

**LIFE SCIENCES
KEY SECTOR REPORT**

**SCOTTISH GOVERNMENT
NOVEMBER 2009**

CONTENTS

CONTENTS	1
1. Overview	2
1.1 Context: Current issues	2
1.2 Description of scope and performance of the sector	4
1.3 Labour Productivity	5
1.4 Rationale for key sector status	6
2. Challenges and Opportunities	7
2.1 Challenges	7
2.2 Opportunities	8
3. Public Sector Interactions and Interventions	9
3.1 Interactions	9
3.2 Interventions	13
4. Assessment of the Effectiveness of Interactions	14
5. International Perspectives	15
6. Concluding Comments	20

1. Overview

1.1 Context: Current issues

At a Glance: Life Sciences in Scotland

The Life Sciences Cluster in Scotland is diverse and encompasses biotechnology and pharmaceutical companies, contract research organisations (CROs), medical device and diagnostic companies, along with specialist suppliers and support organisations.

In 2008, the Life Sciences Cluster¹ (defined broadly to include specialist support activities such as legal services) employed almost 31,500 people in 620 organisations. In 2006 the turnover of the Life Sciences Cluster was estimated at over £3 billion, with gross value added (GVA) at over £1.3 billion.

Scotland is home to the second largest Life Sciences Cluster in the UK, and one of the most sizeable in Europe. It has an established network of over 40 pharmaceutical clinical trials support and contract research organisations and more medical research is carried out per head of population in Scotland than anywhere else in Europe.

Furthermore, Scotland's strong academic base in the Life Science field is an important competitive advantage, with Scotland's universities accounting for 12 per cent of UK research staff and funds, higher than Scotland's share of the UK population.

Such a strong academic base provides companies with the skilled workers they require to undertake research and contributes to the knowledge exchange process through the creation of spin-off and start-up companies which are frequently a source of innovative new products and concepts. The clustering of specialised companies and academic researchers can also increase collaboration and the exchange of ideas and research, further increasing Scotland's attractiveness to potential investors.

Life sciences is a diverse and vibrant global industry which encompasses a wide range of activities, including the discovery, research, development and manufacture of therapeutics; diagnostics; medical devices and platform technologies. It also includes the specialist suppliers of products and services necessary for these organisations to function.

Scotland is also home to one of the largest concentrations of pharmaceutical support networks, especially in clinical and non-clinical research. Investments over the last few years have seen the emergence of potentially major international companies, such as Axis-Shield, Aircraft Medical, Touch Bionics, Optos, and ProStrakan, mainly in the medical technology, diagnostics and therapeutic areas. However, despite investment, indigenous drug discovery business has been less successful, a situation that is similar to the broader UK life sciences sector.

Due to the increasingly ageing global population and the demand for improved longevity and quality of life, the life sciences sector has very strong growth potential. Global life sciences grew by 8.3% in 2007 to reach a value of £553 billion.² Current global trends shaping the life science sector include:

¹ See Section 1.2 for commentary on the scope of this approach compared to the use of standard industrial codes.

² Source: Datamonitor, 2008.

- The emergence of personalised medicine³ and stratified medicine⁴;
- The growing trend by big pharma businesses towards partnering, outsourcing and corporate venturing, which has been driven by the steady decrease in the number of new approved drugs over the last 15 years.
- Increasing move towards translational medicine⁵;
- Increasing convergence in the sector, with further integration between drugs, devices and diagnostics;
- Increasing use of information technology to accelerate drug discovery, streamline clinical development and drive down costs;
- A growing tendency to search for novel therapies for unmet clinical needs;
- an unprecedented increase in biological data (of particular relevance to the fields of genomics and epigenomics) due to acceleration in the development of next generation sequencing technologies.
- A move by electronics companies into the health and wellbeing arena; and
- A move to holistic and preventative healthcare due to the rise of chronic, life style disease and pressures on healthcare budgets.

Despite considerable strengths in life sciences and the associated research base in Scotland, the economic downturn and adverse credit climate may make it more difficult for companies to secure finance for investment and research – particularly as long term and high risk investment is often required within the sector. Concern has been raised by those in the industry that the global financial crisis could delay the discovery and production of many new medicines as access to finance becomes more difficult. In addition to the impact on basic research performed in biotechnology companies, there are concerns that the development of medicines by pharmaceutical companies will also be affected by access to credit and the global economic downturn.

Difficult market conditions have driven consolidation within the life science sector; smaller companies, particularly those involved in drug discovery, are facing a challenging funding landscape and present attractive targets for acquisition by cash rich companies.

Some recent global survey evidence⁶ suggests that pharmaceutical companies are more confident about prospects for growth than those in other industries. Furthermore, pharmaceutical CEOs were reportedly less concerned about the disruption of capital markets and less likely to state that recent problems in the global banking system would delay their investment plans. The level of confidence demonstrated in this survey on global pharmaceuticals may not however be fully reflected in the Scottish sector.

³**Personalized medicine** is the use of detailed information about a patient's genotype or level of gene expression and a patient's clinical data in order to select a medication, therapy or preventative measure that is particularly suited to that patient at the time of administration. The benefits of this approach are in its accuracy, efficacy, safety and speed..

⁴ **Stratified medicine** is the management of a group of patients with shared biological characteristics by using molecular diagnostic testing to select the most optimal therapy in order to achieve the best possible medicinal outcome for that group

⁵ **Translational medicine** is a branch of medical research that attempts to more directly connect basic research to patient care. Translational medicine is growing in importance in the healthcare industry, and is a term whose precise definition is in flux. In the case of drug discovery and development, translational medicine typically refers to the "translation" of basic research into real therapies for real patients. The emphasis is on the linkage between the laboratory and the patient's bedside, without a real disconnect. This is often called the "bench to bedside" definition. Translational medicine can also have a much broader definition, referring to the development and application of new technologies in a patient driven environment - where the emphasis is on early patient testing and evaluation. In modern healthcare, we are seeing a move to a more open, patient driven research process, and the embrace of a more research driven clinical practice of medicine..

⁶ 12th Annual Global CEO Survey – PWC 2008 which surveyed 1,124 CEOs from various sectors across the world from September – December 2008. Available from: <http://www.pwc.com/ceosurvey/download.html>

1.2 Description of scope and performance of the sector

Life sciences in Scotland is characterised by strong, internationally respected and commercially attractive academic research; a publicly-funded universal healthcare system (the NHS), which has the potential to become a champion of innovation; a large number of small, early stage companies; and a number of major international organisations – most notably in the contract research and medical technology sectors.

The key capabilities of Scottish life sciences are in:

- stem cells and regenerative medicine
- experimental and translational medicine and clinical research
- drug development;
- contract research;
- medical technologies;
- diagnostics
- bioinformatics and health informatics

Measuring and Monitoring the Life Sciences Sector in Scotland

The term Life Sciences reflects a wide range of activity including the discovery, research, development and manufacture of therapeutics; diagnostics; medical devices and platform technologies as well as the specialist suppliers of products and services necessary for these organisations to function. As such it is not possible to specifically define the industry in terms of Standard Industrial Classification (SIC) codes, which enable businesses to be classified into industries in order to produce official statistics.

