

Nordic Life Sciences sector study 2014



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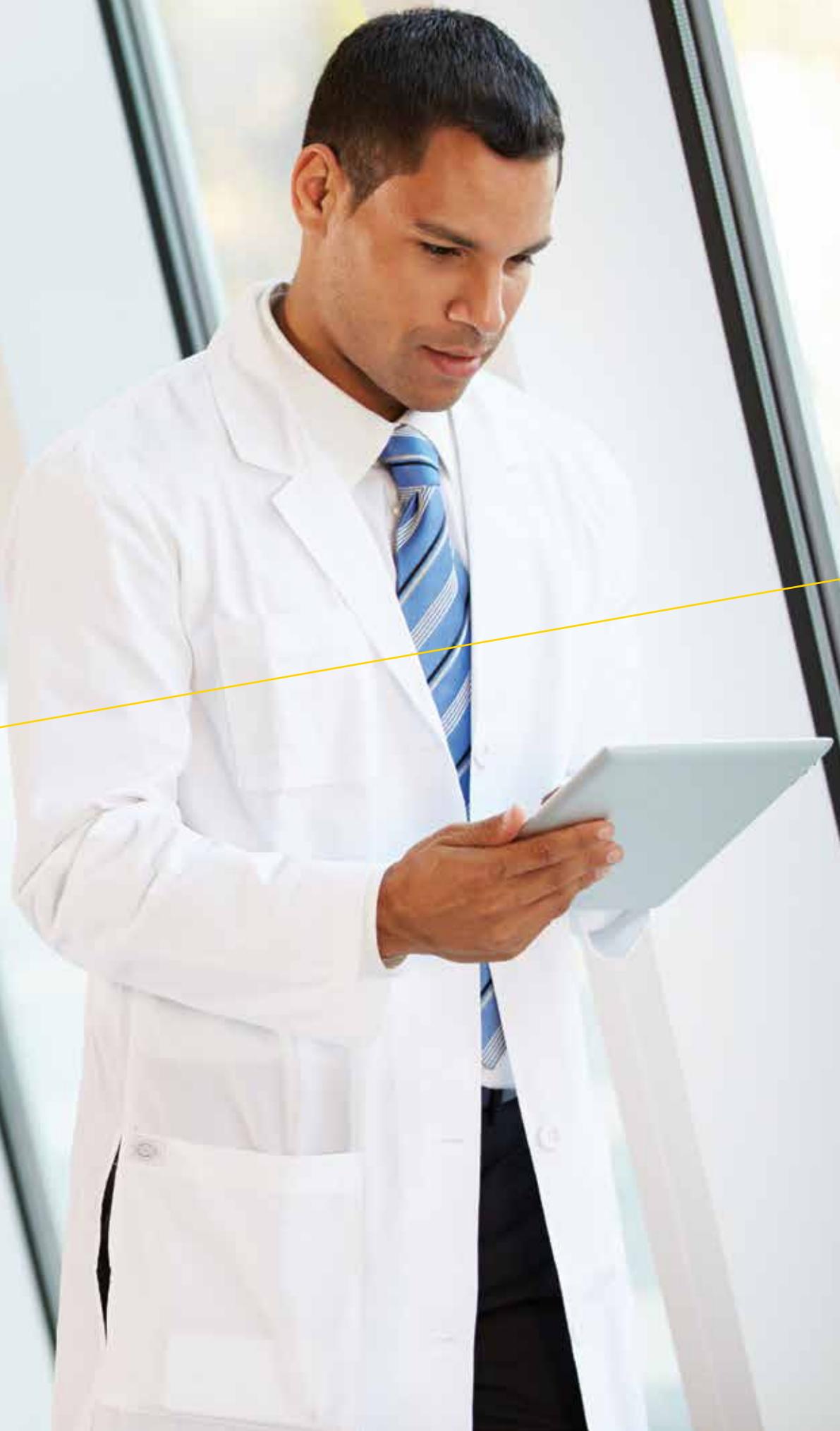
Building a better working world

The Swedish Life Science Industry Organization

swedenBIO

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Introduction

The Nordic Life Sciences sector is, despite a relatively small combined population of ca 25 million inhabitants¹, well-developed and holds some of the world's most innovative and promising projects in its pipeline. The Nordic market is attractive for the Life Sciences sector from a number of perspectives e.g., high degree of education, well-known researchers, well-developed infrastructure, high innovation rate and established data registries. The Life Sciences sector is important to the Nordic business environment with total annual revenue of €11.3 billion, of which €3.98 billion for biotechnology products and €7.30 billion for medical technology products^{2,3}.

With an increased pressure on health care systems and with rapid technology development, the Life Sciences sector is becoming more dependent on innovative business models to make R&D and operations as efficient as possible and to demonstrate the value of products to payers. The concept of patient centricity, where a service or a product is designed around the patient, is gaining momentum within the Life Sciences sector. These trends including patient-empowering and information-leveraging (PI) technologies, eHealth, big data, personalized medicine and orphan drugs are discussed in this study. We also give deeper insight into the challenges and opportunities that exists within the Nordic Life Sciences industry today, for instance with regards to how the Nordic Life Sciences clusters are formed, what the product pipelines look like in the different Nordic countries and how the financing landscape has changed over time.

The study was conducted by EY in June, July and August 2014 and was launched for the Nordic Life Sciences (NLS) Days organized by SwedenBIO, the Swedish life science industry organization. Data from EY studies as well as interviews with representatives from various Nordic Life Sciences companies form the foundation of this report. In addition, external research has been performed to triangulate and validate data.



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1. Norden - The Nordic Region (www.norden.org/en/the-nordic-region), Population, 2014.
2. Beyond Borders, *biotechnology industry report 2013*, EY, 2013.
3. Pulse of the Industry, *medical technology report 2013*, EY, 2013.

Definitions

The Life Sciences sector can be divided in subgroups, representing different technologies, different sets of competencies and different capital requirements. This study covers the following subgroups: biotechnology (including specialty pharma) and medical technology companies within the Nordics. The data does not include bigger traditional pharmaceutical companies, such as e.g., AstraZeneca and Novo Nordisk.

Biotechnology

Biotechnology (biotech) is the field of applying cellular and biomolecular processes to develop products and technologies intended to help improve our lives and health. Biotechnology finds application in e.g., pharmaceutical drug discovery and production, pharmacogenomics, and genetic testing (or genetic screening).

Also, products and technologies that are not defined as biotechnology as such, but are important parts of the biotech value chain, e.g., bioinformatics and technologies and services in the area of drug development, are included in this group.

Not included as core biotech in this study are companies that deal with classic biotechnology (e.g., classic biological methods for sewage treatment or biofilters), classic plant biology (classic plant breeding, seedling production), food and beverage production (beer brewers) or classic industrial biotechnology (fermentation/transformation for the production of antibiotics or fine chemicals, classic enzyme technology). Also not included are companies that only use biochemical analytical techniques (classic lab, clinical and genetic diagnostics), microscopical diagnostics. Companies mainly using established immunology methods (ELISA etc.), offering diagnostic instruments (based on fluorescence or SPR etc.) or producing medical devices or consumables are not included.

Also not included are companies only concerned with the wholesale and distribution of biotech products as well as companies whose main purpose is not modern biotechnology (this includes traditional SMEs and big companies from the pharma and agro industry, even though they work with modern biotech methods).

Specialty pharma companies, although not really applying biotechnological methods, are included in this report. Specialty pharma typically includes drugs for conditions that are high in cost or high-maintenance, i.e., require specialized delivery and administration on a continuous basis (like injectable or infusion therapies).

Medical technology

Medical technology (medtech) companies are primarily designing and manufacturing medical technology equipment and supplies, including medical devices, diagnostics, drug delivery devices and analytical instruments.

Medtech companies are classified into one of five product groups:

1. ***Imaging:*** companies developing products used to diagnose or monitor conditions via imaging technologies, including radiography; magnetic resonance imaging; nuclear imaging; ultrasound; tomography; near-infrared spectroscopy; thermography; tactile imaging; and echocardiography
2. ***Non-imaging diagnostics:*** companies developing products used to diagnose or monitor conditions via non-imaging technologies, e.g., laboratory, ECG, in vitro testing and pathology specimens
3. ***Research and other equipment:*** companies developing equipment used for research or other purposes, including analytical and Life Sciences instruments, specialized laboratory equipment and furniture
4. ***Therapeutic devices:*** companies developing products used to treat patients, including therapeutic medical devices, tools or drug delivery/infusion technologies
5. ***Other:*** companies developing products that do not fit in any of the categories above were classified in this segment

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Executive summary

Nordic Life Sciences clusters are strongly associated with geographical areas close to the capital cities of Sweden (Stockholm), Denmark (Copenhagen), Norway (Oslo) and Finland (Helsinki). In terms of revenues, the pharmaceutical industry is dominating within the Nordics, followed by medtech, with biotech in a distant third place. In terms of European ranking based on absolute numbers of drug candidates, the Nordics is represented by Sweden (6th place), Denmark (7th place), Norway (13th place) and Finland (15th place). The majority of the compounds of the Nordic biotech pipeline are generated in Sweden and Denmark, which together contributed to almost 80% of the total pipeline in 2013.

Capital raised by biotech and medtech companies headquartered in Europe amounted to €4.29 billion and €3.23 billion respectively in 2013 (total of €7.52 billion). The Nordic countries raised a total of €852 million, corresponding to 11.5% of the total capital raised in Europe. (Please note that the study does not include public financing.) Sweden had the highest amount of financings among the Nordic countries in 2013 with a total of €533 million. Financing of R&D activities within the Nordics has decreased since the financial crisis in 2008 as there has been a shift in financing type from venture capital and follow-on financing to increased financing through debt.

Since 2005, an average of 10 major M&A deals has been completed per year within the Nordic Life Sciences industry. The American medtech company Baxter made the largest acquisition within the Nordics, when acquiring the Swedish dialysis specialist Gambro in 2013, for a total value of €3.04 billion. The aggregate potential value and the number of strategic alliances based on biobucks, (financing agreement where a biotech firm typically sells the marketing rights to its drug-under-development for a mix of upfront cash and the promise of future payments), fell with 76% and 54% respectively in 2013, reaching the lowest level of €448 million since at least 2005. In 2013, the most dominant biotech partnerships in the Nordics involved Danish or Swedish companies, with the vast

majority of potential value in the alliances involving companies in Denmark. The largest alliance, with a potential value of €320 million and an upfront payment of 6%, was between the Japanese company Shionogi and the Danish/US company Egalet.

