

Interview with Shane Cooke, President, Alkermes

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Mr. Cooke, you joined Alkermes after the company acquired the Elan Drug Technologies (EDT) unit in 2011—a unit you headed for four years. Can you please begin by introducing yourself to our readers, and explain the rationale and outcomes of the merger?

I was born in Dublin, earned my degree in accounting at University College Dublin (UCD), and have spent my life working in the city. I worked in the commercial aircraft leasing business for approximately ten years, and subsequently, for the last twelve years, I've worked in the Irish biopharmaceutical sector.

I was formerly the Chief Financial Officer (CFO) of Elan, from 2001 until 2011. I was also a board member at the company. In addition to my role as CFO, from 2007 until 2011, I was in charge of Elan's drug delivery business.

As you noted, in 2011, Elan merged its drug delivery unit into Alkermes, and I joined Alkermes as part of the merger. Elan had built up a substantial amount of legacy debt in the 1990s, and throughout my years with the company, my team and I spent a fair amount of time reducing that debt and attempting to return the organization to profitability. The sale of our drug delivery business to Alkermes was the final step in the endeavor to bring Elan to a net cash position.

For a number of years, Alkermes has had a business in the U.S., primarily based in Boston. Much like EDT, that business has historically focused on drug delivery. However, over the last five or six years, our CEO Richard Pops has been repositioning Alkermes as an integrated biotech player with a proprietary line of products. Therefore, prior to the acquisition, Alkermes had an exciting pipeline, but only a couple of products on the market. Elan's drug delivery business, on the other hand, had a much larger number of products on the market, and was generating a lot of cash—but Elan had no pipeline. The beauty of the merger, therefore, was the combination of our strengths. We established a company with both an emerging pipeline, and a broad portfolio of products on the market that could bring in long-term, sustainable revenues.

The Elan transaction was closed in September of 2011, and things have gone extremely well for Alkermes in the intervening period. We looked at our two businesses—one based in the U.S., and the other based in Ireland—and decided that the best location to headquarter the combined organization was Ireland. Our head office is in Dublin, and we have a manufacturing and R&D site in Athlone, Co. Westmeath. That facility has been in operation for 35 years, and is an integral part of the local community—anyone familiar with the Irish biotech story will be familiar with the (legacy Elan EDT) Athlone site.

Mr. Pops recently gave a speech at the Citi Global Healthcare Conference, and noted that Alkermes essentially had two portfolios. As you began to mention, the first is your commercial portfolio—your bread and butter today—and the second is your emerging pipeline. Mr. Pops said, while most of the world has focused over the last year on our commercial portfolio and the news coming from that, almost in the background, our pipeline has been maturing and getting more and more exciting and is filled with all kinds of news events in 2013. Can you elucidate both aspects of the business in greater depth?

Let's begin by looking at our commercial portfolio. Currently, we have five key products that are generating significant revenues for the company, as well as a number of older, legacy drugs. The difference between Alkermes and most similarly sized companies in our niche is the fact that our revenue streams are diversified between several drugs, rather just one or two. Another distinguishing factor for us is the fact that each of our key products has a long patent life ahead of it. We do not face a patent cliff—which, as we well know, is today a major issue for many of the players that we compete with.

Our key products are all leading compounds in their therapeutic areas. Two of the drugs—Invega Sustenna and Risperdal Consta—are long-acting formulations of important schizophrenia products. They are marketed by Johnson & Johnson (JnJ), and are both major franchises for the company.

We also have a compound, in partnership with U.S.-based Acorda Therapeutics, called Ampyra. It is a multiple sclerosis (MS) medication meant to improve sufferers' walking ability. Ampyra was launched three years ago, and was developed over a period of ten years at our facility in Athlone—the first work started in 1998. Ampyra is marketed in Europe by Biogen Idec, which is currently looking to expand use of the drug for additional indications such as combatting cerebral palsy.

Our fourth key product is Bydureon, a diabetes medicine. It is an innovative formulation of Byetta, which allows the patient to receive an injection once weekly rather than twice daily—which, for diabetics, is obviously a huge improvement. We developed this drug alongside Amylin, a company that has now been acquired by BMS. The product has just been launched, and AstraZeneca is interested in marketing it in certain geographies. Diabetes is a growing problem around the world, and we believe Bydureon will be a very important drug.

The final product in the key five is called Vivitrol, approved for alcohol and opioid addiction. A monthly injection, Vivitrol prevents patients from relapsing into addiction. As with our other drugs, we believe this medication will have a leading role to play in its therapeutic area.

Alkermes also has a number of other products that round out our portfolio, but they are less significant for the company and we expect their revenues to steadily decline over time. Our long-term, visible growth will come from our key five.

Currently, we generate \$550Mn USD from our commercial portfolio. We invest a percentage of that revenue back into R&D. Part of the attraction of the merger was to support the growth of our pipeline, and we have made fantastic progress over the last year in moving that pipeline forward in the clinical process.

