Interview with Toby Wilson Waterworth, CEO, Atlantic Healthcare Ltd

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A key milestone for Atlantic Healthcare was the deal with Isis Pharmaceuticals for alicaforsen in 2007. In 2008, alicaforsen acquired orphan drug status in the U.S.; in 2009, orphan status was granted in Europe. Many companies in the UK have named market access as a key challenge—but is that an issue for Atlantic, since its product has the orphan drug status?

The benefit of the strategy that we are taking is that we are looking for the lowest point in being able to access the market and build revenues. We are doing this by focusing on the hospital sector; and by focusing on the most needy patients, with the more challenging forms of disease. We actually believe that we are focusing on the most receptive group: the most receptive patients, most receptive doctors, and most receptive healthcare providers and reimbursement authorities. By targeting these specialist indications, you actually are generating early revenues—and then you can expand the indications from there.

The orphan drug status was important for us. For example, it gives us market protection for up to 10 years, from the date of marketing approval.

Atlantic Healthcare is run by an industry seasoned team. The Company is focused on building revenues through the acquisition of products for the treatment of patients under the management of physicians in the hospital and specialist care environments in Europe and North America. The team have acquired and launched internationally 40 products before.

We are specialists in understanding the hospital sales channels. In analyzing opportunities, we are looking for products on the market or near to revenue. After an assessment of the market, we are looking for good data packages so that we can position or reposition the product with clear differentiation, to meet a clear unmet medical need.

So again, we are very much focused on looking at the market need, first of all; on understanding existing players in the market, and where the spaces and opportunities are.

Our first acquisition for Atlantic Healthcare is alicaforsen: we understand gastrointestinal disorders and inflammatory bowel disease very well, as a team — so we know that there is a major unmet medical need there. It fits our market criteria, in that it is a market that is too small for the big pharmaceutical companies to be interested in. Nevertheless, it is a 2B USD-per-year market—growing at about 10 or 15% per annum, because of unmet needs. We saw in alicaforsen a great opportunity, for a product that had data to demonstrate that it could actually satisfy a market need in a small group of accessible patients—patients that have very, very few effective alternatives for treating their disease.

There is further work that we need to do, but we captured an opportunity. It is an enema product, so we are starting with a disease called pouchitis. There is nothing else approved for pouchitis currently (although there are some off-label therapeutics), so it is an attractive starting point for us. We got the orphan drug designation to protect the opportunity, and we also have a Letter of Fast Track from the FDA, so that gives us acceleration, and saves costs. As a company of our size, it is significant that with the Fast Track letter, we do not pay registration fees in the U.S.; we do not pay them in Europe, either.

It is all about the hurdles that we can overcome, in getting the product into the market in the most efficient way, generating revenues, and building the opportunity from there.

And, given that we also have a lot of clinical data in ulcerative colitis, we will use that data to expand into other disease areas.

How well do you see Atlantic Healthcare positioned for the future?

With alicaforsen, we see ourselves providing a new and effective treatment for patients in late-stage disease—in both ulcerative colitis and pouchitis. We are positioning the product where we see its benefits — and where we actually see very little in the way of competition.

Pouchitis patients are probably going to the bathroom up to 15-20 times a day. Patients experience a relatively uncontrolled evacuation of the bowel; and then you get into the quality of life issues:

fatigue, sweating, etc. The two options for patients, at such a late stage, are either biological or surgery. Surgery to remove diseased tissue cures it, but often creates other problems. We are potentially providing patients with a third alternative.

The benefit of our product is that—as clinical data suggests—it is relatively safe, and there is a significant duration of response. Treatment is once a night for six-weeks. Trials have shown the response growing over those six weeks in parallel with the treatment. The treatment stops at six weeks, but we see the response of patients continue to improve for up to 10-12 weeks. This response is maintained on average for up to six months, before the patient goes back into remission.

Alicaforsen also meets the requirements of the new healthcare agenda for patients under the management of hospital based specialists. This group of patients are typically undergoing continuous treatment. If they are using some of the biologicals, they have to go to the hospital for infusions. Our treatment is an at-home treatment—it fits in with Andrew Lansley's agenda, because it allows patients to move out of hospital. What we do not have is data on long-term use—so we cannot yet claim that this is the Holy Grail. But we do offer potential for a very sensible product for patients in a very difficult position.

Can you discuss some of your upcoming prospects?

We are looking at a number of further acquisitions to help patients managed in the hospital and specialist care environments, including GI, oncology and cardiac products. We are also looking at opportunities for adding convergence technologies where we can bring in complementary devices and diagnostics, especially where we can incorporate them with electronic patients records, health care alerting, and so forth.

