

2008 Annual Review

Expanding *our* horizons

Synexus is the only truly global company specialising in the recruitment and running of clinical trials

THE OUTLOOK

During 2008 Synexus continued to build a solid and robust platform which has enabled the Company to move forward into 2009/10 stronger and more prepared than ever before.

The Company has a solid and growing client base comprising some of the world's leading pharma companies and CROs. Biotech firms are increasingly attracted to the model as it positively impacts on go/no go decisions earlier and at much reduced cost.

As growth in revenues from pharma slows and the number of approved drugs in the pipelines continues to decrease companies will focus more on acquisitions with smaller biotech firms in order to re-energise their pipeline. There has been recent debate regarding the efficacy and economics of drug development in developing countries. Access to larger study populations and the opportunity to lower cost development makes this an attractive proposition for pharma. At Synexus a great deal of investment has been made into ensuring that lower cost does not mean lower standards. Synexus provides a single point of contact and robust framework within which global trials are conducted to uniform standards. Pharma can access larger populations or treatment naive patients without compromising either safety or control of the trial.

Despite the current economic outlook, the business has continued its growth curve, achieving 55 per cent revenue growth in 2008. The Company's commitment to increased international expansion remains paramount with potential acquisitions identified in Central and Eastern Europe (CEE), India and elsewhere. Additionally, two research centres were added to the existing South African hub in Pretoria, an area that has been increasingly rewarding the company under the stewardship of country director Dr Sanet Aspinall.

Factors such as low cost, large patient pools, effective recruitment and strong governmental support will enable India to conduct at least twice as many global clinical trials by 2012. This region remains a high priority for the business.

THE 'NEW WAY'

Professor Trevor Jones, Chairman of Synexus, considers the ways in which pharma must tackle the issues it faces.

The story of the pharmaceutical industry over the past year has been one of innovation, combined, as always, with some controversy. 2008 saw the launch of a number of innovative new treatments which is testament to the value and benefits of pharmaceutical R&D. However, despite these positive launches, and the continued advances made in terms of scientific understanding, the pharma industry still has a number of significant issues to overcome.

It is no secret that despite the continued and considerable rise in R&D costs there has not been a corresponding rise in the number of new and innovative new treatments launched. As regulatory authorities continue to demand larger and larger trials this issue is only going to become even more significant.

Patient recruitment and retention continues to represent a major bottleneck of drug development. Despite this knowledge many companies still seem committed to the 'old way' of doing things. Ways in which to improve patient recruitment and retention, drive down costs and speed up drug development continues to elude many.

The 'new way', or the Synexus model, compares more than favourably to other competing channels of patient recruitment, especially on a cost per patient basis and, as a result, I believe the Synexus model represents the future of clinical trials. This new way of working has the ability to tackle the issues of escalating costs, the need for increased recruitment and access to large pools of patients and hence accelerate speed to the market.

The traditional method of conducting clinical trials relies on health professionals recruiting their own patients ... on average, five patients each! Using the

Synexus network of clinical trial centres hundreds of patients can be rapidly identified with further access to between 500,000 and three million potential patients. The economies of scale opportunities that exist by comparison are immediately recognisable. The Synexus model touches each element of the clinical trial process including feasibility and therefore has far reaching benefits. Because of its broad base of activity Synexus, enables its partners to learn incrementally at each step of the programme and hence shape subsequent trial design and performance; particularly accurately to predict the most appropriate enrolment activities that will need to be undertaken as well as the likely timeframe in which this can be completed.

Because the Synexus model directly addresses the issues currently being faced by pharma, it surely must represent the future direction for clinical development for the pharmaceutical industry. It has proven that it offers considerable cost and time savings and, with its focus and expertise, provides much 'cleaner' data compared to the traditional, more diversified methods.

This model utilises professionals who are focused solely on the recruitment of patients for, and the management of, clinical trials; they are experts in their business. It is not just the process that Synexus professionals excel in, but Synexus as an organisation is also able to offer unrivalled access to a diverse range of patients through its global network. The benefits and indeed, validity, of running trials on a global basis is an issue which is currently the subject of much debate.

However, whichever strategy Companies choose ...global or regional... Synexus is able to offer access to a diverse range of patients either through a global or a regional network or at one single research centre if that is what is required. Regardless of the Synexus research centres utilised sponsors can feel confident that the highest level of GCP and scientific/ethical standards are consistent throughout. The future of clinical trials is changing; and the revolution has begun.

ON REFLECTION

Michael Fort, CEO, Synexus, reflects on 2008.

At the beginning of the year management, in partnership with Lyceum Capital, completed a successful public to private buyout. Just over a year later we have seen our turnover increase by 55 per cent and have more than tripled our order book. In part this is due to the fact that the pharma industry now understands better the workings of the Synexus model. In the early days clients with no experience of using Synexus perceived 'experimenting' with us as a risk and stuck to what they knew. However, we are now in a position of understanding which has enabled us to overcome the significant hurdles faced in our formative years.

