

# Evaluation of Invest NI-funded activities of BioBusiness Ltd



Final Report

## **CONTENTS**

<b>1.</b>	<b>INTRODUCTION</b>	<b>1</b>
<b>2.</b>	<b>CONTEXT</b>	<b>4</b>
<b>3.</b>	<b>PROJECT DEVELOPMENT AND DELIVERY</b>	<b>6</b>
<b>4.</b>	<b>STAKEHOLDER CONSULTATION</b>	<b>14</b>
<b>5.</b>	<b>BENEFICIARY CONSULTATION</b>	<b>21</b>
<b>6.</b>	<b>PROJECT IMPACTS</b>	<b>27</b>
<b>7.</b>	<b>BENCHMARKING</b>	<b>33</b>
<b>8.</b>	<b>CONCLUSIONS &amp; RECOMMENDATIONS</b>	<b>36</b>

## **APPENDIX 1: MARKET AND POLICY CONTEXT**

# 1 INTRODUCTION

## Background

- 1.1. In December 2012, Invest Northern Ireland (Invest NI) commissioned Urbis Regeneration Ltd (Urbis) to undertake an evaluation of its support for BioBusiness Ltd (BBL) during a two year period of funding commencing in August 2011 and concluding in July 2013. BBL is a not-for-profit representative body for the Life and Health Sciences (LHS) sector, with a mission<sup>1</sup> to *'operate as an activity and information hub for...members, with collaborative links and partnerships to academic institutes, clinicians, healthcare organisations, government departments and agencies.'* BBL provides its members with a range of support including
- brokering links between academics, businesses and clinicians to develop new products/services ('ABC' links)
  - industry representation (lobbying with Government and other agencies on issues of relevance to the LHS sector)
  - delivering events and other networking opportunities
  - enhancing market intelligence through research and other related activities
  - delivering one-to-one business support.
- 1.2. As of January 2013 BBL had 34 core business members in Northern Ireland plus a further 7 non-core members including the University of Ulster and QUBIS Ltd, which supports the creation of spin-out businesses at Queens University Belfast. Both organisations are also represented on the BBL Board. Since 2010, BBL has also strengthened its interests in the Republic of Ireland (ROI), where it has developed links with a number of clinicians and other institutions; as of November 2012, 17 ROI businesses were members of BBL. BBL's activities in the ROI are not formally part of this evaluation.
- 1.3. Since its formation in 2004, BBL has received grant support from Invest NI which has covered a significant proportion of its operating costs as an External Delivery Organisation (EDO) for the agency. Invest NI has now provided five rounds of operational support for BBL, totalling over £867,000 and typically on a two year basis with renewal contingent on the outcome of regular post-project evaluation activity. During each period of Invest NI-support, BBL has contracted with Invest NI to deliver a number of different output/outcome targets including
- achieving annual cost savings/monetary benefits for members
  - achieving 70% market penetration of BBL's potential membership base
  - providing support for clinical trials and regulatory advice
  - delivery of events
  - providing a level of bespoke business support for each member
  - securing additional external funding.
- 1.4. BBL also receives income from membership fees alongside other, limited commercial income streams from events and other activity. Since its formation, BBL has also generated income from management fees relating to eight additional programmes/projects delivered for Invest NI, InterTradeIreland and Enterprise Ireland, some of which have focused on cross-border development activity. These have included initiatives to develop all-islands ABC links and Connected Health activity.
- 1.5. In January 2013, BBL issued Invest NI and other key stakeholders with a review of its achievements since 2004<sup>2</sup>. The review indicated that BBL had leveraged over £11.8m in direct support for member companies, made 844 'assists' to members since 2007 and supported the development of over 30 new products in areas including cryotherapy treatment, diagnostics, wireless monitoring and screening and reminiscence therapy. The review also highlights BBL's role in developing an all-island network of clinicians involved in developing and trialling new products and services and, with NISP Connect (an initiative managed by the Northern Ireland Science Park), in preparing a capacity building toolkit. This identifies the key stages in the lifecycle for LHS businesses during which they may require external advice, support and challenge.

<sup>1</sup> <http://www.biobusinessltd.org/#/about/cjpy>

<sup>2</sup> BioBusiness Ltd Ten Year Review 2004-2013, BioBusiness January 2013

- 1.6. During the period from August 2011 which is the focus for this evaluation, the quarterly progress reports prepared by BBL highlight the delivery of a wide range of activities against Invest NI's target framework including:
- cost savings/monetary benefits for members totalling £190,500 in year 1 (to July 2012) and £92,400 to date in year 2
  - ongoing development of a new product support programme for medical device companies, in partnership with Belfast Metropolitan College
  - brokering a series of links between members and the clinicians including between Heartsine (a Belfast-based manufacturer of automated external defibrillators, and University Hospital Galway
  - delivering 17 days of support for members in relation to regulatory and quality management systems during year 1 and 27 days (to date) in year 2
  - delivering 4 events per annum either solely or in partnership; these have included two events in partnership with NISP Connect and the International Medical Device Summit with Opal Events USA.

### The study brief

- 1.7. The Invest NI brief identified a number of separate objectives for the evaluation, including

- review the strategic context for the project and consider its operational fit with the objectives of the Invest NI and DETI Corporate Plans
- review the original market failure rationale for the intervention and the ongoing validity of those arguments with reference to the original project casework
- assess the performance of the project against its original objectives and SMART targets, and the wider contribution of the project to enhancing the performance of the LHS sector in Northern Ireland
- consider the appropriateness of the delivery model adopted, the fit with other Invest NI support for the LHS sector and whether it represents an effective means of supporting the sector
- briefly consider the costs and benefits of BBL operating as an all Ireland body and identify any implications for future Invest NI support for the organisation
- review governance, management and control structures for the project and the effectiveness of BBL and Invest NI in delivering the programme
- identify any other economic, innovation or other outcomes/ impacts which have occurred or are expected to occur including wider and/or regional benefits, in line with Invest NI's Economic Appraisal Methodology
- estimate the counterfactual for the project i.e. what would have happened in its absence, drawing on the original economic appraisal where appropriate
- establish the value for money of the programme through analysis of the economy, efficiency and effectiveness with which public funds have been utilized, and in comparison with the forecast budget
- identify the main risks that have emerged during the delivery of the programme and the effect of any mitigating actions
- take into account the equality impacts of the programme with particular regard to Section 75 of the Northern Ireland Act 1998 and the Disability Discrimination Act 1995
- make clear recommendations including lessons learned and highlight any aspects of delivery and performance which could inform future Invest NI engagement with BBL and other EDOS.

## Research methodology

- 1.8. The evaluation fieldwork took place between January and March 2013. Our research methodology included:
- a desk review of the earlier evaluations; key DETI/INI policy documents and performance management information relating to the project
  - reviewing BBL's performance against Invest NI's target framework and the likelihood of the organisation achieving its targets during the period to July 2013
  - interviews with key stakeholders including Invest NI client executives, BBL's Chief Executive, project manager and Board members and other key stakeholders/partners from the University of Ulster, Queens University Belfast, QUBIS, HSC Research and Development, HSC Innovations, NISP Connect, Belfast Metropolitan College, InterTradeIreland and the Association of British Pharmaceutical Industries
  - undertaking an online survey of BBL member companies to assess their views on the strengths and weaknesses of BBL, its impact on their business and the future support needs of the LHS sector in Northern Ireland
  - benchmarking the project against other comparator initiatives in the rest of the UK and ROI including Bionow and MediWales
  - exploring the counterfactual position for the project, and assessing its value for money based on its economy, efficiency and effectiveness
  - developing clear recommendations on the future of the network.

## Report structure

- 1.9. Section 2 considers the market and strategic context for the project. Section 3 reviews the development and delivery of the project in more detail and presents an overview of its performance against agreed Key Performance Indicators. Section 4 considers the issues raised by the various stakeholders consulted as part of the evaluation and Section 5 summarises the outcome of an online survey of BioBusiness members in Northern Ireland.
- 1.10. Section 6 considers the impact and value for money of the project. Section 7 benchmarks BBL against comparator projects in the UK and Republic of Ireland. Section 8 presents our conclusions and recommendations.

## 2. CONTEXT

2.1 Section 2 considers the strategic and market context for the development of the project including:

- a brief review of market trends in life and health sciences sector
- the strategic/policy framework for the development and delivery of the BioBusiness programme that was in place during the period covered by this evaluation.

2.2 A more detailed contextual analysis is presented in Appendix 1.

### Market context

#### *Global trends*

2.3 The global Life and Health Sciences sector is typically subdivided into four main sub-sectors:

- pharmaceuticals
- medical technology
- medical biotechnology
- industrial biotechnology.

2.4 Recent research by Deloitte<sup>3</sup> notes that the global pharmaceuticals, biotechnology and life sciences sector generated total revenues in excess of \$1.1 trillion in 2011, up from \$855bn in 2007 and achieving a cumulative annual growth rate (CAGR) of 6.7% during this period. Despite this, the LHS sector faces a number of significant challenges moving forward, including the expiration of patents, the growth of generic drugs and increased scrutiny around regulatory and compliance matters.

2.5 The pharmaceuticals market (excluding biologics) accounted for 72% of total LHS revenues in 2011 with prescription sales accounting for 95% of total revenue<sup>4</sup>. The major pharmaceuticals companies moving towards a collaborative, lower-cost approach to the development of new drugs as their patents on 'blockbuster' products expire. Pricing pressures are a key driver of the move towards generic drugs.

2.6 There is also a move towards the convergence of pharmaceutical and biotechnology businesses, with a focus on higher margin biologics – derived from human or animal proteins – to treat, prevent or cure diseases. 34 of the top 100 selling drugs were biologics in 2011 and market parity is anticipated by 2018.

2.7 The global medical technology market had an estimated value of \$325bn in 2011 and achieved a CAGR of 7% between 2005-2011. In 2011, the top 5 medical technology segments by sales were in-vitro diagnostics, cardiology, diagnostic imaging, orthopaedics and ophthalmic activity.

2.8 The industrial biotechnology market has an estimated global market size of between \$50-60bn and this has been forecast to increase to \$300bn by 2030. The biofuels and chemicals markets are likely to drive growth.

2.9 The focus of the global LHS sector is shifting inexorably towards emerging markets. Total spending in the OECD and BRICs countries alone is forecast to increase from \$5 trillion to \$7.24 trillion by 2020<sup>5</sup>.

#### *Life and health sciences in the UK*

2.10 The UK's life and health sciences sectors employ over 167,000 people in over 4,500 companies and generate annual sales of over £50bn<sup>6</sup>. Overall employment increased by 1,500 jobs between 2011-2012. The UK pharmaceutical sector generated a turnover of just over £30bn in 2011. Although 17 of the top 20 global pharmaceutical manufacturers have a presence in the UK, turnover and employment in the pharma sector fell by 5.4% and 9.7% (equivalent to 9,000 jobs) respectively between 2011 and 2012. The medical technology sector has now overtaken pharmaceuticals as the largest employer (71,144 jobs) in the UK LHS sector although its turnover (£16bn) is significantly smaller.

<sup>3</sup> 2013 global life sciences outlook, Deloitte 2013

<sup>4</sup> Strength and opportunity 2012: the landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK, HM Government, December 2012

<sup>5</sup> PWC: Build and beyond: the revolution in healthcare PPPs, PricewaterhouseCoopers, December 2010

<sup>6</sup> Strength and opportunity 2012: the landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK, HM Government, December 2012

- 2.11 The Office for Life Sciences acknowledge<sup>7</sup> that whilst the UK's life science research base ranks second to the US only to the US on share of citations it has *punched below its weight* in seeking to commercialise the intellectual property developed by UK scientists. Barriers include a lack of funding for clinical trials, limited incentives for clinicians to commercialise IP assets and limited take-up of innovations across the NHS.

#### **Life and health sciences in Northern Ireland**

- 2.12 The LHS sector in Northern Ireland is comparatively small when compared with the concentration of firms and activity in some parts of the UK, including the South East and East of England which both have more than 20,000 employees in LHS businesses.
- 2.13 In 2006, research by BioBusiness<sup>8</sup> for Invest NI showed that the sector encompassed 60 firms employing over 4,000 people with a combined turnover of approximately £300 million per annum. Analysis by Invest NI of the employment returns of 48 LHS firms in 2012 (which did not include data for Radox or Norbrook) suggested that 5,737 people were employed in the sector. Thus the actual employment footprint of the sector in Northern Ireland (excluding HSC staff) is likely to be between 6,700-7,500 employees.
- 2.14 The LHS sector in Northern Ireland is characterised by the presence of a handful of larger businesses, each operating in a distinctive area of the LHS market with differing levels of engagement with the Northern Ireland supply chain and research base; a group of small and medium-sized SMEs with niche specialisms and some of which have demonstrated recent growth; and a larger number of microbusinesses, the majority of which employ fewer than five staff.
- 2.15 Northern Ireland also has an internationally recognised research base in several key areas of LHS research. The University of Ulster's School of Biomedical Sciences was the highest ranked facility in the UK in the 2008 Research Assessment Exercise (RAE) The Centre for Cancer Research and Cell Biology at Queen's University Belfast, established in 2007, was ranked within the top 20 UK Universities for cancer studies in the 2008 RAE.

#### **Policy context**

- 2.16 The BioBusiness network lies within a broad framework of UK Government, DETI and Invest NI strategies and policies over the period from 2011-2013; these include:
- the Strategy for UK Life Sciences, published by The Office for Life Sciences in 2011, which sets out a vision for the UK as a *“global hub for life sciences in the future, providing an unrivalled ecosystem....to translate discovery into clinical use for medical innovation within the NHS”*
  - the Life and Health Sciences Horizon Panel report by MATRIX, which remains the only strategy developed specifically for the LHS sector in Northern Ireland and focuses on opportunities for Northern Ireland in the key areas of personalised medicine and telehealth/telecare
  - the Northern Ireland Executive's Programme for Government, which *identifies ‘Growing a sustainable economy and Investing in the Future’* as the key priority and sets out various relevant economic targets
  - the DETI Corporate Plan 2011-2015, which identifies seven strategic objectives for the department, including stimulating innovation, R&D and creativity; helping Northern Ireland businesses compete in the global economy and encouraging business growth
  - the Invest NI Corporate Plan 2011-2015, which sets out the role of the agency in supporting wealth creation in Northern Ireland and incorporates relevant targets including securing £300 million investment in R&D (with at least 20% from SMEs) and supporting 500 businesses to engage in first time R&D and 120 Collaborative R&D projects.

#### **Conclusions**

- 2.17 In broad terms, the BioBusiness network demonstrates a clear fit with DETI and Invest NI objectives and targets developed over successive corporate plans and in particular with those objectives and targets focused on supporting R&D investment and the attraction of jobs and investment by indigenous firms. The BBL project also demonstrates fit with the objectives of the Office for Life Science strategy for the LHS sector.

<sup>7</sup> Strategy for UK Life Sciences, Office for Life Sciences/BIS 2011

<sup>8</sup> NI Life and Health Technologies Sector: Capabilities Study, Gap Analysis and Collaborative Network Assessment, BioBusiness Northern Ireland for Invest NI 2006

### 3. PROJECT DEVELOPMENT AND DELIVERY

#### Introduction

- 3.1 Section 3 presents a review of
- the context for the current BBL programme
  - the economic appraisal and Invest NI Board approval processes
  - the contractual agreement for delivery of the project
  - budget costs and expenditure
  - achievements against Key Performance Indicators to date.

#### Context

- 3.2 Since its formation in 2004, BBL has received grant support from Invest NI which has covered a significant proportion of its operating costs as an External Delivery Organisation (EDO) for the agency. Invest NI has now provided five rounds of operational support for BBL, totalling over £867,000 and typically on a two year basis. Table 3.1 summarises Invest NI's funding support for the agency, identifying both core revenue support and funding for the delivery of specific programmes:

**Table 3.1: Invest NI funding for BioBusiness 2004-2011**

Type of support	Amount	Date
Operating support	£149,983	June 2004
Operating support	£117,453	June 2006
Collaborative Networking programme	£148,802	July 2007
Operating support	£199,996	August 2007
Collaborative Networking programme	£160,500	April 2009
Collaborative Networking programme	£5,250	May 2010
Operating support	£199,858	August 2009
Collaborative networking	£15,000	November 2009
Operating support	£199,998	August 2011
<b>Total</b>	<b>£1,196,840</b>	

- 3.3 Invest NI's support for BBL has been evaluated on a regular basis with the renewal of the agency's contingent on the outcome of post project evaluation. Key findings from the most recent evaluations of the project include
- the evaluation<sup>9</sup> for the period from 1 June 2006-31<sup>st</sup> July 2007 noted that BioBusinessNI (the company changed its name in 2010) had achieved 14 of 18 targets set by Invest NI and had generated high levels of member satisfaction; members highlighted the need for improved marketing and communication with members and to develop a stronger role in promoting the sector to young people whilst acknowledging that additional core funding would be required to expand the network's role; recommendations included strengthening efforts to develop the membership base, aligning targets to the LHS capability study (completed by BBL in 2006) and undertaking a review of opportunities for commercial funding
  - an evaluation by Kappa Consulting<sup>10</sup> for the period from August 2007-July 2009 noted that the network had achieved 22 of its 26 targets and had contributed to the achievement of approximately £1.7m of additional revenue/cost savings for members during this period; the evaluation also considered the network's financial sustainability, recommending an increase in core membership fees alongside other initiatives including the delivery of some business support services on a full cost recovery basis

<sup>9</sup> Evaluation of BioBusinessNI Ltd, BDO Sloy Hayward, 2006

<sup>10</sup> Evaluation of BioBusinessNI, Kappa Consulting with Karen Thompson Consulting and Blu Zebra, June 2009



- Invest NI's CFAAD team undertook an in-house evaluation of the programme for the period from August 2009-July 2011; the study noted that BBL had achieved/was expected to achieve 12 of its 16 targets whilst acknowledging the increasingly divergent needs of the network's membership base and indicated some member dissatisfaction with communication; nonetheless, the evaluation argued that the absence of the network would have a detrimental impact on the LHS sector in terms of strategic direction, lobbying and business development opportunities.