The digitalization and new IT technologies are important enablers driving the trend of increased focus on health outcomes and increased patient centricity. Big data-driven analytics, PI technologies, personalized medicine and orphan drugs are examples of strategic opportunities that are top-of-mind for most life sciences companies. In the new eHealth environment, interconnection is crucial on several levels; corporates need to collaborate with other stakeholders in new ways and IT systems need to be interlinked through common languages and terminology. Due to historic advancements within the ICT sector and within health care-related eHealth specifically, the Nordics should have a solid starting point for continued progress and expansion of the different dimensions of eHealth, including utilizing already established databases, to meet the needs of the future Life Sciences sector.

With venture capitalists looking outside the Nordic borders for investments, there is a challenge to maintain knowledge and know-how. In order for the Nordics to keep up with the upcoming changes in the industry, there is a need for increased collaboration between the Nordic clusters and more explicit communication of benefits of the Nordic market. Sweden's strong research, Norway's financing strengths and Denmark's favorable regulations combined will create a stronger Nordic market and a more favorable future if commonly utilized.

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Part 1: Nordic Life Sciences sector overview

1.1 Clusters by country

Nordic Life Sciences clusters are strongly associated with geographical areas close to the capital cities of Sweden (Stockholm), Denmark (Copenhagen), Norway (Oslo) and Finland (Helsinki). In addition, Danish Copenhagen and the Swedish province of Skåne together form the transnational Life Sciences cluster Medicon Valley. There are also smaller Life Sciences clusters in the northern parts of each Nordic country.

In 2013, pharmaceuticals constituted 11.4% of total exports from Denmark⁴ and 5.2% of total exports from Sweden⁵. Danish and Swedish Life Sciences clusters have historically been formed around Nordic Big pharma companies such as AstraZeneca, pharmacia, Novo Nordisk and Lundbeck. As an example, AstraZeneca built R&D sites in the western, southern and eastern parts of Sweden, and even though only the western site remains, the Swedish Life Sciences clusters are thriving in those areas. The pattern is the same in Denmark, where the presence of larger pharma companies have a positive impact on the emergence of smaller Life Sciences companies.

In terms of revenues, the pharmaceutical industry is dominating in both Sweden and Denmark, followed by medtech, with biotech in a distant third place. Finland has a few pharmaceutical development companies such as Orion pharma, but the main focus of the Finnish Life Sciences sector is biotech. The formation of regional biotech centers of expertise, through a national HealthBIO program, has provided the basis for Finnish Life Sciences clusters.

In Norway, a biotech and medtech cluster has been created in the capital city Oslo. The Norwegian private and public sectors have high investment capacity. Most of this capital is, however, channeled into the oil and gas industry and knowledge-based Life Sciences businesses in their earlier stages lack access to risk capital⁶. The public sector has, however, provided extensive funding for Life Sciences R&D at universities and hospitals over the past years. If early-stage risk capital and Life Sciences expertise are adequately combined in the future, successful companies such as Algeta may emerge within the Oslo Life Sciences clusters.



1. BioMed Community (Aalborg)
2. INCUBA Science Park (Aarhus)
3. Odense Cluster (Odense)
4. Medicon Valley (Öresund region)
5. Biotech Umeå (Umeå)
6. Uppsala BIO, Stockholm-Uppsala Life Science (Uppsala)
7. Flemingsbergs Science, Stockholm Life, Stockholm-Uppsala Life Science (Stockholm)
8. Mjärdevi Science Park (Linköping)
9. Sahlgrenska Science Park (Gothenburg)
10. Medicon Village (Lund)
11. Medeon (Malmö)
12. BioTech North (Tromsø)
13. Heidner Biotek (Hamar)
14. Marineholmen Science Park (Bergen)
15. Oslo Cancer Cluster, Oslo Medtech (Oslo)
16. BusinessOulu (Oulu)
17. Kuopio Innovation (Kuopio)
18. FinnMedi (Tampere)
19. Turku Science Park (Turku)
20. Culminatum Innovation (Helsinki)

4. Statistics Denmark (www.statbank.dk), Table SITC2R4Y, Value of Medicinal And pharmaceutical Products Exports, 2013
5. Statistics Sweden (www.scb.se), Press Release Nr 2014:301, Value of pharmaceutical products Exports, 2013

6. *Life Sciences Rapporten 2012, Menon Publikasjon nr 9, 2012*

1.1.1 Sweden

The Swedish Life Sciences companies are geographically concentrated to the big city regions. The cities of Stockholm and Uppsala contain several different Life Sciences clusters and between them they house companies that employ 50% of the Swedish Life Sciences workforce, while another 20% of the employees reside in the Gothenburg area and 16% work in the southern part of Sweden, where the city Lund is located.

| City/region | Cluster name | Comment | Sector focus |
|-------------------|---------------------------------|--------------------------------|--------------------------|
| Gothenburg | Sahlgrenska Science Park | | Biotech, medtech, pharma |
| Linköping | Mjärdevi Science Park | | Biotech, medtech, pharma |
| Lund | Medicon Village | | Biotech, medtech, pharma |
| Stockholm | Flemingsbergs Science | | Medtech |
| Stockholm | Stockholm Life | | Biotech, medtech, pharma |
| Uppsala | Uppsala BIO | | Biotech, medtech, pharma |
| Uppsala/Stockholm | Stockholm-Uppsala Life Sciences | | Biotech, medtech, pharma |
| Umeå | Biotech Umeå | | Biotech, pharma |
| Öresund | Medicon Valley | Transnational (Sweden/Denmark) | Biotech, medtech, pharma |
| Malmö | Medeon | | Biotech, medtech, pharma |

1.1.2 Denmark

Denmark is geographically small but the country is one of the leaders of European drug development. Life Sciences companies are concentrated to the island of Zealand, containing the capital city Copenhagen. Separating Zealand and the south-western part of Sweden is the strait of Öresund, which has given name to the region. The Life Sciences activities in the Öresund region are collectively gathered in the Danish-Swedish Medicon Valley cluster, which is one of Europe's leading pharma and biotech clusters given its strong research base and support from local pharmaceutical companies.

| City/region | Cluster name | Comment | Sector focus |
|-------------|---------------------|--------------------------------|--------------------------|
| Aalborg | BioMed Community | | Medtech |
| Öresund | Medicon Valley | Transnational (Denmark/Sweden) | Biotech, medtech, pharma |
| Aarhus | INCUBA Science Park | | Biotech, medtech, pharma |
| Odense | Odense Cluster | | Biotech, medtech, pharma |

1.1.3 Norway

Norway's strong marine traditions have been fundamental to the growth of marine biotech, which later has expanded into medical biotech. A large part of the country's biotech industry is currently focused on cancer research, partly due to a strong academic environment and access to large biobanks. The biotech industry is concentrated in and around the capital city, Oslo.

| City/region | Cluster name | Comment | Sector focus |
|-------------|----------------------------|---------|-----------------|
| Hamar | Heidner Biotek | | Biotech |
| Oslo | Oslo Cancer Cluster | | Biotech, pharma |
| Oslo | Oslo Medtech | | Medtech |
| Tromsø | Biotech North | | Biotech |
| Bergen | Marine-holmen Science Park | | Biotech, pharma |

1.1.4 Finland

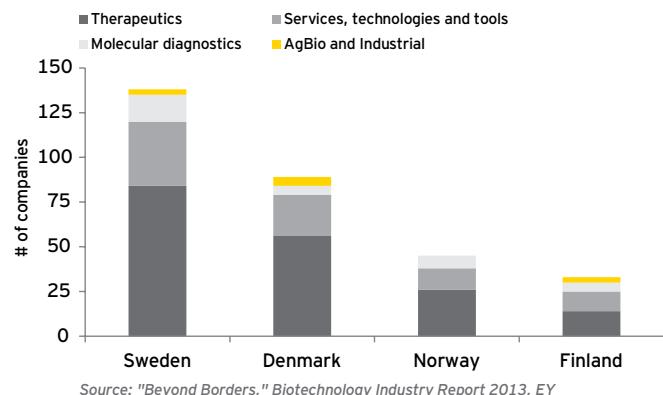
During 2007 through 2013, the Finnish Life Sciences community has been focused on health-related biotech, primarily through the national HealthBIO program. Finland's biotech companies were gathered around five major regional centers of expertise and activities were coordinated at regional and at national level. After the termination of the HealthBIO program, other life sciences initiatives followed, and the original regional biotech clusters have remained and formed the Finnish Life Sciences clusters of today.

| City/region | Cluster name | Comment | Sector focus |
|-------------|-----------------------|-------------------------------------|--------------|
| Helsinki | Culminatum Innovation | Former regional center of expertise | Biotech |
| Kuopio | Kuopio Innovation | Former regional center of expertise | Biotech |
| Oulu | BusinessOulu | Former regional center of expertise | Biotech |
| Tampere | FinnMedi | Former regional center of expertise | Biotech |
| Turku | Turku Science Park | Former regional center of expertise | Biotech |

1.1.5 Sector segmentation

A bar chart illustrating the Nordic countries and their respective number of Life Sciences companies, divided by sector segment, clearly highlights the dominance of Therapeutics in the Nordic Life Sciences sector.

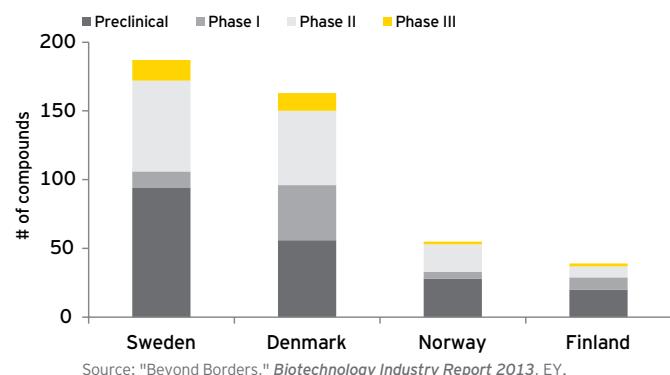
Nordic Life Sciences segments



1.2 Pipeline by country

The majority of the compounds of the Nordic biotech pipeline are generated in Sweden and Denmark, which together contributed almost 80% of the total pipeline in 2013. Almost half of the compounds were in preclinical phase, while the other half were in Phase I, II or III. Within the clinical phases, 27% were in Phase I, 60% in Phase II and 13% in Phase III. Denmark has the biggest drug development pipeline in Europe, measured per capita, alongside Switzerland and Israel, and in terms of European ranking based on absolute numbers of drug candidates, the Nordics is represented by Sweden (6th place), Denmark (7th place), Norway (13th place) and Finland (15th place).

