BUSINESS SWEDEN

CO-CREATION FOR GLOBAL HEALTH

LIFE SCIENCE IN SWEDEN

Business Sweden

Sweden – home of the Nobel prize
Cover photo: Aula Medica at Karolinska Institutet

COVER PHOTO: HENRIK TRYGG/ MEDIABANK.VISITSTOCKHOLM.COM

HEALTH – OUR DRIVER OF INNOVATION

HEALTH AND WELLBEING FOR PEOPLE OF ALL AGES

The life science sector contributes to improved health for all of society by providing results from research and innovative solutions that meet medical needs, ensuring affordable and accessible high quality healthcare and stimulating long-term economic growth.

In addition, research and innovation have a major role to play in addressing the increasing number of global societal challenges, such as cross-border threats to health, an increase in lifestyle-related diseases, and antibiotic resistance. Sweden is well placed to deliver such innovation, and ranks among the most innovative countries in the world. Operating in a research and innovation climate of high quality, transparency, stability and accountability, the Swedish life science sector, i.e academia, healthcare and industry, has a long tradition of successful collaboration.

Acknowledging the importance of the sector and the resulting benefits, the Swedish government has made life science a strategic priority. Sweden wants to stay at the forefront of advances, delivering innovative solutions to turn our societal challenges into opportunities. We are also striving for an equitable and effective healthcare system. Experience tells us that innovative solutions are best found in cooperation between stakeholders from different sectors and disciplines. In other words, cooperation is the key that has already contributed to, and will continue to contribute to, health and growth.

Mikael Damberg

Minister for Enterprise and Innovation

Helene Hellmark Knutsson

Minister for Higher Education and Research

Gabriel Wikström

Minister for Health Care, Public Health and Sport

CUTTING-EDGE CAPABILITIES

SWEDEN HAS THE TALENT AND THE ASSETS

Skype, Spotify, IKEA, Ericsson, Sobi, Elekta and Recipharm, not to forget the Nobel Prize. Today, this Nordic nation of 10 million is seen as one of the coolest and most innovative places on the planet. A country that is technologically advanced, economically successful and committed to sustainability. A country that is a model for stability, freedom of expression and equality, backed by a comprehensive welfare state. A country that not only belongs to the most competitive European economies[1], but also attains top rankings in new concepts such as the Happiness Index[2]. You would not be alone in wondering what the secret of this success is.

At first glance, a number of factors are easily recognizable. Swedes are used to working in teams to get the job done. English is almost a second language for most Swedes, while up to date education and training in disciplines such as ICT and telecoms, cleantech, materials science as well as in automation, law, finance, marketing/PR, and transport/logistics continues to provide a highly skilled, motivated and flexible workforce.

Similarly, in what is one of Europe's largest, yet relatively sparsely populated countries, the government has realised the wisdom of investing heavily in infrastructure. Any visitor can see that Sweden is among the most modern in the world, just one example being that Sweden has the highest Internet and computer usage per capita in the world[3].

Despite the common perception of a high tax economy, Sweden is in fact one of Europe's most business-friendly environments, with a competitive corporate tax rate. Since Viking times, Sweden has also been a trading nation. Swedish companies embraced globalisation long before the term was even coined, with the result that the country is the world's 6th most globalized country[4].

In life science in particular, the talent and asset base is in several respects superior to any other country or region. One in five researchers work in the sector, in internationally renowned powerhouses including in internationally-renowned power- houses such as Karolinska Institutet, Uppsala University, Lund University and the University of Gothenburg. The latest newcomer on the scene, SciLifeLab is also fast making a name for itself.

Yet this breadth of talent and assets would mean nothing without the fundamental attitudes of the Swedes themselves. You may find Swedes can come across as somewhat shy, but underneath, there is a will and determination to succeed. A determination fuelled by curiosity, creativity, open-mindedness, and a willingness to collaborate.

Quality healthcare for all is a cornerstone of the Swedish welfare state, and widely supported. A number of initiatives are currently underway to further improve care for patients; two examples being more patient-centric systems and digital health solutions. Sweden has a long tradition of involvement by our well-educated population in such programs, and patients are generally willing to take part in clinical trials. Our public healthcare system, with access for all citizens, is also a prerequisite for our comprehensive patient registries and functional biobanks.