Life Sciences Sector (defined by SIC Codes)

Although SIC codes do not provide full coverage of the sector, a set of SIC codes can be used as a guide to track changes in the Scottish life sciences. These are SIC 24.4: Manufacture of pharmaceuticals, medicinal chemicals and botanical products, SIC 33.1: Manufacture of medical and surgical equipment and orthopaedic appliances and SIC 73.1: Research and experimental development on natural sciences and engineering. Where this paper refers to statistics for the “Life Sciences Sector” this is based on the narrow SIC-based definition.

Life Sciences Cluster (defined broadly using company lists)

Scottish Enterprise maintain a database of companies involved in Life Sciences activities. This database includes professional service companies that indirectly support the Life Sciences sector e.g. legal services. This broad approach to defining Life Sciences is therefore based on the companies identified as being involved in the sector. However some of these companies may also support sectors outside of life sciences. Scottish Enterprise obtain employment counts directly from companies on the Life Sciences Cluster database. Estimates of turnover and GVA are sourced by matching the Life Sciences Cluster companies with financial data from the Annual Business Inquiry. Where this paper refers to statistics for the “Life Sciences Cluster” this is based on the broad Scottish Enterprise company based definition.

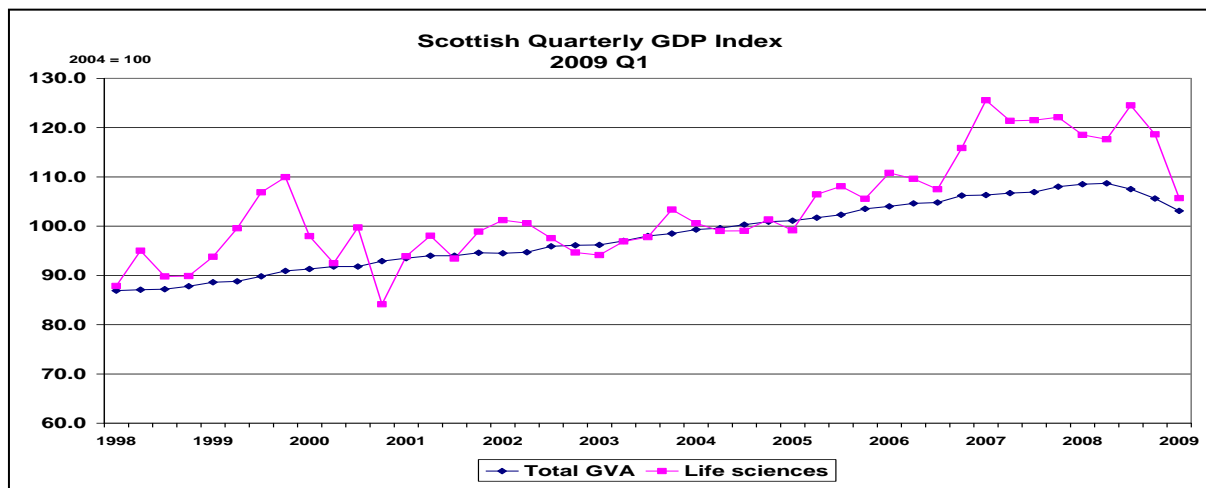
Official statistics, from the Annual Business Inquiry, show that the Scottish Life Sciences Sector (as defined using the SIC Codes) employed 18,400 people in 2007, which is a 12 per cent increase since 2006 and represents 0.7% of employment in Scotland. The Life Sciences Sector employment share in Scotland relative to GB as a whole was 10% in 2007. Turnover in the Scottish Life Sciences Sector stood at £1.6 billion in 2007, while GVA was £763m.⁷

Output (as measured by the quarterly GDP index) in the Scottish Life Sciences Sector (as defined using the SIC Codes) has been fairly volatile over the last decade, but overall has increased by around 20 per cent between 1998 and 2009 Q1. The total value of the Life Sciences Sector exports (as defined by SIC Codes) for 2007 stood at £675 million⁸.

Despite this strong growth performance over the longer term, the most recent data shows substantial falls in output in Scottish Life Sciences Sector in both 2009 Q1, and in the year to March 2009, with output falling by 11 per cent and 4 per cent respectively. This compares to a quarterly fall of 2.4 per cent across the Scottish economy as whole and a fall of 1.2 per cent comparing output in the most recent four quarters to the previous four quarters.

Chart 1 provides the longer term trend in GDP performance in life sciences compared to the Scottish economy over the period 1998 Q1 – 2009 Q1

Chart 1



Source: Scottish Quarterly GDP Index

Using the wider Scottish Life Sciences Cluster definition, there were some 620 organisations, 8 per cent of them academic, employing some 31,500 people in the Scottish Life Sciences Cluster in 2008. It is estimated that this cluster had a turnover of over £3 billion and contributed £1.3 billion in gross value added to the Scottish economy in 2006.

1.3 Labour Productivity

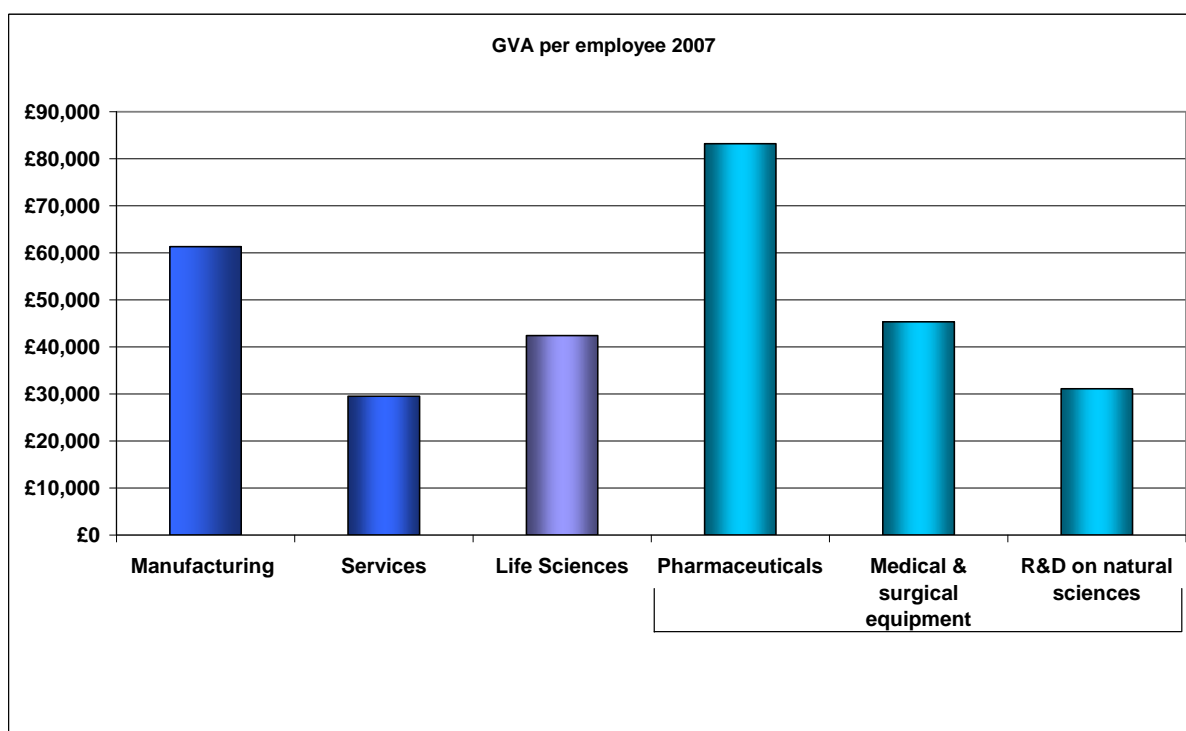
The Annual Business Inquiry can also provide an indication of labour productivity in Scotland’s Life Sciences Sector (as defined using the SIC Codes). It should be noted however that differences observed across sectors using this measure will be partly driven by differences in capital intensiveness. Data for 2007 show that collectively, for the three sectors used to track the Life Sciences Sector in Scotland, labour productivity (as measured in terms of Gross Value Added (GVA) per employee) stood at £42,400 in 2007. As can be

