

# UK REVIVAL:

## Rebuilding a *Life Sciences* World Leader

A long history as a world leader in innovation, talented scientists from well-respected universities, mature biotech clusters, and government incentives to attract innovative companies give the U.K. a clear edge, but this great scientific nation still has challenges with which to contend.

**T**he United Kingdom life-sciences industry is one of the world leaders. A 2011 report from the Department for Business Innovation & Skills points out that life sciences is the third-largest contributor to economic growth in the U.K., with more than 4,000 companies employing about 160,000 people and with a total annual revenue of more than £50 billion (\$77.4 billion).

But recent investment and industry trends point to a downturn, including a decline in start-up activity and cutbacks at large phar-

maceutical companies. The most prominent was the decision by Pfizer in early 2011 to close its research facilities in Kent, resulting in 2,400 jobs lost.

### Government-Based Initiatives

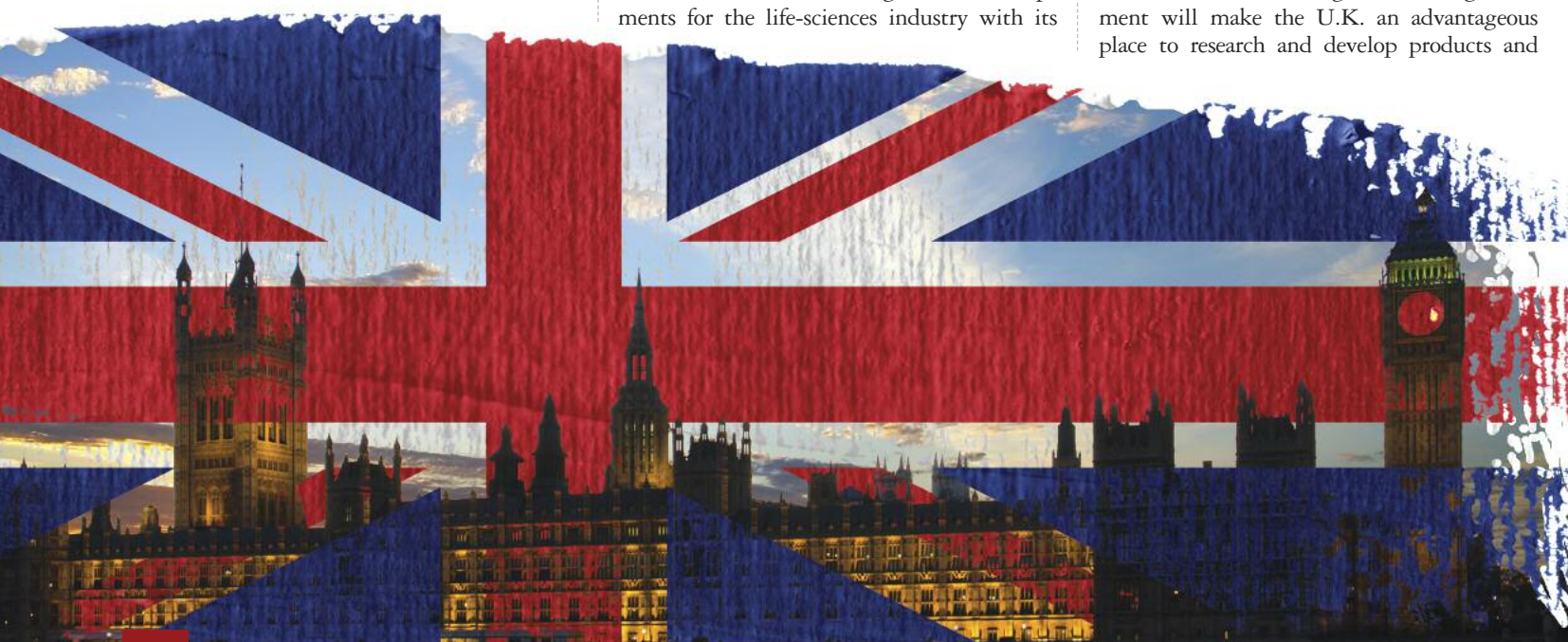
Prime Minister David Cameron, who has made the life-sciences industry one of the cornerstones in his growth strategy, has taken steps to rebuild the U.K. as one of the world's leading bases for innovation.

In December 2011, the U.K. government launched one of the most significant developments for the life-sciences industry with its

Strategy for U.K. Life Sciences and a review of innovation in the National Health Service (NHS) to meet this challenge and attract further investment to the U.K.