[1] The Global Competitiveness Report 2015-2016
[2] World Happiness Report 2015
[3] The Global Information Technology Report 2015
[4] Index of Globalization report, the KOF Swiss Economic Institute, Federal Institute of Technology ETH Zurich

The multi-touch screen visualisation table was developed by Sectra in collaboration with partners including the Center for Medical Image Science and Visualization, CMIV, in Linköping. The table is used for interactive learning and teaching and it also provides the orthopedic surgeon with a pre-operative planning tool providing real-size, interactive 3D views of the patient.

PHOTO: SECTRA

One example of an innovative Swedish-based study, into the causes of cardiovascular disease is the SCAPIS (Swedish CardioPulmonary bioImage Study) study with a budget of 30 million euros. The aim is to identify biomarkers for increased risk of cardiovascular disease.

No less than 30,000 Swedes between 50 and 64 resulting of age will be recruited for the study. The resultant database, including biobank samples and digital images, will be made available to the wider Swedish research community for further research.

As an example, a pilot study including 1,100 individuals, saved 5 lives through acute surgery on identified patients. The Swedish Heart-Lung Foundation is the main sponsor of the study.

PHOTO: THE SWEDISH HEART-LUNG FOUNDATION

JOIN US IN IMPROVING HEALTH AND HEALTHCARE

A PARADIGM SHIFT IS EMERGING

TECHNOLOGY IS DRIVING OUR UNDERSTANDING OF BIOLOGY

Sweden can justifiably claim to be a forerunner within genomics, molecular biology and protein science, and is now further strengthening this position through increased investment in research infrastructure and initiatives. By applying new, innovative methodologies, the aim is to drive development of new modalities for the diagnosis and treatment of major diseases.

Regenerative medicine, cell-based therapies, tissue engineering and gene therapy bring hope for breakthrough therapies. In a key strategic decision, Sweden has created an R&D infrastructure to support the development of new treatments within these fields at Karolinska Institutet, Lund University, the University of Gothenburg and Uppsala University.

GROWING DEMAND FOR DIGITAL SOLUTIONS AND OUTCOMES DATA

Digitalisation is set to reshape both the life science industry and healthcare systems, just as it has already disrupted other business sectors. Implementing digital solutions aimed at improving healthcare offers many opportunities. In hindsight, it may appear that Sweden anticipated the digital revolution long before it happened. This is of course not the case, but nevertheless, the country is one of few in the world already equipped with the skills and resources required to set developments in motion. These include world-leading research, a national healthcare system covering the entire population, patient registries and biobanks, a highly-experienced and competent pool of experts within bioinformatics, big data, ICT and mobile technologies, a vibrant life science community, and a population of early adopters.

INCREASED FOCUS ON PREVENTION

New diagnostic technologies, such as imaging and genetic tests, personalised recommendations on life style changes or early intervention can prevent or postpone disease. By combining registries, biobanks, and expertise in genomics, molecular bioscience and protein science, Sweden is contributing to advancing the understanding of why some of us develop disease while others don't. The SCAPIS project is an example of such an initiative (see picture caption on page 4).

CO-DEVELOPMENT WITH THE PUBLIC SECTOR IS A SWEDISH CHOICE

The model of collaboration between academia, industry and the healthcare sector in early stages of product development is gaining ground among global companies. Furthermore, creating real-life test environments requiring active participation from the public sector is increasingly recognised as an efficient innovation arena when technologies are tested before launch. Swedish universities and healthcare providers have a long-standing tradition of collaborating with industry, putting the country in an ideal position to become an active and efficient partner for companies. We welcome scientists, industry, investors and societies to come and collaborate with their Swedish counterparts on meeting the global healthcare challenges of today and tomorrow. As we succeed, we will be creating value for people, as well as businesses, around the world and, step by step, we will be able to build a foundation for sustainable health.

Sweden tops the Innovation Union Scoreboard 2015[5] and ranks 3rd among the fifty most innovative economies[6].

