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Published in November 2013  
by UK Trade & Investment  
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## How UKTI Can Help Your Business

### UKTI Life Science Investment Organisation (LSIO)

UKTI has established a dedicated unit, the LSIO, to act as your interface with the UK life science sector. The LSIO is your guide to identifying research, development and delivery partners and will support you through every step of investing in and working in the UK. The UKTI LSIO team will work closely with you to understand your needs and requirements, partnering you with the right people in the UK.

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# INNOVATION IS GREAT BRITAIN

Unlock Your Global Business Potential  
**Regenerative Medicine and Stem Cells**

UKTI Life Science Investment Organisation (LSIO)

## Unlock Your Global Business Potential



## ▶ Market Opportunity

In 2012, annual revenue from regenerative medicine products surpassed the **\$1 billion** mark. The global regenerative medicine market is predicted to grow to over **\$35 billion** by 2019.

Europe has the second largest regenerative medicine ecosystem in the world with **>400** companies related to regenerative medicine. Nearly one in three of SMEs active in Europe's Advanced Therapy Medicinal Product (ATMP) market are based in the UK.

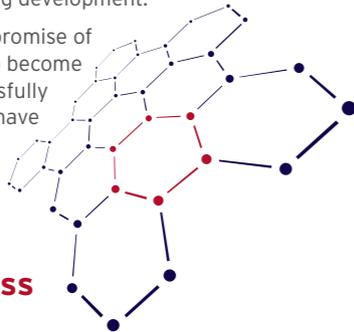
Revenues from European sales of stem cell products alone is expected to reach **\$1.5 billion** by 2016.



### Regenerative medicine has the potential to:

- Tackle the challenge of an ageing population
- Reduce healthcare costs by providing a cure or better management for chronic or hard to treat diseases
- Reduce the time and cost of drug development.

Critically we are now seeing the promise of regenerative medicine starting to become a reality with a number of successfully launched products. Four ATMPs have now been approved in Europe (Glybera, ChondroCelect, MACI and Provenge).



## ▶ Ease of Doing Business

The UK's business environment has changed.

It is now focused on catalysing innovation and commercial success. New fiscal incentives have been put in place to support R&D and business growth.

### The UK offers businesses:

- **Low corporation tax rate**, dropping to 21% by April 2014
- **Patent Box** will reduce corporation tax on profits from UK patents to **10%**
- **R&D tax relief** for both large corporations and smaller companies investing in R&D in the UK, applicable to direct research costs as well as contract research costs
- **Funding for business growth** (in England and the Devolved Administrations), **and R&D funding**.

## ▶ Rich Diverse Ecosystem

### 1 World-class resources: funding, research, talent and facilities

- **Dedicated funding** channeled through leading researchers and centres of excellence
- **£180 million** Biomedical Catalyst funding accessible to industry
- The Technology Strategy Board (TSB) supports Regenerative Medicine themed R&D competitions and in 2013 has already committed a further **£8m** to a competition in this area
- Leading cell and tissue banking facilities
- Access to the talent and expertise needed to make your business a success.

### 3 Manufacturing capabilities: established and ready to work with you

- Established and experienced Good Manufacturing Practice (GMP) and ATMP manufacturing facilities
- **Manufacturing innovation** expertise
- Manufacturing support and expertise through established contract manufacturing organisations (CMOs) and the Cell Therapy Catapult.

### 2 Strong supply chain: fast and cost effective

- Expertise through **NHS Blood and Transplant** and **Scottish National Blood and Transfusion Services**
- High tech **analytical capabilities**
- Established and proven **cold chain logistics**.

### 4 Clinical research infrastructure: efficient clinical trial delivery

- **£500 million** annual investment in health research infrastructure
- Simplified access to the **NHS** through **NIHR** Office for Clinical Research Infrastructure (NOCRI), **NHS Research Scotland (NRS)** Permissions Coordinating Centre and Health Research Wales
- Support through **Clinical Research Networks**, currently enabling more than **25** clinical studies in regenerative medicine within the **NHS**.