The initiative includes a new £180 million (\$278.7 million) catalyst fund to help the next generation of British medical breakthroughs become the next generation of great British companies. This fund will target the funding gap that exists — the so called “valley of death” — between when a new idea is developed in the laboratory and the point when a new drug or technology can be invested in by the market.

“The forward thinking of the U.K. government will make the U.K. an advantageous place to research and develop products and



bring them to the market,” says Adam Sherlock, director, CSC Life Sciences.

The government is also committed to tax incentives to encourage investment and plans to introduce the Patent Box, a measure to reduce corporation tax on profits from patents to 10% beginning April 1, 2013.

“As part of this pending legislation, companies will receive a tax deduction on R&D expenses and, more importantly, profits associated with patents developed in the U.K. will be taxed at a significantly lower rate,” says Pamela Spence, Ernst & Young’s head of life sciences for the U.K. and Ireland.

## Leading the Way

There are a number of factors that make the U.K. an attractive market for pharmaceutical companies. Perhaps most prominent among these is the quality of the science.

“The U.K. has one of the world’s leading university research sectors,” says Darrin Disley, Ph.D., CEO of Horizon Discovery. “One in 11 of all peer-reviewed publications in the scientific literature emanate from U.K. researchers. This fosters pure and applied research with good links between academia and industry.”

The breadth and depth of the U.K. research community allows an intense synergy between the various disciplines involved in healthcare research, says Chris Newton, Ph.D., senior VP of Galapagos Services and managing director at BioFocus.

“In the classical, yet wholly essential (for drug discovery) disciplines, coordination between medicinal chemistry, pharmacokinetics, pharmacology and biochemistry, clinical development, and pharmaceutical development in the U.K. is strong between pharma, biotech, CROs, and charities,” Dr. Newton says.

Another advantage is the U.K. has mature biotech clusters in Oxford, Cambridge, Nottingham, and Edinburgh, Ms. Spence says.

“These biocenters not only fuel R&D efforts of compa-

nies that already call these clusters home, but can serve as magnets for new companies to establish a footprint in the country,” she says.

The U.K. pharmaceutical industry has, like other countries, been seeking collaborative partnerships to deal with the R&D shortfall, including partnerships with university research groups. Among these are University of Manchester’s joint deal with GSK and AstraZeneca to create the new Manchester Collaborative Centre for Inflammation Research, funded by a £10 million (\$15.6 million) contribution from the two companies, according to a report by investment fund Mobius Life Sciences, titled Transition: U.K. Life Science Start-up Report 2011.

GSK also recently signed a deal with Edinburgh University in the field of acute pancreatitis that is similar in many ways to the types of deals that might be made with small biotech companies, including up-front payments, milestones, and royalties, the report continues.

Other deals include University College London’s agreement with AstraZeneca in the field of stem cells and University of Nottingham’s multimillion pound collaboration with Ortho Biotech (Johnson & Johnson) to create an ex-vivo cancer pharmacology center, the Mobius report adds.

## A Challenging Operating Environment

Dr. Newton says while big pharma has heavily curtailed its presence in the U.K., it continues to support drug discovery in biotechnology companies that have “spun out” of closing pharma research sites. “Convergence Pharmaceuticals, an ex-

**“There are opportunities to build strong brands in the U.K. market and across EMEA if marketers use an effective mix of all the marketing disciplines and strategies available to them.”**

**MATT DE GRUCHY**

Ogilvy Healthworld, U.K.

## U.K. Life-Science Start-Ups: An Industry in Transition

The U.K. Life Science Start-up report 2011 is the second comprehensive study of early stage life-science firms. This new study considers companies formed in the period from 2006 to 2010 and allows a comparison with the findings of the 2010 report, which looked at the period of 2005 to 2009. The findings provide an insight into where the new start-up companies are coming from, what fields they specialize in, and the investments they are raising. Among the key findings are:

- » The number of life-science start-ups has dropped in the period 2006-2010 compared with the period 2005-2009.
- » Four-fifths of the decline in the number of start-ups can be accounted for by a drop in university spin-outs.
- » Two-thirds of the new firms are in the service or med-tech subsectors.
- » Almost half of all life-science start-ups are located in a U.K. bioincubator or biopark.
- » Total investment raised by life-science start-ups declined by 12% in the period 2006-2010 (£329 million) compared with 2005-2009 (£372 million).
- » The largest fall in investment activity was seen in the number of companies receiving investment in the sub-£500k range.
- » 74% of total investment into life-science start-ups went to companies in the South East and East of England.
- » Significant funds provided by Imperial Innovations, Oxford, Cambridge, UCL, and Manchester have created a Premier League of institutions, attracting high-quality people and providing a high-quality research base.
- » 40% of the total funding raised by the start-ups is concentrated in just eight companies.
- » Early-stage businesses are starting to turn to China for funding, although this invariably means transferring activities to the country.
- » The increasing professionalization of university drug discovery for large clients is creating new research engines for the pharmaceutical industry.
- » There are greater opportunities for pharmaceutical investment into small firms (£66 million raised annually by the start-ups equates to just 1% of Roche’s annual R&D budget).