[5] European Innovation Scoreboard, European Commission, http://ec.europa.eu/growth/industry/innovation/facts-figures/scoreboards/index_en.htm

[6] BloombergBusiness: http://www.bloomberg.com/news/articles/2016-01-09/these-are-the-world-s-most-innovative-economies

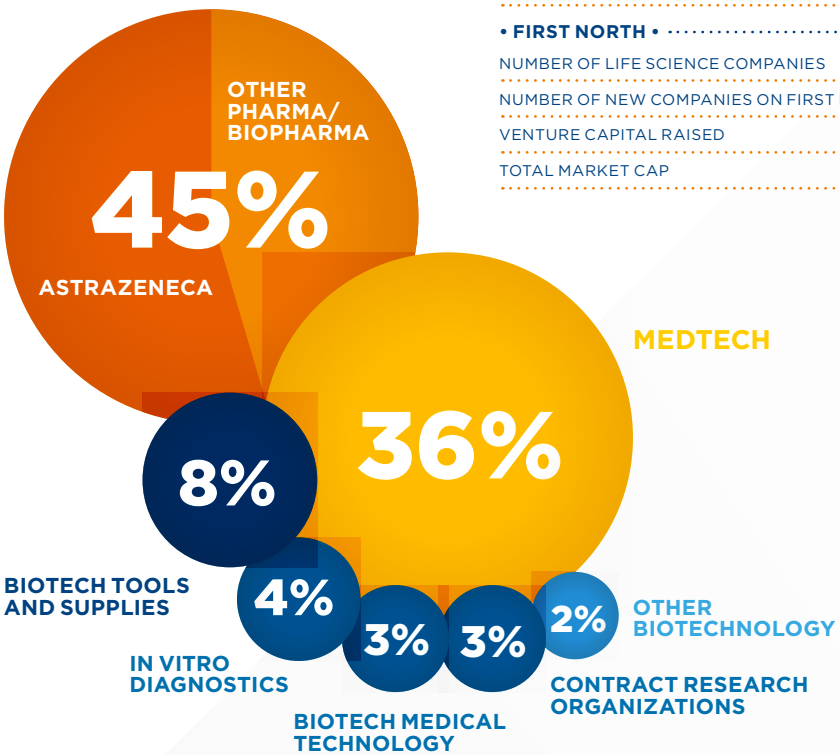
LIFE SCIENCE IN SWEDEN – A SNAPSHOT

WORKFORCE

30,000 Employees

engaged in R&D and manufacturing[7].

Divided by sector:



EXPORT VALUE AND STOCK MARKET

EXPORTS OF LIFE SCIENCE PRODUCTS[7]	EXPORT VALUE (2013)	SHARE OF SWEDISH EXPORT
PHARMACEUTICALS	6 BILLION EURO	4.9%
MEDICAL TECHNOLOGY PRODUCTS	2.2 BILLION EURO	2.8%
BIOTECHNOLOGY		FIGURES NOT AVAILABLE

COMPANIES LISTED ON NASDAQ, STOCKHOLM[8]	2014	2015
• MAIN MARKET •		
NUMBER OF LIFE SCIENCE/HEALTHCARE COMPANIES	51	61
NUMBER OF NEW COMPANIES ON MAIN MARKET	3	4
VENTURE CAPITAL RAISED	204 MILLION EURO	850 MILLION EURO
TOTAL MARKET CAP	149 BILLION EURO	211 BILLION EURO
• FIRST NORTH •		
NUMBER OF LIFE SCIENCE COMPANIES	25	35
NUMBER OF NEW COMPANIES ON FIRST NORTH	8	12
VENTURE CAPITAL RAISED	42 MILLION EURO	73 MILLION EURO
TOTAL MARKET CAP	643 MILLION EURO	1,051 MILLION EURO

Sweden – home of the Nobel Prize

PHOTO: OLA ERICSON/IMAGEBANK.SWEDEN.SE

TOP-RANKING
COMPETITIVENESS AND R&D

Sweden ranks 9th and 5th in Europe among 140 countries worldwide in the Global Competitiveness Index 2015-2016 ranking by World Economic Forum[9].

Sweden ranks 2nd per capita in the world when it comes to R&D investments[10].