Nordic biotech pipeline, 2013



1.2.1 Sweden

| Swedish biotech pipeline, 2013 (2012) | | | | | |
|---------------------------------------|---------------------|-------------------|---------------------|-------------------|---------------------|
| Country | Preclinical | Phase I | Phase II | Phase III | Total |
| Sweden | 94 (73) | 12 (17) | 66 (67) | 15 (16) | 187 (173) |
| Denmark | 56 (59) | 40 (37) | 54 (49) | 13 (18) | 163 (163) |
| Norway | 28 (27) | 5 (7) | 20 (17) | 2 (3) | 55 (57) |
| Finland | 20 (14) | 9 (17) | 8 (9) | 2 (2) | 39 (35) |
| Nordics | 198 (173) | 66 (71) | 148 (142) | 32 (39) | 444 (428) |

The Swedish pipeline is the largest in the Nordics, with the majority of the compounds in 2013 targeting cancer (27%), followed by compounds targeting autoimmune (14%), infectious (14%) and neurological diseases (12%). Examples of companies with several preclinical compounds in each of the therapy areas were BioInvent (cancer), Toleranzia (autoimmune disease), ChronTech pharma (infectious disease) and Neurovive (neurological disease). Phase I compounds were few and almost exclusively targeting cancer (67%), with Active Biotech and BioInvent contributing the most to this pipeline. Phase II was dominated by compounds targeting cancer (26%) and autoimmune disease (14%), with Active Biotech developing several compounds in both areas, and also by infectious disease (18%), where Medivir was the main contributor. Out of the 15 compounds in Phase III, 10 were developed by immune system specialist Active Biotech, Specialty pharma Company Meda or by rare disease specialist Swedish Orphan Biovitrum⁷. Products reaching market during 2013 included Medivir's Simeprevir that was approved for the treatment of genotype 1 hepatitis C in Japan, Canada and the US. During 2014, it also has been approved in the European Union and Russia⁸. Meda's Dymista was approved for the treatment of perennial allergic rhinitis in the Europe during 2013⁹.

1.2.2 Denmark

| Danish biotech pipeline, 2013 (2012) | | | | | |
|--------------------------------------|---------------------|-------------------|---------------------|-------------------|---------------------|
| Country | Preclinical | Phase I | Phase II | Phase III | Total |
| Sweden | 94 (73) | 12 (17) | 66 (67) | 15 (16) | 187 (173) |
| Denmark | 56 (59) | 40 (37) | 54 (49) | 13 (18) | 163 (163) |
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| Finland | 20 (14) | 9 (17) | 8 (9) | 2 (2) | 39 (35) |
| Nordics | 198 (173) | 66 (71) | 148 (142) | 32 (39) | 444 (428) |

If compounds in the preclinical phase are excluded, Denmark has the largest pipeline in the Nordics, with about half of the compounds in 2013 developed within oncology. Major preclinical contributors were Affitech (with compounds against cancer, autoimmune and infectious disease), LiPlasome pharma (with compounds against cancer), Santaris pharma (with compounds against cancer and cardiovascular disease) and Zealand pharma (with compounds against cardiovascular, metabolic and endocrine disease). Half of the Phase I compounds were developed to target cancer, with Topotarget as the largest contributor. The oncology dominance was even more evident in Phase II, with close to 60% cancer compounds and with Genmab, Topotarget and Bavarian Nordic developing almost all of them. In Phase III, 10 out of 13 compounds targeted cancer and 8 of these were developed by Genmab, a company specialized in human antibody therapeutics⁷. In February 2013, Zealand pharma's Lyxumia was granted market authorization in the EU and Japan for treatment of adults with type 2 diabetes¹⁰.

7. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.

8. Medivir.se, 2014

9. Meda.se, 2014

10. Zealandpharma.com, 2014

1.2.3 Norway

| Norwegian biotech pipeline, 2013 (2012) | | | | | |
|---|---------------------|-------------------|---------------------|-------------------|---------------------|
| Country | Preclinical | Phase I | Phase II | Phase III | Total |
| Sweden | 94 (73) | 12 (17) | 66 (67) | 15 (16) | 187 (173) |
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| Nordics | 198 (173) | 66 (71) | 148 (142) | 32 (39) | 444 (428) |

The size of the Norwegian pipeline is approximately one-third of the Swedish pipeline or half of the Danish pipeline. In 2013, close to half of the compounds targeted cancer, while most of the remaining compounds targeted infectious disease. A large portion of the preclinical compounds were developed by APIM Therapeutics (cancer) and Bionor pharma (infectious disease). There were only five Phase I compounds, three of which were against cancer. Almost half of the Phase II compounds were cancer treatments, contributed mostly by Biotec pharmacon, Algeta and PCI Biotech. The only two Phase III compounds were developed by SantoSolve, which specializes in painkillers¹¹.

1.2.4 Finland

| Finnish biotech pipeline, 2013 (2012) | | | | | |
|---------------------------------------|---------------------|-------------------|---------------------|-------------------|---------------------|
| Country | Preclinical | Phase I | Phase II | Phase III | Total |
| Sweden | 94 (73) | 12 (17) | 66 (67) | 15 (16) | 187 (173) |
| Denmark | 56 (59) | 40 (37) | 54 (49) | 13 (18) | 163 (163) |
| Norway | 28 (27) | 5 (7) | 20 (17) | 2 (3) | 55 (57) |
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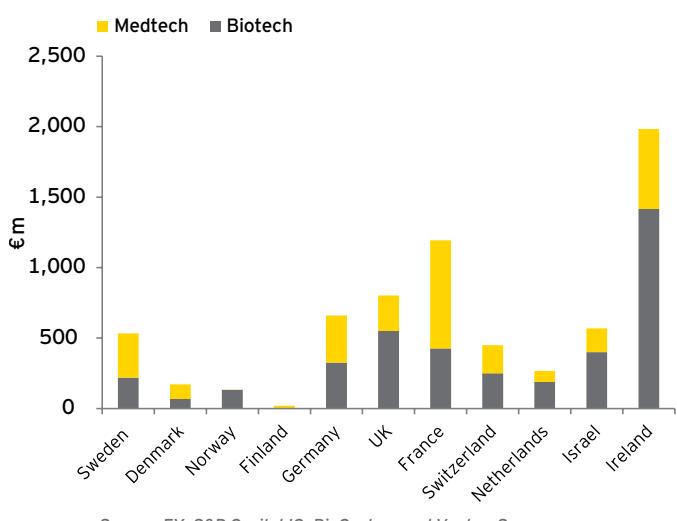
The Finnish pipeline is the smallest in the Nordics, about 20% of the Swedish and about 25% of the Danish in size. Most compounds, about 20%, are developed within neurology, while the rest are spread out between cancer, infectious, autoimmune, cardiovascular and respiratory disease. In the preclinical phase, 60% of the compounds were developed by Biotie Therapies and Faron pharmaceuticals. Biotie Therapies also dominated Phase I, with neurology and dermatology compounds. In Phase II, Biotie Therapies and FIT Biotech were

the main contributors with compounds against neurological disease and substance abuse as well as infectious disease respectively. In February 2013, Biotie's partner Lundbeck received marketing authorization in the EU for Selincro, aimed at reducing alcohol consumption of adult patients with an alcohol addiction¹³. The only two Phase III compounds were developed by Faron pharmaceuticals and targets respiratory disease¹¹.

1.3 Financing

Since the global recession in 2008, the Life Sciences industry funding totals have been increasing. Capital raised by biotechnology and medical technology companies headquartered in Europe measured €4.29 billion and €3.23 billion in 2013, to a total of €7.52 billion. The Nordic countries raised a total of €852 million, contributing with 11.5% of the total capital raised in Europe. Ireland dominated the European Life Sciences market by raising 26.8% of total capital raised^{11,12}. The Irish Industrial Development Agency (IDA) provides financial support particularly to companies that focus on research and development, which in combination with Ireland having the lowest corporation tax in Europe at 12.5% explain the Irish domination in capital raised. In addition to a growing number of companies locating their R&D to Ireland due to the low corporate tax (so called inversion), other companies choose to register their products on Ireland for the same reason¹⁴.

Capital raised by selected European countries in 2013



Source: EY, S&P Capital IQ, BioCentury and VentureSource

11. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.

12. EY, Pulse of the Industry, *Medical Technology Report 2013*

13. Biotie.com, 2014

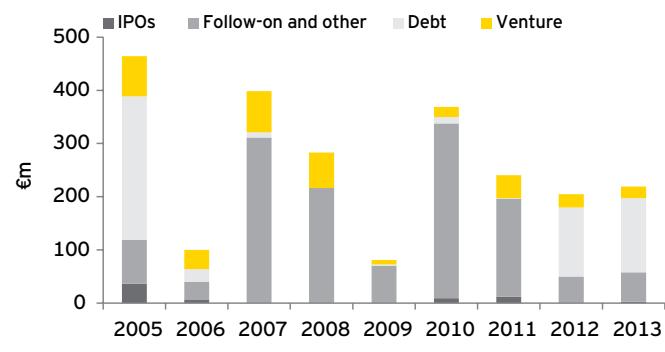
14. Industrial Development Agency of Ireland (www.idaireland.com), Tax Regime, 2014



1.3.1 Sweden

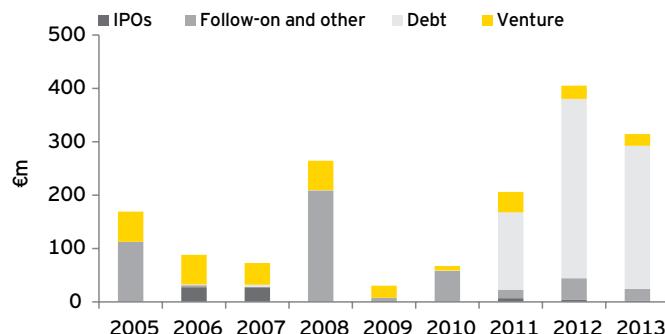
Historically, Sweden's and Denmark's biotechnology industries have together raised the largest amount of capital within the Nordics. This is reflected in the two countries developing 80% of all products in the pipeline, as well as having the strongest Life Sciences clusters in Scandinavia. However, since the financial recession in 2008, Sweden's biotechnology and medical technology industry financings have recovered surprisingly well, as Sweden has raised the largest amount of capital among its Nordic neighbors. Initially, the recovery of biotechnology financing was driven by increased amount of follow-on offerings, but has now been shifted to increased financing by debt. Financing by follow-on offerings within the biotechnology industry have thereby decreased by 393% since 2010, while we have seen an increase of debt by 1,170% to a total of €140 million. The financial crisis inhibited investments other than loans, forcing companies to increase their debt-to-equity ratio in order to avoid bankruptcy. During 2007 to 2013 Meda raised US\$153 million and SOBI US\$119 million through debt financing, corresponding to 59% respectively 30% of the total Swedish biotech debt financing for that period. In 2013, the Swedish biotech financings other than debt increased for the first time by 6.8% since the 2010 recovery from the financial recession. However, compared to 2010, it is still a decrease by 41%. Also notable is that venture financing has decreased to record low levels since 2009, which could be a sign of major issues for companies trying to raise capital in early stages -- implying a threat to their survival. Subsequently the IPO activity through the past years has been on a historically low level. After all, the negative trend has slowed in 2014 due to the listing of Bactiguard and Recipharm^{15,16}.