### Business case and economic appraisal

3.4 In June 2011, BBL submitted a business case to Invest NI for revenue funding over the two year period from 1 August 2011 to 31 July 2013. The business case sought £199,998 of revenue funding to support staff costs and other overheads. The business case highlighted that BBL would undertake a number of activities during this period including:

- developing its advocacy and lobbying role with Government and other stakeholders
- building the capability and capacity of the LHS sector through implementation of the capacity building toolkit and providing a wide range of support for members on issues including regulatory compliance, clinical trials and investment
- developing BBL's strategic impact on the sector.

3.5 Invest NI commissioned an independent economic appraisal<sup>11</sup> of BBL's business case, prepared by Cogent Management Consulting. In considering the need for support for the project, the appraisal concluded that:

- BioBusiness had made a contribution to the achievement of earlier Public Service Agreements and DETI Departmental Strategic Objectives
- on the basis of earlier evaluation evidence, BioBusiness members were largely satisfied with the services provided and consider them to represent good value for money;
- market failure (asymmetric information) had a significant impact on companies' decision to participate in business development activities facilitated by BBL; project level additionality of BBL's previous activities was estimated at between 68-75%; the appraisal concluded that there was no evidence of displacement
- the overall monetary impact of BBL support during the 2009-2011 period (comprising GVA realised from increased sales and the total value of the cost savings incurred was between £326k-£360k, equating to a return on investment of between £1.63 and £1.80 for every pound of Invest NI funding.

3.6 The economic appraisal considered three options for the delivery of the project:

- Option 1: do nothing
- Option 2: delivering the project as per BBL's business case with the proposed level of funding (£199,998); this would realise just over £517,000 in monetary (GVA) benefits resulting in a return of 1:2.6 for Invest NI's investment and generate a Net Present Value of up to £123,315
- Option 3: delivering the first year of the project only at a reduced level of Invest NI funding (£99,999) which would realise £282,000 of GVA benefits, resulting in a higher GVA return on investment for Invest NI (1:2.8) and a lower NPV of up to £88,310.

3.7 The appraisal identified five non-monetary criteria against which the options were also assessed: innovation, knowledge transfer, skills development, University-industry linkages and creating/safeguarding high quality jobs. The appraisal recommended that Invest NI proceed with Option 2 as this realised the highest level of monetary/non-monetary benefits and made the greatest contribution to Invest NI's strategic aims/objectives.

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<sup>11</sup> BioBusiness Ltd Business Case Economic Appraisal, Cogent Management Consulting LLP for Invest NI, August 2011

## Casework and approvals

- 3.8 Building on the outcomes of the economic appraisal, Invest NI prepared a casework submission<sup>12</sup> for consideration by the agency's Managing Director on 1 September 2011. The project fell within the parameters for delegated approval by the Managing Director. The casework submission notes that the project was not subject to competitive tender *"the (BBL) business case has been the subject of an economic appraisal. Therefore a competitive tender has not been used. This approach has been confirmed as reasonable by the Invest NI Finance Team."*
- 3.9 The casework submission reviewed BBL's financial operating model, noting that the network had, to date, operated *"basically on a breakeven basis with costs generally equating to income."* This is considered further overleaf.
- 3.10 The submission benchmarked BBL against a number of comparator LHS networks, including Nexxus (Scotland) and Momentum (the network for the ICT/software sector in Northern Ireland). The benchmarking exercise concluded that BBL provided more direct, 'hands on' business support to members than Nexxus. The casework submission considers a number of risks to the successful delivery of the project, including
- lack of commitment from Board members and BBL's Regulatory and Clinical Advisors others to provide 'in kind' or 'pro bono' contributions; this would be monitored by Invest NI on a quarterly basis
  - reductions in the availability of core staff resources, including the CEO and Chair
  - inadequate corporate governance procedures; the submission refers to the outcomes of a recent external EDO inspection which highlighted a number of issues (considered later in section 3) and proposed that these should be rectified by BBL before Invest NI provided funding.
- 3.11 The submission noted that the economic appraisal concluded that the project *"broadly provided Invest NI with value for money"* on the basis of GVA return on investment, non-monetary benefits to businesses and contribution to DETI Public Service Agreements. It also cited the findings of the economic appraisal in relation to the high level of additionality associated with BBL activity. The casework submission noted that *"there are no other organisations that provide the same range of support/activities that are offered by BioBusiness"* and that, in the absence of the network, market failure (and in particular asymmetric information) would be a key factor limiting business engagement in the type of activity delivered by BBL.
- 3.12 The submission concludes that *"the Client Manager believes that the proposed funding is key to ensuring that BioBusiness can continue to support the Northern Ireland life sciences sector."* The submission recommended approval of Invest NI funding support totalling £199,998 over a two year period commencing in August 2011. It also set out a number of pre-conditions for drawing down grant expenditure, considered further below and overleaf.
- 3.13 Invest NI's Managing Director raised a number of issues at the casework meeting on 1 September 2011. These included whether the programme provided value for money, including the per diem rate for the BBL Chairman; questions regarding the deadweight/additionality and displacement assumptions made in the economic appraisal; risks identified in KPMG's EDO audit (see overleaf) and the potential to leverage additional private sector funding for the network.
- 3.14 The Managing Director's approval was dated 26<sup>th</sup> September 2011. The approval allowed BBL to claim against eligible expenditure incurred from 1 August 2011.

## Financial Assistance letter

- 3.15 Invest NI issued BBL with a letter confirming the award of operating support grant for the project on 6 October 2011, subject to a number of terms and conditions. These required BBL to
- use its best endeavours to maintain the support of the LHS sector
  - provide quarterly progress reports on performance against targets (see overleaf) and costs

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<sup>12</sup> EDO Submission to Managing Director on behalf of BioBusiness Ltd, Invest NI August 2011

- provide an estimate of forecast expenditure alongside each quarterly grant claim
- secure Invest NI's prior written consent before incurring any additional costs
- provide a detailed written proposal/business case by the end of April 2013 should BBL seek funding support for the period beyond 31 July 2013
- provide details of service level agreements between BBL and its Chief Executive, Chairman, Administrator and the Centre for Competitiveness
- consult with Invest NI on an ongoing basis in relation to the corporate governance safeguards in place for the project.

3.16 The letter made provision for a quarterly review of BBL's performance against KPIs and for grant payments to be suspended or terminated if "*sufficient progress has not been or is not being made against KPIs.*"

#### **Delivery, governance and management arrangements**

3.17 Building on the approach adopted in previous years, BBL delivered the project through a combination of sub-contracted staff under service level agreements, in-kind contributions from the Chairman and other Board members and pro-bono contributions from two specialist advisors on regulatory compliance and quality management issues. BBL does not have any employees as a result of the risks and liabilities associated with employing staff relative to the size of the organisation.

3.18 Based on the day rates set out in Invest NI's casework submission and the eligible annual costs identified in the Financial Assistance letter, it was anticipated that BBL staff would deliver the following annual time inputs against the contract:

- Chief Executive: 150 days (equivalent to 12.5 days per month)
- Chairman: 28.8 days (this includes 14.4 days of paid input and a further 14.4 days of in-kind support)
- Administrator: 125 days.

3.19 BBL's delivery model is strongly dependent on in-kind support by Board members, most notably from the Chairman. During 2 quarters of the project (year 1 quarter 4 and year 2 quarter 1) BBL identified almost £35,000 on in-kind (i.e. non-funded) support provided by the Board and project team. The project is also heavily reliant on pro-bono support from two business support consultants advising on regulatory compliance, quality management and clinical trial support. One of the KPIs for the project – target 8 (see overleaf) – is entirely dependent on pro-bono support.

3.20 Responsibility for the day-to-day management of the project has been held by three different client executives within Invest NI's Life Sciences and Creative Division since August 2011. We also understand that the quarterly review meetings between Invest NI and BBL have been held infrequently in recent months although these have now been reinstated.

3.21 In February 2012, KPMG completed an External Delivery Organisation inspection of BBL on behalf of Invest NI. The inspection found that BBL had "*limited risk management, control and governance arrangements in place.*" The report noted the absence of a formal tendering process in accord with public sector procurement guidance and a data protection/information management policy, and recommended that these should be put in place.

#### **Project outputs and performance indicators**

3.22 Invest NI established 16 targets against which BBL's performance would be monitored on a quarterly basis alongside its grant claims. These targets were an evolution of those previously agreed by Invest NI and BBL:

- the 2007-2009 programme included 24 output-based targets clustered around the themes of advocacy, sector support, collaboration, skills development and management.
- the 2009-2011 target framework included 16 targets, including measures to support the work of the MATRIX Life Sciences Horizon Panel (see section 2) and provide 56 days of assistance per annum to core members, equivalent to at least one day per member.

3.23 The target framework for 2011-2013 was largely (but not exclusively) based on the 2009-2011 framework. Table 3.2 overleaf summarises BBL's performance against the agreed targets between August 2011-July 2012 and from August 2012 to date:

**Table 3.2: BioBusiness: Performance against Invest NI targets**

Target	Performance year 1 (1 August 2011-31 July 2012)	Performance year 2 to date (1 August 2012- 31 December 2013)	Comment
1: Achieve cost savings/ monetary benefits for members of at least £300k p.a.	<ul style="list-style-type: none"> <li>£190,505</li> </ul>	<ul style="list-style-type: none"> <li>£92,400</li> </ul>	<ul style="list-style-type: none"> <li>Revised basis for calculation in agreement with Invest NI during yr 1 q3</li> <li>Did not achieve year 1 target; have achieved 30.8% of year 2 target after q2</li> <li>Quarterly reports don't identify 'in kind' input consistently</li> <li>Risk that year 2 target will not be achieved</li> </ul>
2: Core member representation to be at least 70% of the NI life science business community	<ul style="list-style-type: none"> <li>34 core members</li> </ul>	<ul style="list-style-type: none"> <li>34 core members</li> </ul>	<ul style="list-style-type: none"> <li>2011 casework assumes 50 LHS firms in NI – but Invest NI data indicates between 50 -70 firms engaged in some LHS activity.</li> <li>assuming 50 members, failed to achieve year 1 target by 1 member; however, 3 firms identified as members by BBL may have ceased trading or no longer be members</li> <li>Risk that target of 34 members will not be achieved</li> </ul>
3: Broker 2 research links p.a. between core members and the academic community	<ul style="list-style-type: none"> <li>Brokered links between Future Healthcare NI, CIGA Healthcare and Belfast Met College</li> <li>Ongoing development of new product support programme with BMC</li> </ul>	<ul style="list-style-type: none"> <li>Brokered links between Heartsine and Belfast Met College and ongoing development of new programme with BMC that could engage with several members</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> <li>Achieved 50% of year 2 target to date</li> <li>Strong focus on links with Belfast Metropolitan College rather than with LHS research-based Universities</li> </ul>
4: Broker 2 clinical links p.a. between core members and the clinical community	<ul style="list-style-type: none"> <li>Brokered link between Heartsine and University Hospital Galway</li> <li>Brokered link between Future Healthcare NU and HSC Innovations</li> </ul>	<ul style="list-style-type: none"> <li>No activity claimed by end q2</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> <li>Some risk that year 2 target may not be achieved</li> </ul>
5: Support development of one new product p.a. by core member	<ul style="list-style-type: none"> <li>Supported Intelesens V-Patch remote monitor – clinical trial commenced January 2013</li> </ul>	<ul style="list-style-type: none"> <li>Supported Intelesens V-Patch remote monitor – clinical trial commenced January 2013</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> <li>No specific companies identified for year 2 to date</li> <li>Some risk that year 2 target may not be achieved</li> </ul>
6: Support one core member p.a. to achieve funding from external sources for product development	<ul style="list-style-type: none"> <li>Supporting Future Healthcare NI to achieve funding from NISPO and NISP Connect 25k awards</li> </ul>	<ul style="list-style-type: none"> <li>Judging and supporting companies in NISP Connect 25k awards</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> <li>No specific companies identified for year 2 to date</li> </ul>
7: Support 2 commercial opportunities p.a. between core members and NISP Connect	<ul style="list-style-type: none"> <li>Future Healthcare pitched to NISP Connect VC network</li> <li>Almac Discovery to pitch to NISP Connect in Sept 2012</li> </ul>	<ul style="list-style-type: none"> <li>Provided mentoring support to four individuals in collaboration with New Horizons Global</li> </ul>	<ul style="list-style-type: none"> <li>Only 1 firm pitched to NISP Connect in year 1 although second firm pitched during 2012/13</li> <li>No firms pitched to NISP Connect in year 2 to date</li> <li>Some risk that year 2 target may not be achieved</li> </ul>
8: Provide 24 days of support p.a. to core members for regulatory and quality management systems	<ul style="list-style-type: none"> <li>Delivered 27 days support to 8 firms</li> </ul>	<ul style="list-style-type: none"> <li>Delivered 17 days support to date</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> <li>Likely to achieve year 2 target</li> </ul>

Target	Performance year 1 (1 August 2011- 31 July 2012)	Performance year 2 to date (1 August 2012- 31 December 2013)	Comment
9: Provide support to one core member for one clinical trial p.a. (separate to target 8)	<ul style="list-style-type: none"> <li>Supported 2 clinical trials (Intelesens, Future Healthcare NI) totalling 31 days input</li> </ul>	<ul style="list-style-type: none"> <li>Supported Intelesens V-Patch remote monitor – clinical trial commenced January 2013</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target (Future Healthcare NI)</li> <li>Achieved year 2 target (Intelesens)</li> </ul>
10: Provide assistance to core members of – on average -2 days p.a. to each core member (separate to target 8/9)	<ul style="list-style-type: none"> <li>delivered 60 days support for 20 members, including 9.5 days for McElwaine Smart, 7 days Intelesens, 6 days Heartsine and 5 days Pharmacell</li> </ul>	<ul style="list-style-type: none"> <li>delivered 25 days support for 25 members including 3 days for Intelesens and 2 days each for 8 member firms</li> </ul>	<ul style="list-style-type: none"> <li>did not achieve year 1 target which would have required delivery of 68 days at average of 2 days per member</li> <li>achieved 36.8% of year 2 target after quarter 2</li> <li>Some risk that year 2 target may not be achieved</li> </ul>
11: Provide 5 case studies p.a. for core members (10 case studies over 2 years, must relate to different members)	<ul style="list-style-type: none"> <li>Prepared case studies for Pharmacell, Armstrong Medical, CIGA Healthcare, Labceutics/ Diaceutics and Naturelle</li> </ul>	<ul style="list-style-type: none"> <li>Prepared case studies for Intelesens and I-Innovations</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> <li>Achieved 40% of year 2 target after quarter 2</li> </ul>
12: Leverage a minimum of £100k in respect of a new project or programme over the next 2 years (excluding INI funding)	<ul style="list-style-type: none"> <li>Part of consortium delivering Supply Chain Initiative under Interreg IVa programme worth £51k p.a. to BBL</li> </ul>	<ul style="list-style-type: none"> <li>Programme commenced October 2012, launched February 2013</li> </ul>	<ul style="list-style-type: none"> <li>Achieved target</li> </ul>
13: Deliver 4 events p.a. either solely or in partnership	<ul style="list-style-type: none"> <li>Delivered 4 events in 2011/12 – 1 independently and 3 in partnership with NISP Connect, Dundalk Institute of Technology and Belfast Metropolitan College</li> </ul>	<ul style="list-style-type: none"> <li>Delivered 3 events to date in partnership with Opal Events USA, NISP Connect and HSC Innovations</li> </ul>	<ul style="list-style-type: none"> <li>Achieved year 1 target</li> </ul>
14: Promote core members in literature and on BioBusiness website	<ul style="list-style-type: none"> <li>Ongoing activity including eBulletins, BBL website and social media</li> </ul>	<ul style="list-style-type: none"> <li>Ongoing activity including eBulletins, BBL website and social media</li> </ul>	<ul style="list-style-type: none"> <li>Achieved target through ongoing activity. Target not SMART as no means of quantifying or measuring quality</li> </ul>
15: Promote and advance NI life sciences skill development	<ul style="list-style-type: none"> <li>Representation on STEM Implementation Group and National Skills Academy and through workshops to support curriculum development</li> </ul>	<ul style="list-style-type: none"> <li>Implemented MOU with Belfast Met College</li> <li>Representation on STEM Implementation Group and National Skills Academy and through workshops to support curriculum development</li> </ul>	<ul style="list-style-type: none"> <li>Achieved target through ongoing activity. Target not SMART as no means of quantifying or measuring quality</li> </ul>
16: Achieve a minimum 80% core satisfaction rating for the period 1.8.11-31.7.13	<ul style="list-style-type: none"> <li>Not independently validated by BBL – awaiting interim and final evaluation</li> </ul>	<ul style="list-style-type: none"> <li>Not independently validated by BBL – awaiting interim and final evaluation</li> </ul>	<ul style="list-style-type: none"> <li>Not independently validated by BBL – awaiting interim and final evaluation</li> </ul>

## 3.24 Analysis of BBL's delivery against its KPIs highlights the following issues:

- although it has substantially achieved its targets for the provision of business support/advice to members (particularly in relation to targets 8 and 10), based on its own reporting, BBL has struggled to translate this activity into quantifiable business benefits (e.g. cost savings/increased turnover); the network failed to achieve its annual target (£300,000) for such benefits in year 1 and, by the end of the second quarter of 2012, was almost £60,000 behind its mid-year target for cost savings/monetary benefits
- the number of 'core' Northern Ireland-based, business members of the network has remained constant at 34 since August 2011 although there is some uncertainty around whether 3 businesses included on BBL's membership list remain members or are still trading; it is also difficult to establish whether Invest NI's target of achieving representation of 70% of the LHS sector has been achieved as Invest NI does not appear to hold a definitive list of LHS sector companies upon which this could be based
- in building links between members and the academic research community, BBL has focused on developing a relationship with Belfast Metropolitan College rather than, or at least as well as, with the research-based Higher Education Institutions of Queens University Belfast and the University of Ulster; although there are established research links between the two Northern Ireland Universities and the large firms (Almac/Norbrook/Randox) there would appear to be much less engagement with SMEs/microbusinesses
- similarly, via its informal Clinicians Network, BBL has focused primarily on developing links with clinicians/institutions based in the Republic of Ireland; we explore this further in section 4
- BBL's approach to delivering its events programme has been to develop collaborative partnerships with NISP Connect, Belfast Metropolitan College and other partners; BBL considers that it does not have the dedicated resource to deliver large scale events in its own right and whilst this is almost certainly the case, this also impacts on the network's ability to develop an events-based income stream
- some of the targets are not SMART, with no real basis for either quantitative or qualitative measurement (targets 14 and 15) or for ongoing measurement during the delivery of the programme (target 16).