Umeå:
- Umeå University
- Swedish University of Agricultural Sciences
- University Hospital of Umeå

Stockholm-Uppsala:
- Karolinska Institutet, *Stockholm*
- KTH Royal Institute of Technology, *Stockholm*
- Stockholm University
- Swedish University of Agricultural Sciences, *Headquarters in Uppsala*
- Uppsala University, *Uppsala*
- Karolinska University Hospital, *Huddinge and Solna*
- Uppsala University Hospital, *Uppsala*
- SciLifeLab, *Stockholm/Uppsala*
- Medical Products Agency, *Uppsala*
- Uppsala Monitoring Centre, *Uppsala (founded by the WHO)*
- The European Centre of Disease Prevention and Control (ECDC), *Stockholm*
- AstraZeneca's manufacturing site, *Södertälje*

Örebro:
- Örebro University
- Örebro University Hospital

Gothenburg:
- Chalmers University of Technology
- University of Gothenburg
- Sahlgrenska University Hospital
- AstraZeneca's research site, *Mölndal*

Linköping:
- Linköping University
- Linköping University Hospital

Region Skåne:
- Lund University
- Skåne University Hospital, *Lund and Malmö*
- Max IV and ESS, *Lund*

[7] Global trends with local effects – The Swedish Life Science Industry 1998-2012. VINNOVA Analysis VA 2014:03
[8] Numbers supplied by Nasdaq team
[9] World Economic Forum, the Global Competitiveness Index 2015-2016 ranking, http://www3.weforum. org/docs/gcr/2015_2016/Global_Competitiveness_Report_2015_2016.pdf
[10] Passport, Euromonitor, http://www.portal.euromonitor.com/portal/account/login

ENGAGE WITH OUR VIBRANT ECOSYSTEM

SWEDEN'S LARGE POOL OF INNOVATIVE COMPANIES

Sweden is home to several hundred entrepreneurially driven companies in various stages of development within drug development, biotech tools, diagnostics and medtech, including digital health. As Sweden is a small country with a very limited domestic market, companies typically plan for the global market from day one. Thus, a natural part of the business and tradition is to actively seek international collaborations, licensing and financing in order to broaden the critical mass and secure a global reach. And, there are good opportunities to engage with local VC, Business Angels or public players for co-investments.

"In my experience, having met a number of Swedish pharma companies, they are generally characterised by a strong foundation in science, highly-competent local investors, board members with relevant international industry experience (often from Astra or ex- Pharmacia), and efficient, team-orientated managers".

John Shields, Director, JGSbiopharma Ltd., with long-standing experience of investment management in pharma.

THE SWEDISH DRUG DEVELOPMENT PIPELINE 2015[11]

Of Sweden's 123 drug development companies, 58 were collectively running 107 projects in clinical phases in 2015.

Ongoing Clinical trials	Number of projects
Phase I	30
Phase II	70
Phase III	7

38 Oncology
21 Other
12 CNS
7 Diabetic/Metabolism
6 Gastrointestinal
5 Cardiovascular
5 Transplantation
5 Pain
4 Infection
4 Dermatology

COMPANIES ENGAGED IN R&D AND/OR MANUFACTURING WITH <250 EMPLOYEES – SUB-SECTORS OTHER THAN PHARMACEUTICALS[12]

BUSINESS SEGMENT	NUMBER OF COMPANIES
• MEDICAL TECHNOLOGY •	
IN VITRO DIAGNOSTICS	35
BIOTECH MEDICAL TECHNOLOGY	30
CRO	22
HEALTHCARE FACILITY PRODUCTS AND SINGLE USE PRODUCTS	107
IMPLANTABLE DEVICES - ACTIVE AND NON-ACTIVE	37
ANAESTHETIC AND RESPIRATORY DEVICES	11
ELECTROMECHANICAL MEDICAL DEVICES	52
RADIATION AND IMAGING DEVICES	32
INFORMATION AND COMMUNICATION TOOLS	64
ASSISTIVE PRODUCTS FOR PERSONS WITH DISABILITY	37
• BIOTECHNOLOGY •	
BIOTECH TOOLS AND SUPPLIES	70

PHOTO: CAMILLA SONALLY

Nordic Life Science Days in Stockholm 2015. Reception in the blue hall of Stockholm City Hall.

PAY SWEDEN A VISIT

Why not pay Sweden a visit? Foreign companies interested in partnering, in-licensing or investing can typically meet their Swedish counterparts at Nordic Life Science Days (held in September) or other international meetings, such as JP Morgan, Bio Europe Spring, BIO, BIO Europe etc.

NLSDAYS 2016
Nordic Life Science Days

Nordic Life Science Days is the Nordic region's largest partnering conference serving the global Life Science industry.

digital | health days

Digital health Days – A forum for discussion on how digital solutions can transform healthcare.

