SCRIP
CITELINE COMMERCIAL

25 Nov 2016 |

From Y/Z To Goodbye: Lechleiter's Lilly Legacy

by Jo Shorthouse

Outgoing Eli Lilly CEO and president John Lechleiter looks back over his biggest strategic decisions while at the helm of the pharma major and pinpoints some of the key navigational markers for the next phase in Lilly's lifespan.

When John Lechleiter took the reins of *Eli Lilly & Co.* back in 2008, the outlook was not very rosy for the Indianapolis-based company. Tasked with leading the company's 41,000 employees through what he terms the "Y/Z period" [the years 2011-2014 where patent losses punctuated the big pharma's financial performance], he had to create solid strategies that would guide the company back to its glory days.

Lechleiter had already worked for Lilly since 1979, beginning his career as an organic chemist before winding his way around various company functions including project management, regulatory affairs, product development, and pharma operations. In 2005, he was named president and chief operating officer and joined the board of directors. He jokingly explains that when he became CEO, he had to deal with the challenges that he had helped to create as part of the senior leadership team. At the time, Lilly faced the loss of patent exclusivity on four of its biggest products: the anticancer *Gemzar* (gemcitabine) in 2010; the antipsychotic *Zyprexa* (olanzapine) in 2011; the antidepressant *Cymbalta* (duloxetine) in 2013; and the anti-osteoporotic *Evista* (raloxifene) in 2014. The board knew the company would need a strategist that could unwaveringly stick to the message: R&D investment will get us out of this.

"We'd have to have a strategy for navigating through a difficult period, so we put a lot of emphasis on advancing the pipeline. We began to think about opportunities to look outside our walls for innovative molecules," he recalls. The first evidence of this would be the $6.5bn purchase of *ImClone Systems Inc.* in October 2008 for reasons centered solely on the pipeline. The pipeline in question, at that time, had four molecules that were in clinical stage development;

Cyramza (ramucirumab), currently in Phase III for second-line liver cancer, *Portrazza* (necitumumab), which is cleared for first-line squamous NSCLC, and cixutumumab, which ultimately fell by the wayside. The soft tissue sarcoma drug *Lartruvo* (olaratumab) was recently granted conditional marketing authorization in Europe. (Also see "*Lilly's Sarcoma Drug Likely To Be Used Widely Despite EU Conditional OK*" - Scrip, 14 Nov, 2016.)

In hindsight, it seems as though Lechleiter's first big move as CEO has worked in Lilly's favor. At the time, though, the company was at one of its darkest hours and Lechleiter knew he wasn't going to have it easy. "I'd been on the senior management team and so this [patent loss] was not unexpected, and in this industry it's really hard to avoid: you can't arrange your products like pieces on a playing board. When patents go, patents go," he states.

"I think we had a fair degree of confidence in early 2008 that we had a pipeline that would enable us to begin to replace some of the lost revenue and then grow from there. What we didn't count on was the number of pipeline failures. That, to some degree, surprised us, several of them occurring in Phase III, obviously. I think that increased the challenge – or the degree of difficulty of the challenge – that we faced," he says.

It was the board's decision, led by a resolute Lechleiter, to continue the company's heavy investment in R&D, and to increase this investment every year up to 2014, when it fell to "reflect the maturation" of the company's Phase III pipeline. Lechleiter acknowledges that R&D spending was cut also because of the huge revenue hit caused by the patent losses on Evista and Cymbalta but he simply describes this as "playing the hand you're dealt".

John Lechleiter led the company's heavy investment in R&D to counter upcoming patent losses of some of its biggest brands

"I knew what my tenure would likely encompass, this whole Y/Z challenge, I'd been here through what we called Year X, which was when we lost the *Prozac* (fluoxetine) patent in 2001, so the nature of the challenge wasn't new, but obviously the magnitude was much greater this time," he recalls.

Restructure

Hit by high-profile Phase III failures and bracing itself for the upcoming tide of patent losses, Lilly's restructure and downsizing were inevitable. In September 2009 the company was reorganized into business areas to allow it to focus on core therapeutic sectors including diabetes, oncology and what it called Bio-Medicines. Lechleiter

says he knew at the time that this was the right move for the company, calling it a "wonderfully helpful decision". Staff embraced it and it made an immediate difference to the company's competitiveness in its Y/Z period, he says.