### Financial model

3.25 Table 3.3 below presents a high level summary of BBL's sources of income and profit and loss position based on its published annual reports published in March 2010, 2011 and 2012 respectively:

**Table 3.3: BioBusiness profit and loss**

	2009/2010	2010/2011	2011/2012	Change 2010-2012
Turnover (details below)	£234,046	£291,159	£188,292	(£45,754)
<i>Membership subscriptions</i>	£11,971	£11,186	£17,198	£5,227
<i>Conferences/seminars</i>	£2,090	£16,358	£2,776	£686
<i>Consultancy</i>	£2,000	0	£1,552	(£848)
<i>Invest NI</i>	£184,219	£186,875	£84,680	(£99,539)
<i>Intertrade Ireland</i>	£22,930	£72,971	£82,753	£59,823
<i>Enterprise Ireland</i>	£10,836	£3,859	(£667)	(£10,169)
Direct costs	£24,511	0	0	(£24,511)
Gross profit	£209,535	£291,159	£188,292	(£21,243)
Operating expenses	(£209,937)	(£289,571)	(£181,911)	(£28,026)
Profit/loss before taxation	(£402)	£1,591	£6,383	£6,785

- 3.26 Our analysis shows that BBL's income fell sharply between the 2010/11 and 2011/12 financial years as a result of a steep decline in income from programme management fees from Invest NI. In earlier years more than half of BBL's income was generated through programme management fees for additional activity outwith the core Invest NI contract (£218,000 in 2010, including £184,000 from Invest NI for the delivery of Collaborative Network programmes). Although the 2012/13 annual report is not yet available, this is likely to demonstrate a further fall in programme management income as BBL is currently involved in delivering only one 'external' contract – the Interreg IVa programme – in addition to its core Invest NI-funded activity.
- 3.27 Income from member subscriptions rose significantly during 2011/12 as a result of the increase in membership fees and BBL's decision to open up membership to organisations in the ROI, although they accounted for only 9.1% of income that year. Table 3.4 below details current membership fees:

**Table 3.4: BioBusiness membership fees**

Band	Employees	Annual Fee
1	1-5	£150 + VAT
2	6-25	£250 + VAT
3	26-50	£450 + VAT
4	51-251	£750 + VAT
5	250 +	£2,000 + VAT

- 3.28 Although events income increased significantly in 2010/11 to £16,358, it fell back sharply again in 2011/12. Events are not regarded as a key income stream by BBL as a result of the significant costs involved in delivering such activity.
- 3.29 Invest NI's operating support grant has not increased since August 2007, when it was set at the current figure of just under £100,000 per annum. BBL, in its June 2011 business case in support of the current programme, had sought to increase the CEO's per diem rate from £350 to £500 per day but Invest NI's casework submission notes that "*the (Invest NI) client manager had advised...that she could not recommend an increase.*"

### Project budget and expenditure

- 3.30 Table 3.5 below presents an analysis of annual expenditure against the agreed budget for the project:

**Table 3.5: Project budget and expenditure**

Item	2011/12 budget £	2011/12 expenditure £	Variance against budget £	2012/13 budget £	2012/13 expenditure to date £	Variance against budget
CEO costs	52,500	52,425	(75)	52,500	26,250	-
Chairman	11,520	11,520	0	11,520	5,760	-
Finance	13,300	12,915	(385)	13,300	5,630	(1,020)
Administration	12,500	12,288	(212)	12,500	6,144	(106)
Hosting	5,400	6,646	1246	5,400	4,349	1649
Travel	4,779	3,909	(870)	4,779	2,867	477
Total	99,999	99,703	(296)	99,999	51,001	1002

\*note BBL is de-registered for VAT purposes

- 3.31 The project achieved a slight underspend (-£296, or 0.3%) against its year 1 budget. Hosting costs were significantly higher than forecast (+23%) although these were offset by savings against travel and other budget headings. The interim position for year 2 (for the period to the end of January 2013) shows an overspend of just over £1,000 against the mid-year budget forecast of £50,000. Hosting and travel costs are both higher than forecast but these are offset against savings in finance costs.

## 4. STAKEHOLDER CONSULTATION

4.1 As part of the evaluation process Urbis undertook both face to face and telephone interviews with key stakeholders including

- Invest NI Client Executives with responsibility for management of the project during its development and delivery phases
- BBL's Chairman, Chief Executive, project manager and three other Board members
- other key stakeholders/partners from the University of Ulster, Queens University Belfast, QUBIS, HSC Research and Development, HSC Innovations, NISP Connect, Belfast Metropolitan College, InterTradelreland and the Association of British Pharmaceutical Industries.

### Context – the LHS sector in Northern Ireland

- 4.2 There was a considerable degree of stakeholder consensus on the current state of the LHS sector in Northern Ireland and the extent to which this impacted on the operation of the BioBusiness network. Stakeholders acknowledged the international success achieved by the limited number of 'home grown' indigenous firms which dominate the LHS landscape in Northern Ireland – most notably Almac, Randox, Norbrook and Warner Chilcott, which evolved from Galen, another NI firm. There were very few examples of UK-owned firms that had achieved this level of growth.
- 4.3 Despite the recent growth of Northern Ireland's larger firms (some of which has taken place outside Northern Ireland) most stakeholders considered that the LHS sector remained both imbalanced and embryonic and as yet had failed to realise its potential. Whilst Northern Ireland had some acknowledged strengths (e.g. in clinical trials, medical devices), the large firms were mainly operating in niche markets (e.g. veterinary medicine) and had limited interaction with each other or with a Northern Ireland-based supply chain. Northern Ireland does not have a significant pharmaceutical sector presence (in UK terms this is concentrated in the South East of England) and most stakeholders considered that this scenario was unlikely to change in the foreseeable future.
- 4.4 There was only limited evidence of convergence of technologies (e.g. in the biologics space) and collaboration. In this sense, most of the LHS sub-sectors in Northern Ireland had comparatively little depth or breadth and there was no real evidence of the operation of either vertically or horizontally-integrated clusters of activity.
- 4.5 Some firms had developed R&D links with Northern Ireland Universities (e.g. Almac/QUB) but commercially-oriented research tended to be supported by global pharmaceutical companies or other multinational businesses outside Northern Ireland. For example, much of the University of Ulster's intellectual property in biomedical sciences is commercialised in France, rather than the UK and in the LHS space, QUB has a strong focus on licensing rather than spin outs as the costs and risks are perceived to be particularly high. Most stakeholders considered that the Universities had comparatively limited links with Northern Ireland's base of microbusinesses/SMEs in the LHS sector and that there was a need for both larger firms and SMEs to play a stronger role in driving early stage research activity.
- 4.6 Although there were some examples of mid-sized SMEs (e.g. Armstrong Medical, James Leckey Design) that had grown from the start-up stage and a few high profile examples of University spin outs (e.g. Fusion Antibodies, Almac Diagnostics), there had been very few examples of high growth start-ups or more mature SMEs experiencing growth in Northern Ireland. Access to substantial equity/venture capital investment and Northern Ireland's relative peripherality from the centre of UK venture capital activity was a key constraint; the lack of 'exits' from earlier NI LHS start-ups was a further barrier to investment.
- 4.7 Most stakeholders highlighted the importance of focusing future support for the sector on start-up/SME growth activity, whilst emphasising the need for Invest NI and other stakeholders to establish a robust ladder of support or 'eco-system' which addressed current gaps in provision. We address this further in subsequent paragraphs.



- 4.8 Stakeholders also pointed to the challenges associated with developing and diffusing innovation across the HSC, in driving up research activity across the organisation and in commercialising the IP developed by clinicians. These challenges were common across much of the NHS in the rest of the UK. Some of the barriers included limited incentives for clinicians to commercialise IP within the framework of the HSC and difficulties in securing funding to ‘back fill’ clinician’s work in the NHS/private sector to free-up time for research activity.
- 4.9 Whilst there are benefits in the scale and integrated nature of the HSC in Northern Ireland, some stakeholders considered that this did not necessarily translate into a more research-oriented environment. Several stakeholders highlighted the need for a significant increase in the amount of pre-clinical research activity undertaken by both academic and clinical research institutions in order to generate more clinical trials and commercialisation opportunities. Others pointed to the need for a clear framework to drive innovation across the HSC, potentially similar to the ‘Innovation, Health and Wealth’ strategy and delivery framework developed by the NHS in England.

#### Strategic framework for LHS sector

- 4.10 The majority of stakeholders considered that Northern Ireland’s LHS sector lacked a strategic framework to establish clear priorities for action and coordinate the actions of the public and private sector. Several stakeholders considered that the catalytic opportunity created by the MATRIX report (published in 2008) had not been capitalised upon and the priorities set out in that report had not been operationalised. This could have contributed to the comparatively ‘uneven’ growth of the sector in Northern Ireland over the last five years.
- 4.11 It was acknowledged that neither Invest NI nor BBL had filled the strategic vacuum for the sector which resulted from the perceived failure to capitalise on the work of the MATRIX panel. As a consequence, interventions by Invest NI and others tended to be very project-focused rather than reflect a more strategic approach. Moving forward, several stakeholders highlighted the need to establish a high-level forum, comprising key public and private sector interests, to create a long-term strategy for the LHS sector and oversee its delivery.
- 4.12 Stakeholders also considered the support available to LHS sector businesses in Northern Ireland and identified a number of gaps in the support eco-system, although they did not infer that BBL could or should play a key role in addressing all of them. The gaps in provision included:
- incubator facilities – there were no sector-specific business incubators available for LHS firms in Northern Ireland with clean rooms or other high specification laboratory facilities; neither of the Universities provided accommodation of this type nor was this available at the Northern Ireland Science Park or the Clinical Translational Research and Innovation Centre (C-TRIC) at Derry/Londonderry and some stakeholders considered this to be a precursor to efforts to enhance both the quantity and quality of start ups in the sector
  - improving the alignment of the academic research of Northern Ireland’s Universities with the business needs of LHS firms, and in particular SMEs
  - increasing access to finance for seed stage businesses with growth potential and more mature firms; levels of venture capital investment in Northern Ireland are comparatively low and the public sector venture funds which are available through Invest NI’s access to finance strategy may be insufficient to meet the long-term needs of the sector, particularly where lengthy clinical trials and regulatory compliance processes are in place
  - foreign direct investment; we consider FDI in more detail in subsequent paragraphs.

#### Market failure rationale for the project

- 4.13 The majority of stakeholders considered that the market failure rationale for the project – essentially based on asymmetric information and the limited knowledge held by academics, businesses and clinicians about other key players in the commercialisation process – was still firmly in place. Several cited the fragmented nature of the LHS sector prior to the establishment of BioBusiness in 2004 and pointed to improved networking within and between key stakeholder groups whilst acknowledging that further improvement was still required.

- 4.14 Although some specialist business support was available for LHS firms (for example around regulatory compliance issues or access to finance) stakeholders recognised that there were no other organisations operating in Northern Ireland with BBL's objectives of encouraging collaboration and brokering links between academics, businesses and clinicians. Nonetheless, several stakeholders considered that the economic value of such activity was often unclear or difficult to measure in conventional terms.

### Strategic direction of BioBusiness

- 4.15 Several stakeholders commented that BBL appeared to have lost some of its strategic focus or direction, citing a number of reasons for this. Some highlighted the network's difficulties in operating in what they perceived to be a policy vacuum; others suggested that the target framework agreed by Invest NI and BBL (iterated, as we demonstrate in section 3, over a series of funding rounds) was overly complex and could create conflicting priorities for the organisation. Some stakeholders suggested that BBL faced an inherent tension in operating as both a member-led trade organisation and as a public sector-funded economic development body charged with delivering wider economic benefits; this was reinforced by the imbalance in BBL's funding between member subscriptions and Invest NI support. We revisit BBL's target framework in subsequent paragraphs.
- 4.16 BBL staff and Board members emphasised the importance of the network's brokering and enabling role, bringing together actors from different parts of the LHS sector, alongside BBL's specialist business support activity (with a particular focus on BBL's knowledge of regulatory issues and the clinical trials process) and new areas of focus including supporting 'lean' start ups and developing supply chain competitiveness. The Board saw these as key areas of activity for BBL moving forward.
- 4.17 Some stakeholders considered that whilst BBL had developed an effective role as a bottom-up 'enabling' body (through its efforts to promote collaboration within and beyond the sector) it had played an increasingly less prominent role as a lobbying organisation, representing the interests of the sector in engagement with Government and other key groups. BBL still played this representative role around aspects of the skills agenda.
- 4.18 A number of stakeholders felt that, moving forward, BBL should strengthen its lobbying activity and act as a catalyst to bring together key public/private sector stakeholders to create a strategic focus on key barriers to growth of the LHS sector – for example in driving up clinical research and diffusing innovation across the HSC. However, most recognised that any attempt to broaden or diversify the network's role would require the level of resources made available to BBL to be re-evaluated.
- 4.19 Other stakeholders acknowledged that BioBusiness members could have quite different support needs, with micro-businesses and SMEs lacking in capacity or expertise and more likely to utilise BBL's enabling/facilitative role more than the sector's key players. As a consequence, stakeholders perceived that the majority of BBL's services for members were focused on the needs of smaller businesses. Others argued, however, that the larger LHS firms still needed to be 'embedded' in the local economy to engage more effectively with the Northern Ireland supply chain, and that BBL should play a role in facilitating this; moving forward, this could include facilitating collaborative bids to the Technology Strategy Board or the post 2014 replacement for the EU's Seventh Framework research programme (FP7).
- 4.20 Some stakeholders questioned how BBL staff prioritised the needs of different members in the face of conflicting demands on their time. One of Invest NI's targets required BBL to deliver at least two days of support for each member, over and above activities in support of other targets; in some circumstances BBL delivered a much higher level of support than the '2 day assist' inferred by the target, particularly where the business lacked capacity to address key issues (e.g. the clinical trial process) without additional support.
- 4.21 Although this was less pronounced in 2012/13, in the previous financial year four members had received more than five days of BBL support for their membership fee. As a member-led organisation, this created a dilemma for BBL who wished to respond positively to members support needs. BBL expressed a degree of frustration in relation to what they perceived to be their inability to develop a deeper and more strategic understanding of the needs of all of their members and to tailor support accordingly. The Interreg IVa programme would afford some opportunity to address this.

- 4.22 BBL's Board members highlighted that the organisation's future direction had been an important focus of the Board's deliberations over several months. This had included considering a number of different funding scenarios.

### Outcomes of brokering/enabling activity

- 4.23 As highlighted overleaf, several stakeholders questioned whether BBL's brokerage of links between academics, businesses and clinicians or other networking activity had delivered tangible economic benefits, particularly as product or service innovations in the LHS sector tended to have particularly long lead-in times. BBL pointed to a number of new products – at least 10 - which had been introduced to the market or reached an advanced stage of development in which they had played a key role, including
- a Cryotherapy Device and Treatment for Equine and Human Health
  - an Asthma/COPD Measurement and Monitoring Device with Remote Monitoring
  - a Remote Compliance Assessment and Tracking solution for the Healthcare Sector
  - a Wireless Atrial Fibrillation (AF) Stroke Screening Device
  - a Reminiscence Therapy Device and Web-based Solution
  - an Automated Thrombolysis System for Hospital Use.
- 4.24 BBL had supported Belfast-based firm Intelesens to develop a new AF Stroke Screening product. The process involved brokering links with ROI-based clinicians, who provided early market feedback on Intelesens existing device and created the opportunity to develop a specific optimised device for screening AF over 5 days. BBL subsequently developed the clinical investigation documentation and set up the clinical trial for the product, recruiting all of the key stakeholders.
- 4.25 Whilst acknowledging the difficulties associated with confidentiality and other issues during the pre-market phase of new product development, some stakeholders considered that BBL should articulate its role and contribution towards new product development more effectively.