The bigger picture is: how can we both improve treatments for patients in this hospital environment and reduce overall treatment costs? Part of the answer is to be an enabler for moving reactive treatments, to being proactive treatments? Proactive for the patient and proactive for the healthcare professionals who are managing those patients.

Atlantic is a company that bases its business on partnerships. For example, you recently signed a deal with Clinigen for distribution in Europe. What do you look for in a partner? Conversely, why do companies choose you as a partner?

To build our business we look to work with complementary experts. A partner company must be flexible, pro-active and meet our needs. But what is also important is that there is a cultural fit. We

are knowledgeable, goal orientated and very entrepreneurial. We want to work with partners who have a similar outlook, who want to work with us to create win-win situations. We want two plus two to equal seven.

With Clinigen, we found a very responsive team, which was very professional, very experienced, and very flexible. What I liked about them is their desire to build their business, and their wanting to do that through providing a good service to their customers—such as Atlantic. I have found, in developing businesses, that you always get really good results when someone is motivated to build their business in parallel with you building yours.

In terms of why we are chosen as a partner, I can give you a few reference points. Why did Isis choose us? We were a start-up company, after all. But it was our commercial expertise and experience in the market, and our capabilities and understanding of GI that sealed it. And it was the swiftness and efficiency of the team, and our ability to be able to execute on the asset. We are taking other people's products which they have no interest in commercialization themselves, so they are trusting us to do a good job in optimizing their returns. They look to us to provide that expertise that they do not have.

There was a recent case of that expertise, when we were negotiating the acquisition of a product from a major pharmaceutical group. We did not get – you do not get them all!. Having satisfied their due diligence on our ability to execute we sat down and went through some due diligence on the product with the company. At the end of the meeting they apologized to us, and said, "You know more about this product than we do, and we own it!" They were embarrassed. That is a measure of the depth of the team and its capabilities.

Importantly the team has met up to due diligence by larger pharma and investors alike. Although this cannot be assumed of most small companies, you can easily expand internationally—given your cost-effective and expedient business model. We already see you doing that, with directors in North America and Australia as well as Europe. What are the key markets that can be of major importance in expanding your business in coming years?

We are aware that we must walk before we run and build the business in a controlled manner. We are focused, at the moment, on building our hospital sales channels across Europe. Outside our core markets, we commercialise through trusted third party organizations; we licensed the rights to alicaforsen, for Australia and New Zealand to Orphan Australia (which has subsequently been bought by Sigma Pharmaceuticals; and which itself is in the process of being bought by Aspen).

It is important that we have Board members who compliment the core team who are on the ground and that understand local customs and local business. We work in a decentralized manner so employing very competent people locally, to drive the business locally is very important. We have Board members in North America and Australia as well as Europe.

When asked in another interview what differentiates Atlantic from any other company, the first thing you said was “people.” How did you manage to put a good, experienced team together?

At the end of the day a business is only as good as its people and connecting with good people is all about the power of the network. Simple as that. I have a philosophy of employing the best people we can and we work together, as a team. Then we treat people as we want to be treated. The serious point of that is about being open, fair, and decent. We have a culture that centers on honesty and professionalism. We have done deals on a handshake, without a contract. I am not suggesting that is something that is appropriate in all circumstances, but I think that it is a measure of the people that we are happy to work with and who are happy to work with us.

That comes through strength of your network, through relationships, trust and reputation. I have spent many years building an international network, at many levels. I have been able to assemble the team that we have today and identify a lot of the opportunities we are looking at through that network.

I am fortunate that we have very good people, and they all know what they are doing. We do not have to sit down and say, “this is the process that we must follow.” We do not have volumes of SOPs that tell everybody how they should be doing things—we agree our objectives, who does what and get on with it – there is lots of personal responsibility.

They also share in the beliefs and vision of the company. That is important, because when you share a vision, not everybody gets the vision. Atlantic is about getting very experienced people, with deep roots and connections, who want to work in a new way and build a business through trusted partnerships and relationships – win-win!.

How do you define your managerial style?

I am a delegator. I set the vision with the team, and we share the tasks — and then I monitor and adjust things as necessary.

What are the main milestones for Atlantic over the past three years?