⁷ Annual Business Inquiry

⁸ Scotland’s Global Connections Survey, 2007. Data for 2008 will be available in December 2009.

seen in Chart 2, within the sub-sectors used to track life sciences, the highest GVA per employee level can be seen in the pharmaceutical manufacturing sub-sector (£83,200), followed by the medical and surgical equipment manufacturing sub-sector (£45,300) – compared to £61,300 for the manufacturing sector in Scotland in 2007. The research and development on natural sciences and engineering service subsector had the lowest GVA per employee out of three Life Sciences Sector (£31,100), reflecting the low capital intensity of this sub-sector compared to the manufacturing Life Sciences sub-sectors (see Chart 2). The GVA per employee for the research and development on natural sciences and engineering service subsector was slightly above that for the services⁹ sector in Scotland (£29,500) in 2007.

Chart 2



Source: Annual Business Inquiry

1.4 Rationale for key sector status

The Scottish Government's overarching aim is the delivery of higher levels of sustainable economic growth - creating a wealthier country and society - so that the Scotland that emerges from the downturn is stronger, wealthier and fairer. As a key sector of the Scottish economy, a vibrant life sciences community makes an important contribution to the wealth and health of the nation.

This is a sector where Scotland has an international comparative advantage, with high growth potential and capacity to boost productivity. Research has identified Scotland as being home to the second largest life sciences cluster in the UK and one of the most sizeable in Europe.¹⁰ In 2007 Fierce Biotech, an independent source of research and knowledge on the sector, named Scotland as one of the world's top 5 emerging locations for life sciences.

⁹ The Annual Business Inquiry, from which the statistics are derived, covers approximately two thirds of the economy. The main sectors **not** covered are the financial sector and some of the public sector.

¹⁰ Source: Young Company Finance (2007)

Scotland's strong academic base in the life science field is an important competitive advantage, with Scotland's universities accounting for 12 per cent of UK research staff and funds, higher than Scotland's share of the UK population.¹¹ The sector brings together key strengths in innovation, technology, research, and enterprise and will therefore have a direct impact on business competitiveness and growth. Creating a supportive environment for the life sciences is consistent with achieving the national outcome of creating "a better educated, more skilled and more successful, renowned for our research and innovation" Scotland. The promotion of life sciences will also support delivery against some of our key national indicators, such as at least halving the gap in total research and development spending compared with the EU average by 2011, and improving the rates of knowledge transfer from universities.

2. Challenges and Opportunities

2.1 Challenges

To secure economic benefit, it is important that Scotland addresses specific challenges which life science companies face globally, such as: high attrition rates (whereby the introduction of new drugs to the market involves a very lengthy process of experimentation, research, clinical trials, regulatory approval, etc); large funding gaps; access to highly specialised workforce; affordable speciality accommodation; and – for the drug discovery and development process – increased time to market over other industries.

High risk is an integral element of the life sciences, especially for fledgling biotechnology firms attempting to bring or introduce new drugs to the market. For this reason, the possibility of failure is part and parcel of investment in the life sciences. The challenge is to support a wide range of activities (for example, drug discovery, clinical trials, stem cell and regenerative medicine, medical technologies, etc) to increase the likelihood of developing a diverse sector.

Recent research completed in the University of Glasgow's Centre for Public Policy for the Regions highlights a number of challenges more specific to the Life Sciences in Scotland¹².

- The need to facilitate better working relationships between firms and universities (see also discussion of opportunities, below), which could be strengthened by better coordination of knowledge transfer activities.
- Some inconsistency between funding schemes offered by public organisations.
- Limitations to the business angel community's ability to finance the growth of life sciences firms, and in particular the lack of large, long-term investment is highlighted as a disadvantage to Scottish firms because it restricts company growth strategies. In addition, the limits of specifically 'Scottish' late-stage investment inhibit the achievement of a critical mass of medium and large firms which could provide the stability and market that smaller firms need.
- The lack of critical mass may make it difficult for Scottish firms to attract people with management experience.
- Recent change in approach towards stem cell research in the US is likely to result in significant increase in public resources directed towards this area of activity.

Recent work by the Scottish Government and Scottish Enterprise has also looked at skills challenges that the sector is facing. The Association of the British Pharmaceutical Industry

¹¹ Source: Research council data provided by Department of Innovation, Universities & Skills.

¹² Centre for Public Policy for Regions (2009), Strengthening the Life Sciences in Scotland: Policy Report, University of Glasgow.

(ABPI) Report on Skills (2008) identified three main areas of concern across the UK – basic mathematical capability, practical skills and an ability to apply scientific and mathematical knowledge. However, although this may represent the views of some of the industry in Scotland, only three of the 30 employers surveyed were based in Scotland. Indeed, there is a lack of quantitative data across the sector in Scotland to direct future support and interventions in the skills area. To address this, a comprehensive skills survey for life sciences in Scotland is being carried out; this will identify where the true challenges are on skills and provide the information required to identify key areas requiring support.

In addition, there are perceptions within the industry that skills challenges for the life sciences sector also include: (i) ensuring the continuing supply of appropriately qualified staff at all levels from technician to CEO level; (ii) attracting, retaining and developing Board level and senior managers with relevant international commercial experience in life sciences to both grow spin-out firms and technologies with growth potential, and help develop critical mass within the industry; and (iii) ensuring Scottish graduates with commercial aspirations and junior managers stay in Scotland to pursue their careers (see Section 3.2 for a discussion on how the Government is responding to these challenges).