### Clinicians Network

- 4.26 Most new products developed with support from BBL had benefited from early access to and market feedback from clinicians. BBL developed its informal Clinicians Network to facilitate such access and provide support on clinical trials and other network activity. Through the network, BBL has provided a route to market for IP developed by partner clinicians.
- 4.27 The network evolved from the 'ABC Collaborations' research and network programme which was subsequently supported by InterTradelreland. BBL acknowledges that the network has a greater representation of clinicians from the Republic of Ireland (including, for example, from Beacon Hospital Dublin, which is operated by the University of Pittsburgh). BBL argue that this is primarily because of the barriers to innovation facing the HSC in Northern Ireland (paragraphs 4.8 and 4.9 refer) and as a result of what BBL perceive to be more flexible attitudes to IP held by institutions operating in the ROI.

### Pro-bono and in-kind support

- 4.28 Some stakeholders expressed concerns about the continuation of the current project delivery model which is predicated on significant pro-bono and in-kind support by specialist business consultants and the BBL Board. BBL's achievement of target 8 (which involves delivering pro-bono regulatory and quality management advice) appears wholly dependent on the willingness of the specialist consultants to provide free advice. Whilst both individuals clearly identified a commercial benefit to their organisations in supporting BBL in this way, this model was questioned for a number of reasons, including:
- the risks/liabilities to BBL associated with the provision of 'free advice' to businesses and whether this was reflected in contracts or service level agreements in place between BBL and the consultants
  - BBL's liabilities in relation to the Invest NI contract should its informal arrangements to deliver this part of the contract cease to operate

- the principle that the project should be funded by Invest NI on a full cost recovery basis without requiring BBL to utilise pro bono support.

4.29 Other stakeholders noted that BBL staff, the Chairman and other Board members provided a significant level of 'in kind' support to the project and that, in effect, this had become an essential part of BBL's delivery model to achieve the KPIs set by Invest NI. However, it was noted in section 3 that BBL's quarterly reports did not provide details of in kind support by the Board or staff members on a consistent basis.

### Key performance indicators

4.30 A number of stakeholders cited concerns around the perceived complexity and inflexibility of the framework of targets/key performance indicators agreed by BBL and Invest NI to manage the performance of the project. Some stakeholders argued that the number of the targets was disproportionate in relation to the scale of Invest NI funding received by BBL; others suggested that

- the targets required BBL to deliver activities which were too diverse and did not all contribute to the organisation's strategic objectives;
- BBL had become overly focused on achieving the KPIs and that this had contributed to the loss of strategic direction which some attributed to the organisation
- some of the KPIs were very difficult to achieve (target 1 was frequently cited in this respect), particularly as some of BBL's support was often delivered during the early stages of commercialisation activity some way in advance of the generation of tangible economic impacts
- some KPIs (for example target 10) were unrealistic in requiring BBL to deliver a limited degree of high level support to all of its members, irrespective of whether they had a clear demand for BBL's services; some stakeholders argued that BBL should have greater flexibility to meet the needs of members, including providing more in-depth support where this was required
- the level of administration required to evidence achievement of the targets, along with wider administrative requirements, appeared disproportionate to the size of the grant received from Invest NI.

### Republic of Ireland members

4.31 Although BBL's activities in the ROI are not an explicit focus of this evaluation, some BBL staff/Board members emphasised the increasing importance of an all-Ireland delivery model for BBL moving forward. Some of the benefits for BBL of working with ROI based clinicians and academic researchers have already been highlighted in section 4; BBL also cited the demand for 'bottom up' brokerage and business support from ROI firms as a clear gap in the market, and its complementarity with other networks. In particular, BBL saw a clear fit between its activities and those of networks like the Irish Medical Devices Association (IMDA), which focuses on lobbying and sector representation and has a membership base which reflects the stronger presence of large scale pharmaceutical and medical technology businesses in the ROI.

4.32 Whilst acknowledging that, in the current public sector funding climate, it was unlikely that economic development agencies in the ROI or with a cross-border remit would provide core funding to support BBL's activities, some stakeholders considered that there may be further opportunities for BBL in delivering specific collaboration or business support programmes on an all-Ireland basis.

### Foreign Direct Investment

4.33 Several stakeholders highlighted the potential for BBL – and in particular its member companies – to play a stronger role in Invest NI's efforts to attract foreign direct investment (FDI) within the LHS sector. Most acknowledged that, as a precursor, Invest NI should work with partners to establish a definitive Unique Selling Proposition for FDI purposes and that this should be based around Northern Ireland's niche strengths.

- 4.34 With this in place, BBL members could play a key ambassadorial role and utilise their networks to identify target businesses. Most stakeholders considered that it was highly unlikely that Northern Ireland could compete globally in the attraction of large scale pharmaceutical investments.

#### Future funding models

- 4.35 A number of stakeholders, including BBL staff and Board members, considered the future funding models open to the network. All highlighted the importance of securing continued core funding from Invest NI to sustain the delivery of what BBL considered to be non-commercial activities, including for example brokering 'ABC' links. Should Invest NI funding not be available in future, there was no obvious source of replacement funding for these activities.
- 4.36 Most stakeholders considered that BBL's ability to generate additional income from its members through annual subscriptions was particularly limited. Earlier increases in membership fees had resulted in a reduction of between 6-10 members (in particular a number of microbusinesses had not renewed their membership) and this had in effect countered the impact of the price increase. Whilst this suggests that membership fees for SMEs/microbusinesses may be particularly price sensitive, some stakeholders acknowledged that there may be some scope to increase fees for the handful of larger firms who are members of BBL.
- 4.37 Stakeholders considered that there was also limited scope to increase the number of Northern Ireland members of BBL; dependent on the definition of the sector, there are between 15-35 LHS businesses who are not members of the network and thus it is unlikely that BBL will achieve a significant increase in membership from Northern Irish firms. BBL has already secured around 17 members from the ROI since 2010 and there may be further scope to increase network membership from this source, although assuming membership fees remain at or around their current level, this is also unlikely to have a major impact on BBL's income. Nonetheless, moving forward, BBL is likely to have an increasing focus on the development of its ROI activities as it highlights a number of operational benefits for the network from increased engagement with ROI clinicians, academic researchers and businesses. On this basis, BBL may explore further opportunities for programme delivery and/or to develop other income streams in ROI or on an all-island basis.
- 4.38 BBL emphasised the importance of programme management as a key income stream, although constraints on public sector expenditure and a decline in cross-border collaboration initiatives had seen levels of activity decline in recent years. Moving forward, BBL staff/Board members saw programme management as a core income stream for the network, building on its ongoing Interreg IVa project, whilst acknowledging that attracting additional programme management funding from the major economic development agencies in Northern Ireland and the ROI was likely to prove challenging in the current climate.
- 4.39 Finally, a number of stakeholders considered the scope for BBL to increase the level of commercial income to fund the activities of the network. Most recognised the need to develop a more balanced mix of income streams moving forward and to reduce BBL's dependency on public sector core funding, although a number of factors were likely to impact on this:
- conferences and other events represented a potential income stream for BBL although the network currently lacked the resources required to organise its own events and did not have the financial reserves to underwrite large scale conferences, which could expose BBL to significant risk; as a consequence, most staff/Board members considered that its current model of partnership working was a more sustainable model whilst accepting that this would impact on future income streams
  - BBL had previously considered the potential to deliver low cost support for members in addition to the 'two day assist' currently offered to all members as part of the Invest NI contract; however, more than half of BBL's current members are microbusinesses or small SMEs and businesses in the pre-revenue or early growth stage may be unable to pay commercial rates for BBL support and BBL considered that the ability to provide low cost support/capacity via BBL membership was a key selling point for members of this type

- BBL staff and Board members highlight the importance of maintaining the network's independence/ neutrality in meeting the needs of its membership as a whole; some considered that this would be compromised if the network developed as a commercial entity with a focus on selling services in competition with other providers and did not want BBL to become 'just another consultancy'
- moving forward, BBL was considering the potential to deliver business support services on a part-subsidised basis, incorporating a mix of private sector funding alongside existing public sector funding programmes including Innovation Vouchers/R&D tax credits and, at least in the short-term, Invest NI's Proof of Concept programme; there was also potentially scope to consider longer-term sources of funding including the use of royalty payments or taking a modest equity stake in businesses supported by BBL to ensure that the network was able to share in the future profits generated through new products.

## 5 BENEFICIARY CONSULTATION

- 5.1 Urbis undertook an online survey of BioBusiness members to assess their views on the strengths and weaknesses of BBL, its impact on their business and the future support needs of the LHS sector in Northern Ireland. The findings are presented in section 5.

### Survey respondents

- 5.2 19 responses were received from a total of 36 BioBusiness members who were surveyed, including 32 core members and 4 non-core members. The survey was not circulated to three core members identified by BBL who were no longer trading or claimed that they were no longer a member and was not forwarded to non-core members who had been interviewed in their capacity as a Board member or key stakeholder. This represents a 52.7% response rate and equates to a confidence interval of +/-15.5% at the 95% confidence level.
- 5.3 The majority (10) of the 18 respondents who were prepared to identify themselves had received at least 2 days support from BBL since August 2011; 3 respondents had received between 6-10 days of support. By the same token, 8 respondents (including 3 non-core members) had not received any direct support from BBL. A total of 24 firms received a 'two day assist' from BBL from August 2011 to date. This suggests that a broadly similar number of beneficiaries and non-beneficiaries of direct BBL support participated in the survey and that this balance was also reflected in those firms who did not respond. On this basis, the overall effect of non-response bias is likely to be normal for a survey of this type.
- 5.4 All of the respondents were businesses. The majority of respondents were engaged in more than one area of LHS activity, with 8 businesses involved in medical devices and professional/business services respectively, 5 in medical software and 4 each in pharma/speciality chemicals and medical biotechnology/therapeutics. 3 firms were involved in clinical trials and 2 each in telehealth/telecare and general manufacturing.
- 5.5 10 respondents were microbusinesses, employing 10 or fewer staff; 8 respondents employed fewer than 4 people, emphasising the strong representation of microbusinesses across the network as a whole. 6 respondents were SMEs employing between 11-250 staff (although two-thirds of this group had fewer than 49 employees) and 3 employed more than 500 people. Two of the larger firms had some staff employed outside Northern Ireland.
- 5.6 The strong representation of microbusinesses within the sample was also reflected in respondent's most recent annual turnover. 2 respondents were not yet trading and a further 4 had a turnover of less than £99,999. 4 respondents had a turnover of between £100,000-£499,999; 3 respondents turnover was between £500,000 and £999,999. 5 respondents had an annual turnover in excess of £3,000,000.

### Reasons for membership of BioBusiness

- 5.7 9 respondents had been a member of BioBusiness for at least 4 years and a further 3 had held membership for at least three years. The remaining 7 respondents had been a member of BioBusiness for at least a year. This suggests that there is a comparatively high level of membership renewal whilst also emphasising that there are comparatively few new members joining the network – none of those surveyed had become members within the last year.
- 5.8 9 members had found out about the network through direct contact from BBL and a further 6 through word of mouth. 3 respondents had been referred to BBL via a professional and just 1 had joined the network as a result of engagement via the website. No respondents had found out about the network through press/media coverage. Whilst the high proportion of direct contact/word of mouth referrals via established networks is very positive this also suggests that BBL could further exploit its website and social media activity to widen its engagement, particularly with those businesses that are on the periphery of the LHS space.

5.9 BioBusiness members had joined the network for a diverse mix of reasons, most identifying 3 or 4 key reasons for becoming members; the most popular reasons included:

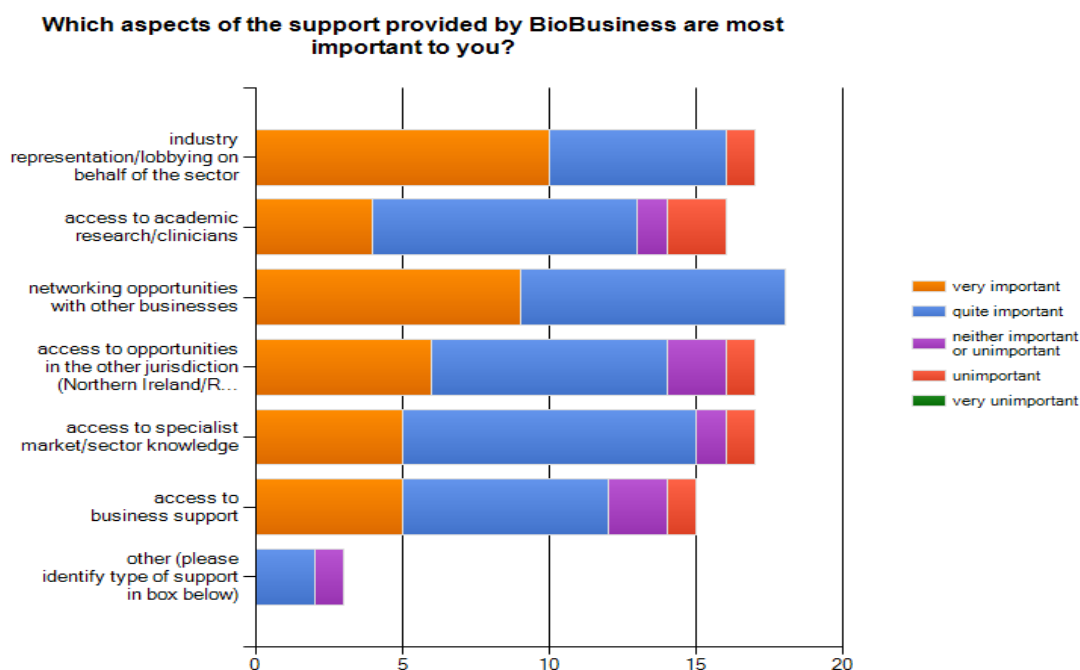
- networking opportunities with other businesses (15 respondents)
- industry representation/lobbying on behalf of the sector (13 respondents)
- access to opportunities in other jurisdiction (NI/ROI) (11 respondents)
- access to business support (10 respondents)
- access to academic research/clinicians (9 respondents)
- access to specialist market/sector knowledge (8 respondents).

5.10 A resounding 18 members (all but one of those responding to the survey) stated that they had fulfilled or achieved their original reason for joining BioBusiness. Only 1 had not, noting that *“personal restraints and a young family restricted networking opportunities.”*

### Value of BioBusiness activities

5.11 Most respondents had participated in between two and three BioBusiness activities. 12 respondents had participated in BBL conferences or seminars and 13 respondents had participated in ‘other networking events’. 8 respondents had participated in one to one business support and links with academics or clinicians; just 1 had participated in a BBL case study. This suggests that most respondents engaged with a comparatively wide range of BBL activity during the evaluation period.

**Figure 5.1: Value of BioBusiness support to members**



5.12 The majority of respondents highlighted two key services provided by BBL - industry representation/lobbying and networking opportunities with other businesses as being ‘very important’ to their business. These were given the highest priority by 10 and 9 respondents respectively. Three other activities – access to opportunities in the opposite jurisdiction, access to specialist market/sector knowledge and access to business support were of lesser importance than the top two activities. None of BBL’s activities were rated ‘very unimportant’ by members.

5.13 Perhaps the most significant finding in this part of the survey relates to the priority afforded by members to industry representation/lobbying. BBL had effectively reduced their role in this area in recent years to focus on brokering links and the provision of business support, although the survey suggests that members retain an appetite for BBL to strengthen this area of its support.



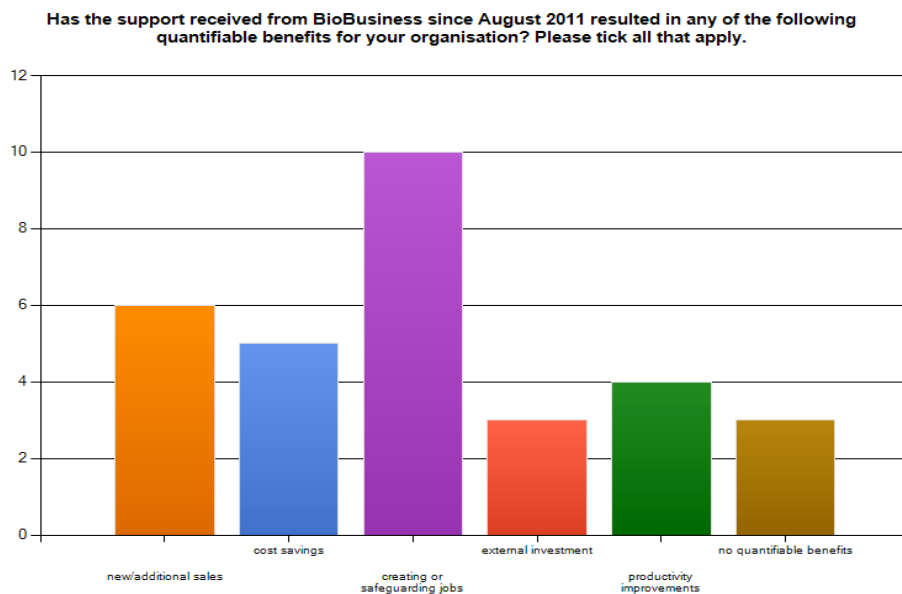
## Communication

- 5.14 11 respondents considered that BBL communicates ‘very effectively’ with its members and a further 5 thought that it communicated ‘effectively’. 2 respondents were neutral about the effectiveness of BBL’s communication. This appears to represent a significant improvement on the 2011 evaluation when 30% of respondents rated BBL’s communication as very effective ( $n=20$ ) and on the 2009 study when just 23% of respondents gave BBL the highest ranking ( $n=34$ ).