It has been a tough environment, from a funding standpoint—because we have been funding the development of the product. We have had to get the manufacturing completed and in place, and we have done that successfully. We have also been out across Europe, preparing the product in readiness for generating revenues, meeting all the country-leading gastroenterologists and rectal surgeons. Everyone has said, “Absolutely, we need alicaforsen for our patients, for pouchitis and left-sided colitis.” Nobody has said that they do not need it! It is nice to hear people saying to us that our decision to license alicaforsen was the right one.
We are at the point where we are responding to treatment requests from physicians across Europe and elsewhere under various named patient supply regulations. Revenues commenced this year.

Now we are ready to take the company onto the next stage of growth. It took a lot of hard work to get to this point. The team has been fantastic, sometimes working 24/7 —covering U.S and Europe and Australia, etc. We have people in all three continents on the board calls supporting us.. I am proud of how the team has been able to deliver.

How do you expect the market to take your product this year? What do you hope and expect for performance?

Alicaforsen is currently an unlicensed medicine so we are not in a position to be marketing it. Under our Named Patient Programme, we respond to unsolicited physician requests—so we are not in a position to say what those are going to be.

Having said that, we are looking forward to obtaining full market approval of Alicaforsen. The plan is to complete Phase III clinical trials—possibly with a U.S. licensing partner (we have interest, at the moment, from the U.S., Canada, and the Middle East). The Phase III, with orphan-designation and Fast Track, is envisaged to comprise a single pivotal double-blind placebo-controlled trial, which is more typical of orphan indicators. Essentially, we plan to repeat what was seen in Phase II. There is nothing approved in this field, so there is no gold standard comparator. We hope that interest in alicaforsen will continue to grow as the medical community becomes more aware of Atlantic and the potential of alicaforsen. It meets an important, currently unmet need for many patients. We see alicaforsen as being a market opportunity for Europe and North America peaking at around 200M GBP.

More generally we hope interest in Atlantic will continue to grow amongst biotechs and pharma companies seeing us as their partner of choice and expert in commercialisation. Management companies seeing us as their commercial partner of choice experts in the hospital and specialist care environment.

You have said that your team is very knowledgeable in GI. How do you see them positioned in other prospective areas for Atlantic, such as oncology?

The team is very knowledgeable in a lot of areas having acquired and launched 40 products before, and where we are not experts we know experts. Our focus is to build around a number of therapeutic areas, we will see where the opportunities for good terms lie.

The team will grow in parallel with the activities although we would like to stay as a small corporate team, managing acquisitions and the business; and managing relationships with investors, shareholders, and so forth. We will also find more like-minded, entrepreneurial, go-getters to join us who have a lot of experience, who perhaps want to try to work in a different environment to drive and look after our in-country operations: we feel that is far more enterprising and personally rewarding.

Why is it rewarding to work at Atlantic?

First of all, our people make an impact. I delegate, and I encourage people make a difference, to participate and grow. I want to see people come up with ideas and solutions. Those are the people that we attract to Atlantic, and the people to whom we give the freedom to operate and grow in ways that they may not do so easily in larger companies.

There was a board director at a global pharma company, who recently told me that he had no control over his diary. That is amazing! How can you flourish in that sort of environment, where everybody else is in control of what you do and whom you meet? I am an entrepreneur; entrepreneurs tend to be results orientated and have an aversion to all those controls.

At Atlantic our people have the freedom to maximize their potential. How would you define your company today, and how would you define your company in two years' time?

Today, we are an emerging pharmaceutical company—a specialty pharma company, perhaps. Our focus is on the provision of medicines for unmet patient needs, managed by physicians based in hospitals and specialist-care environments. Further, we define ourselves as an international company, based in the UK. Principal markets are—for the moment—Europe and the United States.

In due course, we intend to add devices, diagnostics, and software and communications offerings. We have a plan as to how those four areas will converge for improved patient care. How do you treat patients better, for less money! The only way you can do that is through the adoption of new approaches and new technology.

We are working on further licensing and acquisition opportunities at the moment, and I hope you will start to see some of the fruits of this convergence occurring over the next few years.

What is your final message to the international readers of Pharmaceutical Executive Magazine?

I think that working in the pharmaceutical industry is tremendously rewarding. It is an exciting time to be helping people and being able to make a real difference, managing different resources and different skills, and bringing them together internationally—in a very flexible way, to deliver patient benefits in a much-improved manner.

However, I think certain parts of the industry remain stuck, doing things the same way that they have always been done. There is a real opportunity for change, starting by looking at needs of patients and healthcare providers and working back from there.

The pharmaceutical and healthcare industries are moving into a new environment with lots of change, and lots of opportunities ahead – these are very exciting times.

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