While the company reshuffled it also announced the elimination of 5,000 positions. Lechleiter recalls this as his most difficult decision but one that was necessary to "keep the company off the skids". "That impacts people, it impacts families, it's not something that I think any CEO could ever not lose sleep over. At the same time the decision was necessary to make sure that ultimately the enterprise succeeded and of course we have so much more there at risk, 35,000 or 38,000 jobs, so you do these things because you have to, and must, in certain situations," he explains.

Lilly's Next Phase

As one would expect, Lechleiter is Lilly's biggest cheerleader. His steadying influence and stoic focus when keeping to the company's strategy has worked in the past when a firm hand was required on the rudder. "I've said publicly I think Lilly's best days are ahead and when I look back at the challenges of the work that we had to do between 2008 and today, I think the good news out of that is that Lilly is well placed and well positioned today to be successful in the future based on what we have been able to put in place.

In May, the company made clear its ambitions to launch 20 new drugs in the decade between 2014 and 2023. It has launched six already, and two are under regulatory review. Overseeing this next period of potential growth will be David Ricks, Lilly's current president of Lilly Bio-Medicines since 2012, having previously led Lilly's business operations in Canada, China and the US.

During the press briefing to announce the CEO succession, Lechleiter said that Ricks "has significant experience in aspects of our business the board believes is essential to success: the development of new products, sales and marketing, and public policy, both in Europe and the US and globally."

Revenues are going in the right direction, with third-quarter revenues up by 5% from the comparable period of 2015, led by sales of diabetes drugs *Trulicity* (dulaglutide), *Jardiance* (empagliflozin),

Lilly BioMedicines Head Ricks Tasked With Overseeing Growth Phase As Next CEO

By Jessica Merrill

27 Jul 2016
Long-time CEO John Lechleiter, who led the company through a challenging period of enormous patent expirations, will step down at year's end.

SCRIP
CITELINE COMMERCIAL

Cyramza and psoriasis drug *Taltz* (ixekizumab). Lilly has a stated goal of generating at least 5% average annual revenue growth rate from 2015 to 2020. (Also see "*Can New Drugs Meet Lilly's Revenue Goals If Solanezumab Fails?*" - Scrip, 25 Oct, 2016.) However, with the most recent Phase III failure of solanezumab (sola) in patients with mild dementia caused by Alzheimer's disease, the third Phase III failure in a row, a shadow has been cast over Lilly's AD pipeline portfolio. Analysts had attributed up to $1.4bn in peak sales to sola. However, as a Credit Suisse analyst said in a recent note which explained why it was retaining its Outperform rating of the company, it was "based on much more than just sola".

Read the full article here

Final Thoughts

"If I was going to look at Lilly in 10 years my hope is that we have a substantial neurodegeneration presence. I believe we will continue to be able to build a leading diabetes business with today, in essence, a molecule or a drug in most of the key classes or categories," Lechleiter says.

He points to Lilly's four core therapy areas: diabetes, oncology, neurodegeneration and immunology. He also highlights two "very interesting" Phase III molecules in pain; tanezumab, a nerve growth factor (NGF) antibody partnered with Pfizer to treat cancer pain, chronic lower back pain and pain related to osteoarthritis, and galcanezumab, a calcitonin gene-related peptide (CGRP) receptor antagonist in development for cluster headaches and both chronic and episodic migraine. "That's an area where we really, really need new treatments, we need alternatives to opioid therapies," he stresses.

Pride, he says, is the overall feeling that will accompany him when he retires on Dec. 31. He is notably proud of Lilly's place as the last non-merged major pharma company, a position of independence that has been earned, he says, by winning the approval of shareholders with its plans for the future. "I think that where we are currently compared to where we were only a few years ago is clear evidence that we are back in favor with shareholders, we can make a claim for that independence."

Despite Lechleiter's tumultuous presidency at the company, he is very upbeat about the future of the industry as a whole. Despite the challenges brought on by "navigating through an ever more complex world from a payer perspective", the good news is, he says, that there is going to be a "tremendous demand" for the products that the industry generates. "The scientific substrate has never been more robust. This has to be the golden age of pharmaceutical science when you look at what we're able to learn, to use and to capitalize on more quickly to come up with decent drug candidates and to get those into human testing."

He is realistic about his fortunes and performance as a CEO, and about Lilly as a company, stating that you have to aim high and expect some failure along the way, especially when the stakes are as high as they are in drug development. "No organization is perfect, the path is never straight and there have been many challenges over the years. We've made mistakes, but we've had some brilliant success."