## Benefits and impacts

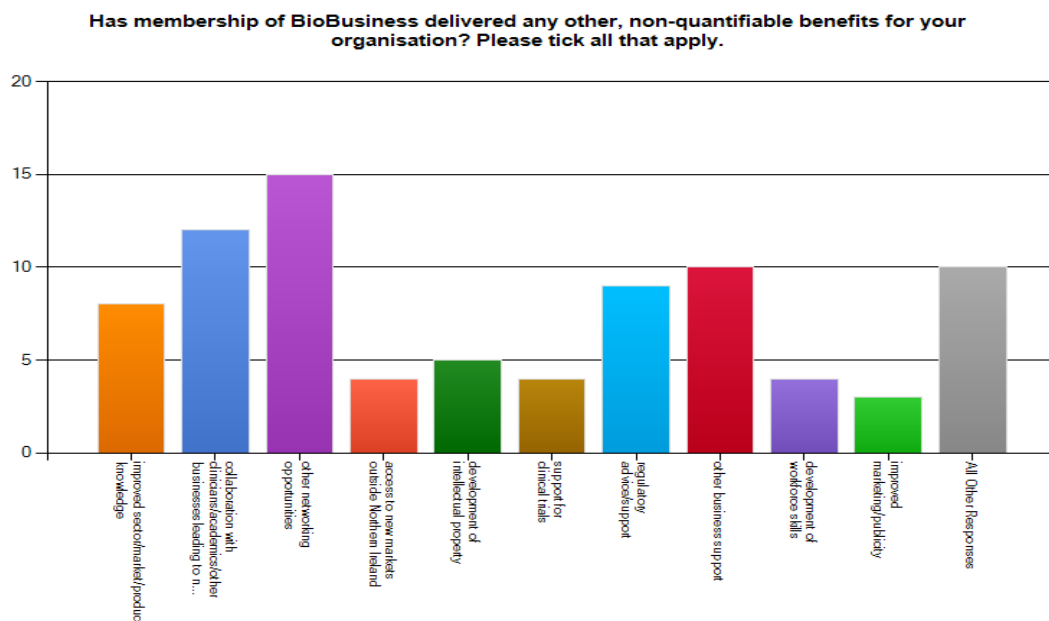
- 5.15 17 respondents had witnessed some form of positive and quantifiable economic benefit flowing to their business as a result of BBL support since August 2011. 10 respondents had created or safeguarded jobs as a result of BBL support and 6 had generated new/additional sales. Figure 5.2 presents further details:

**Figure 5.2: Quantifiable benefits of BioBusiness support**



- 5.16 Further details of the specific economic impacts of the network and their attribution by members to BBL are considered in section 6 of the report.

**Figure 5.3: Other non-quantifiable benefits of BioBusiness support**



- 5.17 Respondents also considered the non-quantifiable benefits realised as a result of their membership of BioBusiness. 16 of 19 respondents identified at least one non-quantifiable benefit to their business that had flowed from the programme. 15 respondents highlighted networking opportunities and 12 identified “collaboration with clinicians/academics or other businesses leading to new products or services” as benefits arising as a result of their membership of the BioBusiness network. 10 identified business support other than regulatory advice and 9 identified regulatory advice. The least cited benefits were ‘access to investors’ (identified by just 2 respondents) and ‘improved marketing and publicity’ which was identified by 3 respondents.

### Customer satisfaction

- 5.18 11 respondents were ‘very satisfied’ with the support provided by BBL since August 2011 and a further 5 were ‘satisfied’. Just 1 respondent was ‘neither satisfied or dissatisfied’ and no respondents were dissatisfied or very dissatisfied. 2 respondents did not answer this question.
- 5.19 The proportion of respondents (85%) who were very satisfied/satisfied with BBL is significantly higher than the satisfaction ratings achieved in the 2011 survey (65%,  $n=20$ ) and on a par with those achieved in 2009 (82%  $n=34$ ). Taking into account the confidence interval for the 2013 survey (+/- 15%) at the 95% confidence level it can be assumed that at least 70% of members are very satisfied/satisfied with BBL’s performance, which also represents a significant improvement on the 2011 evaluation results if the same confidence level/interval is applied.

### Value for money

- 5.20 17 respondents (100% of those who responded) considered that BioBusiness represented value for money, compared to 80% in 2011 ( $n=18$ ) and 82.4% in 2009 ( $n=34$ ). However, when respondents were asked whether their organisation would be prepared to pay higher membership fees or purchase additional services from an LHS sector network in the future, 9 responded positively but 8 stated that they would not pay additional fees or purchase further services. This suggests that for almost half of BioBusiness members, a further increase in rates could impact on their decision to remain a network member.

### Future of the network

- 5.21 8 respondents considered that the network could be improved and 8 felt that no improvements were required. Responses by the former group were diverse and included:

*“Perhaps more measured deliverables for start-up companies”*

*“By having more structure and individuals made available to follow through with further assistance for company development”*

*“More support/funding from government to increase number of Biobusiness staff. Better promotion of Biobusiness by government both nationally and internationally”*

*“More informal events”*

*“It may be possible to improve the business/academia networks and awareness within NI. This is a small community but there are internal NI win-wins that are not being fully grasped i.e. partnerships with external organisations where internal providers are available.”*

*By reaching out to more medical device companies cross border. By providing continued support in terms of funding, lobbying to promote clinical and pre-clinical studies*

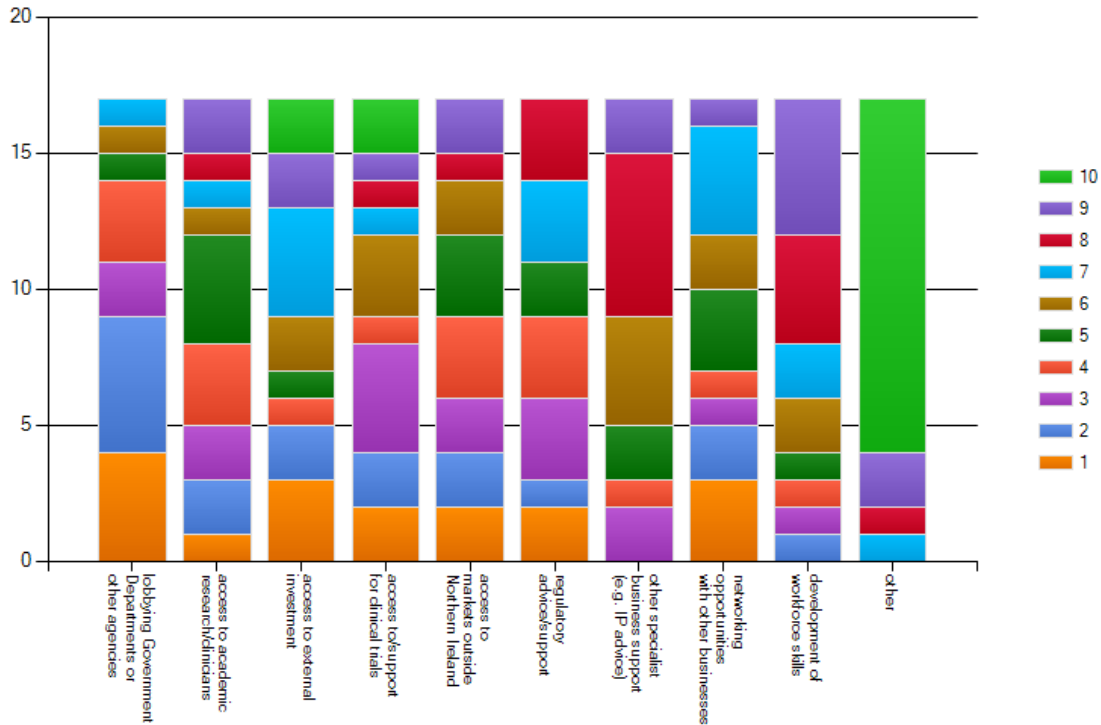
*“Play an increased role in sector promotion/lobbying and in strategic industry led initiatives.”*

- 5.22 Respondents highlighted a number of consistent themes for improvement including providing follow-on business support for members, the need for more promotion and lobbying for the sector and to secure additional resources for network activity.

5.23 Respondents were asked to rank future priorities for support for the LHS sector in Northern Ireland. The outcomes are summarised in figure 5.4 below:

**Figure 5.4: Future priorities for the LHS sector in Northern Ireland**

**From your organisation's perspective, what are the future priorities to support life and health sciences businesses in Northern Ireland? Please rank your responses where 1 is the most important and 10 the least important answer.**



5.24 9 respondents ranked ‘lobbying Government Departments or other agencies’ as priority 1 or 2; 5 respondents each ranked ‘networking opportunities with other businesses’ and ‘access to external investment’ as priority 1 or 2 whilst 4 respondents each prioritised ‘access to support for clinical trials’, ‘access to markets outside Northern Ireland’ and ‘regulatory advice/support.’ This suggests that whilst lobbying and sector representation is a clear priority for the sector moving forward, there is less consensus on other priorities.

5.25 17 responded positively to the question “should Invest NI continue to provide funding for a network for life and health sciences businesses in Northern Ireland?” Taking into account the confidence interval, this suggests that if this question was put to the BioBusiness membership as a whole between 85-100% of members would respond positively to this question.

5.26 Finally the survey asked respondents for any further comments on BioBusiness that had not been covered elsewhere in the questionnaire. 6 responses were received for this question, and included:

*“It is absolutely essential that BioBusiness is funded on an ongoing basis. There is a need to integrate the knowledge/expertise with Invest NI. BioBusiness must remain in place to help drive the sector so that NI reaps the benefits of job and wealth creation on similar magnitude to that experienced in Scotland and Republic of Ireland.”*

*“BBNI is our sector's only umbrella organisation and offers support in any way asked of it. Not only is BBNI a unique resource it also represents extraordinary value for money.”*

*“Biobusiness has the potential to add real value to the NI life science sector if it is properly funded and supported. Targets set by INI need to be realistic and the amount of auditing Biobusiness is asked to do to justify the very modest funding it receives has to be reduced as this is taking up a disproportionate amount of time and effort. “*

*The value multiplier Biobusiness has consistently achieved surpasses that of many other organisations and makes it a top performer in terms of added value and this should be capitalised on and Biobusiness's role expanded by government if they are serious about expanding and developing this very important sector within NI."*

*"Biobusiness provide a very valuable service - this is a key growth sector and we must be able to optimise our internal opportunities - and place ourselves to maximise exports. We need to reinforce our capabilities."*

*"The life sciences participate in globalized business, Biobusiness can assist in making the NI Assembly & Government aware of current issues. Currently Government is too parochial."*

## Conclusions

- 5.27 The survey of beneficiaries generated very positive feedback for the BioBusiness network, with a significant proportion of respondents being microbusinesses or small SMEs reflecting the broad composition of the network. Members particularly valued the lobbying, brokerage and business support activities delivered through the network and moving forward wished BBL to play a stronger role in representing the sector to Government and other key stakeholders.
- 5.28 The network has improved its customer satisfaction rating from recent independent evaluations and also scored highly on value for money. Over 80% of members had derived tangible economic benefits from their membership of the network since August 2011 and others had realised non-quantifiable benefits. 100% of respondents considered that Invest NI should continue to provide support for a network for LHS sector businesses in the future.

## 6 PROJECT IMPACTS

### Introduction

6.1 Section 6 considers the economic and other impacts of the project, including:

- achievement of project objectives and contribution to higher level objectives including DETI PSAs and the DETI/Invest NI Corporate Plans that were extant at the time of the project
- economic impacts and wider and regional benefits
- establishing the counterfactual or additionality arguments – what would have happened in the absence of the project, considering deadweight and displacement effects
- value for money
- equalities impacts.

### Achievement of objectives

#### Project level objectives

6.2 Invest NI's project casework did not explicitly identify any project level objectives for this initiative. However, we note that BBL's vision statement for the LHS sector in Northern Ireland is

*"A vibrant, innovative and globally competitive health technology and biotechnology sector, where our businesses are fully supported and promoted by all stakeholders."*

- 6.3 BBL's vision for the sector provides an important starting point for our assessment of the achievement of the project's objectives. In this context, it is important for the evaluation to establish the extent to which the LHS sector in Northern Ireland has achieved, or its moving towards achievement of this vision.
- 6.4 We analyse the sector in sections 2 and 4 of this report. Our analysis suggests that whilst there is clear evidence of the consolidation and growth of the handful of large, indigenous firms in Northern Ireland this has not necessarily been reflected in the overall development of the sector. There are few growing SMEs or start ups; supply chain or collaborative links between the larger and smaller firms are limited; barriers to developing and diffusing innovation across the HSC remain in place (although BBL take the view that these issues are less problematic in the ROI) and there is a disconnect between the research programmes of the major Universities which are driven by UK or overseas-based multinationals and the local supply chain.
- 6.5 In this context, it is clear that whilst the sector has demonstrated growth in turnover and employment it remains dependent on a handful of key players who, despite being 'home grown' firms, are not fully embedded within the Northern Ireland economy. As a result, the LHS sector has not yet attained the status outlined in BBL's vision although there are some signs of progress.
- 6.6 Invest NI's casework submission notes that "as a business association the following 3 key areas are core to BioBusiness's function:
- representative and lobbying body on behalf of its membership
  - membership support – providing brokering, facilitation, project management and networking opportunities
  - sector support – providing analysis, facilitation, brokering and networking support across the Academic, Business and Clinical (ABC) stakeholders.
- 6.7 On this basis, for the second part of our assessment we have considered BBL's contribution to each of these 'key areas' in turn. Dealing with the first, whilst BBL is clearly driven by the needs of its members, it has played a lesser role in the area of sector representation and lobbying in recent years, with the exception of its activities around the skills/STEM agenda.

- 6.8 The beneficiary and stakeholder surveys detailed in earlier sections of this report suggest that there is broad consensus that BBL should play a more strategic role through high level engagement on key issues/barriers to growth, as well as providing the bottom up/hands on support for which it is recognised. This suggests that the network has been only partially successful in relation to the first objective.
- 6.9 Beneficiaries clearly valued the membership support provided by the network, emphasised by high levels of customer satisfaction and positive perceptions around value for money. In particular members valued opportunities for networking and collaboration as well as the in-depth support for project development and delivery provided by BBL staff. Whilst BBL expressed frustration that they were unable to provide the in-depth support required by some members due to the limited resources available to the network, in our view over the period from August 2011 to date BBL has made a significant contribution to the area of membership support.
- 6.10 Turning to the area of sector support, it is clear that many members of the network particularly value the opportunities for networking and collaboration facilitated by BBL, particularly where this has brought together academic, business and clinicians to develop commercialisation opportunities. It is apparent that BBL has been 'selective' in the academic and clinical partners with which it has worked, favouring Belfast Metropolitan College rather than developing strong links with research-based institutions like QUB and the University of Ulster and developing its informal clinical network with a particular focus on the ROI. BBL cited clear reasons for this focus. Whilst in moving forward, Invest NI may wish BBL to strengthen its academic and clinical relationships within Northern Ireland, we believe that BBL has also made an important contribution in this area.

#### **High level objectives**

- 6.11 The evaluation also considers the contribution of the project to Invest NI's strategic objectives as detailed in the 2011-2015 Corporate Plan that was extant at the time the current funding round for the project commenced in August 2011. These in turn contribute to the DETI and Programme for Government objectives that were in place during the project delivery period.
- 6.12 In particular the network has contributed to Invest NI's objectives of 'stimulating innovation, R&D and creativity' and 'encouraging business growth' and Invest NI's targets to
- secure £300 million investment in R&D (with at least 20% from SMEs).
  - support 500 businesses to engage in first time R&D and 120 Collaborative R&D projects.
  - support 40 Proof of Concept projects (University based).
  - deliver 800 Innovation Vouchers.
- 6.13 The network has also contributed to DETI Corporate Plan targets to promote 6,300 jobs, £400m of investment commitments and £120m in new wages/salaries through locally owned companies. This in turn contributes to the Northern Ireland Executive's Programme for Government 2011-2015 objective of 'Growing a sustainable economy and Investing in the Future.'

#### **Economic impacts**

- 6.14 In its recently published 10 year review, BBL estimated that it had leveraged £11.8m in direct support for member companies (a leverage ratio of 6.6:1 based on a total public sector funding contribution of £1.8 million over this period) and helped to access a further £43 million in terms of the market opportunities created for member firms. Invest NI's most recent casework submission for the project did not identify specific employment or GVA impact targets.
- 6.15 The KPI framework agreed by BBL and Invest NI identified the core target to realise £300,000 per annum in monetary benefits (increased turnover and cost savings); the economic appraisal for the project converted these impacts into a total GVA impact of £376,165 over the two years of the programme.
- 6.16 5 respondents to the beneficiary survey identified increased turnover or cost savings benefits arising from the project since August 2011. The combined increases in turnover totalled £490,000, including three respondents who had achieved a six figure increase in turnover since their engagement with the network. The quantifiable benefits also included:

- cost savings of £433,500 including three respondents identifying six figure cost savings
- additional productivity improvements totalling £230,000
- 10 FTE jobs created or safeguarded
- the attraction of external investment totalling £500,000.

6.17 Taking increased turnover, cost savings and productivity improvements into account the survey suggests that actual monetary benefits of £1,153,000 have been realised by survey respondents as a result of their engagement with the network since August 2011. The actual impacts have been scaled up to estimate the total impact of the BBL programme on the 36 member companies in Northern Ireland, taking into account the confidence interval (+/-15.5%) for the survey sample. The scaled up/estimated impacts are as follows:

- increased turnover - £784,515 to £928,421
- cost savings - £694,056 to £821,368
- productivity improvements £368,241 to £435,789
- jobs created or safeguarded – 16 to 18.9 gross FTE jobs
- external investment - £800,525 to £947,368.