Swedish biotech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

Swedish medtech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

15. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.

16. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013



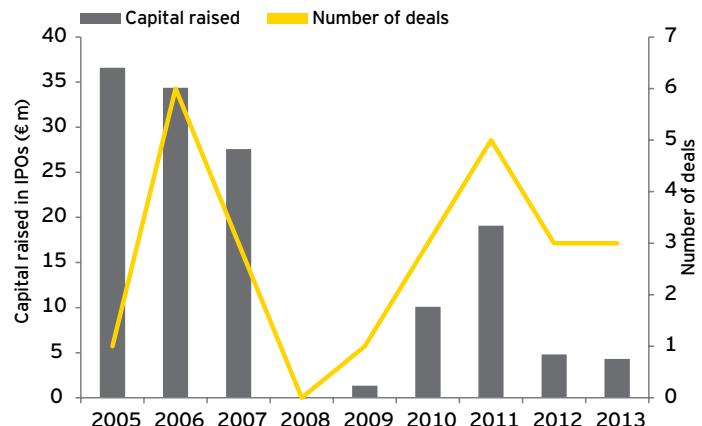
The financing decline in 2008 and the shift from financing through follow-on offerings to debt can also be seen within the Swedish medtech industry. The amount of capital recovered in 2011 has decreased ever since by 455%, from €19.3 million to €4.2 million in 2013.. The high level of debt in 2012 contributed to the highest financing figures over the last 10 years. Funding by debt decreased in 2013 by about 20%^{17,18}.

The Swedish Life Sciences industry has experienced a major reduction in capital raised from IPOs since the financial recession in 2008. The amount of capital recovered in 2011 but has decreased ever since by 77%, from €19.1 million to €4.3 million in 2013. Even if the capital raised has decreased since the financial recession in 2008, the number of IPO deals has increased. Because of this, more and more Swedish Life Sciences companies are hence looking for public financing, including both biotech and medtech companies, but the deals are much smaller and raise much less capital than before the crisis. For example, in 2013 only three companies were listed and they raised less than €5 million^{17,18}.

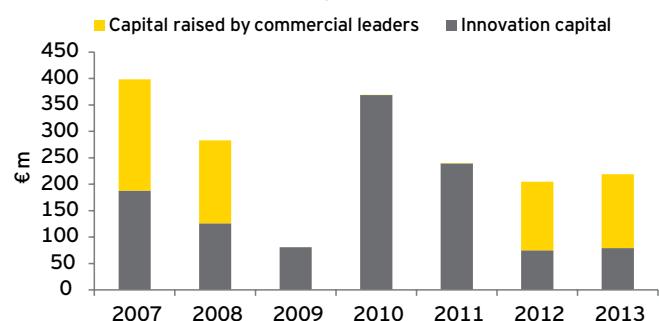
Over the last 10 years, the Nordic countries have seen the highest numbers of IPOs within Life Sciences in Sweden.

In Sweden, both the total amount and the share of innovation capital (equity capital raised by companies with revenues of less than US\$500 million) within biotechnology have been fluctuating during the last ten years. However, the amount of innovation capital raised by Swedish companies was essentially unchanged between 2012 and 2013, at about €75 million. The share of innovation capital has been decreasing since 2010^{17,18}.

Swedish Life Sciences IPO per year



Share of innovation capital within biotech in Sweden



Source: EY, Capital IQ, BioCentury and VentureSource
Innovation capital is equity capital raised by companies with revenues of less than US\$500 million. Commercial leaders have revenues above US\$500 million.

17. "Beyond Borders," Biotechnology Industry Report 2013, EY, 2013.
18. "Pulse of the Industry," Medical Technology Report 2013, EY, 2013

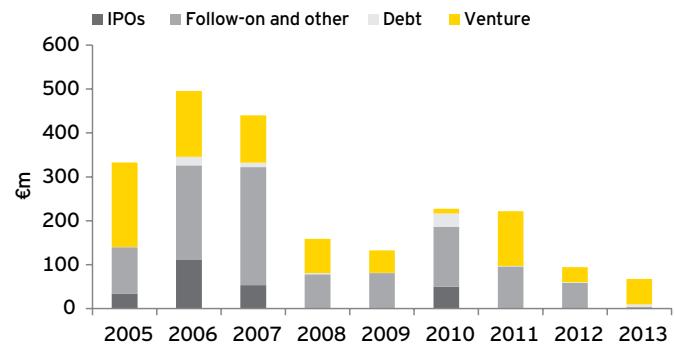


1.3.2 Denmark

The Danish Life Sciences industry took a major hit during the financial crisis in 2008. Capital raised within biotech increased slightly in 2010 but has reached its lowest point of €67 million in 2013, a decrease of 338% since 2010 and 740% since 2006. The decrease is mainly due to follow-on financings, which in 2013 were almost non-existent. This is also the case with IPO activities; the last time IPOs contributed to biotech financings was in 2010. Despite decreased financing volumes within the Danish Life Sciences industry, venture capital increased by 50% from 2012 to 2013 to a total of €68 million^{19,20}.

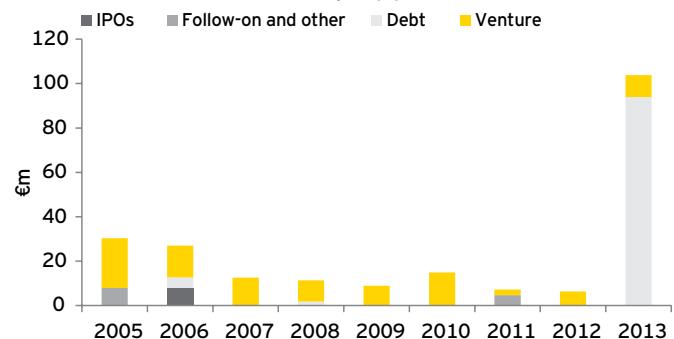
The Danish medtech industry has historically been weaker than the biotech industry. Venture financing has historically constituted the vast majority of the industry's total funding and the follow-on financing has been almost absent. However, in contrast to the biotech industry, the medtech technology industry raised a large amount in debt financings in 2013. Ambu is the single contributor to this figure as the hospital device supplier secured a €94 million bond agreement. In general, the medtech industry has been offered more attractive debt terms compared to the biotech industry, due to the high risks of biotech R&D^{19,20}.

Danish biotech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

Danish medtech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

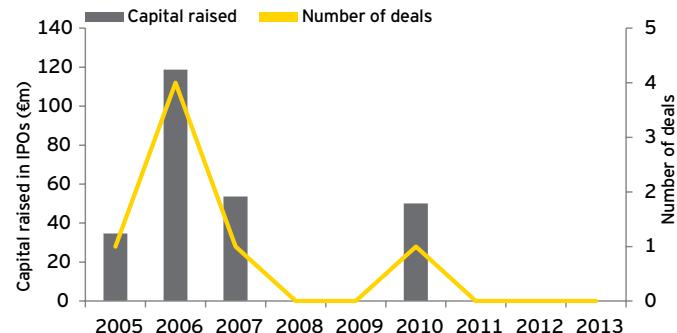
19. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.
20. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013



Similar to Sweden, the Danish Life Sciences industry has experienced a major reduction in capital raised from IPOs since the financial recession in 2008. Only one IPO deal has been initiated since 2008, when Zeeland pharma raised €50 million in connection with an IPO in 2010. However, IPOs within the Danish Life Sciences industry are awaiting an upturn in 2014 as two IPOs with a total value of €45.6 million have already been initiated. Both IPOs were within biotech, where Egalet represents the majority of the capital with an overallotment option worth €43.6 million and Saniona raised €1.96 million^{21,22}.

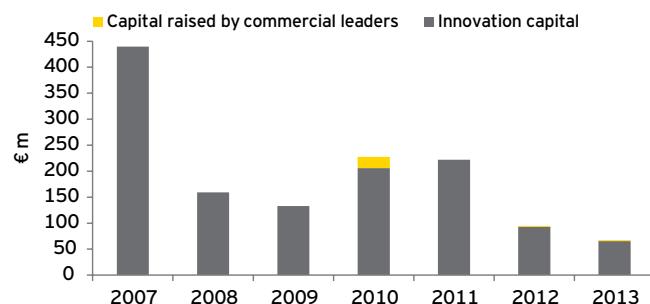
The amount of innovation capital for the biotechnology sector in Denmark has been decreasing since the financial crisis in 2008 though and has not recovered to its prior years. Since 2008, the industry has raised an average of €146 million a year in innovation capital, compared to €440 million during 2007^{21,22}.

Danish Life Sciences IPO per year



Source: EY, Capital IQ, BioCentury and VentureSource

Share of innovation capital within biotech in Denmark



Source: EY, Capital IQ, BioCentury and VentureSource
Innovation capital is equity capital raised by companies with revenues of less than US\$500 million.
Commercial leaders have revenues above US\$500 million.

21. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.
22. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013

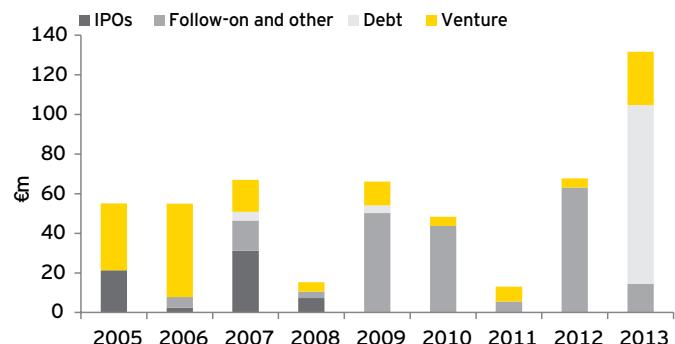


1.3.3 Norway

The Norwegian Life Sciences industry activities have historically been more modest than in Sweden and Denmark. As in the other Nordic countries, the financial crisis in 2008 as well as the aftershock in 2010 hit biotech financing in Norway hard. However, the Norwegian biotech industry financings have recovered quickly, raising equivalent amounts of capital as during pre-crisis years. In 2013, the Norwegian biotech industry raised the largest amount of financing over the last nine years amounting to a total of €132 million. This is partly due to the increase in venture capital financing by 540% since 2012 to a total of €27 million, but the major source of impact is an increased amount of debt financing to a total of €90 million in 2013. Algeta is the single contributor to this figure as the oncology specialist secured a €90 million bond agreement. Financing from follow-on initiatives has historically been the major financing type, but decreased with 454% in 2013^{23,24}.

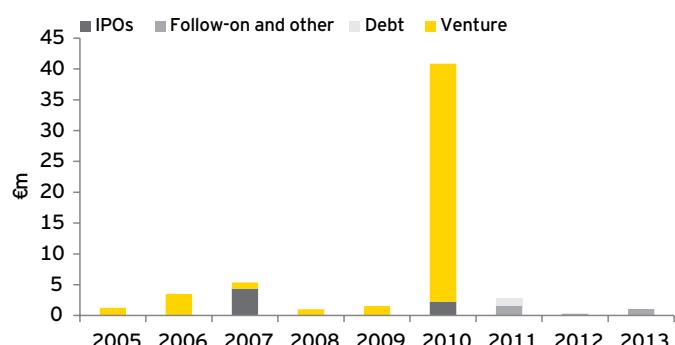
The majority of financings are within the biotech industry, with medical technology representing an average of only 3.3% of the Norwegian Life Sciences industry financings, raising less than €5 million a year. However, in 2010, the Norwegian nasal specialist OptiNose received an investment of €36.6 million, generating the highest financing from venture capital within the Norwegian medtech industry over the last nine years^{23,24}.

Norwegian biotech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

Norwegian medtech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

23. "Beyond Borders," Biotechnology Industry Report 2013, EY, 2013.

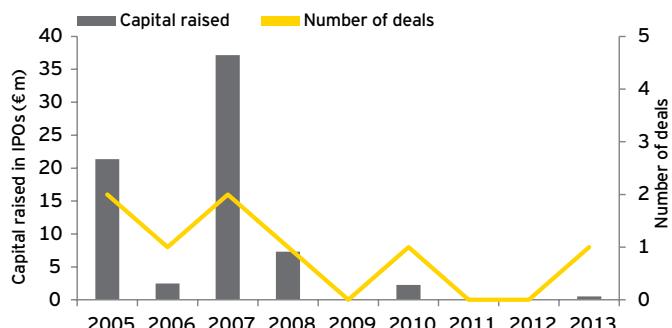
24. "Pulse of the Industry," Medical Technology Report 2013, EY, 2013



Like its Nordic counterparts, here the Norwegian Life Sciences industry has experienced a major reduction in capital raised from IPOs since the financial recession in 2008. Only two IPOs have been initiated, one within medtech in 2010 and one within biotech in 2013, both less than €2.5 million^{25,26}.

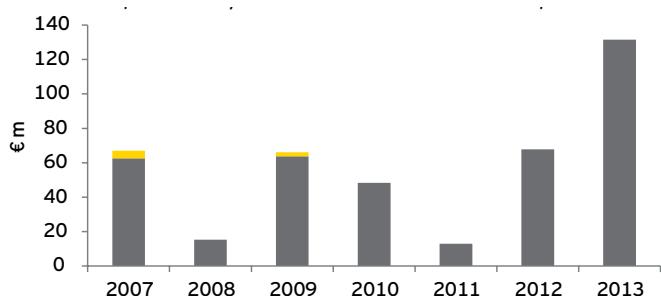
As in Denmark, the share of innovation capital within biotechnology in Norway is high. However, while most of the Nordic countries experienced a decline in volume in connection with the financial crisis in 2008, the Norwegian biotechnology industry has experienced an increase in innovation capital, with the exception of 2011. The innovation capital totals reached €132 million in 2013, which is the highest volume since at least 2007 and an increase by 94% since 2012. The increase was mainly due to Algeta raising a convertible bond of €90 million^{25,26}.

Norwegian Life Sciences IPO per year



Source: EY, Capital IQ, BioCentury and VentureSource

Share of innovation capital within biotech in Norway



Source: EY, Capital IQ, BioCentury and VentureSource
Innovation capital is equity capital raised by companies with revenues of less than US\$500 million. Commercial leaders have revenues above US\$500 million.

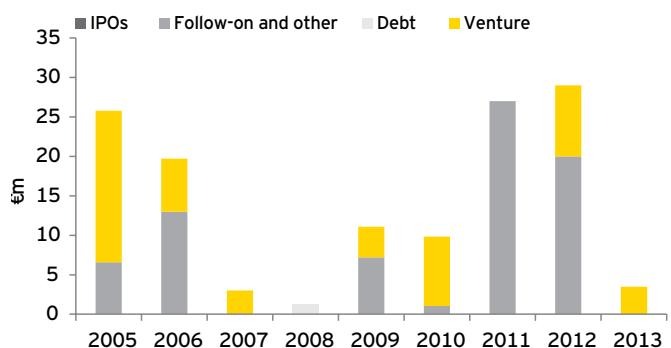
25. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.
26. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013



1.3.4 Finland

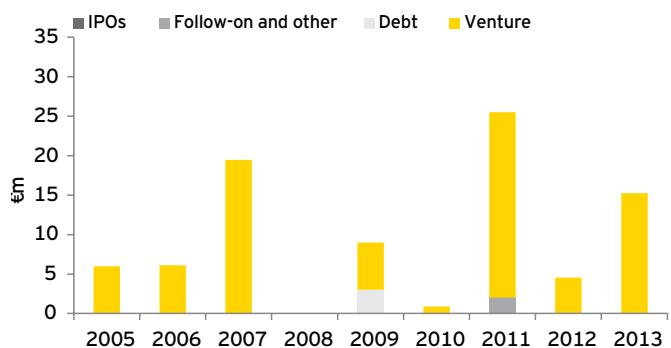
As in the other Nordic countries, the Finnish Life Sciences industry took a big hit during the financial crisis in 2008, when all types of financings were almost non-existent. However, the industry recovered well, showing the same type of financing pattern as before the crisis. Finland is the smallest Life Sciences market in the Nordics, with an average total financing of €25.5 million a year between 2005 and 2013. In 2013, the Finnish Life Sciences industry financings decreased by 44% to a total of €19 million, of which biotech financings decreased by 829% to a total of €4 million and medtech financings increased by 300% to a total of €15 million. The Finnish Life Sciences industry is represented mainly by two financing types, where the biotech industry is mainly dependent on follow-on financing and the medtech industry relies most heavily on venture capital. The amount of debt has historically been very low, and companies raised debt only during the financial crisis in 2008 and 2009. The most recent IPO was in June 2014 when Herantis pharma raised €14.5 million. Prior to that, there has been no IPOs since Biotie Therapies raised €18.4 million through an IPO in 2000^{27,28}.

Finnish biotech financings by year



Source: EY, Capital IQ, BioCentury and VentureSource

Finnish medtech financings by year



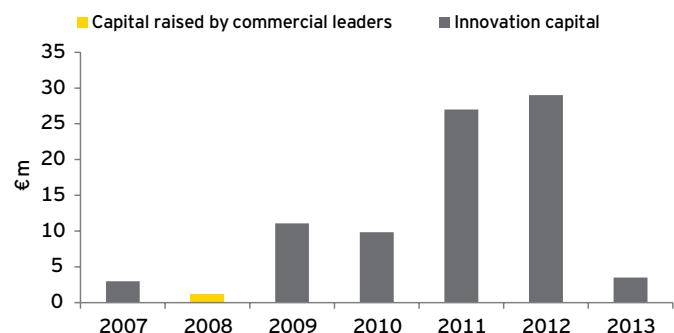
Source: EY, Capital IQ, BioCentury and VentureSource

27. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.
 28. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013



The Finnish biotechnology industry recovery is reflected by the increase of innovation capital after 2008, but since its peak in 2012 it has been decreasing again. Between 2012 and 2013, financing through innovation capital in Finland decreased by 88%, reaching a total value of €3.5 million in 2013^{29,30}.

Share of innovation capital within biotech in Finland



Source: EY, Capital IQ, BioCentury and VentureSource

Innovation capital is equity capital raised by companies with revenues of less than US\$500 million. Commercial leaders have revenues above US\$500 million.

29. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.
30. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013

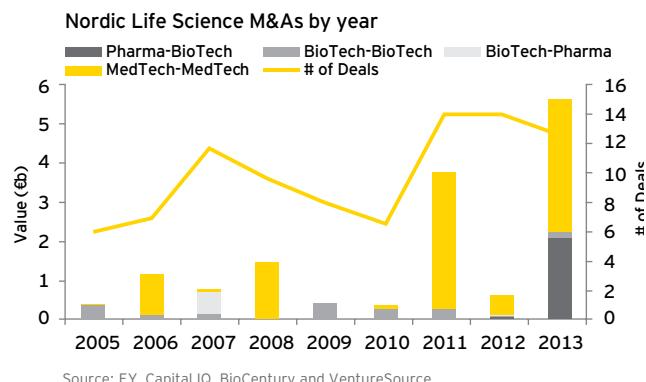
1.4 M&As and partnerships

The number of major Nordic M&As has been relatively stable between 2011 and 2013, with 14, 14 and 13 annual deals, respectively. Since 2005, 10 major M&A deals a year have been made on average within the Nordic Life Sciences industry. However, the aggregated M&A values have fluctuated during those recent years - a high of €3.79 billion was reached in 2011, when Japanese Terumo acquired CardianBCT, a subsidiary of the Swedish medtech company Gambro for €2.63 billion. This was followed by a low of €0.64 billion in 2012, and then a record €5.65 billion in 2013, when American medtech company Baxter acquired Gambro for €3.04 billion and German pharmaceutical company Bayer acquired Norwegian Algeta for €2.18 billion. The most recent aggregated values between 2011 and 2013 have been dominated by medtech-medtech M&As^{31,32}.