We typically highlight three products within the pipeline that we believe will fuel our evolution into the next decade. The drug nearest to the market is aripipazole lauroxil, a monthly formulation of Abilify. Abilify is one of the most widely used schizophrenia drugs in the world, generating approximately \$7Bn USD in revenues per year. An enduring challenge has been to develop a long-acting version of the compound, because one of the major issues with schizophrenia is compliance. We believe that we have developed a viable long-acting formulation candidate, which is currently in the late stages of

development. We expect the final data to come in at the end of the year, and will then plan to launch the product ourselves by 2015.

We have a good deal of experience with schizophrenia because of our existing drugs in the field, Invega Sustenna and Risperdal Consta. These franchises together generate approximately \$2.5Bn USD for JnJ, and we see huge growth potential in the market because the savings benefit to the healthcare system from the assurance that schizophrenia patients are taking their medications is enormous. Otsuka recently received marketing authorization for their own long-acting version of Abilify, but we view that as a positive: the more patients have access to long-acting formulations, the better. More product choice will also be a major benefit for doctors and healthcare systems looking to better understand how to treat schizophrenia.

Aripipazole lauroxil is a very exciting product for us, because we believe its revenue potential is in the realm of several hundred million dollars. As a \$550Mn USD per annum company, the success of aripipazole lauroxil will be a major milestone for us.

We also have a very interesting product in CNS, which we plan to move to Phase II of clinical development this year. It is a technology that is focused on opioid receptor modules. Today, when people take painkillers, they may become intoxicated because of the drugs' impact on opioid receptors. At Alkermes, we have developed proprietary compounds that can block that action. We have found that our technology can have an impact not just on drug addiction—an area where, as I have mentioned, we are already active—but also on other kinds of addiction, such as binge eating and other disorders driven by the body's reward system.

Olanzapine, marketed as Zyprexa for schizophrenia, is acknowledged as one of the most effective products for the disease. However, one of the biggest issues with Zyprexa is weight gain. About 70% of patients that go off the drug cite weight gain as the primary reason for discontinuing use. At Alkermes, we are conducting tests to determine whether it would be possible to combine our technology with Zyprexa, and successfully attenuate the weight gain. We also see positive signs that the product could be used for alcohol addiction. Again, this benefit would well complement schizophrenia treatment, as many schizophrenics are also alcohol abusers. In all, we have high hopes that this product will be a best-in-class drug for schizophrenia, having all the efficacy of Zyprexa while attenuating weight gain and having an impact on alcohol addiction.

The final product I'd like to highlight is a Phase II drug for which we expect data to emerge in the next few months. The drug aims to treat major depression and, again, employs our opioid receptor module technology—this time, in combination with Buprenorphine.

Buprenorphine is an opioid that has been recognized for its impact on depression, but is known to be addictive. Alkermes is trying to utilize the opioid's benefits in battling depression, while counter-acting its addictive properties with our own compound. In Phase I studies, we saw very interesting results: efficacy impact was almost immediate, and there was no evidence at all of addiction or intoxication. We hope that the data that will emerge from our current, 230-patient Phase II study will further validate our early results. We are talking about a whole new mechanism of action—and if it reaches approval, this drug will be the most innovative product in many years to reach patients suffering from depression.

We have a number of other ongoing projects, but these are the three that we are currently most excited about. Each drug is in the CNS space, and each is geared towards a huge potential market. Most importantly, they will offer real benefit to patients.

Between the products that we have on the market, and the products we expect to launch in the coming years, we are in a great place. And again, financially, we are in a sound position—we are generating well over 100Mn USD per year in cash. Hence, we have the resources to continue to expand our business and progress our company into the future.

Alkermes has traditionally partnered with larger players to bring products to the market—but is now shifting toward wholly owned compounds. What has been your typical partnership structure until this point, and what has been the impetus behind the shift?

As a smaller company, it is very difficult to finance the development and marketing of your own products. Hence, Alkermes built a business that offered our technologies to Big Pharma partners. They would develop the products to the final stage, while we would input our expertise and sometimes take part in the manufacturing effort. The partner would then take charge of selling the drug. We would be awarded a royalty on the product, plus reimbursement for manufacturing costs. For a product like Risperdal Consta, we receive a royalty of seven percent and approximately two and half percent to cover manufacturing. We have a similar deal with JnJ for Invega Sustenna.

For Ampyra, however, we actually brought the product idea ourselves further along the development pathway—through Phase II. Only then did we license the intellectual property to a partner. Because we brought the drug further along, and took on more risk, we were able to secure a better deal, and share in more of the profits. In Ampyra's case, we receive 18 percent of revenues.