2.2 Opportunities

Scotland has a science base producing a large number of graduates and world-leading scientific research. There is also substantial public sector support for life science activities in the form of grant funding, co-funding and other financial schemes.

Better integration: while the science base is impressive and public sector support substantial, there are challenges related to the links between the science base (university research), and clinical and commercial applications. Recent research by the Centre for Public Policy Research for Regions at the University of Glasgow has shown that universities are not always the easiest organisations for the business sector to work with, nor is it necessarily easy to access their resources. Opportunities also exist in stronger synergies between the NHS (clinicians and researchers), research institutes (including universities), and commercial applications. There are potentially huge opportunities for innovation in clinical applications and demand-driven commercial development in health that could arise from closer interactions between the NHS, the research base, and business.

Commercialisation and knowledge transfer present an opportunity for the Scottish Government, its enterprise agencies and the Scottish Funding Council (SFC) to re-think the link between science, and clinical and commercial applications. Current work, for instance on translational medicine and regenerative medicine, is underway to help unlock the value from our existing sciences base (see Section 3). Different models of knowledge transfer should be considered to maximise opportunities from the existing knowledge base. Scottish Health Innovations Ltd provides one example of successful spin outs and developing and licensing technology from the NHS.

Remote Healthcare (the delivery of health and care where those receiving treatment/care are remote from the medical professional/carer) is an emerging market which is growing rapidly due to significant global drivers: the need for increased efficiency in delivering healthcare, a global aging population and pressure to reduce carbon footprints. The Scottish academic base is well placed to contribute to the growth of this market which is incorporating an increasing number of Scottish companies.

Non-human biotechnology: Scotland's life sciences sector has traditionally focused on human healthcare, however, there are significant and emerging opportunities for Scotland's

expertise and capabilities to be applied to industrial, marine, environmental and veterinary biotechnology.

Focus on sub sectors, (see also later section) the international focus should be on

- **Drug discovery and development**, an area that presents complex funding challenges given its high attrition rate and long time to market nature, within which the focus is currently on Scotland's key strengths, such as research excellence in leading therapeutic areas, clinical research organisations, (CROs), and pharmaceutical support companies;
- **MedTech** including medical devices and diagnostics;
- **Stem cells and regenerative medicine; and**
- **Clinical, experimental and translational medicine.**

The last 2 sub-sectors above - Stem Cells/Regenerative Medicine and Clinical/Translational Medicine (TM) - are two areas within Life Sciences in which Scotland has world leading expertise and there are excellent international opportunities which we need to exploit. The direct commercial returns will however be in the longer term given that Scotland's current strengths in these areas are in the academic sector and the NHS, rather than in commercial operations. In other areas like drug development and medical technologies the commercial returns are much quicker and currently much larger. A balanced approach is therefore being adopted which is both short and long term, and it is critically important to recognise that these sub sectors are inextricably interlinked in that, stems cells and TM, for instance, are integral components of future drug discovery and development.

Life Sciences Scotland as a brand: There is also a very strong sense of Life Sciences community and brand in Scotland. In targeting international opportunities we must maximise the potential of our networks (in Scotland and overseas) and increase our collaborative working across industry, academia, NHS and Government if we are to capitalise fully on our potential in key areas such as clinical/TM. This should be reflected in the approach we take to developing new initiatives and targeting major global pharma companies.

Edinburgh Bio-Quarter: More specifically, there is a strategic imperative to support the development of the Edinburgh BioQuarter and work with SE and Alexandria Real Estate to attract an anchor tenant, linked to Scotland's strengths (most particularly stem cells, TM and drug discovery/development).

Cross-sector opportunities: the life science market is becoming increasingly diverse presenting cross sector opportunities. The rise of nutraceuticals, digital health and preventative healthcare are examples of significant markets that reach outside of the traditional boundaries of life sciences, nevertheless present significant markets for Scottish companies.

3. Public Sector Interactions / Interventions

3.1 Interactions

The overall framework for Scottish Government interaction with the sector is the Scottish Life Sciences Strategy, which was refreshed in 2008. The Strategy aims to achieve critical mass of activities in the life sciences sector in Scotland, and to help Scotland develop a globally oriented, sustainable and fully connected life sciences sector. The Strategy focuses on five main themes as critical elements of sectoral growth: (1) People; (2) Technology; (3) Capital; (4) Infrastructure; and (5) Collaboration.

The vision set out in the Strategy is that by 2020 Scotland will have:

“A globally oriented, sustainable, fully connected life sciences sector built on collaborative action that exploits strengths in scientific excellence, financial services and innovative business models, and develops, retains and builds upon Scotland’s talents”.

Scotland’s enterprise, innovation and investment agencies - **Scottish Enterprise (SE)** and **Highland and Islands Enterprise (HIE)** - support the Life Sciences Strategy, particularly in those areas where the industry in general has limited experience and where its own expertise will have the greatest impact, for instance, in bringing ideas, technologies and innovation closer to markets, and in leveraging funding for company start-ups and early-stage investment. At a strategic level, SE and HIE aim to:

- Retain, build and attract the necessary world-class businesses which will contribute to the Life Sciences Scotland vision.
- And stimulate and attract new companies while supporting the existing company base.

These aims are progressed through a series of initiatives designed to improve skills within the sector, facilitate the provision of investment, support commercialization and the provision of a world class infrastructure and to encourage collaboration.

Scottish Development International (SDI) fosters the link between Scottish companies and international investors, thereby strengthening the connectivity of Scottish Life Sciences to an industry that is global in its nature. SDI’s work has included promoting a ‘Scotland brand’ in various key sectors, including the life sciences. One of the key messages is that “with a world-class education system, several thriving economic sectors and a long-standing culture of innovation, Scotland is the ideal destination for business investment.” These efforts also tie well with Scottish Enterprise’s leadership in creating a broad brand, titled ‘Life Sciences Scotland’, to act as a common umbrella and strengthen the identity of the sector.

The **Life Sciences Advisory Board (LiSAB)**, established in February 2009, is the focus for collaborative engagement between the public sector and the industry. There is a strong and long tradition of such engagement in Scotland: LiSAB builds on the work of the former Life Sciences Industry Advisory Group (IAG), which among other things developed the industry led [Life Sciences Strategy](#) in 2005, and oversaw its update in 2008.

LiSAB has a varied remit which includes: setting the overall strategy for the growth of the life sciences sector of Scotland; providing advice to the wider public sector on key issues facing the industry, both within Scotland and internationally; and advising how the partners can address those key issues of national significance for the growth of the industry in Scotland, including on current and proposed interventions within the sector and with suggestions for improvements as the marketplace changes.