In 2014 major Nordic M&A events are Meda's acquisition of Rottapharm with a consideration of €2.4 billion and Roche's acquisition of Copenhagen-based Santaris Pharma with a consideration of €186 million.

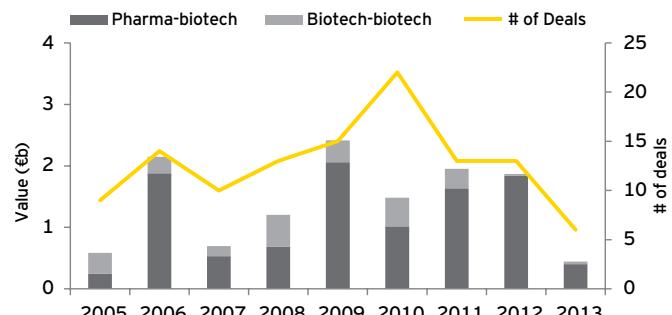
In 2013, the aggregate Nordic potential value and the number of strategic alliances based on biobucks fell 76% and 54%, respectively, compared to 2012 - reaching the lowest level since at least 2005. The low numbers are a result of the downward trends of the number of alliances and the reduced value of these, starting in 2010 and 2011, respectively^{31,32}.

Nordic Life Sciences M&As by year



Source: EY, Capital IQ, BioCentury and VentureSource

Nordic Strategic alliances based on biobucks by year



Source: EY, Capital IQ, BioCentury and VentureSource

31. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.
 32. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013

Important Nordic biotech partnerships, 2013

| Nordic biotech partnerships 2013 | Country | Partner | Country | Up-Front Payments (€m) | Total potential value (€m) |
|----------------------------------|---------------|--------------------------|-------------------|------------------------|----------------------------|
| Camurus | Sweden | Novartis | Switzerland | ND | 515.0 |
| Shionogi | Japan | Egalet | Denmark/US | 19.0 | 320.0 |
| BARDA | US | Bavarian Nordic | Denmark | ND | 171.7 |
| Bristol-Myers Squibb | US | Santaris pharma | Denmark | 7.5 | 75.3 |
| Swedish Orphan Biovitrum | Sweden | Auxilium pharmaceuticals | US | ND | 30.1 |
| Galena Biopharma | US | Orexo | Sweden | 7.5 | 11.3 |
| Baxter International | US | Genmab | Denmark | 7.5 | 7.5 |
| Moberg pharma | Sweden | Bayer Healthcare | Germany | ND | 3.6 |

In 2013, the largest biotech partnerships in the Nordics involved Danish or Swedish companies, with the vast majority of potential value in the alliances involving companies in Denmark. The largest alliance, in terms of potential value, was between Japanese Shionogi and Danish/US Egalet, where the up-front payment was about 6%. The Shionogi-Egalet alliance was a collaboration and license agreement concerning the development and commercialization of abuse-deterring painkillers, of which there are currently no products on the market^{33,34}.

1.4.1 Sweden

Top Swedish M&A deals, 2013

| Acquiring/merging company | Country | Acquired/merged company | Country | Sector | Deal Value (€m) |
|---------------------------|---------------|-------------------------|---------------|---------|-----------------|
| Baxter | US | Gambro | Sweden | Medtech | 3044.7 |
| Investor Sweden | Sweden | Permobil | Sweden | Medtech | 635.4 |
| Meda | Sweden | Acton pharmaceuticals | US | Biotech | 150.6 |
| Getinge | Sweden | PULSION Medical Systems | Germany | Medtech | 140 |
| Ossur | Iceland | TeamOLMED | Sweden | Medtech | 41.6 |
| Novavax | US | Isconova | Sweden | Biotech | 22.3 |
| Unimedic | Sweden | Medivir/Cross pharma | Sweden | Biotech | 14.4 |
| Meda | Sweden | ZpearPoint | Sweden | Biotech | 8.9 |
| Mertiva | Sweden | Protein Sciences | US | Biotech | 6.3 |
| Alligator Bioscience | Sweden | MYOS | US | Biotech | 5.7 |
| Spago Imaging | Sweden | Archaea pharma | Sweden | Medtech | 1.1 |
| C-Rad | Sweden | Cyrpa International | Belgium | Medtech | 1.1 |
| Vitrolife | Sweden | HertART | Sweden | Medtech | 0.4 |

In 2013, the aggregated deal value of top Swedish M&As in the Life Sciences industry reached a total of €4.07 billion, with medtech contributing the majority with €3.86 billion and biotech contributing the remaining €0.21 billion. The largest Swedish M&A was within medtech, where the medtech company Baxter acquired the dialysis products company Gambro for €3.04 billion. Within biotech, the largest deal was Specialty pharma Company Meda's €0.15 billion purchase of Acton pharmaceuticals, which develops asthma inhalers^{33,34}.

33. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.

34. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013

1.4.2 Denmark

Top Danish M&A deals, 2013

| Acquiring/merging company | Country | Acquired/merged company | Country | Sector | Deal Value (€m) |
|---------------------------|---------|-------------------------|---------|---------|-----------------|
| Novozymes | Denmark | IOGEN | Canada | Biotech | 58.5 |
| William Demant Holding | Denmark | Neurelec France | France | Medtech | 57.4 |
| Origio | Denmark | Mediculit China | China | Medtech | 2.4 |
| Ambu | Denmark | First Water | UK | Medtech | 2.1 |

The aggregated value of top Danish M&As during 2013 was €0.12 billion, evenly divided at €0.06 billion each for biotechnology and medical technology deals. The biotech company Novozymes made the biggest biotech purchase at €58.5 million for biofuel company IOGEN, while the health care company William Demant Holding made the largest medtech acquisition at €57.4 million for cochlear implant developer Neurelec France^{35,36}.

1.4.3 Norway

Top Norwegian M&A deals, 2013

| Acquiring/merging company | Country | Acquired/merged company | Country | Sector | Deal Value (€m) |
|---------------------------|---------|-------------------------|---------|---------|-----------------|
| Bayer | Germany | Algeta | Norway | Biotech | 2183.3 |
| Serodus | Norway | Phlogo | Denmark | Biotech | 0.6 |

On the Norwegian M&A front, the German pharmaceutical company Bayer made the largest acquisition by far within the Nordics, when acquiring the oncology specialists Algeta for a total value of €2.18 billion^{35,36}.

1.4.4 Finland

Top Finnish M&A deals, 2013

| Acquiring/merging company | Country | Acquired/merged company | Country | Sector | Deal value (€m) |
|---------------------------|---------|----------------------------|---------|---------|-----------------|
| Biohit | Finland | Euroclone/Euroclone Gastro | Italy | Medtech | 1.1 |
| Biotie Therapies | Finland | Neurelis | US | Biotech | 0.8 |

Two deals were made in Finland in 2013, with a total value of €1.9 million. Finnish Biohit acquired the Italian medical technology company Euroclone for €1.1 million and Biotie Therapies acquired the American biotech company Neurelis for €0.8 million^{35,36}.

35. "Beyond Borders," *Biotechnology Industry Report 2013*, EY, 2013.

36. "Pulse of the Industry," *Medical Technology Report 2013*, EY, 2013



Part 2: Trends and opportunities

2.1 Global megatrends within the Life Sciences sector

The health care environment, and thus the Life Sciences sector, is fundamentally disrupted by two global megatrends:

1. New incentives. First, the challenge of maintaining a sustainable level of health care costs has caused an emergence of new incentives. Patients and systems across the globe are struggling to balance the cost level with the increased number of welfare problems, such as a looming chronic disease epidemic, aging populations, expanding access and rising expectations for health care in the burgeoning middle classes across emerging areas. To address these sustainability challenges, there has been a shift from pay-for-service systems to pay-for-performance models - meaning that public and private payers are increasingly paying for value and outcomes rather than volume and activity³⁷.
2. New technologies. Side by side with this shift is the second megatrend: the emergence of big data, personalized medicine and new patient-empowering, information-leveraging (PI) technologies, such as social media, smartphone apps, wirelessly connected devices, sensors and more. These new technologies change the setting dramatically, allowing empowerment and engagement of the patients by making information more transparent and giving them more control over their own health. They are also potentially game-changing for managing chronic diseases³⁸.

These two megatrends fundamentally disrupt the traditional business models within the Life Sciences industry, now challenging the companies to go beyond the pill or device, and in that respect develop multiple business models to meet the needs of a broader and more fragmented customer base.

Companies are required to develop a broader set of skills than those in-house, in order to be able to build multiple business models across diverse channels to serve diverse customers. These include, among others, sophisticated analytics capabilities, social media platforms, customer segmentation experience and more. Historically, the primary focus of companies has been on providers, i.e., sales forces that targeted doctors and hospitals. We are now moving toward a world in which payers and patients will become relatively more influential and more important from a customer perspective³⁸.

The changed market dynamics presents opportunities for non-traditional Life Sciences and health care companies. Non-traditional entrants from a wide range of industries such as information technology, data analytics, mobile telephony, retail trade and others are attracted to the Life Sciences industry, being drawn by the opportunity to apply their strengths to the challenge of making health care more sustainable³⁸.

2.1.1 The opportunities of the future Life Sciences industry

The digitalization and personalization of the Life Sciences industry generates opportunities for Life Sciences players to take the industry to the next level. In order to gain benefits, it is crucial to take an early advantage of the upcoming opportunities within high-tech areas involving PI technologies, eHealth and big data as well as developing into a more patient-centric business.

PI Technologies and eHealth

Recently, we have started to see a host of new patient-empowering and information-leveraging (PI) technologies. The smartphone revolution spawned by the release of the iPhone in 2007 and the development of Apple's App Store that followed has started to make its way into health care. Medical device companies have been influenced by the emerging PI technologies and are also developing smartphone apps that enable patients to monitor implanted devices. A prime example is the American Medtronic's CareLink network, which connects cardiac device patients with clinicians and thus provides 24/7 monitoring through a smartphone app. Drug developing companies also benefit from improved patient adherence to therapeutic regimes, including lower probability of adverse events, side effects, reinfections, relapse rates and the emergence of treatment-resistant pathogens. An example of increased patient adherence facilitated by PI technologies is American Johnson & Johnson's launch of Care4Today Mobile Adherence, which is a combined messaging platform, smartphone app and website that reminds patients of medicine ingestion, prescription refills and doctor's appointments³⁹.