The more the company has grown—and this was part of the reason for the merger—the more revenues we have had, and the easier it has been for us to carry products further through their lifecycle. Our current strategy is to bring that idea to its logical conclusion: we want to bring drugs to the market ourselves, from discovery to development to production to sales and marketing.

We have not taken on any partners for any of the three pipeline products I've mentioned. As they get closer to market, we will determine whether we can sell them ourselves. We already have some commercial business: we market Vivitrol in the U.S. with our own sales force, and have done so for four years. It is a relatively small product, with revenues of about 60Mn USD per year—but our volumes are growing, and we expect our sales to be quite sizeable in time.

We believe that our teams in the U.S can also sell the next product we expect to launch, aripipazole lauroxil. The market for that product is relatively small, and does not require too many feet on the ground. The major factor for building sales will be a strong interaction with the payer—something we now have great experience with. Hence, we do not plan to take on partners in the U.S. for aripipazole lauroxil. Outside of the U.S., we may choose to collaborate, because we do not yet have a global sales network in place and would prefer to work with a company that has already established itself in the relevant markets.

For the other pipeline products we spoke about, we will see how things go. What we are sure of is that we do not plan to develop large, primary care sales forces at this time, so it may be appropriate to create new partnerships to market these drugs. However, our target, in five or ten years' time, is to independently sell a much higher percentage of our portfolio—and at the moment, our focus will be on the CNS space, where we believe we may bring some potential blockbusters to areas of significant unmet need. We want to achieve full integration.

As the company itself likes to say, Alkermes is in a phase of growth that very few biopharmaceutical companies reach. What have you done right?

Both in Alkermes's original business, and in the legacy EDT business, we have always focused on what we are very good at—and what we are very good at is analyzing known disease biology and known pharmacology, and using our technologies to develop new compounds that we know can add a huge amount of value for patients.

Typically, pharma and biotech companies will have their researchers try to discover how a given disease functions, identify targets, and try to develop a compound that can go after those targets—while being unsure of whether those targets are the right targets. This is the approach we see in areas like Alzheimer's disease. At Alkermes, on the other hand, we have focused on better-known disease areas, where the risk is lower.

We don't need to spend a billion dollars to get a drug to the market. And if you look at the drugs we have, that model has served us well. The combination of our technologies with known compounds has created some great products.

How have investors responded to your strategy? Last year, one analyst wrote, "For a large part of its history, Alkermes (ALKS) never quite seemed to get its due from the Street. Given its business plan of helping other pharmaceutical/biotech companies develop drugs in exchange for modest royalties, perhaps that's not so surprising." Are you getting your due today?

The reason we began to develop our own products is the fact that as a drug delivery business, you will find that there is a limit to how large you can become. If you're basing your business on modest royalties, as the analyst noted, then you are not in control of your own destiny as a company—because if your partner decides that the product is no longer a significant part of their portfolio, you are directly impacted yet have no influence.

As we've discussed, we have moved away from being a drug delivery business toward a fully integrated biotech model. We currently have a broad range of revenue streams from a number of products that have been developed over the last ten to twenty years—but we also have an unpartnered pipeline that is set to accelerate our growth.

Historically, Wall Street has not thought of our pipeline as a proprietary pipeline. They thought of us as a drug delivery company, and therefore a company that would earn royalties on its pipeline, rather than selling the drugs and enjoying the full economic benefit ourselves. Investors have valued us based on our revenues, and largely ignored the potential value of the company's developing assets.

But Wall Street's perspective is beginning to change. We find, when we speak with analysts and investors today, that most of the discussions are around our pipeline.

What is this company's ultimate ambition? Are you chasing the story of biotech like Amgen and Genzyme?

We are. We want to be the next big biotech!

What part of its success does Alkermes owe to its Irish roots?

Ireland is a major part of our history. In 1969, when Don Panoz started the Elan drug delivery business in Athlone, he got huge support from the Irish government in all aspects of the business. Elan was actually the first Irish company to list on the New York Stock Exchange. We are speaking of a huge heritage, and a very close connection between Elan, the community, and the state. Alkermes is one part of the Elan story, but there have been a huge number of spinout businesses that have come from Elan over the years.

I have experienced this effect in other Irish industries one company is a trailblazer, and the people who work at that company learn the industry, make contacts, want to grow a business from Ireland, and start companies of their own. For a country of only four and a half million people, we are very well represented within the industry. If you go to any of the biotech or pharma conferences, you will meet many Irish people that are looking to bring business back to the country.

Ireland is a great place for us to do business. The country's track record is hugely important, and the talent that exists here both from a science and business perspective is excellent. The tax environment, too, is attractive, and the certainty around that environment is very important as well.

What motivates you, as the president of Alkermes?

We all share the dream of building the next big biotech company. For me, helping to build that company, from within Ireland, is what keeps me coming to the office. I believe we can grow this business to become very significant. From an Irish base, we can expand globally beyond the U.S. I am excited about what we are set to achieve!

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