship learning and commitment in the internationalization process. *Journal of international entrepreneurship*, 1(1), 83-101.
46. Jorm, A. F., Van Duijn, C. M., Chandra, V., Fratiglioni, L., Graves, A. B., Heyman, A., ... & Soininen, H. (1991). Psychiatric history and related exposures as risk factors for Alzheimer's disease: a collaborative re-analysis of case-control studies. *International Journal of Epidemiology*, 20(Supplement 2), S43-S47.
47. Kalia, M. (2013). Personalized oncology: recent advances and future challenges. *Metabolism*, 62, S11-S14.
48. Kanter, R. M. (1984). *Change masters*. Simon and Schuster.
49. Karran, E., & Hardy, J. (2014). A critique of the drug discovery and phase 3 clinical programs targeting the amyloid hypothesis for Alzheimer disease. *Annals of neurology*, 76(2), 185-205.
50. Karran, E., Mercken, M., & De Strooper, B. (2011). The amyloid cascade hypothesis for Alzheimer's disease: an appraisal for the development of therapeutics. *Nature reviews Drug discovery*, 10(9), 698-712.

51. Kelly, T., & Littman, J. (2008). Ten faces of Innovation: IDEO's Strategies for defeating the Devil's Advocate and driving creativity throughout your organization. Profile Books Ltd.
52. Kline, J.K. and Rosenberg, N. (1986). An Overview of Innovation in R. Landau and N. Rosenberg (eds) The Positive Sum Strategy: Harnessing Technology for Economic Growth Washington DC.
53. Klunk WE, Engler H, Nordberg A, et al. (2004). Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B. *Ann Neurol* 2004;55:306-319
54. Klunk, W. E., Engler, H., Nordberg, A., Wang, Y., Blomqvist, G., Holt, D. P., ... & Långström, B. (2004). Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B. *Annals of neurology*, 55(3), 306-319.
55. Knowledge@Wharton (2005). Why do so many mergers fail?. The Wharton School. University of Pennsylvania.
<http://knowledge.wharton.upenn.edu/article/why-do-so-many-mergers-fail>
56. Kola, I., & Landis, J. (2004). Can the pharmaceutical industry reduce attrition rates?. *Nature reviews Drug discovery*, 3(8), 711-716.
57. Kola, I. (2008). The state of innovation in drug development. *Clinical Pharmacology & Therapeutics*, 83(2), 227-230.
58. Lawrence, P. R., & Nohria, N. (2002). *Driven*. Jossey-Bass.
59. Loftus, P. (2010). Lilly To Acquire Avid Radiopharma. *The Wall Street Journal*.
60. Madison, J. H. (1989). Manufacturing Pharmaceuticals: Eli Lilly and Company, 1876-1948. *Business and Economic History*, 72-78.
61. Marshak, R. J. (2004). Morphing: The leading edge of organizational change in the twenty-first century. *Organization Development Journal*, 22(3), 8.
62. McKhann, G. M., Knopman, D. S., Chertkow, H., Hyman, B. T., Jack, C. R., Kawas, C. H., ... & Phelps, C. H. (2011). The diagnosis of dementia due to Alzheimer's disease: Recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. *Alzheimer's & Dementia*, 7(3), 263-269.

63. Meier, F. (1982). The problem of nature in the esoteric monism of Islam. *Spirit and nature: Papers from the Eranos yearbooks, Bollingen Series 1*.
64. Mochly-Rosen, D., & Grimes, K. (2014). *A Practical Guide to Drug Development in Academia: The SPARK Approach*. Springer.
65. Morgan, G. (2006). *Images of organization*. Beverly Hills, CA: Sage.
66. Mullin, R. (2014). Cost to develop new pharmaceutical drug now exceeds \$2.5 B. *Scientific American*, 24.
67. Navaretti, G. B., Dasgupta, P., Mäler, K. G., & Siniscalco, D. (Eds.). (2013). *Creation and transfer of knowledge: institutions and incentives*. Springer Science & Business Media.
68. Nisbet, R. M., Polanco, J. C., Ittner, L. M., & Götz, J. (2015). Tau aggregation and its interplay with amyloid- β . *Acta neuropathologica*, 129(2), 207-220.
69. Oliver, C. (1990). Determinants of interorganizational relationships: Integration and future directions. *Academy of management review*, 15(2), 241-265.
70. Osnato, M. (1923). The Pathogenesis of epilepsy: a critical review with a new interpretation of the available data. *Archives of Neurology & Psychiatry*, 9(4), 488-505.
71. Powell, W. W. (1998). Learning from collaboration: Knowledge and networks in the biotechnology and pharmaceutical industries. *California management review*, 40(3), 228-240.
72. Quinn, J. B. (1987). *Managing Innovation: Controlled Chaos*: Harvard Business Review. 2(4), 485.
73. Quinn, R. E., Faerman, S. R., Thompson, M. P., McGrath, M. R., & L.S., S. C. (2010). *Becoming a master manager: A competing values approach* (Fifth ed.). New York: John Wiley & Sons.
74. Risacher, S. L., & Saykin, A. J. (2013). Neuroimaging and Other Biomarkers for Alzheimer's Disease: The Changing Landscape of Early Detection. *Annual Review of Clinical Psychology*, 9, 621-648. doi:10.1146/annurev-clinpsy-050212-185535
75. Saxe, J. G., Lathen, D., & Chief, B. (1963). *The Blind Man & the Elephant*. McGraw-Hill Company.

76. Schumpeter, J.A. (1912). *The Theory of Economic Development*. Tenth printing 2004, Transaction Publishers.
77. Schumpeter, J.A. (1934). *The Theory of Economic Development: An Inquiry into Profits, Capital, Credit, Interest and the Business Cycle*. Harvard Economic Studies, Vol. 46.
78. Stake, R. E. (1995). *The art of case study research*. Sage.
79. Steenhuysen, J. (2013). Lilly to acquire Alzheimer's imaging agents from Siemens. Reuters. April 2013
80. Sullivan, M. G. (2014). Two Alzheimer's Immunotherapy Drugs Fail in Four Studies. *Caring for the Ages*, 15(3), 4-5.
81. Torbert, W. R., & Torbert, B. (2004). *Action inquiry: The secret of timely and transforming leadership*. Berrett-Koehler Publishers.
82. Yin, R. K. (2013). *Case study research: Design and methods*. Sage.
83. Zaltman, G., Duncan, R., & Holbek, J. (1973). Innovations and organizations. *Wiley*. 10(1), 123-167.

ENDNOTES

ⁱ Although not covered within this capstone, Lilly's option to "buy" and not "rent" Avid's services suggest Avid was more than an acquisition target for their pipeline. I can see an extension from this paper that would explore the differences between routine acquisition and a strategic partnership through acquisition.

ⁱⁱ Private Source, internal at Avid

ⁱⁱⁱ Internal Communication, Company Meeting September 2015

^{iv} Internal Communication, Company Meeting September 2015

^v Internal Communication, Management Meeting December 2015

^{vi} Working in the "now: is a common expression used by leadership at Avid

^{vii} Common euphemism used at Lilly and Avid to describe Lilly's culture