A number of key result areas have been identified as being crucial to being able to realise this vision and work streams, which report directly into the Life Sciences Advisory Board (LiSAB), have been formed around each of the 5 themes to progress actions and address key barriers:

- [People](#) – to retain and attract the best and provide them with serial opportunities for employment, providing the highly specialised skills required
- [Technology](#) - to invest in innovation, develop a streamlined process for commercialisation and embed company business activity in Scotland, recognising the long lead times to market and high attrition rates among LS businesses

- [Capital](#) – to create an academic and business environment that sources of capital will seek to support, addressing significant funding gaps for LS businesses
- [Infrastructure](#) – to provide facilities and communications to facilitate research and its exploitation and meet the specialist accommodation needs of LS businesses
- [Collaboration](#) - working together (as [Life Sciences Scotland](#)) to maximise the opportunity for attracting business to Scotland, increasing scale and effective R&D and to enable us to compete more effectively globally

There are also important interactions taking place between Scotland's life sciences policy and the policies of other jurisdictions. Most notable is the relationship between the Scottish Government and the newly established **UK Office for Life Sciences (OLS)**. OLS was created by the Prime Minister on January 2009 and is led by Lord Drayson, UK Minister for Science and Innovation. OLS seeks to transform the UK environment for life sciences companies and ensure faster patient access to cutting-edge medicines and technologies. The OLS forms part of the UK Government's active industrial policy. Scottish Government officials have been closely involved with the work of OLS to ensure that it takes into account Scotland's distinctive context and policy structures. An important element of this work has been to enhance Scotland's position within the UK Life Sciences 'Super Cluster'.

There is also a **European Commission Strategy on the Life Sciences and Biotechnology** (published in 2002), which proposes a comprehensive roadmap up to 2010, bringing the sector to the forefront of the frontier technologies which will help the EU achieve the long-term jobs and growth targets established by the Lisbon European Council. The strategy consists of two parts: policies, and a 30-point plan to transform policies into action. It sets out what is needed from the European Commission and the other European institutions, but also suggests what action is required from other public and private stakeholders. The strategy therefore provides a framework and a reference both for individual action by the many stakeholders, and for co-operation between them. The European Commission has monitored the implementation of the strategy and published regular [progress reports](#). In 2007, the Commission carried out a mid-term review of the strategy, based on an in-depth assessment of the progress made since 2002, and the "Bio4EU" study. This study (requested by the European Parliament) examined the economic, social and environmental consequences of biotechnology. It includes many concrete examples of biotechnology being used in health, food and the environment. The Commission has taken the study as an opportunity to revise the strategy, and the revision will be presented by President Barroso.

Other interactions include:

- **Scottish Academic Health Sciences Collaboration (SAHSC)**. This is one of Scotland's newest initiatives, supporting research for patient benefit and fostering related economic development. It was launched in June 2009. The Collaboration brings together four strong partnerships between each of the research-intensive health boards in Aberdeen, Dundee, Edinburgh, and Glasgow, and their respective research-led medical schools. Increasingly, these boards operate through innovative partnerships to develop and carry out cutting edge research. SAHSC will strengthen the joint working of health boards and universities, and will establish in Scotland a world-leading research infrastructure, including some 250 research positions to make the link between patient-oriented research, clinical applications, and commercial innovations. The partnership will expand to include an even wider range of professions and disciplines over time. The initiative will serve as an engine for increased investment and economic development throughout Scotland. SAHSC will encourage and facilitate large collaborations, which may be similar to the already

successful Translational Medicine Research Collaboration (TMRC)¹³. Indeed, TMRC was a catalyst for the formation of SAHSC, and underlines the economic and health benefit of collaboration.

- **The Edinburgh BioQuarter development.** This project capitalises on the location of Edinburgh University's Medical School next to the Edinburgh Royal Infirmary and the Queen's Medical Research Institute to facilitate knowledge transfer, research and development (R&D) activity, and commercialisation. The project is a £600 million public-private collaboration that is unique in the UK. This figure represents investment to date in the buildings and infrastructure connected with the project (The Edinburgh Royal Infirmary, the Queen's Medical Research Institute, and the University of Edinburgh's Medical School)¹⁴. The project could potentially attract a number of companies which would create jobs and further investment. The BioQuarter commercialisation programme has recently seen the commitment of £6 million of Scottish Enterprise direct funding and £6 million of University of Edinburgh funding.
- **The Scottish Centre for Regenerative Medicine (SCRM)** at the University of Edinburgh is a £59 million world-leading centre linking cutting-edge stem cell research and clinical excellence. SCRM is already one of the largest critical masses of basic and clinical researchers in this area in Europe. An example of recent success is the discovery of a way to deliver foreign genes to reprogramme cells without using viruses in mouse and human cells, ultimately making them safer to use in humans. From 2010 it will be co-located in a new state-of-the art building on the Edinburgh Bio-Quarter site shared by the Edinburgh Royal Infirmary and the University's Clinical Research facilities.
- **The Office for Strategic Coordination of Health Research (OSCHR)** was initially set up in January 2007 to ensure cohesion between major public sector health research funders. Scotland became a full partner in OSCHR in 2008 and has committed a total of £4M over the next 2 years towards a set of strategic research programmes with a total value of £80M.
- **The Technology Strategy Board (TSB)**, has been established by the UK Government and operates at arm's length as a business-led executive non-departmental public body. It is sponsored and funded by the Department for Business, Innovation and Skills (BIS). TSB is dedicated to promoting technology-enabled innovation across the UK. Its vision is for the UK to be seen as a global leader in innovation and a magnet for technology-intensive companies, where new technology is applied rapidly and effectively to create wealth. Its mission is to promote and support research into and development and exploitation of science, technology and new ideas for the benefit of business, in order to increase sustainable economic growth and improve the quality of life. A key area of activity is its £18 million programme to enhance innovation and stimulate the commercial value of regenerative medicine, with which Scottish Enterprise and the wider life sciences community is currently engaged.
- **Stem Cells for Safer Medicine (SC4SM)** was established some two years ago on the advice of the Technology Strategy Board. The collaboration draws upon scientific expertise within pharmaceutical companies - especially in relation to safety

¹³ TRMC was established in 2005 in collaboration with Wyeth Pharmaceuticals.

¹⁴ Investments commitments to the project came from the Edinburgh Royal Infirmary (£210m), the Queen's Medical Research Institute (£100m), the University of Edinburgh, and ancillary costs for nursery, the Scottish Blood Transfusion Service, etc.

assessment of new medicines - academic stem cell experts in the UK and seek engagement with third parties including biotechnology companies.

- **The Highland Diabetes Institute** (Centre for Health Science, Inverness). This institute brings together academia (UHI), industry (LifeScan) and the NHS (NHS Highland) in a collaborative partnership and acts as an example of both open innovation and translational medicine.