6.18 It is notable that the beneficiary survey has highlighted levels of monetary benefit realised by BioBusiness members that are significantly higher than those reported by BBL through the quarterly reporting process (to the end of the second quarter of the 2012/13, the reported benefits totalled just under £181,000. It will be important for Invest NI and BBL to clarify the reasons for this disparity as soon as possible and we return to this issue in our recommendations in section 8. We present an interim assessment of the net economic impact of the BBL network in the following section of the report.

#### **Additionality, deadweight and displacement**

6.19 Establishing the counterfactual – what would have happened in the absence of the project or intervention – is an important outcome for any evaluation. This can be calculated on either a quantitative or qualitative basis. Firstly, we consider the factors underpinning additionality, deadweight and displacement in qualitative terms.

6.20 Deadweight represents the quantification of outcomes under the reference case. In this case, as BBL's interventions are focused in areas of activity (for example networking or fostering collaboration) which are subject to market failure and unlikely to be delivered by the private sector in their own right, we conclude that the project demonstrated low levels of deadweight.

6.21 Displacement arises where the intervention takes market share (known as product market displacement) or labour, land or capital (referred to as factor market displacement) from other existing firms within the geographical area of the project. In this case, there are two factors to consider:

- Invest NI's casework for the project concluded that there were no other dedicated business support programmes for the LHS sector and that BioBusiness would not displace other support
- the beneficiary survey indicated that of those businesses deriving quantifiable benefits from the network, 8 respondents (63% of those who responded) had increased market share as a result of BBL support relative to competitors in Northern Ireland.

6.22 On balance, whilst the project itself demonstrates low levels of displacement, beneficiaries of the network have generated product market displacement. Therefore, on balance, we conclude that BioBusiness has demonstrated medium levels of displacement.

6.23 In conclusion, based on triangulation of data from the beneficiary survey, economic appraisal and BIS/DETI benchmarks (considered in more detail overleaf) we conclude that the project demonstrates high levels of additionality, low levels of deadweight and medium levels of displacement.

6.24 We have also sought to quantify the gross and net employment and GVA impacts of the BBL programme, drawing on evidence from the survey of beneficiaries and additionality benchmarks from BIS and DETI. We have not undertaken a full assessment utilising the additionality logic chain approach although this should be undertaken as part of the final evaluation of the programme.

- 6.25 As a benchmark, BIS research<sup>13</sup> suggests that the mean net additionality for sector/cluster support projects like BioBusiness is 42.4% at the regional level and 26.8% at sub-regional level. DETI additionality ratios range from 90.9% to 48.9% for projects of this type.
- 6.26 There is also some project specific evidence upon which an assessment of the additionality of the project can be made. The original economic appraisal for the project estimated that the additionality of BBL support was been 68% and 75% whilst our survey of project beneficiaries indicated that 67% of respondents who had realised some form of quantifiable economic benefit as a result of the project stated that this would not have happened at all without BBL; a further 33% stated that the benefits would have happened more slowly without BBL support, demonstrating partial additionality.
- 6.27 On this basis, reflecting actual evidence from the beneficiary survey we propose to apply a net additionality ratio of 65% to the BioBusiness network. Although in isolation, additionality levels were considered to be high, they have been scaled back to reflect 'medium' levels of product market displacement arising from the programme, but remains significantly higher than the BIS benchmark cited in paragraph 6.25. On this basis, we conclude that the BBL programme has, to date, supported the creation or safeguarding of between 10.4 and 12.3 net FTE jobs.
- 6.28 We have estimated the GVA impact of the programme by drawing on evidence from the Northern Ireland Annual Business Inquiry to establish the average GVA per worker for 'professional, scientific and technical activities.' In 2010, this was £40,677.
- 6.29 For the purposes of this analysis we have assumed that the GVA benefits of the programme have applied for just one year (i.e. as yet there are no cumulative GVA impacts) and we have not considered the future potential (i.e. forecast) GVA benefits associated with Invest NI's support for BBL. Thus we estimate that, to date, the programme has generated net GVA impacts of between £423,041 and £500,327. This is significantly higher than the GVA impact forecast in the economic appraisal.
- 6.30 Paragraph 3.31 notes that, up to the end of January 2013, Invest NI had provided core funding support for the programme totalling £151,000 (against a total budget of £199,998 over the two years to August 2013). On this basis, we estimate that to date the network has generated a GVA return on Invest NI's investment of between 2.8 to 3.3 to 1. Whilst only an interim figure, this ratio is higher than that forecast in the independent economic appraisal for the programme (1:2.6) and comparable with that achieved for Invest NI's Knowledge Transfer Partnership programme.

### Wider and regional benefits

- 6.31 The economic appraisal for the BBL network identified a number of wider and regional benefits likely to arise from its implementation, including:
- facilitating the pursuit of innovative projects amongst NI Life and Health Sciences companies resulting in the development of innovative products and processes
  - facilitating knowledge transfers between the academic, business and clinical communities
  - promoting skills development of BioBusiness Ltd members through providing access to much sought after clinical and regulatory advice
  - promoting linkages between the universities and industry
  - acting as a conduit to support the growth of the NI Life and Health Sciences sector which has potential to create/safeguard high value jobs and provide opportunities for home grown talent.

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<sup>13</sup> Research to improve the assessment of additionality, Occasional Paper no 1, BIS October 2009



6.32 Our analysis suggests that the network has realised each of these wider and regional benefits to a greater or lesser extent. Many BBL members valued its role as a 'voice' for the LHS sector whilst encouraging it to play a stronger advocacy/lobbying role; the network has promoted links between members and FE/HE institutions although these could undoubtedly be further strengthened. 'ABC' linkages have been facilitated by BBL and are highly valued by members whilst the clinical and regulatory support provided by the network has played an important role in accelerating the development of a number of new products.

### Value for money

6.33 In considering the value for money achieved by the project *economy*, *efficiency* and *effectiveness* are critical factors:

- economy measures are concerned with demonstrating that the inputs (the resources used to deliver the project and realise its outputs) have been obtained at least cost
- efficiency addresses the inputs/processes developed to deliver the project and relates the costs or other resources used in delivering the project in relation to the scale or value of the outputs realised
- effectiveness relates to the impact of the project on longer-term outcomes or strategic objectives.

6.34 The position on economy is complex. The project has never been subject to a formal competitive tender and BBL has now been re-appointed by Invest NI on five separate occasions to deliver the network. Invest NI support has been limited to the level of funding available to the Managing Director under their delegated responsibilities. On each occasion BBL has prepared a business case for support which has been subject to an independent economic appraisal and revised accordingly. Invest NI's most recent casework notes that "*this approach has been confirmed as reasonable by the Invest NI Finance Team.*"

6.35 It is of course conceivable that another operator could have delivered the contract on a lower cost basis, although this remains an entirely hypothetical question; the per diem rates adopted for the purposes of the contract by BBL's CEO and Chairman appear significantly lower than those that would be adopted by a mainstream management consultancy for a contract of this type.

6.36 Moving forward, Invest NI will of course wish to consider whether to continue to provide support to the network and, if so, on what basis this should be procured. We return to this issue in section 8.

6.37 Invest NI's funding support for each two year funding period has not increased since 2007 and, in effect, the core funding available to BBL to deliver the network has declined in real terms. Quarterly project review meetings have not been held on a regular basis during the current contract period. Although these have now been reinstated, there has been limited dialogue between BBL/Invest NI to manage costs on an ongoing basis.

6.38 Turning to *efficiency*, the total economic appraisal noted that the total cost of the project, including 'in kind' contributions from BBL, was £400,836 over a two year period including a contribution of £199,998 from Invest NI. It has not been possible to complete our analysis of project costs against budget (this will be completed shortly ) although it is anticipated that project costs will be broadly in alignment with the agreed budget.

6.39 In cost per job terms, the beneficiary survey suggests that BBL supported the creation or safeguarding of between 10.4-12.3 net FTE jobs, at an interim cost per job (based on Invest NI expenditure to January 2013) of between £12,276 and £14,519. This is broadly comparable with the achieved cost per net job of some £14,221 for RDA business support activity identified in PWC's research on the net economic impact of the former Regional Development Agencies.

6.40 The project's effectiveness is related to its impact on longer-term outcomes and to the strategic objectives of Invest NI and DETI. These are explored overleaf and also in section 2. In summary we conclude that the project has contributed to the objectives and targets set out in the 2011-2015 Corporate Plans of both organisations.

## Equalities impacts

- 6.41 Section 75 and Schedule 9 to the Northern Ireland Act 1998 came into force on 1 January 2000 and placed a statutory obligation on public authorities, in carrying out their various functions, to have due regard to the need to promote equality of opportunity between:
- persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation
  - men and women generally
  - persons with a disability and persons without
  - persons with dependants and persons without.
- 6.42 Section 75 of the 1998 Act highlights a number of equality of opportunity or good relations categories who should be given particular consideration in identifying the equalities impacts of public sector interventions, including religious belief, political opinion, racial group and sexual orientation. Invest NI has a ratified Equality Scheme in place which sets out its commitment to the Section 75 Statutory Equality Duties and contains a timetable for undertaking a series of Equality Impact Assessments (EQIAs).
- 6.43 The BioBusiness project was subject to a policy screening process by Invest NI to determine whether an EQIA was required and was 'screened out' as it was not expected to have an impact on any of the Section 75 categories and thus were not subject to EQIA. The evaluation found no evidence that Invest NI delivered the project in a way which is likely to have a detrimental impact on the Section 75 equality of opportunity or good relations categories.

## 7 BENCHMARKING

7.1 Section 7 benchmarks the BioBusiness programme against comparator projects elsewhere in the UK, identifying any key lessons learned which are of relevance to the evaluation. Section 7 considers the following projects/programmes in more detail:

- BioNow, the network for the LHS sector in the North of England
- MediWales, the life sciences network for Wales.

### Bionow

- 7.2 Bionow supports business growth, competitiveness and innovation within the biomedical and life science sectors across Northern England. It was formed in March 2000 as a cluster network for the life and health sciences in the North West of England. The North West was identified as one of the top 3 regions for biotechnology in the UK in work led by Lord Sainsbury. The network was originally funded by the now defunct North West Development Agency
- 7.3 Cluster mapping reports were prepared in 2000, 2002, 2007, 2009 and 2012 detailing significant growth of the cluster and Bionow was recognised as a 'best practice' case study in the Knowledge Economy White Paper in 2001. During this early phase of its development, Bionow played a key role in developing the underpinning infrastructure for the LHS sector including the establishment of the National Biomanufacturing Centre in Liverpool and the Core Technology Facility, part of the University of Manchester Innovation Centre which provides over 16,000 sq.m of biotechnology laboratory and incubator facilities.
- 7.4 Bionow was recognised nationally as a leading cluster organisation, and awarded the UK Cluster Mark Award in 2010. Bionow Ltd was established in 2011 as a Company Limited by Guarantee to continue supporting the biomedical community following the abolition of the Regional Development Agencies. Bionow and the North East Centre for Excellence in Life Sciences (cels, formerly supported by RDA One North East) merged in June 2012 to form a single life sciences membership company spanning the North of England. The network secured its 150th member in October 2012 and held its first BioCap conference in November 2012, attracting over 150 delegates.
- 7.5 Bionow delivers tailored packages of support for both early-stage young firms and established growth-oriented businesses in the biomedical and life sciences sectors involving a range of specialist services, expert guidance and knowledge sharing, and focused networking events.
- 7.6 Start-ups and small companies are nurtured through BioNow's Going for Growth business support programme. This includes professional guidance on investment-readiness, marketing and regulatory compliance and a programme of networking events and training courses, culminating in the annual BioCap conference. Members also benefit from
- business promotion to other members and networking
  - discounted attendance at both global conferences and at Bionow events
  - preferential rates from preferred suppliers.
- 7.7 For larger, growth oriented firms, Bionow offers a tailored version of its Going for Growth programme which enables members to access market intelligence to support engagement with the NHS and other stakeholders and provides support around regulatory needs, access to finance and innovation for new product development. Bionow has also developed partnerships with a number of key LHS sector suppliers, claiming to save members at least 40% in specialist consumables purchasing. Premium members access a number of free and discounted business services offered by Bionow's preferred suppliers in key areas including e-learning, recruitment, insurance and specialist procurement.
- 7.8 Although Bionow and Cels were originally core funded through Regional Development Agencies with a limited requirement to generate commercial income, Bionow's funding model has altered significantly in a comparatively short space of time following the abolition of the RDAs in 2010. The network generates income through five main sources:

- sponsorship from partners including Astra Zeneca, the University of Manchester, the University of Liverpool and Lancaster University
- membership subscription fees
- consultancy income
- conferences and exhibitions
- commercial relationships with preferred suppliers.

7.9 Table 7.1 below presents a summary of the membership fee structure:

**Table 7.1: Bionow membership fees**

Company Size	Member	Premium Member
Individual / Consultant	£100 + VAT	n/a
Startup*	£150 + VAT	£600 + VAT
Micro SME (< 10 staff)	£250 + VAT	£1,000 + VAT
Small SME (< 50 staff)	£375 + VAT	£1,500 + VAT
< 100 staff	£500 + VAT	£2,000 + VAT
< 250 staff	£750 + VAT	£3,000 + VAT
250+ staff	£1,250 + VAT	£5,000 + VAT
Not for Profit Organisations**	£250 + VAT	£1,000 + VAT

\* Incorporated within the last two years and employing <10 people

\*\* Not for profit organisations include public bodies, research institutes, hospitals & government bodies.

### MediWales

- 7.10 MediWales is the life sciences network for Wales, funded through the Welsh Government, commercial sponsorship from Geldards (a legal firm) and GX Design Engineers and membership subscriptions. MediWales is owned by its members and managed through a board of member-elected non-executive directors. MediWales has 145 members drawn from a wide range of Universities, businesses, clinicians, business support organisations and professional services firms.
- 7.11 MediWales promotes and supports its members via an extensive events programme; a series of regularly updated publications including the quarterly MediWales Review and the biannual UK Life Science Industry magazine developed by Medilink UK; the MediWales website; and lobbying to government in order to represent the sector's needs. The network also publishes an Annual Directory of members and their services/specialisms. MediWales also organises a regular events programme and an Annual Innovation Awards, offering members access to free exhibition space at these events.
- 7.12 The network offers a comparatively simple structure for membership fees, as follows:
- Sole traders, start ups or firms with fewer than 3 employees - £220 +VAT per annum
  - SMEs or Universities £475+VAT p.a.
  - Large firms £680 +VAT p.a.

### Conclusions

- 7.13 The short case study examples highlight a number of potential lessons for BioBusiness:
- Bionow offers a more structured programme of business support for both start ups and more mature firms rather than ad-hoc, project based support; BBL has the opportunity to develop this approach to its business support offer through the Capacity Building Toolkit and this should be prioritised by BBL
  - MediWales delivers a wide range of marketing and promotional publications including regular briefings/newsletters and an annual directory of member firms; there are opportunities for BioBusiness to develop a more structured offer of this type for members
  - MediWales has a broad range of members including a significant number of non-core members (including Universities and professional services organisations); BBL should explore the potential to diversify and expand its non-core membership

- Bionow's standard membership fees are broadly comparable with those of BBL and MediWales (and in fact membership for large employers is cheaper in both comparator networks) although Bionow offers a premium membership programme offering access to value-added services including discounted procurement; BBL should explore the potential to offer value added services for members
- both Bionow and MediWales have embraced commercial sponsorship whilst retaining their key role as an independent lobbying/representative organisation; moving forward, BBL should explore the potential for commercial sponsorship from professional services firms and/or Northern Ireland's Universities and Colleges
- both networks deliver an extensive range of events and seminars and in Bionow's case, the BioCap Annual Conference and Awards; notwithstanding the comparatively limited membership/market in Northern Ireland, BBL should explore how it can develop its events offer for members and to diversify its commercial income streams, potentially in partnership with an established events provider.

## 8 CONCLUSIONS AND RECOMMENDATIONS

- 8.1 Section 8 presents our conclusions and recommendations, reflecting the terms of reference for the evaluation which are summarised in paragraph 1.7.

### Contribution to DETI/Invest NI strategic objectives

- 8.2 In broad terms, the BioBusiness network demonstrates a clear fit with DETI and Invest NI objectives and targets developed over successive corporate plans and in particular with those objectives and targets focused on supporting R&D investment and the attraction of jobs and investment by indigenous firms. The BBL project also demonstrates fit with the UK Government objectives of the Office for Life Science strategy.

### Market failure rationale and ongoing validity

- 8.3 Research<sup>14</sup> has identified the pivotal role of effective, business-led networks and partnerships in sector/cluster development. BioBusiness was established in 2004 as a member-led representative body for the life and health sciences sector in Northern Ireland and to stimulate collaboration between key actors in the sector, activities which were unlikely to be delivered by the private sector in their own right. The original market failure rationale for the network was based on asymmetric information, relating to the imperfect market intelligence held by both consumers of LHS products and services and businesses across the sector.
- 8.4 Our research suggests that, despite the success of Northern Ireland's 'big four' indigenous businesses, the LHS sector in Northern Ireland remains imbalanced and embryonic and, as yet, has failed to realise its potential. In this context, there was strong stakeholder consensus on the need for a network to represent the interests of the sector and to strengthen links between key stakeholders. We therefore conclude that the market failure rationale for the sector continues to be valid.