A WELL-CONNECTED LIFE SCIENCE COMMUNITY

Sweden's life science community is well connected with the rest of the world, thanks to its engagement in many international activities, including being a lead participant in the EU-funded Health program. Swedish companies and scientists typically attest that one of the most valuable outcomes from their participation in EU-funded projects is the expanded networks they create. The life science industry sector in Sweden is also well connected, partly due to the strong heritage and long-lasting impact of companies such as Astra, Pharmacia and Gambro.

These comprehensive networks are invaluable for both stimulating international collaboration and enabling companies working with Swedish partners to extend their own networks. Additionally, for non- European parties, engaging with Sweden facilitates interactions with the rest of the EU.

[11] The Swedish Drug Development Pipeline 2015, Published in December 2015 by SwedenBIO with support from Vinnova

[12] Global trends with local effects – The Swedish Life Science Industry 1998 - 2012. VINNOVA Analysis VA 2014:03

INVEST IN PROTEIN SCIENCE

MAJOR NAMES INVEST IN SWEDEN

Protein research in Sweden dates back to the invention of the ultracentrifuge by The Svedberg, Nobel Laureate in 1926. Sweden has held a position in this field thanks to both the long-standing presence of experts versed in the complexity of protein science, and close interactions between healthcare providers and industry. Protein research is conducted in all major Swedish universities, and many biotech-based products and solutions on the world market are based on Swedish innovations within this area.

BIOLOGICS IN FOCUS

Building on a world-leading position within protein science and biopharmaceutical production, the Swedish government, AstraZeneca and Sweden's leading, private, research funding body, the Knut and Alice Wallenberg Foundation aim at further advancing the field by investing in next generation biologics. The two parallel investments exceed 90 million euro.

The Swedish government will fund an 8-year research program, aimed at taking a lead in the development and production of biologics. With this program, implemented via Vinnova (Sweden's innovation agency) and the Swedish Research Council, the government wishes to further enhance the collaboration between academia, industry, and public and private funding in this field. At the newly-established Wallenberg Centre for Protein research, AstraZeneca and three Swedish universities will collaborate (see next page for details). The program will focus on developing new technologies for biologics production and identifying new targets for disease research in the ground-breaking area of the Secretome (research into the function and interactions of all proteins secreted by a cell or exposed to the outside of the cell from within the cell membrane).

"We're tremendously excited to be part of this innovative collaboration as we explore what science can do to advance medical research. It will help us to identify new biomarkers and drug targets, and ultimately develop next-generation biological treatments".

Pascal Soriot, CEO, AstraZeneca

GE HEALTHCARE DOUBLES CAPACITY

GE Healthcare invests 90 million euro in doubling protein purification production capacity in its Uppsala-based facility. The facility, 45 minutes north of Stockholm, is home to GE Healthcare's global R&D and manufacturing centre for the chromatography medium used in the purification of biopharmaceuticals. Over 90% of today's approved biotech drugs globally rely on equipment and media from this state-of-the-art facility. The proven performance of the highly-skilled workforce was cited by GE as the key reason to continue investing in Uppsala rather than other locations.

THE PROTEIN ATLAS – NEXT STEPS

The Human Protein Atlas aims to map all human proteins to their location in the body. The project has to date annotated over 13 million images showing the localisation of our proteins in the human body on a cellular and subcellular level. All images and data are publicly available at www.proteinatlas.org.

"I am very excited about the possibility of leveraging results from the Human Protein Atlas project to build an enhanced resource of knowledge and reagents for further studies of the human proteome. The ultimate aim is to enable the creation of new applications in human medicine".

Mathias Uhlén, Director of the Wallenberg Centre for Protein Research and professor at KTH Royal Institute of Technology

"What differentiates good investments from not so good investments is the people. That's why we want to do more here and expand."

John Rice, vice chairman GE

PHOTO: STAFFAN ELIASSON

WALLENBERG CENTRE FOR PROTEIN RESEARCH (WCPR)

WCPR is a new research centre established in cooperation between KTH Royal Institute of Technology, Uppsala University, Chalmers Technical University and AstraZeneca. Both the Human Protein Atlas project and the new centre are funded by the Knut and Alice Wallenberg Foundation.

The centre will focus on protein research and bioproduction, and run the following programs:

- Developing an innovative platform for production of biopharmaceuticals.
- Providing recombinant proteins for research, drug development and diagnostic applications.
- Devising new concepts for therapeutic antibody design.
- Offering knowledge resources for exploring the human proteome.
- Integrating omics technologies to explore the druggable proteome.