3.2 Interventions

Sectoral policy development lies within the responsibility of Innovation and Industries Division (I&ID) in the Scottish Government (SG). I&ID has also the responsibility of linking the Life Sciences to the overall innovation, investment and business growth policy of the SG, and of providing support to Ministers in relation to the Life Sciences industry and its interface with economic and health policy.

SE and HIE have the responsibility for delivering various mechanisms of support for the sector, through their Life Sciences Key Sector Team. SE has recently integrated the Intermediary Technology Institutes (ITIs) into its activities. The foresighting and Intellectual Asset Development functions of the Life Sciences ITI are becoming part of SE's industries approach. The function undertaken by the ITI to bridge the gap between publicly-funded early stage research and privately-backed commercial development will be strengthened by closer integration with work to ensure Scottish companies have a capacity to exploit emerging technologies. To date, ITIs have committed around £50 million to R&D activities.

Scottish Development International (SDI) encourages inward investment and helps Scottish life sciences companies to develop international business linkages.

Other Scottish Government policy interventions cover the following areas:

- In the past year the life sciences sector received more than **£12 million of investment in Research and Development, and Regional Selective Assistance.**
- The establishment of a new **Scottish Institute for Cell Signalling** in Dundee, with a £10 million Scottish Government investment. The new institute will concentrate on an emerging area of 'cell signalling' which has great potential for the development of drugs to treat cancer and chronic inflammatory diseases.
- A new Modern Apprenticeship for Life Sciences, in response to industry demand for more practically trained technicians.
- **Initiatives by the Office of the Chief Scientific Advisor to develop a new science strategy** and to promote science in Schools. Also, additional investment into clinical research infrastructure and related works streams
- **Scottish Funding Council (SFC)** efforts to enhance Scotland's knowledge base. A key feature of this has been the establishment of the Scottish Universities Life Sciences Alliance (SULSA) in 2007 as a research pooling partnership between the Universities of Aberdeen, Dundee, Edinburgh, Glasgow, St Andrews and Strathclyde. SULSA aims to maintain and advance Scotland's global position in the life sciences field by recruiting international research leaders and funding world-class research facilities. SULSA's initial investments are focused in three broad interrelated research themes: cell biology, systems biology and translational biology.

- **Scottish Health Innovations Limited (SHIL)**, which was established in 2002 to support the development and commercialisation of innovations arising within the NHS in Scotland¹⁵.

Recent interventions have also sought to address the skills challenges to the sector, both in the immediate and the long term. One of the workstreams of the Life Sciences Advisory Board (LiSAB) is to take forward work and actions required around the 'People' Objective of the Life Sciences Strategy. The People work stream is scoping the skills and human resources challenges for the sector. There is a lack of good Scotland-wide evidence on for life sciences skills. Accordingly, a Scotland-wide survey of life sciences companies is being carried out to provide the evidence base for actions on skills.

The Scottish Government have introduced Life Sciences Modern Apprenticeship (MA) Frameworks at Level 2 and 3 from August 2009. The Life Sciences MA will have a positive impact on Scottish recruitment, retention and upskilling within the Life Sciences Sectors and:

- Attract younger people from schools and colleges into the sector
- Encourage those already working in the sector to acquire recognition, skills and qualifications
- Engage a higher number of small to medium size employers who have previously failed to engage with training

The Scottish Government has also guaranteed that where apprentices are made redundant, they have opportunity to complete appropriate and relevant training. Employers can receive £2000 for each redundant apprentice they recruit.

In 2008 the Scottish Government announced the creation of a programme to promote and encourage young people prepare for and pursue careers in science, engineering and technology. "The Path is SET" is currently being developed and will launch later this year.

4. Assessment of the Effectiveness of Interactions / Interventions

The key to success in Life Sciences is the ability of multi sector agencies to work well together, an area in which Scotland has an advantage on account of its size. The formation of LiSAB is a significant step in promoting industry-led system interactions and collaborations. In the context of the Life Science Strategy, LiSAB enables assessments about the sector, and decisions about necessary actions, to be made, which include:

- Recognition that the industry in Scotland is well-placed to withstand the economic down-turn, and that this actually presents a number of opportunities for Scotland;
- Current recruitment difficulties for skilled staff to be addressed by collaboratively attracting staff out with Scotland affected by the downturn. The work of Talent Scotland is particularly important in this context as it can help attract skilled life sciences professionals from overseas;
- As they cut back on in-house R&D, pharma companies are accelerating their moves to outsource R&D which provides an excellent opportunity for Scotland's biotech and support companies. LiSAB members and Scottish Development International are

¹⁵ An example of successful innovation is a learning concept called 'Let's Move'. Let's Move is an innovative programme designed to help children with a range of sensory motor difficulties such as coordination difficulties, Dyspraxia, Autistic Spectrum Disorders (ASD) and also attention, concentration and sensory dysfunction. The programme comes as pack containing DVD, 40 therapeutic activity cards and hand book. Let's Move was developed with Paediatric Occupational Therapists from NHS Dumfries and Galloway and commercial partner, Midgibyte Creations, a creative and multimedia company based in Glasgow. The package is already being used in Dumfries and Galloway schools, and is now being offered to education authorities all over Scotland.

working together to refine key messages about the sector in Scotland, and help refine the companies to be targeted.

SE supports the delivery of the Life Sciences Strategy in ways that capitalise on SE's expertise and resources. Over the last year SE has sharpened its focus on interventions that contribute to the growth of a sustainable company base and delivering connected, world class transformational projects such as the Edinburgh BioQuarter. SE engages with 180 life sciences companies through account management. In addition, SE provides companies with access to life science expertise through a number of sector-specific products and programmes (such as the Life Sciences Business Advisory Service, and the Stem Cell Translational Fund) which facilitate growth.

HIE has begun to focus on activities and expertise within the Highlands and Islands (and Scotland's) Life Sciences community that represent growth opportunities in challenging conditions in the healthcare markets. A focus on remote healthcare, wellbeing and preventative medicine and natural products (for pharmaceutical, nutraceutical and cosmeceutical markets) relates to global trends that are driving growth in these areas thus ensuring the Life Science sector in will continue to grow in the face of challenging market conditions.

SDI fosters the link between Scottish companies and international investors, thereby strengthening the connectivity of Scottish Life Sciences to an industry that is global in its very nature.

The **effectiveness of SE, HIE and SDI's efforts** has been demonstrated during 2008 when a range of international life sciences companies announced plans to safeguard over 690 jobs in Scotland¹⁶. Scottish Government Regional Selective Assistance (RSA) and R&D grants support have been major factors in this development with the acceptance of RSA/R&D grants totalling £12.3 million for projects with planned capital expenditure of £78.3 million¹⁷.