37. Progressions, Navigating the Payer Landscape, Global pharmaceutical Report, EY, 2014

38. Life Sciences Foresight Institute, Personalized Medicine, 2013

39. mHealth, Mobile Technology Poised to Enable a New Era in Health Care, EY, 2012



A few years ago, one could download an app interfacing with a glucometer. Now, the non-traditional entrant Google has announced a special contact lens that can read the glucose level in a user's tears. The development is swift and apps that were developed a couple years ago and seemed astonishing at the time have now become a routine presence in many people's lives. This trend challenges the traditional business model in the sense that the PI technologies empower individuals with more information and control over their own health, thereby changing the patient's expectations and requiring Life Sciences companies to find new ways of engaging these increasingly influential customers⁴⁰.

In most industries other than health care, consumer-centric information technology has increased productivity and lowered costs, unfolding the potential of the PI technologies to bring about the same effect in the arena as well. Additionally, as patients evaluate the comparative effectiveness of different drugs, it is possible that future products may find themselves implicitly competing not just with each other but also with other inventions⁴⁰.

Big data and data analytics

The emergence of data registries, social media platforms, smartphone apps and other digital advancements allow for an increased availability of large amounts of data. Information has hence become more widely available, giving a broad range of stakeholders the ability to use big data mining in order to make informed decisions about the relative value of different interventions. In reaction to this, new approaches have emerged over the last few years within health care and Life Sciences, seeking to combine large and diverse data streams to understand the comparative effectiveness of diverse options.

Much of this has happened through collaborations between companies from different parts of the health care and Life Sciences ecosystem, sometimes including a non-traditional entrant that was not historically associated with health care or Life Sciences. Such efforts are in many cases initiated by larger companies in the system, often in collaboration with providers and other stakeholders. An example of such a partnership is that between HealthCore, the health outcomes research subsidiary of WellPoint, and AstraZeneca, which has been conducting analysis in 16 American states using real-world data since 2011. At the same time, new data analytics companies are entering the health space, seeking to apply their expertise on a, for them, new area⁴⁰.

Personalized Medicine

The concept of personalized medicine was born in 2001, when the human genome was sequenced. The strength of personalized medicine is that it enables identification of patients for which a specific treatment is beneficial, as well as those for which it is not. Populations of patients can thus be divided into subgroups, in order to facilitate development of drugs and therapies⁴¹. Personalized medicine has made major strides in the last five to 10 years and targeted therapeutics and companion diagnostics have become increasingly common in research, especially within oncology, where large Life Sciences companies targeting cancer have several initiatives. With the deep sequencing of the human genome and further expansion of bioinformatics, we are able to understand molecular pathways in new ways and draw linkages between diseases. In this respect, the increasing use of big data can help us unlock personalized medicine, which can lead to safer therapies.

40. Life Sciences Foresight Institute, Personalized Medicine, 2013

41. mHealth, Mobile Technology Poised to Enable a New Era in Health Care, EY, 2012

2.2 How the Nordics are responding to the megatrends

The Nordic countries have established a strong position in Europe in terms of eHealth deployment in technical and clinical applications. Electronic Health Record (EHR) systems are almost standard in all of the Nordic countries and ePrescriptions are more widespread in Nordic hospitals than in other European countries. Looking at the use of telemonitoring systems, the hospitals in Denmark and Sweden are in the forefront. Several of the hospitals in Norway and Sweden also offer in-country exchange of patient information, which is something that does not exist in other Member States of the European Union⁴².

The Nordic countries also have joined the trend of personalized medicine. What underlies the trend of personalized medicine is the movement toward value and outcome orientation. In an environment of increased scrutiny from payers, Life Sciences companies have flocked to targeted therapeutics, where it is easier to demonstrate that products are well differentiated and effective. In recent years, there have been several mergers and acquisitions in the Life Sciences sector, with the specific purpose of targeting personalized medicine. A Nordic example is the biotech product developer Thermo Fisher's acquisition of Swedish allergy and autoimmune disease diagnostics company Phadia⁴³.

2.2.1 Sweden

Zooming in on Sweden in particular, the commitment to eHealth has been longstanding at a regional level and was brought together in a national eHealth strategy in 2006⁴⁴, intending to reform and improve the handling of information technology in health and medical care. Examples include electronic patient records, ePrescriptions and web portals providing health care information. In fact, a report from EU shows that Sweden is the European country that has the broadest and most routine use of electronic journal systems⁴⁵. Recently, Uppsala county developed a clinical information system (CIS) called MetaVision⁴⁶. MetaVision generates electronic medical records, offering minute-by-minute patient information collection and display. Still, the Swedish EHR system market is concentrated and five players (EVRY, Siemens, Cambio, CompuGroup and

the Norrbotten county) account for 96% of the market⁴⁷, the majority of which have foreign ownership. One initiative currently in technical test phase is the enabling of eReferrals across councils and/or between caregivers⁴⁷.

Another initiative is The Patient Data Act, which aim is to enable health care employees, with the patient's consent, to gain electronic access to patient records from different care providers across organizational boundaries.

Sweden is unique in the sense that a favorable collaboration has been established between suppliers, county councils and national actors. An example of this collaboration is an initiative from Karolinska Development's portfolio asset Pharmanest, specialized in analgesics for gynecology treatments. With support from Karolinska Development and a contract research organization (CRO), Pharmanest's patients received a smartphone and answered 32 questions on a daily basis about their conditions during treatment. The initiative helped Pharmanest to monitor their patients as well as increasing their understanding of treatment cycles. There is also an emerging desire for collaboration with non-traditional players, such as large telecommunication companies⁵².

An example is the smartphone app E-Brilique developed by AstraZeneca, which helps patients who have experienced a myocardial infarction with guidance in their change of life style, reminders for taking medication and tips on nutrition and foods⁵¹. Also, the organization ARIA (Allergic Rhinitis and its Impact on Asthma), has started the launch of an app that simplifies doctor's judgment on patient's medicine needs, making the patient put in data that is assessed using the ARIA Guidelines and the app then gives the doctor suggestions on the recommended medication. Meda has been supporting and have been involved in the development of the app⁴⁸. Shire is also developing apps in order to increase patient treatment adherence since in some areas it can be as low as 50% in the industry⁴⁹.

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42. Healthcare Information and Management Systems Society, Defining and Testing EMR Usability, 2009
 43. European Commission, eHealth Benchmarking III, 2011
 44. Life Sciences Foresight Institute, Personalized Medicine, 2013
 45. Center för eHälsa i Samverkan, eHälsa i Landstingen, 2013
 46. Businesswire.com ,2014
 47. Inera (www.inera.se), Nyhetsbrev, Tekniskt Pilotprojekt Påbörjat Elektronisk Remiss, 2013
 48. Meda, Interview with Märten Österlund, 2014
 49. Shire, Interview with Francesco De Rosa, 2014

There also are ongoing big data initiatives within the Swedish Life Sciences industry. For the Swedish medtech company Elekta, Big Data in the form of cancer informatics is core business. The company maintains a global medtech database covering a large amount of cancer patients and their respective treatments. In the future, Elekta envisage common and more comprehensive cancer registries with treatment and outcomes information. Further, Elekta envisage that such registries are being developed together with the technology industry to secure future development and maintenance⁵⁰. As another example, AstraZeneca made a large observation study of chronic obstructive pulmonary disease, with a large dataset covering 20,000 patients over an 11-year-period. The study was made in collaboration with academic research partner Uppsala University, which managed the data analysis⁵¹, and the study generated many valuable new insights published in medical journals.

Also, Swedish Life Sciences companies have a continued focus on orphan drugs, despite the challenge to generate sufficient returns on investments. According to AstraZeneca, the main issue of investment returns could for example be countered with revised remuneration models for drug development, involving risk sharing and outcome-based payments⁵¹. Another Swedish company that is investing in orphan drugs is Karolinska Development, which specifically targets cancer through its portfolio company Aprea⁵².

50. Elekta, Interview with Sören Johansson, 2014

51. AstraZeneca, Interview with Niklas Lindarck and Petra Eurenius, 2014

52. Karolinska Development, Interview with Torbjørn Bjerke, 2014



2.2.2 Denmark

Denmark has long been a frontrunner in terms of eHealth advances in many fields and has numerous interesting and innovative approaches to information and communication technology (ICT) use in hospitals as well as in fields like telemedicine. A first strategy for the development of EHR systems was launched in 1996, when decentralized, regional pilots identified the need for standards and common terminology. The National Strategy for Information Technology in Hospitals was published over a decade ago, in 1999, with the main objective of establishing electronic patient records as the core of IT systems in hospitals⁵³. Furthermore, Denmark recently initiated a large-scale big data project, in which it was decided that all registries of patient journals and sequenced genome were to be copied and gathered into one single institution. The institution has thereafter been made available to the Danish population. The Zealand region recently completed a tender offer process in which the American company Epic won and is to offer an integrated and coherent IT system for all health care givers in the region, in order to better support the health care personnel in their everyday work⁵⁴. Another Danish big data initiative is the Danish National Biobank, funded largely by the foundations of Danish drug development companies Novo Nordisk and Lundbeck, which contains more than 15 million biological samples collected from millions of Danes⁵⁵.

A recent global patient-centric study on diabetes called DAWN2 (Diabetes Attitudes, Wishes and Needs, study nr 2), was conducted by Novo Nordisk and a number of affiliated organizations. The aim of the study was to gain insights on the unmet needs of diabetic patients and to establish an international benchmarking system for patient-centric diabetes care. A total of 15 000 stakeholders, including patients, family members, physicians and care givers from 17 different countries participated in the study, which concluded that diabetes education is associated with better patient self-management and psychological well-being⁵⁶.

2.2.3 Norway

Already in 1997, Norway issued its first national action plan for IT development in the health and social sectors, adopted by the Ministry of Health and Social Affairs and named "More health for each bit." The country has a dedicated health care network that interconnects its four health regions and the use of EHR has been well-established throughout the country for many years. Primary care facilities, contract specialists, emergency rooms, pharmacies and surgical supply stores across Norway have been using ePrescriptions from 2011 and hospitals are expected to fully implement ePrescriptions in their daily routines before the end of 2014.