### BioBusiness delivery model and mix of activities/engagement

- 8.5 The survey of BBL members emphasised that the network is highly valued by its membership base, many of whom are microbusinesses and SMEs although the 'big four' LHS firms are also represented. There is strong member support for the activities delivered by BBL although members want the network to play a stronger advocacy and lobbying role. Members perceive that network communications have improved in recent years.
- 8.6 There is little or no overlap with other Invest NI-funded business support activities and evidence that BBL is connected with other, complementary programmes including NISP Connect and the Halo business angel network. Although some elements of the current programme (most notably pro-bono regulatory/quality management advice) are unlikely to be sustainable in the long-term, we conclude that the BioBusiness delivery model is fit for purpose and that both the mix of activities delivered through the network and the means of engagement with key stakeholders is appropriate.

### Achievement of targets

- 8.7 BBL achieved 12 of its 16 targets in year 1. It has achieved or is highly likely to achieve 9 of year 2 targets. There is a risk that it will not meet a further 5 targets and, in our view, it is very unlikely to meet 2 of its year 2 targets. Table 8.1 overleaf presents a 'traffic light system' to review BBL's performance against its year 2 targets; green signifies that BBL have achieved or in our view are likely to achieve the target; amber denotes that they are unlikely to achieve the target and red that they are very unlikely to achieve the target:

<sup>14</sup> A practical guide to cluster development, EOCTEC for DTI and the English Regional Development Agencies, 2002

**Table 8.1: Actual/forecast performance against targets**

Target	Forecast achievement yr 2
1: Achieve cost savings/ monetary benefits for members of at least £300k p.a.	
2: Core member representation to be at least 70% of the NI life science business community	
3: Broker 2 research links p.a. between core members and the academic community	
4: Broker 2 clinical links p.a. between core members and the clinical community	
5: Support development of one new product p.a. by core member	
6: Support one core member p.a. to achieve funding from external sources for product development	
7: Support 2 commercial opportunities p.a. between core members and NISP Connect	
8: Provide 24 days of support p.a. to core members for regulatory and quality management systems	
9: Provide support to one core member for one clinical trial p.a. (separate to target 8)	
10: Provide assistance to core members of – on average -2 days p.a. to each core member (separate to target 8/9)	
11: Provide 5 case studies p.a. for core members (10 case studies over 2 years, must relate to different members)	
12: Leverage a minimum of £100k in respect of a new project or programme over the next 2 years (excluding INI funding)	
13: Deliver 4 events p.a. either solely or in partnership	
14: Promote core members in literature and on BioBusiness website	
15: Promote and advance NI life sciences skill development	
16: Achieve a minimum 80% core satisfaction rating for the period 1.8.11-31.7.13	

### Management and delivery of the programme

- 8.8 As we highlight overleaf, member support for the programme delivered through BBL remains strong and levels of customer satisfaction have improved since post project evaluations completed in 2009 and 2011. This has been achieved in the context of static core funding for the programme (and in effect a modest real term decline) from Invest NI since 2007. This notwithstanding, through the consultation process, BBL staff, Board members and other stakeholders identified a number of issues relating to the role and performance of the project:
- concerns around the strategic direction of BioBusiness and the sense that it had, to some extent, ‘lost its way’
  - a recognition that BBL’s membership base is diverse and generates different and sometimes conflicting requirements for support through the network given the level of resource available to the network
  - tensions between BBL’s role as a membership-led representative body and in addressing economic development objectives as an External Delivery Organisation for Invest NI
  - uncertainties around the long-term outcomes of some of BBL’s networking/collaborative activity
  - concerns around the complexity of the KPI framework in relation to the level of funding received from Invest NI.
- 8.9 Despite these issues, we conclude that the delivery of the programme has been effective but that there is scope to improve collaboration between Invest NI and BBL on the management of the network. Some aspects of the management of the programme should be revisited, including the target framework; and quarterly project review meetings between BBL and Invest NI should be reinstated.

### Outcomes, impacts and wider regional benefits

- 8.10 The BBL programme has, to date, supported the creation or safeguarding of between 10.4 and 12.3 net FTE jobs and has generated net GVA impacts of between £432,041 and £500,327. We also estimate that, to date, the network has generated an interim GVA return on Invest NI’s investment of between 2.8 and 3.3 to 1, higher than forecast in the independent economic appraisal of the 2011-2013 programme.

- 8.11 The network has delivered a number of wider and regional benefits. Many BBL members valued its role as a 'voice' for the LHS sector whilst encouraging it to play a stronger advocacy/lobbying role; the network has promoted links between members and FE/HE institutions although these could undoubtedly be further strengthened. 'ABC' linkages have been facilitated by BBL and are highly valued by members whilst the clinical and regulatory support provided by the network has played an important role in accelerating the development of a number of new products.

#### **Additionality**

- 8.12 Based on triangulation of data from the beneficiary survey, economic appraisal and BIS/DETI benchmarks we conclude that the project demonstrates high levels of additionality, low levels of deadweight and medium levels of displacement. Both the 2011 economic appraisal for the project and the beneficiary survey suggested that levels of net additionality range between 65%-75%.

#### **Value for money**

- 8.13 The network was evaluated in terms of its economy, efficiency and effectiveness. In relation to economy, the project has never been subject to a formal competitive tender and BBL has now been re-appointed by Invest NI on five separate occasions to deliver the network. Invest NI support has been limited to the level of funding available to the Managing Director under their delegated responsibilities and subject to an independent economic appraisal. Nonetheless, we conclude that it is unlikely that another operator could have delivered the contract on a lower cost basis.
- 8.14 In relation to *efficiency*, the beneficiary survey suggests the interim net cost per job of the programme (based on Invest NI expenditure to January 2013) is between £12,276 and £14,519. This is broadly comparable with the achieved cost per net job of some £14,221 for the former Regional Development Agencies in England.
- 8.15 The project's effectiveness is related to its impact on longer-term outcomes and to the strategic objectives of Invest NI and DETI. These are explored overleaf and also in section 2.

#### **Equalities considerations**

- 8.16 The BioBusiness project was 'screened out' of any requirement for an equalities impact assessment as it was not expected to have an impact on any of the Section 75 equality of opportunity or good relations categories. The evaluation found no evidence that Invest NI or BBL delivered the project in a way which is likely to have a detrimental impact on the Section 75 categories.

#### **Implications of an all-island delivery model**

- 8.17 BBL has now secured around 17 members from the Republic of Ireland and, moving forward, is likely to have an increasing focus on the development of its ROI activities. BBL highlight a number of operational benefits for the network from increased engagement with ROI clinicians, academic researchers and businesses. Invest NI should explore whether its partner economic development agencies (e.g. Enterprise Ireland, InterTradeIreland) wish to provide support for NI/ROI collaborative activity moving forward.

#### **Benchmarking**

- 8.18 The programme was benchmarked against comparator networks in the north of England (Bionow) and in Wales (MediWales). Bionow is now operated on a commercial basis and has a large pool of potential members, whilst MediWales is funded through a similar mix of membership subscriptions and grant support.
- 8.19 The comparator case studies highlighted a number of potential lessons for BioBusiness. These included the opportunity to offer a more structured and defined programme of business support for members; the potential to generate income through sponsorship and marketing/promotional activity for members; and the delivery of value-added services, including events.



## Ongoing rationale for intervention

- 8.20 Our research findings suggest that BioBusiness and Invest NI have reached a key point in the evolution of the project. There is strong demand from members to sustain investment in a member-led network for the LHS sector but also concerns about the future role and sustainability of the network.
- 8.21 In the future, BBL faces the very real challenge of moving towards a more sustainable funding model whilst maintaining its independence as a member-led body for the sector. In our view, given the size and maturity of the LHS sector in Northern Ireland, it is unlikely that a member-led network would be sustainable based on member subscriptions alone although evidence from elsewhere suggests that sponsorship or commercial income streams can be developed without compromising the integrity or independence of member-led networks.
- 8.22 As we note overleaf, there may be scope for BBL to further broaden its membership base in the ROI. This may create further opportunities to promote cross-border collaboration and will be an important consideration for Invest NI and partner agencies including InterTradeIreland and Enterprise Ireland in exploring future support for the network.
- 8.23 Most stakeholders, including BBL staff and Board members, concluded that it was in no-one's interest to simply maintain the status quo in terms of the current arrangements for operating support. We explore these issues further in the following recommendations.

## Recommendations

- 8.24 The evaluation identifies a series of recommendations for Invest NI, BioBusiness and other stakeholders that are summarised in table 8.2 below and overleaf. These relate both to the wider policy environment (identified by the prefix 'P' in parentheses) in which Invest NI's business support programmes operate and also to specific aspects of the delivery of future projects (identified by the prefix 'D').

**Table 8.2: Recommendations**

No	Recommendation	Justification
1(P)	Invest NI, DETI or other key stakeholders should initiate the establishment of a high level working group to develop a new long-term strategy and action plan for the Life and Health Sciences sector in Northern Ireland. The working group would include representation from Invest NI, DETI, DHSSPS, DARD, HSC, the Universities and key private sector representatives with the role of developing the strategy/action plan and providing oversight and challenge for its implementation. Building on the outcomes of the evaluation, the strategy should address the ongoing need for a collaborative network for the LHS sector.	Stakeholders highlighted the strategic vacuum in which development of the LHS sector is taking place and a loss of momentum following the work of the MATRIX panel. The strategy would provide a clear framework against which future projects could be commissioned.
2 (P)	As part of the process outlined in recommendation 1, HSC should review current mechanisms for fostering and diffusing innovation across the health and social care sector in Northern Ireland	The research highlighted a number of continuing barriers and disincentives for clinical research and innovation.
3(P)	Invest NI should prepare and regularly update a schedule of the performance of businesses within the LHS sector footprint in Northern Ireland, including both client and non-client firms and employees/turnover generated within and outside Northern Ireland	The research highlighted the need for a more consistent baseline, including all relevant NI firms, against which to measure the development and growth of the sector.

No	Recommendation	Justification
4 (D)	<p>Subject to the outcome of recommendation 1, Invest NI should commit to commissioning a future programme of support for a business-led network for the Life and Health Sciences sector in Northern Ireland from 2013/14. The network should focus on two key areas:</p> <ul style="list-style-type: none"> <li>• lobbying/member representation</li> <li>• fostering collaboration between academics, businesses and clinicians.</li> </ul>	<p>Strong evidence of continued need/demand for an LHS network from a clear majority of BBL members surveyed as part of this research.</p> <p>Clear evidence of demand from BBL members for lobbying and collaboration activity moving forward.</p>
5 (D)	<p>Subject to the outcome of recommendation 1, Invest NI should undertake a review of the commissioning and procurement process associated with recommendation 4, in accord with current best practice and with appropriate advice from DETI and DFP, to establish whether the proposed network should be subject to an open tender process or a single source tender can be justified.</p>	<p>The procurement of support for the LHS sector has not been subject to a competitive tender process since 2004 and the project has been commissioned within the parameters of the delegated approval process. In the view of the evaluator, it would represent good practice to review procurement processes for the project.</p>
6 (D)	<p>Subject to the outcome of recommendations 1 and 5, Invest NI should prepare a brief setting out clear objectives for the delivery of an LHS network, ideally for a three year period against which tender(s) can be assessed. The brief should also set out clear expectations for how the network should balance its dual role as a member led and Invest-NI funded economic development body and consider the long-term sustainability of the network. This could include providing a tapered stream operating grant support to encourage exploration of commercial income streams.</p>	<p>Good practice from project development/delivery elsewhere suggests that Invest NI should develop a clear framework against which tender(s) for the network can be assessed.</p>
7 (D)	<p>Subject to the outcome of recommendation 1, Invest NI should undertake a comprehensive review of the KPI/target framework for the LHS sector network. The aim should be to identify a much smaller number of SMART targets to support performance management of the network. These should focus on the outputs/outcomes associated with</p> <ul style="list-style-type: none"> <li>• lobbying/strategic representation</li> <li>• brokering collaborative links</li> <li>• monetary benefits realised by members</li> </ul> <p>annual customer satisfaction rates.</p>	<p>Strong consensus from the research that the current KPI framework is too complex and creates conflicting and sometimes unrealistic demand on BBL's time.</p>
8 (D)	<p>BioBusiness should revisit the needs and expectations of its members in relation to its member representation/lobbying role and review its strategic engagement in key developmental areas for the LHS sector, including skills</p>	<p>Strong member views that BBL should be playing a stronger role in this area.</p>
9 (D)	<p>Subject to the outcome of recommendation 1, Invest NI and BioBusiness should undertake an early review of the data and process used to determine the network's progress against KPI target 1 (cost savings and monetary benefits).</p>	<p>The beneficiary survey and BBL's quarterly monitoring reports provide conflicting evidence, with the former suggesting that the network has generated higher levels of monetary benefit than is being reported through QMRs.</p>

No	Recommendation	Justification
10 (P)	<p>Invest NI should undertake a review of the current LHS sector proposition/offer for Foreign Direct Investment in consultation with key private sector stakeholders. This should include a review of competitor offers in key areas including medical devices, diagnostics, biotechnology and pharmaceuticals and the development of a clearly defined UPS for FDI purposes.</p> <p>As part of this process, Invest NI should review the potential for key businesses, including BBL members, to support the FDI process and strengthen their ambassadorial role.</p>	<p>Stakeholders and businesses highlighted the need for greater clarity on Northern Ireland's FDI offer for the sector and to build firmly on niche strengths. Recommendations 10, 11 and 12 would be implemented by teams outside the Life Sciences and Creative Industries Division in Invest NI.</p>
11 (P)	<p>Invest NI, working with the Universities, Northern Ireland Science Park and key private sector businesses, should undertake a short review of current incubator facilities for the LHS sector in Northern Ireland and develop a new incubation strategy for the sector which explores a partnership approach to delivering new facilities with the private sector.</p>	<p>Stakeholders and businesses highlighted the lack of appropriate incubator facilities with full clean room/laboratory specification as a potential barrier to growth of the sector</p>
12 (D)	<p>Subject to the outcome of recommendation 1 and linked to recommendation 12, Invest NI should consider commissioning a separate business support programme for the LHS sector with a focus on accelerating the growth of seed stage firms and supporting SME growth. This should be separate from the wider network support function detailed in recommendations 4-7 and should be closely aligned to the activities being delivered through Invest NI's Access to Finance Strategy</p>	<p>Stakeholders and businesses highlighted the need for a more structured business support programme and good practice elsewhere (including the Bionow initiative in the North of England) supports this view.</p>
13(D)	<p>Building on lessons from LHS networks elsewhere in the UK, BioBusiness should give further consideration to developing additional member services with the potential to generate commercial income streams.</p> <p>These could include commercial sponsorship; generating advertising revenue through the preparation of Member Directories and reviewing its subscription rates for large firms. BBL should also consider the development of a tiered membership structure offering added value services and delivering business support on a more commercial basis utilising Innovation Vouchers, R&amp;D Tax Credits and other forms of available support.</p>	<p>BBL staff and Board members acknowledged the need to explore a more diverse mix of funding and to reduce the network's dependency on public sector funding whilst emphasising their view that a member-led network of this type in Northern Ireland is unlikely to be entirely self-financing. Such activities should be designed to ensure that they would not compromise BBL's independence as a member-led body.</p>

## APPENDIX 1: MARKET AND POLICY CONTEXT

### Market context

#### Global trends

The market can be segmented in several different ways and there is a degree of overlap between some of the elements; recent research for the UK Office for the Life Sciences identified four key sub-sectors of the UK's life and health sciences sector:

- pharmaceuticals – comprising research-based companies undertaking clinical research and/or developing/producing drugs using a range of technologies; manufacturers of generic pharmaceuticals; and contract manufacturers
- medical technology, including companies producing a wide range of medical and orthopaedic devices, in-vitro diagnostics, cardiovascular, neurology and radiotherapy technologies and professional services
- medical biotechnology – including a wide range of research and development activity in key areas including therapeutics and blood and tissue products
- Industrial biotechnology – comprising businesses which develop and manufacture products which use biological material as catalysts or feedstock to make industrial products.

Recent research by Deloitte<sup>15</sup> notes that the global pharmaceuticals, biotechnology and life sciences sector generated total revenues in excess of \$1.1 trillion in 2011, up from \$855bn in 2007 and achieving a cumulative annual growth rate (CAGR) of 6.7% during this period. Despite this, the LHS sector faces a number of significant challenges moving forward: Deloitte note that

*“A changing health care landscape, expiring patents and generic competition, pricing pressures, heightened regulatory scrutiny, expansion into emerging markets, increasing alliances and acquisitions, and a persistent economic slowdown are prompting global life sciences companies to adopt new business models designed to counter slowing sales growth and declining profitability, deliver better patient outcomes at lower cost.”*

The pharmaceuticals market (excluding biologics) accounted for 72% of total LHS revenues in 2011 with prescription sales accounting for 95% of total revenue<sup>16</sup>. The Americas represented the largest share (46%) of the global market. The major pharmaceuticals companies moving towards a collaborative, lower-cost approach to the development of new drugs as their patents on ‘blockbuster’ products expire. Drugs worth \$103bn lost their patents between 2009-2012 and a further \$29 bn of patents were expected to become generic in 2013<sup>17</sup>.