5. International Perspectives

International Policy Lessons

Systematic and rigorous international comparisons of life sciences policy is scant. One of the few robust analyses was conducted in 2005 by researchers at the Economic and Social Research (ESRC) Centre for Research on Innovation in Genomics. The study compared biotechnology innovation systems in Scotland, Sweden and Denmark.¹⁸ All three countries have been found to have comprehensive innovation and technology policy frameworks characterised by systematic and interventionist approaches that aim to stimulate innovation and entrepreneurship in the life sciences. Compared to Scotland, Denmark and Sweden have relatively more mature clusters, characterised by the presence of established players (mostly big pharmaceutical firms). All three countries have a specific focus on promoting interaction, especially between industry and academia. The study concludes that "critical challenges remain as regards meeting demand for both technical and managerial skills, whereas investing in the local soft and physical infrastructure remains a priority in order to achieve critical mass". In addition, the comparative study has found that the presence of prominent scientists and the availability of funds to finance new ventures play a crucial role in the growth of the sector. An efficient system of transferring intellectual property (IP),

¹⁶ Source: Scottish Enterprise: Scottish Life Sciences 2008 Review.

¹⁷ Source: Scottish Enterprise: Scottish Life Sciences 2008 Review.

¹⁸ Source : Rosiello, A, (2005), Comparing Biotechnology Innovation Systems, Innogen Working Paper 35, University of Edinburgh and the Open University, <http://www.genomicsnetwork.ac.uk/innogen/publications/workingpapers/title.2717.en.html>

accessing skills, money and international markets, and a friendly regulatory environment are also of high significance (it may also be interesting to note that unlike Scotland and Denmark, Swedish professors enjoy full ownership over IP generated by academic research).

Scotland's Science Base

In international terms the research base is identified as a significant strength – research has found that the productivity of Scotland's research base ranks it first among 26 comparator nations that together account for 95 per cent of the world's research, and 2.5 times better than the comparator group average on citations relative to GDP. The number and share of citations per unit gross R&D (GERD) was also found to be very high. In terms of citations per unit of higher education R&D (HERD), Scotland has led the comparator group in the past but fell back slightly more recently and is now 2nd to Switzerland but its performance has remained almost twice the comparator group average. The top performing research fields in Scotland were identified as health and related sciences (1st in world), clinical sciences (2nd in world) and biological sciences (3rd in world).¹⁹

Overall Global Life Sciences Market & Trends

The global market for pharmaceuticals, medical devices and biotechnology is huge (\$997bn in 2007) and according to Oxford Intelligence 2008, projected to grow by 38% to \$1,374 bn by 2012. Undoubtedly this projected figure has been and will continue to be significantly affected by the economic slowdown but nonetheless the pharmaceutical and health related industries has so far fared relatively better than some other major industries in the current situation. One of the trends that has emerged as pharma adapts to the changing global circumstances has been earlier outsourcing and, while divesting themselves of parts of their own business, there is an increased willingness to invest in other companies which will help to strengthen their drugs pipeline. This offers potentially good opportunities for Scottish organisations.

The sub sectors which offer most potential are **drug discovery/development, stem cells and regenerative medicine, translational and clinical medicine, and medical technology** and the opportunities are detailed below.

Drug Development

This is a broad area which is characterised by strong, commercially attractive, academic and clinical research, a number of small early stage companies and a number of major international organisations, particularly contract research organisations (CROs; Scotland has the strongest concentration of CROs in Europe – a real strength). Over 50% of the industry's turnover in Scotland is attributable to this sub sector, with the vast bulk of the contribution coming from pharma, pharma support companies and CROs. This sub sector comprises about 220 drug discovery and development companies plus 53 academic and research institutes. (In addition there are a large number of companies providing professional services).

The geographic market which offers the most opportunity is the US particularly East coast (major pharma and CROs) and West coast (major biotechs). In Europe the greatest opportunities are in France, Germany, Switzerland, Scandinavia and England but to a large extent it is not so much about countries as about the major global players and where they

¹⁹ Source: <http://www.scotland.gov.uk/Topics/Business-Industry/science/16607/research-1>

are located. In Asia the priorities are in Japan, Korea, China and India, with pharma companies in particular. To give a sense of relative scale of markets, the estimated value of revenue from drug discovery/development is as follows:

- US 45%;
- Europe 28%; and
- Asia 26%.

The nature of the opportunities in all of these markets relate both to internationalisation of companies and inward investment. East & West Coast US has the strongest cohort of target companies and is seen by Scottish companies and universities as an excellent opportunity to win business through outsourced R&D and collaborations with major global pharma companies, mid – large biotech companies with the appropriate clinical/development profile, and CROs. \$12bn of global contract research revenues are generated annually from the US and consequently this market is critical for Scotland's very strong CRO base (the key players in which are US owned companies). The major European markets (France, Germany, Switzerland, Scandinavia, England) and Asian pharma companies (Japan & Korea) offer similar types of opportunities, albeit typically on a smaller scale in Asia.

In all major markets, the therapeutic focus is on major disease areas aligned to Scotland's strengths including oncology, cardiovascular, metabolic, neuroscience and inflammation. These therapeutic areas are the primary focus of global drug research.

In the current climate, a major focus of activity in 2009-10 will be on working closely with existing investors which form the bulk of private sector investment in Life Sciences in Scotland (ie CROs and manufacturers) to try to safeguard existing operations and look for expansion opportunities.

Consolidation in the industry presents a challenge to retaining Scotland's position in the international map of global pharmaceutical industries: .

There are also strong linkages between the drug discovery/development sub sector and the speciality/fine chemicals sub sector which supply the pharmaceutical industry with materials and equipment.

Stem Cells and Regenerative Medicine

The global stem cells market was valued at \$2.7bn in 2005 and is expected to reach \$10bn by 2013. The main emerging areas are therapeutics and drug discovery tools. Scotland is genuinely a global leader in this field with internationally renowned expertise not only in the Scottish Centre for Regenerative Medicine in Edinburgh but in other centres including Glasgow and Aberdeen. At present the Scottish capability is largely academic, although the focus is now very much on translational medicine, and stem cell and regenerative medicine, ie moving basic research into clinical and commercial applications. In addition, there is a world leading commercial organisation in Cellartis in Dundee and the company base in Scotland is growing.

The main market opportunity is the East & West coast US followed by Japan, Korea, China and Scandinavia. The nature of the opportunity is primarily inward investment and there is particular potential in relation to major pharma companies which are attracted by our academic capability and could be interested in establishing a high profile Centre of Excellence in Scotland. The plan is to review top 10 pharma to establish which do not currently have a Centre of Excellence in Europe and agree a list of potential targets. A Centre of Excellence could in turn lead to stem cell manufacturing opportunities.

It is expected that the US will adopt a more positive approach to funding of stem cell research. On the one hand, this is a potential threat. On the other, there is the potential to collaborate with key US organisations (eg Bill Gates Foundation) and leverage what could be a huge opportunity by playing to Scotland's strengths in this field (eg niche stem cell platforms). This whole area will be a major focus in activities to recruit an anchor tenant for the BioQuarter.