Source: Transition: UK Life Science Start-up report 2011





**“The U.K. possesses one of the strongest environments in Europe for conducting R&D, claims the largest clinical-phase drug target pipeline in Europe, and had the highest level of VC investment in biotech in 2010.”**

**PAMELA SPENCE** / Ernst & Young

GSK subsidiary, is one such company,” he says. “Other spin-out companies, including BioFocus, Argenta, Sygnature, and Domainex, are the result of other big pharma centers closing in the U.K. or have recruited widely from such closing centers. The result is one of the strongest national groupings of CROs in a single country, performing drug discovery for all types of companies and organizations located anywhere in the world.”

He adds that the location of the European Medicines Agency (EMA) in London encour-



**“It is essential that the U.K. retains and attracts high-quality talent if it is to build a world-leading knowledge-based economy.”**

**DR. DARRIN DISLEY** / Horizon Discovery

ages companies to have a development presence in the U.K.

Life-sciences start-up companies, however, have seen a decline in more recent years. The Mobius Life Sciences report points to a decline in new start activity in the 2006 to 2010 period, when 290 new life-sciences companies were formed, compared with the 2005 to 2009 period, when 315 were formed. This has coincided with a 12% drop in investments made in emerging businesses. There has also been a decline in public sector funding in recent years, which has fed through to investment funds.

The report’s findings are echoed by the companies, with Horizon’s Dr. Disley pointing out that there is limited local, regional, or national government financial support and small companies trying to get started are burdened with high rents and business rates.

“This lack of support and incentives, combined with smaller and less flexible investment instruments compared with the United States, China, Germany, and Japan often lead to the early exit of innovation from the U.K.,” he says.

Dr. Newton adds that while the government invests in new infrastructure, notably at the new Stevenage Science Park and at the Babraham Institute (near Cambridge) for laboratory space for start-up companies, the operating cost base and transport infrastructure



**“The forward thinking of the U.K. government’s Strategy for U.K. Life Sciences announcement in early December will make the U.K. an advantageous place to research and develop products and bring them to the market.”**

**ADAM SHERLOCK** / CSC Life Sciences

## FAST FACT

**THERE ARE MORE THAN 4,000 LIFE-SCIENCES COMPANIES IN THE U.K., EMPLOYING AROUND 160,000 PEOPLE AND WITH A TOTAL ANNUAL REVENUE OF MORE THAN £50 BILLION (\$77.4 BILLION).**

need to be addressed if research is to flourish in the U.K.

Another challenge for the industry is miscommunication by the press, Mr. Sherlock says.

“Mistrust of the industry is fueled by well-publicized adverse events with medicines or vaccines that are hyped by the U.K. press,” he says. “The extent of hype and miscommunication by the press is unique to the U.K.”

## Growth Opportunities

An area experiencing growth in the U.K. biopharma sector is translational genomics.

“The rapid growth in translational genomics builds on the U.K.’s participation — via the Sanger Institute — in the sequencing of the human genome,” Dr. Disley notes. “Cancer research will be a primary beneficiary of this.”

He adds that the U.K. is also at the forefront of many technology innovations, including personalized medicine, clean technology, and stem cells.

Dr. Newton says many U.K. research groups are focusing on the novel drug discovery paradigm of epigenetics.

According to Dr. Disley, recent government initiatives both direct and via the Technology Strategy Board (TSB), the U.K.’s national innovation agency, are investing in technologies that will reduce the overall cost

of healthcare delivery while delivering improved clinical outcomes for patients.

The U.K. pharma industry has also been progressive in adapting to a challenging reimbursement climate by including pharmacoeconomics, comparative effectiveness, and data mining of electronic health records to demonstrate product superiority, Ms. Spence says.

The U.K. is taking a lead in how to accelerate learnings from postlaunch drug use and thus actual health benefit and outcome as opposed to prelaunch clinical trial data, she says.