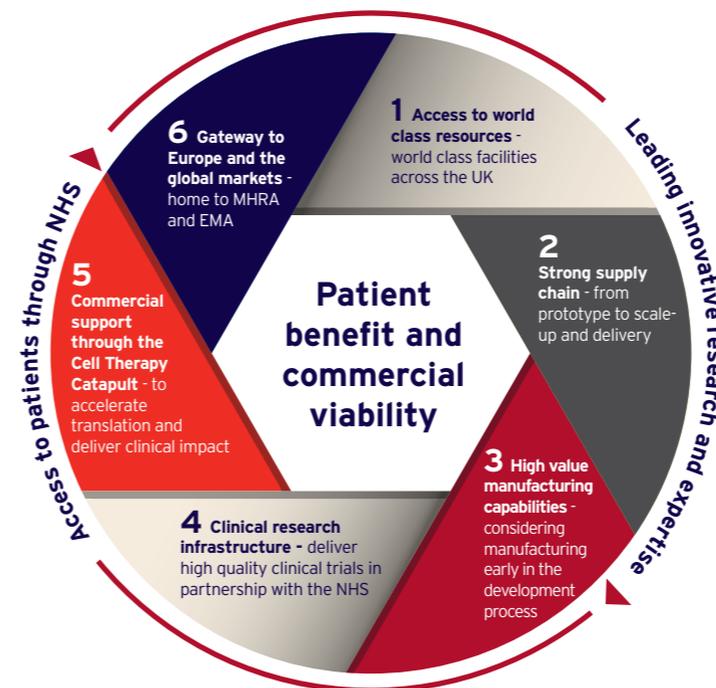
### 5 Commercial support through partnership with the Cell Therapy Catapult

The **Cell Therapy Catapult** has been established to accelerate delivery of therapies to the patient and will work with industry to:

- **Deliver clinical trials**
- **Provide manufacturing expertise** and infrastructure
- Access the **NHS and clinical partners**
- Provide **business and regulatory expertise**.

### 6 NHS, your gateway to Europe & the global markets: reach your market with confidence

- **National Institute for Health and Care Excellence (NICE)** provides world class health technology assessment
- **Academic Health Science Networks**, facilitate adoption and dissemination of innovative technologies in the NHS helping product uptake
- Globally-respected regulators, the **Medicines and Healthcare Products Regulatory Agency (MHRA)** and the **European Medicines Agency (EMA)**, both located in the UK.



## ▶ Market Success

Join other international and UK businesses in exploiting the market and accessing expertise and opportunities that can facilitate success.

ReNeuron has been awarded a **£1.5 million grant** from the **Technology Strategy Board (TSB)**, an innovation agency of the UK Government, under its Supporting Regenerative Medicines & Cell Therapies Competition. The grant part-funds the company's **Phase II clinical trial of its ReN001 stem cell therapy for disabled stroke patients**. The trial is expected to commence in the UK at the end of 2013. The company was previously awarded two further grants from the TSB under its Biomedical Catalyst scheme, to part-fund its programmes targeting critical limb ischaemia and retinitis pigmentosa. ReNeuron is also receiving support from the Cell Therapy Catapult with regard to the processes used to manufacture the company's cell-based therapeutic candidates.



**Athersys (Cleveland, OH, US) is conducting Phase II clinical trials in Stroke in the UK and accessing UK manufacturing facilities to deliver them.**

In April 2013, the Medicines and Healthcare products Regulatory Agency (MHRA) approved Athersys' application to expand its ongoing Phase II study evaluating the administration of MultiStem® therapy to patients who have suffered an ischemic stroke. Ethics Committee review was successfully completed in August, 2013, and enrolment at multiple UK sites will commence following the completion of final preparations at participating clinical centres. The study is expected to enrol approximately 136 patients in total.

**GE Healthcare invested £3 million in state of the art laboratories in Wales.**

In 2012, GE Healthcare Life Sciences, a business unit of GE Healthcare, opened its new £3 million cell science laboratories in Cardiff, Wales. The state-of-the-art investment at the company's Maynard Centre creates a world-class facility for research and technology innovation in cell science, to help advance the rapidly emerging fields of cell therapy and cell bioprocessing, and to support the development of new, more effective and safer medicines.