Pricing pressures are a key driver of the move towards generic drugs; the generics market is expected to realise a CAGR of 10% per annum over the period to 2015. Between 2008-2011, R&D expenditure by the global pharmaceuticals industry fell by 3% as pricing pressures and regulatory costs impacted on profit margins, reducing the level of investment available to develop new products. Deloitte note that

*“a dramatic shift is taking place in the type of products coming out of life sciences company research labs – the reality of a few billion dollar blockbusters is being replaced by a focus on developing targeted treatments, which requires that companies invest and bring to market more products to fill the pipeline.”*

These changes include an increasing focus on the development of personalised medicine, including ‘orphan’ drugs, which have extra patent protection and a streamlined regulatory review process in some countries. There is also a move towards the convergence of pharmaceutical and biotechnology businesses, with a focus on higher margin biologics – derived from human or animal proteins – to treat, prevent or cure diseases. In 2011, medical biotechnology products captured 19% of the global pharmaceutical market, amounting to \$142bn of sales and representing a 7% increase in market share between 2004-2012<sup>18</sup>.

<sup>15</sup> 2013 global life sciences outlook, Deloitte 2013

<sup>16</sup> Strength and opportunity 2012: the landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK, HM Government, December 2012

<sup>17</sup> 2013 global life sciences outlook, Deloitte 2013

<sup>18</sup> Strength and opportunity 2012: the landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK, HM Government, December 2012

34 of the top 100 selling drugs were biologics in 2011 and market parity is anticipated by 2018, when the medical biotechnology market is forecast to be worth \$215bn. There is a strong pipeline of products currently in clinical trials<sup>19</sup>, although some biologics will also come off patent during this period.

The global medical technology market had an estimated value of \$325bn in 2011 and achieved a CAGR of 7% between 2005-2011. In 2011, the top 5 medical technology segments by sales were in-vitro diagnostics, cardiology, diagnostic imaging, orthopaedics and ophthalmic activity. In vitro-diagnostics are expected to remain the largest sub-sector over the next 6 years, although overall growth rates for the medical technology are expected to decline to 4.4% over the period to 2018<sup>20</sup>.

The industrial biotechnology market has an estimated global market size of between \$50-60bn and this has been forecast to increase to \$300bn by 2030, with the biofuels and chemicals markets likely to drive growth; currently less than 12% of chemicals used in consumer products are made through industrial biotechnology processes. Biodiesel production quadrupled between 2005 and 2010; the market for biofuels is forecast to be 65m barrels by 2020<sup>21</sup>.

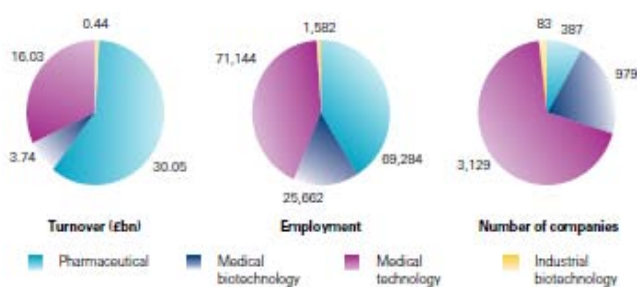
The extension of health insurance to more than 30 million uninsured US citizens in 2014 is likely to have a positive impact on the US healthcare market. However, the focus of the global LHS sector is shifting inexorably towards emerging markets. Factors including demographic change (involving both an increasingly ageing and affluent society in most BRICs countries), the rise of chronic diseases, technological change and evolving clinical practice are driving rapid increases in global health expenditure - total spending in the OECD and BRICs countries alone is forecast to increase from \$5 trillion to \$7.24 trillion by 2020<sup>22</sup>. China is becoming an increasingly successful inward investment location for the LHS sector as a result of its lower cost R&D environment and heightened regulatory and compliance activity in Europe and the USA.

### Life and health sciences in the UK

The UK's life and health sciences sectors employ over 167,000 people in over 4,500 companies and generate annual sales of over £50bn<sup>23</sup>. Overall employment increased by 1,500 jobs between 2011-2012.

The UK pharmaceutical sector generated a turnover of just over £30bn in 2011. Although 17 of the top 20 global pharmaceutical manufacturers have a presence in the UK, turnover and employment in the pharma sector fell by 5.4% and 9.7% (equivalent to 9,000 jobs) respectively between 2011 and 2012.

**Figure A.1: Turnover, employment and number of companies in the UK LHS sectors 2012**



Source: Strength and opportunity 2012: the landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK, December 2012

The medical technology sector has now overtaken pharmaceuticals as the largest employer (71,144 jobs) in the UK LHS sector although its turnover (£16bn) is significantly smaller. Employment grew by 5% between 2011 and 2012. However, the number of new medical devices developed by UK firms that have secured approval for marketing in the US – the world's largest medical technology market – has fallen from around 100 per annum in 2008 to just 60 in 2012. The industrial biotechnology sector increased sales by 15% and employment by 21% between 2011 and 2012, albeit from a low base of £440m.

<sup>19</sup> Key Biotechnology Indicators, OECD 2011

<sup>20</sup> World Preview 2018: A consensus view of the Medical Device and Diagnostic Industry, Evaluate Medtech 2012

<sup>21</sup> Key Biotechnology Indicators, OECD 2011

<sup>22</sup> PWC: Build and beyond: the revolution in healthcare PPPs, PricewaterhouseCoopers, December 2010

<sup>23</sup> Strength and opportunity 2012: the landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK, HM Government, December 2012

The Office for Life Sciences also acknowledge<sup>24</sup> that whilst the UK's life science research base ranks second to the US only to the US on share of citations it has *punched below its weight* in seeking to commercialise the intellectual property developed by UK scientists. Barriers include a lack of funding for clinical trials, limited incentives for clinicians to commercialise IP assets and limited take-up of innovations across the NHS. The UK hosted just 1.4% of global clinical trials in 2010, compared with 6% in 2000<sup>25</sup>. The Strategy for UK Life Sciences notes that

*"We have under-utilised our strengths....the drive for cost-effective solutions in the NHS combined with regulatory approvals can mean that uptake (of innovation) is slow.....more importantly, patients lose out through late adoption."*

### **Life and health sciences in Northern Ireland**

The LHS sector in Northern Ireland is comparatively small when compared with the concentration of firms and activity in some parts of the UK, including the South East and East of England which both have more than 20,000 employees in LHS businesses.

In 2006, research by BioBusiness<sup>26</sup> for Invest NI showed that the sector encompassed 60 firms employing over 4,000 people with a combined turnover of approximately £300 million per annum. Incomplete data from Invest NI on the performance of 71 client companies in the LHS sector in 2011 indicated that

- the sector generated a turnover of over £569m, of which over 76% was contributed by the Almac Group of companies and just under 11% by Warner Chilcott's operations in Northern Ireland
- the LHS sector employed just over 5,050 people, of which 88% were employed by the Almac Group;

Analysis by Invest NI of the employment returns of 48 LHS firms in 2012 (which did not include data for Randox or Norbrook) suggested that 5,737 people were employed in the sector; Randox are believed to have approximately 1,000 employees (including staff based in London and outside Northern Ireland); we understand that Norbrook employs 1,500 people at its site in Newry and Almac employs up to 1,500 staff in the US. The HSC also employs almost 3,700 clinical staff in Northern Ireland. Thus the actual employment footprint of the sector in Northern Ireland (excluding HSC staff) is likely to be between 6,700-7,500 employees; this is significantly smaller than in the main regional concentrations of the LHS sector in England (e.g. the South East, West Midlands and East of England) but is approximately 70-75% of the LHS sector in Scotland.

We conclude that although the number of businesses in the sector has not increased significantly since 2006, employment has grown substantially, primarily through the expansion of Almac, Randox and a handful of other firms, some of which has been focused on overseas operations. The sector is characterised by the presence of a handful of larger businesses, each operating in a distinctive area of the LHS market with differing levels of engagement with the Northern Ireland supply chain and research base; a group of small and medium-sized SMEs with niche specialisms and some of which have demonstrated recent growth; and a larger number of microbusinesses, the majority of which employ fewer than five staff. 24 of the 48 firms included in Invest NI's 2012 LHS dataset were microbusinesses. Some of the larger LHS businesses in Northern Ireland include:

- Almac, the largest LHS business in Northern Ireland; founded by Sir Allen McClay in 2002, the firm has a diverse range of interests including the development of biomarkers and companion diagnostics, development of Active Pharmaceutical Ingredients (APIs) and outsourcing and clinical trials; the firm, which remains independently owned, also has a US presence in Pennsylvania
- Randox, another indigenous Northern Ireland business, which develops and manufactures diagnostic kits for biochemistry and endocrinology laboratories including a wide range of biomarkers and diagnostic reagents; the firm is also a contract manufacturer of diagnostic products for OEMs
- Norbrook Laboratories, founded by Lord Ballyedmond in the 1960s and now the largest privately-owned pharmaceutical company in the world specialising in veterinary, farm animal and equine health care

24 Strategy for UK Life Sciences, Office for Life Sciences/BIS 2011

25 <http://www.bbc.co.uk/news/health-15876289>

26 NI Life and Health Technologies Sector: Capabilities Study, Gap Analysis and Collaborative Network Assessment, BioBusiness Northern Ireland for Invest NI 2006

products and the development and manufacture of APIs; headquartered in Northern Ireland, the firm also has sites in Australia, Kenya and the USA

- Warner Chilcott is the only multi-national pharmaceuticals company with a presence in Northern Ireland; founded in Northern Ireland (as Galen) by Sir Allen McClay in the 1960s, the firm is now a global speciality pharmaceutical company focused on gastroenterology, women's healthcare, dermatology and urology, achieving this status through the acquisition of Proctor and Gamble's global pharmaceuticals business in 2009; its Northern Ireland manufacturing operation employs approximately 215 staff
- Perfecseal Inc, part of the Bemis group of companies and a world leading manufacturer of medical and pharmaceutical packaging including combination drug/device packaging and medical device and diagnostic packaging; the firm's Londonderry/Derry facility employs over 290 staff
- Terumo BCT, a global manufacturer of blood collection and apheresis systems with a facility in Larne employing just under 200 staff
- James Leckey Design, a manufacturer of postural support and therapy equipment for young people and adults with disabilities; the firm recently acquired new premises in Lisburn and employs almost 100 staff alongside an international network of product and sales advisors
- Armstrong Medical, a Coleraine based designer and manufacturer of respiratory disposables for anaesthesia and critical care including AMSORB PLUS, a carbon dioxide absorbent patented worldwide.

Northern Ireland has an internationally recognised research base in several key areas of LHS research. The University of Ulster's School of Biomedical Sciences was the highest ranked facility in the UK in the 2008 Research Assessment Exercise (RAE) and the University's Biomedical Sciences Research Institute (BMSRI) specialises in the study of the biological mechanisms associated with degenerative diseases including cancer and diabetes. The Centre for Cancer Research and Cell Biology at Queen's University Belfast is focused on developing an understanding of the cellular, genetic, epigenetic and molecular mechanisms in the pathogenesis of cancer through the development of biomarkers and biologically-determined targeted therapies.

Although it was only established in 2007, the CCRB was ranked within the top 20 UK Universities for cancer studies in the 2008 RAE. QUB has spun out a number of successful businesses including Almac Diagnostics and Fusion Antibodies.

The Northern Ireland Clinical Research Network (NICRN) supports the clinical research community in Northern Ireland. The network aims to improve access to clinical research for patients and health care professionals, enhance the quality of clinical research undertaken within HSC and integrate clinical research within and across HSC structures and services. The network supports ten regional research groups in key areas including cardiovascular, critical care, dementia, diabetes, respiratory health and stroke.

### Policy context

The BioBusiness network lies within a broad framework of UK Government, DETI and Invest NI strategies and policies over the period from 2011-2013; the most significant are summarised in the following paragraphs. A more detailed analysis of the policy context is presented in Appendix 1.

### Office for Life Sciences

The Office for Life Sciences was established by the Labour Government in 2009 to support the development and growth of the LHS sector in the UK. The OLS published the Strategy for UK Life Sciences<sup>27</sup> in 2011, recognising the major changes taking place in global healthcare and the need to ensure the long-term competitiveness of the UK industry. The report notes that *"the UK must capitalise on its strengths: its world-class science and clinical research, talent base of pioneering life science researchers, and the NHS, where discovery can be translated into results for patients"* but emphasises the need for the NHS *"to play a more active role in realising innovation."*

<sup>27</sup> Strategy for UK Life Sciences, Office for Life Sciences/BIS 2011

The strategy sets out a vision for the UK as a “*global hub for life sciences in the future, providing an unrivalled ecosystem....to translate discovery into clinical use for medical innovation within the NHS.*” The strategy sets out three core objectives to realise this vision:

- building a life sciences ecosystem – to develop more effective partnerships between Universities, clinicians, businesses and the NHS to make it easier to commercialise academic research, encourage adoption and diffusion of innovation in the NHS and promote the UK as a global centre for LHS investment
- attracting, developing and rewarding the best talent through promoting life sciences as a career option, improving international workforce mobility and strengthening collaboration between industry and academic and clinical researchers
- overcoming barriers and creating incentives for the promotion of health care innovation through changes to the tax system to incentivise R&D investment, including the introduction of the Patent Box to reduce corporation tax on profits from patents, increasing access to seed stage venture capital funds and streamlining the UK’s regulatory and compliance regime.

OLS published ‘*Strategy for UK Life Sciences: one year on*<sup>28</sup>’ in December 2012 which detailed progress against these objectives. Some of the key actions implemented to date included investing £1bn per annum through the National Institute for Health Research; introducing the Biomedical Catalyst investment fund to address the funding gap and implementing some of the key measures in the NHS Chief Executive’s report ‘*Innovation, Health and Wealth*<sup>29</sup>.’ These include the roll out of assistive (telehealth/telecare) technologies to 3 million people over the period to 2017 and rapid implementation of fluid monitoring technology although the report does not apply to the HSC in Northern Ireland.

#### ***The economic importance of the health technologies and life sciences sector: MATRIX report***

In October 2008 MATRIX– Northern Ireland’s science and industry panel – published its report on the LHS sector<sup>30</sup>. Whilst the report was prepared just under three years before the Invest NI funding round which is the subject of this evaluation commenced, the MATRIX report remains the only strategy developed specifically for the LHS sector in Northern Ireland.

Building on a review of global trends and drivers (including the increase in chronic diseases, cost pressures, the shift towards prevention and collaborative product development), the MATRIX strategy focuses on opportunities for the Northern Ireland LHS sector in two key areas:

- personalised medicine – the study suggests that the personalised medicine sector could capture up to 25% of pharmaceutical sales in the future and highlights the potential for Northern Ireland to become a centre for integrated research and development through a focus on commercially-targeted R&D projects; this would require closer integration of existing biotechnology and biomedical research strengths with research capabilities in areas including bioinformatics and advanced materials
- home-based telehealth/telecare, which was forecast to become a \$4.5bn global market opportunity by 2010; MATRIX proposed that the HSC should implement a whole system demonstrator programme to enable technology/service providers to use Northern Ireland as a test bed and create opportunities for businesses specialising in medical devices, telecommunications, data analysis and home care response.

There is limited evidence of partnership working between Universities, clinicians, businesses and the HSC to deliver the kind of integrated approach to unlocking the opportunities associated with personalised medicine that was advocated in the MATRIX report. However, Northern Ireland is now delivering one of the largest telehealth/telecare programmes in the UK through the Centre for Connected Health and Social Care (CCHSC). Via an £18m grant from the Department of Health and in partnership with the TF3 provider consortium CCHSC is rolling out the Telemonitoring NI service to 8,000 patients across Northern Ireland to provide remote monitoring of patients with chronic diseases.

<sup>28</sup> Strategy for UK Life Sciences: one year on Office for Life Sciences/BIS 2011

<sup>29</sup>

<sup>30</sup> Life & Health Sciences horizon panel report: prosperity and health delivered by science, PWC for MATRIX, October 2008



### **Programme for Government**

The Northern Ireland Executive's Programme for Government 2011-2015 identifies 'Growing a sustainable economy and Investing in the Future' as the key priority for the Executive. The Programme for Government sets out a number of relevant commitments including

- supporting the promotion of 25,000 jobs
- achieving £1 billion of investment in the Northern Ireland economy through foreign direct investment and indigenous firms
- supporting £300m of business investment in R&D, of which at least 20% is to be from SMEs
- increasing the uptake of economically relevant STEM courses by 700 places.

### **DETI Corporate Plan 2011-2015**

The 2011-2015 DETI Corporate Plan<sup>31</sup> identifies seven strategic objectives for the department, including:

- stimulate innovation, R&D and creativity
- help Northern Ireland businesses compete in the global economy
- encourage business growth.

The Corporate Plan sets out a number of relevant targets for the BioBusiness network over the 2011-2015 period, including promoting 6,300 jobs, £400m of investment commitments and £120m in new wages/salaries through locally owned companies, with 50% paying salaries above the NI Private Sector Median.

### **Invest NI Corporate Plan 2011-2015**

Invest NI's 2011-2015 Corporate Plan<sup>32</sup> sets out the role the agency will play to support wealth creation in Northern Ireland through a framework to both rebalance and rebuild the economy with six core themes:

- stimulating innovation, R&D and creativity
- improving employability and the relevance and use of skills
- competing in the global economy
- encouraging business growth
- developing our economic infrastructure
- promoting employment and employability.

Under the first of these themes, the plan notes that *"innovation remains at the core of all our actions, driving business growth, productivity growth, and economic growth"* whilst emphasising that *"there remains a significant challenge in mobilising individuals and firms, particularly SMEs, to increase their capacity and capability to innovate."* The plan sets out a number of relevant targets including

- secure £300 million investment in R&D (with at least 20% from SMEs).
- support 500 businesses to engage in first time R&D and 120 Collaborative R&D projects.
- support 40 Proof of Concept projects (University based).
- deliver 800 Innovation Vouchers.

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31 Corporate Plan 2011-2015, Department for Enterprise, Trade and Industry, 2011

32 Corporate Plan 2011-2015, Invest NI 2011