"It was recently announced that the NHS will be making anonymous health data from these records available to researchers, enabling companies to mine these data for new real-world learnings for R&D at a scale that has not yet been seen before globally," she says.

### Education and Promotion

The process of Continued Professional Development forms the basis of a significant proportion of medical education in the U.K. This is compulsory and helps to ensure licensed

doctors remain up to date, says Adrian Brown, director at ApotheCom ScopeMedical.

Industry-sponsored medical education should, therefore, ideally include some form of accreditation, and precludes the marketing of a pharmaceutical brand in any way, experts say.

Both medical education and marketing are covered by The Association of the British Pharmaceutical Industry (ABPI) code of practice.

"The ABPI regulates all pharma communications activity and most importantly prevents the marketing of a pharmaceutical brand to consumers in any capacity," says Matt de Gruchy, CEO, Ogilvy Healthworld, U.K.

Mr. Brown notes that social media offers additional opportunities to reach patients already on a medication. Digital communications open an enormous number of channels for marketers to exploit in terms of how doctors and other HCPs access information and in turn communicate with patients. But he notes that currently companies are understandably cautious about using these media for fear of infringing the ABPI code of practice and internal regulatory guidelines.

### The Regulatory and Reimbursement Landscape

The NHS is the principle healthcare provider and is publically funded and free at the point of use for all U.K. residents. Costs of pharmaceutical products are controlled by ensuring that new products meet a number of health technology assessment (HTA) criteria. The National Institute for Health and Clinical Excellence (NICE) is the main HTA body for the NHS and assesses all new medicines within two years of launch to ensure that they show clinical benefits and cost-effectiveness against current standards of care.

Failure to meet NICE approval means the product will no longer be reimbursed nationally, which can necessitate regional negotiations where certain NHS trusts may decide to reimburse a product and others do not, commonly referred to as a "postcode lottery," Mr. Brown says.

"The U.K. is one of the more aggressive countries in Europe in terms of linking reimbursement levels with the future efficacy of a

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drug, which requires companies to propose innovative approaches for demonstrating differentiated improvements on outcomes,” Ms. Spence says. “This approach, however, will ultimately drive a better return on investment for all parties and organizations in the health-care ecosystem. Recently, such approaches have included clinical risk-sharing agreements wherein a company will agree to pay for non-responding patients while the payer agrees to cover the treatment of responders, and dose capping plans whereby a company agrees to pay for additional patient doses beyond an agreed-upon level.”

In addition, there has been increased focus on adverse event monitoring, which can make it much more difficult to maintain a clean label, Mr. Sherlock says.

“The AE signals come from many different directions today due to the greater transparency requested of the industry with respect to its clinical data, which allows academics, clinicians, etc. to analyze a company’s data in ways and depths previously not possible,” he says.

## The Clinical Connection

The U.K. is one of the best-established locations for clinical research worldwide, with both a strong infrastructure and renowned researchers. Over the years, however, both the number of pharmaceutical companies and the placement of simple clinical trials have declined. Figures from the Association of the British Pharmaceutical Industry show the U.K.’s global share has fallen from 6% in



“The NHS is poised to play a growing role in allowing access to patient data and facilities required to discover novel therapies.”

DR. CHRIS NEWTON / BioFocus

2000, to 2% in 2006, and 1.4% in 2010.

Yet the U.K. is attractive for many reasons, experts say.

“The research ethics committee (REC) application and approval process has been centralized and streamlined with predictable timeframes from submission through to approval,” says Keith Berelowitz, director of operations at Richmond Pharmacology. “For example, an early-phase clinical study will typically be approved three weeks from submission, and researchers have the ability to choose from multiple RECs with meetings taking place almost every week across the U.K.”

The regulatory authority, the MHRA, has a reputation for efficient response to applications — between 14 days and 21 days for early phase research. This compares with much longer review times elsewhere in Eu-



“One major restriction in the U.K. is that no prescription medicine can be promoted directly to the consumer.”

ADRIAN BROWN

Apothecom ScopeMedical

rope, sometimes around 60 days, Mr. Berelowitz notes.

While cost is often cited as a reason to shift trials to other areas, for example, Eastern Europe, experts say this can be a false economy.