Norway has been placing considerable importance on multi-national cooperation in the field of eHealth during the past years. Cooperation with the other Nordic countries is well established at the level of national competence centers, and the Nordic cooperation at political and governmental levels with regards to eHealth has also been strengthened⁵³. Examples of ongoing initiatives on a national level are the "One patient, one Medical Record" initiative, telemedicine solutions to ensure a greater availability of home-based services, as well as the establishment of a national health portal, where patients and their families have easy access to information about their disease and treatment. In time, the national health portal will provide additional services, such as electronic appointment, renewal of prescriptions and remote consultations and dialogue⁵⁷.

Norway still has a journey ahead to ensure its citizens the same level of services and innovations as their neighbors in the other Nordic countries though. Norway has faced challenges both with coordinating digital initiatives on a national level and the timing and standardization of individual initiatives. Norwegian pilot projects have been less focused on defining and measuring quantitative results compared to other Nordic counterparts. There is a wealth of promising local initiatives, often initiated by enthusiasts with a strong wish to solve a specific issue in their everyday life, but for future success there is a need for united forces and an established set of regulations, financial support and consistent policies^{58,59}.

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- 53. European Commission, eHealth Benchmarking III, 2011
 - 54. Region Hovedstaden (www.regionh.dk), Nyheder Arkiv, Region Sjælland og Region Hovedstaden Peger på Epic som Leverandør af Sundhedsplattformen, 2014
 - 55. Danish National Biobank (www.biobankdenmark.dk), 2014
 - 56. Novo Nordisk, DAWN Study (www.dawnstudy.com), DAWN2, 2014
 - 57. Helsedirektoratet, Nasjonal Helseportal (http://www.kith.no/templates/kith_WebPage____3604.aspx), 2014
 - 58. eHealth and Innovation Conference, NSF, Hamar, Norway, June 12-13, 2014
 - 59. EY, The State of Remote Care in Norway - Enabling a Sustainable Welfare State, 2011

2.2.4 Finland

Finland has a longstanding history of strategy development and implementation of eHealth systems. The Ministry of Social Affairs and Health established its first Strategy for the utilization of Information and Communication Technologies in Welfare and Health in May 1996, as part of Information Society policies aimed at facilitating information transfer between organizations. The strategy was built around the principle of citizen-centered, seamless service structures. Among the main targets were the horizontal integration of services (social, primary and secondary care) and the development of shared, coordinated services delivered closer to home⁶⁰.

Current initiatives within Finnish Life Sciences industry include the Finnish genetic information company Abomics, which develops products based on eHealth and digitalization, such as a smartphone medication apps and database products. Abomics envisages point-of-care diagnostics and individual health records run on cloud computing basis as future trends. Another Finnish actor, Biotie Therapies, also has a link to eHealth, as its partner has developed a smartphone drug app for the licensed Nalmefene product. In general, Finnish companies also seem to recognize the personalized drugs trend^{61,62}.

2.3 Nordic market opportunities

The Life Sciences clusters are considered as an important foundation and driver for the industry as a whole, e.g., according to Biotie Therapies, Finnish Life Sciences clusters provide important networking channels⁶². When speaking to different industry players, a request for increased collaboration across the clusters in the different Nordic countries was raised though. There is an existing transnational cluster in the form of Medicon Valley (Sweden and Denmark), but the potential benefits would be much higher if increased Nordic collaboration is established. According to both Karolinska Development and AstraZeneca, the Nordics is a small market and it would be good with an overall strategy and mission for the Nordic clusters altogether^{63,64}. Also within each Nordic country the collaboration across different clusters needs to be improved

according to AstraZeneca – it would be better to discuss Sweden as a whole and not the Västra Götaland Region (VGR) separately⁶³. This view is further emphasized by Abomics, which also indicates that the sector as a whole would benefit from having a powerful actor that could push the whole ecosystem forward⁶⁵.

According to Karolinska Development there are a number of things the Nordic countries can leverage from each other. Sweden has strong competence in the medical field with strong universities and research competence. Norway has a better financing situation though since tax deductions can be made for research investments and the access to capital is better than in the other Nordic countries. Denmark on the other hand still has a very strong pharmaceutical industry, due to its regulations, which helps drive the creation of smaller companies and the growth of the industry as a whole⁶⁴.

The Nordic Life Sciences industry players would also like to see an increased openness from and collaboration with both the clusters and the health care industry. According to Medivir, the collaborations with the Oslo Cancer Cluster works pretty well and they have a more open view toward the industry than other clusters. It's important that the industry also is involved in the strategic discussions, not only in the studies themselves⁶⁶. Elekta also argues that there are too few initiatives and that the collaboration with the health care industry is not strong enough. The industry is seeking collaboration with hospitals with regards to patient care processes and not necessary isolated research initiatives outside of the care delivery. Noteworthy is that certain innovation initiatives has very limited budget in comparison to the total cost of hospital operation. Financing of health care development needs to be part of any hospital operation and to be appropriately financed⁶⁷.

When it comes to the Nordic financing climate all the Life Sciences companies we interviewed find it more difficult to get financing for projects nowadays compared to a couple of years ago. The number of venture capitalists in Sweden has been reduced according to Karolinska Development. Also, financing from institutional investors has decreased⁶⁴.

60. European Commission, eHealth Benchmarking III, 2011

61. Abomics, Interview with Jari Forsström, 2014

62. Biotie Therapies, Interview with Antero Kallio, 2014

63. AstraZeneca, Interview with Niklas Lindarck and Petra Eurenius, 2014

64. Karolinska Development, Interview with Torbjörn Bjerke, 2014

65. Abomics, Interview with Jari Forsström, 2014

66. Medivir, interview with Henrik Krook, 2014

67. Elekta, Interview with Sören Johansson, 2014

In Denmark, the Novo Nordisk and Lundbeck funds are important investment funds for the Life Sciences sector. However, according to Azanta the reduction of investments also can be seen in Denmark and a lot of the investors who were allocating money to the Life Sciences industry before are not doing it anymore. Even though the access to capital is difficult in the Nordics, compared to the US, where the risk appetite as well as the number of investors is much higher, the Nordics has managed to create a lot of new products over the last couple of years. For instance, Genmab, Bavarian Nordic and Zealand pharma are examples of success stories in Denmark. The problem with the fact that financing is more attractive in the US is that companies have to set up major part of the operations in the US and to be perceived as a US company to get sufficient trading. Because of this, there is a risk that a lot of the activities will move away from the Nordics⁶⁸.

When it comes to health care reimbursement models the industry is generally positive to change the focus from "cost of drug" to the "effect of drug." All the interviewed Life Sciences companies are increasingly focusing on communicating parameters other than just the price of the drug, for example, patient outcomes, environmental effects, certificates, delivery security and breadth of indications, during the tender processes.

According to Shire, most product plans developed in the industry are now emphasizing the shift from "cost of drug" to "cost of treatment"⁶⁹. Elekta, which is a medtech company, also promotes a shift to more outcomes-based reimbursement models, that should include the total economic outcome, in order for the health care providers to take the total cost of care into account when comparing different treatment options. New medical technology is often changing treatment processes and hence the cost of care which sometimes is the driver for introducing new technologies⁷⁰.

68. Azanta, interview with Claus Møller, 2014

69. Shire, interview with Francesco De Rosa, 2014

70. Elekta, Interview with Sören Johansson, 2014





Summary and conclusion

This study has analyzed the Nordic Life Sciences sector in terms of cluster collaborations, product pipelines within biotech and medtech, as well as the financial situation within the Nordic Life Sciences sector. Sweden and Denmark continue to dominate R&D on upcoming compounds, which also are represented by the Nordic financings being projected into these two countries. However, we have during a number of years faced a decline in Nordic Life Sciences venture financing, as a consequence of fewer local venture financing firms, capital being allocated to other industries and geographies and comparatively less favorable tax and incentive systems in the Nordics. Life Sciences companies need early investments in order to progress in research, but unfortunately there are a limited number of Nordic investors that have the long-term view required for Life Sciences investments and hence inhibit the development, creating a tough environment for innovation organizations. Ireland, which had the largest amount of financing by far in 2013 due to its favorable tax and incentive system, could be an example for the Nordics to follow. There is a need for regulation of the Nordic Life Sciences ecology with tax reductions for R&D investments and facilitation of new innovation organizations, in order to raise the Nordic Life Sciences industry to its potential.

The study also has explored the Nordic Life Sciences sector's progression within the two global megatrends new incentives and new technologies, through the concepts PI technologies, eHealth, big data, personalized medicine and orphan drugs. The system needs efficiency improvements to face the challenges of a rapidly aging population and a growing chronic disease epidemic. Digitalization and information technology are enablers of changing efficiency and structure of the systems toward more focus on health outcomes and more centricity around the patient.

Due to historic advancements within the information and communication technology sector generally and within eHealth specifically, the Nordics should have a solid starting-point for continued progress and expansion of the different dimensions of eHealth, including utilizing already established databases, to meet the needs of the future Life Sciences sector. The perception within the Life Sciences industry is that big data-driven analytics and patient centricity, including PI technologies, personalized medicine and orphan drugs are top-of-mind in terms of strategic opportunities. The progression of implementing strategies varies from nothing at all to somewhat progressed in relation to utilization of big data registries or implementation of increasingly patient-centric offerings.

In the new eHealth environment interconnection is crucial on several levels; corporates need to collaborate with other stakeholders in a new fashion and IT systems needs to be interlinked through common languages and terminology. From our research we have seen tendencies of new collaborations among Life Sciences companies and register providers. Also, mainly in relation to smartphone app development, traditional IT companies have been engaged to assist in development of patient-centric solutions or apps that supports physicians in their decision making. In our research we also have encountered a number of Life Sciences companies building their business model around big data analytics, to support decision making in health care and drug development, or devices combined with apps, to promote patient self-care, remote monitoring and chronic disease management.

Despite the challenges, the wheels are in motion as Nordic Life Sciences companies and stakeholders have acknowledged the importance of implementation of initiatives to develop a more patient-centric and outcome-based health care. By further collaborations, the opportunities within the digitalization and personalization of the Life Sciences industry could be realized and within the near future we will certainly see some success stories arise from the Nordic region.



EY has a global network of more than 5,000 professionals working within Life Sciences

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