BIOMARKERS

Biomarker discovery research is conducted at several leading Swedish centres, including Lund University, Sahlgrenska Academy in Gothenburg, Umeå University, Uppsala University, SciLifeLab and Karolinska Institutet. This has led to Sweden becoming home to a critical mass of biomarker and molecular diagnostics companies, ranging from start-ups to more established companies with approved products on the market.

EARLY DIAGNOSIS PROVIDING HOPE

Pancreatic cancer is one of the deadliest forms of cancer. In a majority of cases, the cancer is diagnosed when it is too late to cure. CREATE Health at Lund University, led by Professor Carl Borrebaeck, focuses on biomarker discovery for the early diagnosis of cancer. Their diagnostic platform technology, developed for the global market by Immunovia, is now being evaluated by leading clinics around the world. Pancreatic cancer has been selected as the number 1 priority.

The test platform creates a biological snapshot of an individual's immune-response by analysing serum proteins that change as a sign of disease. The technology combines many years of clinical immune-proteomics research from Lund University, the development of serum protein biomarker signatures, and bioinformatics algorithm and software to interpret clinical test data. A simple blood test provides all the necessary information for enabling early diagnosis, as well as for following disease progression, and/or therapy monitoring.

"Treatment for pancreatic cancer is improving, and it could cease to be a death sentence if it can be picked up early enough. However, 80% of the patients are beyond treatment with curative intent by the time they are diagnosed. Our collaboration to further validate Immunovia's test in a prospective study will enable us to take a potentially lifesaving test into the clinic".

Dr. Bill Greenhalf, Operational Director of Liverpool Good Clinical Laboratory Practice Facility and Lead Scientist of EUROPAC[13].

"Did you know that the term "protein" was coined by the Swedish scientist Jöns Jacob Berzelius at Karolinska Institutet in 1838."

[13] EUROPAC, is Europe's biggest registry of individuals at high risk of pancreatic cancer. Several European countries participate.

RESEARCH INFRASTRUCTURE

The Swedish government has made major investments in the country's life sciences research infrastructure, with the latest research bill setting new record levels. SciLifeLab and Max IV are both positioned as national resources, accessible by all Swedish scientists and open to collaboration with industry. ESS, The European Spallation Source, which is intended to become a resource for European scientists, is under development. There are already countless examples of these facilities stimulating cutting-edge research, advancing the understanding of human biology and thereby leading to new innovations in the fields of prevention, diagnosis and treatment.

LIFE SCIENCE; A SWEDISH PRIORITY

Supporting life science research has long been a priority for the Swedish government. State-of-the-art research infrastructure has already been built, and life science research continues to receive a large share of the overall state research budget. Swedish companies and researchers also actively participate in EU-funded and other international projects. Professors at medical faculties can be co-appointed to university hospital positions, which has proven instrumental in stimulating translational research. In addition, Swedish academia has always shown a willingness to collaborate with industry. And you will find opinion leaders in many research fields.

Swedish medical research is leading in a number of areas. The government's pinpointed areas for strategic funding include the areas listed below (complementing the areas highlighted elsewhere in the brochure):

- Ageing and health
- Clinical Therapy Research
- Diabetes
- Epidemiology
- Further expanding the use of and improving the quality registries
- Infection and antibiotic resistance
- Neuroscience
- Oncology and regional cancer centres

As a complement to to the funding of strategic areas listed above, the government, through Vinnova, has invested in two long-term strategic innovation programs, SWElife and Medtech4Health. Academia, healthcare providers, and research infrastructure including biobanks, incubators, investors and industry, are all involved, and the aim is to accelerate innovation and collaboration within drug development and medtech. Sweden has several well-established testbeds and innovations hubs that are actively engaged in the programs in order to co-create new innovative treatments.

Sweden is a top participant in the EU funded program Health[14].

Sweden is ranked number 8, participating in 73 projects with a total funding of 51 million euros[14].

Karolinska Institutet is ranked number 4, receiving 17,5 million euros[14].