“For example, a colleague noted that a recent trial in the U.K. and Czech Republic took six weeks for sign off in the U.K. but close to six months in the Czech Republic,” Mr. Berelowitz says. “This extra time can reduce the cost benefit.” **PV**

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# Commitment to EXCELLENCE



**I want the great discoveries of the next decade happening in British labs, the new technologies born in British start-ups, says David Cameron, U.K. Prime Minister.**

**T**he United Kingdom government launched its life sciences strategy and a review of innovation in the National Health Service (NHS) to attract further investment to the U.K. The measures bring the country's science base and the NHS together to ensure the U.K. is the best place in the world for companies to invest in the discovery, development, and commercialization of medical innovations.

"We can be proud of our past, but we cannot be complacent about our future," Prime Minister David Cameron said. "The industry is changing; not just year by year, but month by month. We must ensure that the U.K. stays ahead; we've got a leading science base, we have four of the world's top 10 universities, and, we have a National Health Service unlike any other. But these strengths alone are not enough to keep pace with what's happening, we've got to change radically the way we innovate, the way we collaborate, the way we open up the NHS."

The Prime Minister noted the ambition is not just to hang on with a significant foothold in the global market, but to take an even bigger share of that market in the years to come.

"I want the great discoveries of the next decade happening in British labs, the new technologies born in British start-ups," he said.

The strategy includes a new £180 million (\$278.7 million) catalyst fund to help the next generation of British medical breakthroughs become the next generation of great British companies. This fund will target the funding gap that exists, the so-called "valley of death" between the moment that a bright new idea is developed in the laboratory and the point when a new drug or technology can be invested in by the market.

**Government initiatives are positioning the U.K. life-sciences industry for growth and success.**

"Our life-sciences industry is a vital driver of growth and employs tens of thousands of people, but it is rapidly changing," Minister for Universities and Science David Willetts said. "We need to keep ahead of the game and make the U.K. one of the best places for companies to invest in innovation.

"To do this we need to create the right environment for scientists and business to work together and translate research into new, cutting-edge technologies and medicines," he continued. "This will boost our economy, create new jobs, and lead to better treatments for patients."

In its response, the Association of the British Pharmaceutical Industry (ABPI) noted that the recommendations within the report, if adopted, will mean much of the red tape and bureaucracy within the NHS, which prevents patients receiving the very best of treatments, will be removed. Not only will patient health improve as a result, but removing the barriers to innovation will aid the long-term growth of the life-sciences sector and the U.K. economy.

"The Prime Minister has identified the life-sciences sector as an integral part of the U.K. economy and one which can continue to thrive and prosper if supported in the right way," said Stephen Whitehead, chief executive of the ABPI. "The proposals outlined by government will contribute toward patients receiving better treatments more quickly and build the U.K.'s attractiveness as a leading hub for medical and health research.

"Specifically, we welcome the introduction of a NICE compliance regime to reduce variation of medicines uptake, increase compliance with NICE technology appraisals, and ensure rapid and consistent implementation throughout the NHS," he continued. "The confirmation that NICE technology appraisal recommendations will be automatically included into appropriate local formularies is a significant step forward. Moreover, establishment of the NICE Implementation Collaborative is a helpful move that will provide practical support and advice to the NHS to implement NICE guidance promptly. We are also pleased

that the government will be opening up access to public datasets, including health data on prescribing, with appropriate protection for patient confidentiality. This will allow life-sciences firms to better understand how patients respond to particular treatments, which in turn will further aid companies' research and development efforts."

Key points from the strategy include:

- » The automatic inclusion of NICE recommended treatments on formulary, meaning that clinicians now truly have the choice to prescribe the medicine that they think most appropriate for their patients.
- » The establishment of a NICE Implementation Collaborative (NIC) to support prompt implementation of NICE guidance, bringing all partners into the process of helping with barriers to patients accessing medicines.
- » Development and publication of an innovation scorecard allowing a clear understanding of whether the reforms to NICE are really working, and which examines if patients are getting the best new medicines.
- » An emphasis on clinical trials, aiming to re-establish the U.K. as a thriving center for research and exploiting the benefits of this for patients.
- » Better access to health data, with appropriate protection for patient confidentiality. This opens up the U.K.'s unique offering to provide a true picture of health challenges and benefits within the NHS.
- » The commitment by government to earlier access to medicines where appropriate, allows patients to benefit earlier from promising medicines whilst improving knowledge about how these medicines work.
- » Plans to simplify regulation, reducing gold plating, and unnecessary bureaucracy will help industry move further and faster, and make the U.K. a more attractive place for investment. The initiative of a group of experts including industry to meet regularly to discuss regulation is welcomed. **PV**

Sources: Department for Business Skills and Innovation, [bis.gov.uk](http://bis.gov.uk), and ABPI, [abpi.org.uk](http://abpi.org.uk)

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