In addition to big pharma, there are also internationalisation/collaboration opportunities for Scottish companies/universities with small to medium biotechs with a research/therapeutic interest in stem cells, and with specialised stem cell product/service companies. There are also opportunities to attract investment from companies working in the drug discovery/tools area or small scale/scale up manufacturing aligned to Scotland's regenerative medicine capability.

Stem cell 'line' creation is therefore seen as being something that is commercially viable. ITI Life Sciences invested £9.5 million in a Stem Cell Technology programme to help produce stem cell in large numbers. In addition, Roslin Cells has been setup with £1.7 of SE funding and are doing something similar utilising unviable eggs from IVF as a starting point.

Experimental, Translational & Clinical Medicine

The pharmaceutical industry is very research intensive and spends approximately \$90bn per annum on R&D. It takes up to \$1bn to get a drug to market and a drug failing at phase 2 or 3 clinical trials has serious financial consequences. All pharma companies are striving to reduce the drug failure rate, strengthen their drugs pipeline and reduce costs. In essence, this is what experimental and translational medicine is about, hence the huge opportunity. Biomarkers are, for example, a core component and the market is expected to quadruple to \$21bn by 2012. Through the expertise in our universities and NHS and a joined up, pan Scotland approach, Scotland is in a strong position to deliver scientifically complex, early stage clinical - translational studies. In this way we can capitalise on this major global opportunity.

Merck, Pfizer and GSK are among the global pharmaceutical companies with presence in Scotland. This presence has been affected by the global trend of consolidation, mergers, acquisitions and take-overs. These trends make it clear that the policy environment and interventions need to ensure as much as possible that these activities remain in Scotland.

The translational medicine opportunity is investment related and is focused on 10-15 major global pharma companies headquartered in East/West coast US, Switzerland, UK, Germany, France and Japan. It involves research in clinical exploratory development and biomarkers which could ultimately result in large scale FDI.

This is illustrated by the \$50m which Wyeth (now owned by Pfizer) have to date invested in the Translational Medicine Research Collaboration (TMRC) projects and created 100 jobs, together with the opportunity for commercial development of biomarkers. The TMRC collaboration has also had additional economic impact through its catalytic effect, (eg acquisition of Haptogen in Aberdeen, funding of other research, business for Scottish service companies,) none of which would have happened without Pfizer's presence in Scotland.

Scotland also has a strategic opportunity to make the most out of the first emerging global market in Stratified Medicine. In a recent article in the scholarly journal *Nature Reviews – Drug Discovery*, by researchers at the MIT Center for Biomedical Innovation, it is argued that "the potential to use biomarkers for identifying patients that are more likely to benefit or

experience an adverse reaction in response to a given therapy, and thereby better match patients with therapies, is anticipated to have a major effect on both clinical practice and the development of new drugs and diagnostics.”²⁰ Scotland’s access to biomarkers provides Scotland with a distinctive advantage in this area. Recent activities by the UK Office for Life Sciences and the Technology Strategy Board can enhance the potential to stimulate innovation in this field, and the Scottish Government and its enterprise agencies are engaged in this process.

Medical Technologies

About 25% of the industry’s turnover in Scotland comes from MedTech. Of this figure, exports accounted for about 50% in 07-08 (£387m).

The global med tech market was estimated to be worth \$197bn in 2007 (Oxford Intelligence 2008) with over 40% coming from the US, over 30% from Europe and most of the remainder from the leading Asian economies and the Middle East. Within the Life Sciences industry, med tech companies have the advantage over pharma companies of a much shorter time to market for approval of devices and diagnostics and consequently they tend to be profitable more quickly which in turn makes them an attractive investment proposition.

Diagnostics and medical devices are two important sub-sectors within this category of life sciences activities.

Diagnostics

Diagnostics is a major strength in Scotland’s Life Science community. The volume of activity in terms of the number of small, innovation-led companies and Proof of Concept Fund projects is an indicator of Scotland’s growing strength. This is backed up by a number of large, internationally focused medical diagnostics companies. International organisations such as LifeScan Scotland complete all R&D and process development in Scotland. Axis-Shield and Optos are also examples of successful Scottish Diagnostics companies.

Scotland’s position is further strengthened by its academic excellence in diagnostics, which includes:

- Optics Group, Department of Physics (Glasgow)
- School of Biological and Clinical Laboratory Sciences (Edinburgh)
- School of Clinical Sciences and Community Health (Edinburgh)
- Institute for Integrated Micro and Nano Systems (Edinburgh)
- School of Molecular and Clinical Medicine, School of Physics (Edinburgh)
- Royal Dick School of Veterinary Studies (Edinburgh)
- Department of Bioengineering (Strathclyde)

Medical Devices

In terms of geographic focus for Scotland, the main global markets of opportunity are Western Europe, the US, particularly the mid West, and the East & West Coasts. For the approximately 100 Scottish based companies in this sub sector which undertake R & D and product development, these markets are critical for investment, research collaboration and sales. The Middle East markets and Japan, China and Russia also offer emerging internationalisation opportunities for Scottish based organisations.

²⁰ *Nature Reviews Drug Discovery* 6, 287-293 (April 2007)

The investment focus is primarily on large medical device companies in the US, Western Europe and Japan. The leading sources of FDI med tech projects are US, Germany, Japan and Switzerland with emerging opportunities in China, according to Oxford Intelligence 2008. Over the next year a major focus of activity in this sub sector, will be to work to secure the major existing investors in Scotland and seek to identify opportunities for expansion where possible.

Remote Healthcare

As mentioned in Section 1, Remote Healthcare (the delivery of health and care where those receiving treatment/care are remote from the medical professional/carer) is an emerging market which is growing rapidly due to significant global drivers: the need for increased efficiency in delivering healthcare, a global aging population and pressure to reduce carbon footprints. In the United States, for instance, recent research has suggested that remote patient monitoring devices will experience a remarkable growth over the next few years, registering an exponential 77% compound annual growth rate that will result in almost \$950 million in revenues.²¹

The Scottish academic base is well placed to contribute to the growth of this market which is incorporating an increasing number of Scottish companies.

6. Concluding Comments

The life sciences sector in Scotland enjoys high level of public sector support and strong government commitment. The sector has strong foundations in Scotland's scientific excellence and in its clinical base. Scotland has world-class expertise in specialist technology and across a range of clinical and therapeutic areas. A highly skilled workforce is also a key feature of the life sciences sector in Scotland. Collaboration across the sector and between the Government, its economic development and innovation agencies, academia, the health service, and industry gives Scotland a distinctive advantage and an excellent platform for collaborative innovation. The Scottish Government and its partners are strongly committed to working together to enhance Scotland's position as a world-class centre for the Life Sciences.

²¹ Enterprise Innovation, 5 October 2009, available at:
<http://www.enterpriseinnovation.net/content/remote-healthcare-devices-grow-exponentially-2014>