[14] eCORDA (external Common Research Datawarehouse) 2015-10-30

PHOTO: MIKAEL WALLERSTEDT

SCIENCE FOR LIFE LABORATORY (SCILIFELAB)

SciLifeLab is a Swedish national research centre for molecular biosciences, with the mission to develop, use and provide advanced technologies for applications in health and environmental research. The centre, with sites at ten universities, hosts several platforms providing high throughput technologies in areas such as genomics, proteomics and bioimaging, including bioinformatics services. National funding makes services and expertise available to researchers throughout Sweden. The centre also welcomes international collaborations.

SciLifeLab comprises more than 1,200 researchers and personnel in a centre hosted by four universities; Karolinska Institutet, KTH Royal Institute of Technology, Stockholm University and Uppsala University. The cross-disciplinary research setting, together with the multitude of technologies that the centre provides, spurs academic collaborations, as well as effective interaction with healthcare providers, regulatory authorities and industry.

One focus area is precision medicine, where SciLifeLab is collaborating directly with clinics. For example, researchers at SciLifeLab have developed a genetic screening panel for inborn metabolic diseases that is now in routine use at the Karolinska University Hospital. Furthermore, tumors from more than 500 patients with colon and lung cancer have been analysed with new technology to assemble gene panels, which have enabled successful interventions with new, targeted cancer drugs.

SciLifeLab also collaborates with biobank organisations to standardise sample handling for more effective use of the valuable resources they offer, in order to strengthen clinical research and improve Swedish healthcare. Another focus area is whole-genome sequencing, where SciLifeLab supports the sequencing of thousands of genomes to stimulate internationally-competitive Swedish research in human genomics and biodiversity.

One of SciLifeLab's ten platforms is devoted to early drug discovery and development. This platform provides academic researchers with industry standard infrastructure, expertise, and strategic support to help progress projects towards a preclinical proof-of-concept.

MAX IV AND ESS

The two largest research facilities ever built in Sweden – the MAX IV Laboratory and the European Spallation Source (ESS) - are currently being constructed in Lund. Together, they will form a key hub in Europe's joint research infrastructure.

Max IV will be an infrastructure resource serving several science areas including life science. ESS is one of the largest science and technology infrastructure projects currently under construction in the world, and is scheduled to open in 2025.

ADDITIONAL RESOURCES

However, the Swedish research infrastructure offers much more than just the resources listed above. To take just two examples, ultra-hightech clean rooms for advanced nano- and microsystem R&D are widely available in the universities and research institutes focusing on material science. Sweden is also home to one of the few P4 laboratories in Europe enabling studies on pathogens such as ebola.

BENEFIT FROM PATIENT REGISTRIES

EVIDENCE-BASED HEALTHCARE SOLUTIONS

GROWING NEED FOR DATA

Sweden's patient registries can provide data from ongoing patient care ("real world data"), including diagnoses, use of drugs and medical devices, compliance with prescribed treatments, and follow-up of outcomes on a large population scale. Combining the use of registries with biobanks paves the way to more in-depth studies on, for example, genetic factors and biomarkers. The Swedish government has invested more than 150 million euros over the last 5 years, and work is underway to further enable the use of patient registries for research, development and follow-up.

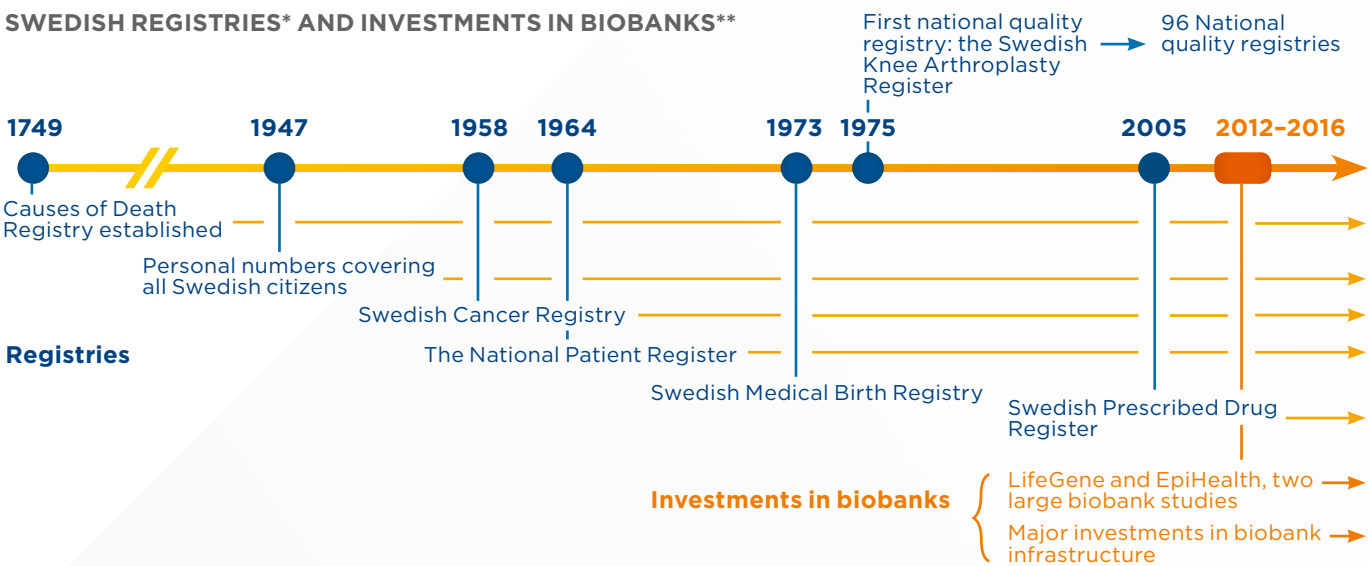
A TREASURE TROVE FOR LARGE POPULATION STUDIES