Many more pharma, biotechs and CROs are now recognising the benefits of working with us. We have been able to prove reliability and we are now entrusted with studies which require the recruitment of many thousands of patients.

Our success in recruiting patients quickly and efficiently is now well-known across a range of therapies. In March 2009 the JUPITER trial was presented at the American College of Cardiology and published in the Lancet. Synexus recruited 2,452 of the 17,802 patients who took part in the trial. This equates to 14 per cent of the participants from less than one per cent of the 1,315 sites taking part in the study. This was an indicator of the quality of work we undertook for our client as out of the total number of patients we recruited only two failed to complete the study.

Good order

Good order is the foundation of all sound businesses and a theme consistent throughout 2008 was ensuring that our business is well structured and supported. This applied to the people, processes and locations of our business and has been key in ensuring our growth is well managed. 2008 saw us

significantly strengthen our International Management Team with appointments made across a wide range of disciplines and geographies. Project management, feasibility, patient outreach, GP liaison, quality and regulatory affairs and site management were all areas which were significantly enhanced during the year, in addition to significant spend on the business's IT infrastructure.

We also created a Global Medical Affairs Department which underlines our commitment to developing a robust support structure for international expansion and our continuous process of quality improvement. Regardless of which Synexus site is chosen, our customers experience the same high level of standards. They also undergo the same consent process ensuring that each and every patient on a Synexus trial understands the purpose of the clinical trial and to what they are contributing.

There are over 40,000 GPs in the UK; between 30 and 40 per cent of whom are based within an accessible distance of Synexus. However, we were conscious of the need to continue to engage even more GPs as pharma looks to us to provide more and more patients for trials. As a result we made an innovative investment in a professional GP sales force. This is an important development enabling us to further extend our patient outreach in the UK.

During the year we made a considerable investment in DXA scanners, increasing our capacity by 50 per cent. This investment was put to good use in the final quarter of 2008 when we embarked on an osteoporosis pre-screening campaign targeted at screening over 50,000 women.

Internationally Central and Eastern Europe (CEE) were key contributors to our success with impressive results particularly from our Polish operation in Wroclaw. Positive progress was also made in Budapest, Hungary and Sophia, Bulgaria, with the latter contracting to supply patients to its first

international study. Since the end of the year we have continued to search for further research centres in this area as we believe that CEE will continue to be a pivotal player in international clinical trials. To this end we have recently committed to the formation of a dedicated CEE management team, based from our Budapest, Hungary hub, which will be charged with creating a specific identity for the region at the same time as more fully integrating the individual business units into the international group.

The broadening of our geographical reach has also added to our therapy offering. The Company principally provides services in chronic disease therapies, mainly in primary care. However, the more traditional areas of expertise have been added to with franchises in infectious diseases, paediatrics, limited secondary care, and certain CNS areas. Further to this, 2009 will see investment in new therapy areas, particularly ophthalmology as we continue to seek to increase our client offering.

During 2008 we were also able to further extend the scope of our services to include Phase IV trials following increased demands on clients from regulatory authorities.

By utilising the Synexus model pharma can access many more GPs, and subsequently patients, without having to time burden the GP. Our model also ensures that each doctor is provided with information about the performance of the trial; thus solving both issues.

In summary, during 2008, we recruited almost 10,000 patients internationally, screened over 50,000 potential patients and communicated with many hundreds of thousands more through our innovative outreach methods. We engaged with the world's leading pharmaceutical companies and continued to establish positive working relationships with CROs. We have further strengthened the foundations on which the business is based and go forwards with anticipation of the good things to come.

Key milestones

January

Turnover in 2008 increased by more than 55%

March

Launch of Trial Boost for failing studies

April

Doubled DXA capacity across the company

May

Launch of Global Medical Affairs Department

June

Patient database exceeds 400,000

July

Closure of the JUPITER Study where Synexus randomised more than 2,000 patients

August

Completed randomisation of more than 1,300 patients for global hypertension trial

September

Launch of osteoporosis screening campaign – contact with more than 100,000 potential patients

October

Launch of UK sales force to GPs

November

Randomised more than 1,300 flu patients in two weeks
Chairman of Synexus chairs Partnerships in Clinical Trial Congress

December

Synexus sponsors Best Pipeline award at Scrip Awards

GLOBAL ACCESS

Synexus is a world leader in the recruitment of patients into clinical trials at its own research centres in Europe, Asia and Africa on behalf of its clients in pharma, biotech and CROs.

UK

Seven research centres strategically placed across the UK offering access to a large and diverse patient population

HUNGARY

The Synexus research centre in Budapest adjoins the Synexus CEE Head Office

POLAND

Expansion of existing Wroclaw facilities in 2009 and acquisition of new sites in major conurbations

BULGARIA

New site opened in a major public hospital in centre of Sofia

INDIA

Synexus has access to millions of treatment naïve patients through its presence in India

SOUTH AFRICA

Three research centres in South Africa located in the greater Johannesburg and Pretoria area