Every Swedish citizen has a unique personal identity number. As the number identifies the individual in connection with his/her contacts with the healthcare system, a range of registry-based studies are made possible. For example, when introducing a new method for early diagnosis in, say 50,000 people with increased risk of disease, 90 to 95 per cent of the patients can typically be found 10 years later when it is time for follow-up.

The potential applications of such data are exciting:

- Systematic and continuous development and securing quality of care.
- Clinics can compare outcomes and learn from best practices thereby driving quality of care.
- Opens avenues for collaboration with industry and international institutes.
- Enables prospective, randomized trials at a fractional cost of traditional randomized trials.

SWEDISH REGISTRIES* AND INVESTMENTS IN BIOBANKS**



CASES

1

NOW OPEN FOR COLLABORATION - SWEDEN'S LARGE SCALE, INTEGRATED HEALTHCARE INFRASTRUCTURE, WITH STRUCTURED INFORMATION AND BIOBANK SAMPLES FROM 9,000 CANCER PATIENTS

Uppsala-based U-CAN, with its continuously-growing repository of unique material from longitudinal studies, welcomes collaboration projects aimed at improving diagnosis, prognosis, treatment and ultimately patient outcomes. As of spring 2016, U-CAN has already initiated such collaborations with both leading pharmaceutical companies and international cancer institutes.

"Companies can come here to tap into our environment and resources for longitudinal collaboration studies aimed at investigating new markers for early diagnosis and monitoring of therapies or exploring new drug targets".

Tobias Sjöblom, Senior lecturer at the Department of Immunology, Genetics and Pathology, Uppsala University

2

JANSSEN AND KAROLINSKA INSTITUTET ARE ADDRESSING THE GROWING DEMANDS FOR "REAL WORLD DATA"

"We are now collaborating with Karolinska Institutet in order to explore how real world data can be used to provide meaningful insights from ongoing patient care into research and development. We see Sweden as the best place for conducting such studies, thanks to access to national patient registries and the opportunity to collaborate with a world-leading team mastering this complex field."

Johan Liwing, Director Market Access RWE Partnerships at Janssen.

3

PATIENT REGISTRIES – A POWERFUL TOOL FOR IMPROVING QUALITY OF CARE

A clear example of the power of Swedish patient registries comes from a study published in 2014 in The Lancet[15]. Short-time survival over a six-year period (2004 – 2010) in all Swedish (390,000 patients) vs. UK patients (120,000 patients) treated for myocardial infarction was studied. There were distinct differences in patient care modalities between the countries, and mortality was 30 percent lower 30 days after a heart attack in Swedish patients than in UK patients. The data suggest that the difference in mortality can be attributed to the quality of Swedish cardiac care being higher and more consistent.

4

REGISTRY-BASED CLINICAL TRIALS - HIGH QUALITY DATA AT A FRACTION OF THE COST OF TRADITIONAL METHODOLOGIES

The world's largest randomised trial to date of a medical device in myocardial infarction patients was performed by applying the Swedish patient registry SWEDEHEART. No less than 7,244 patients were included in the study, and with minimal extra work, as patient data was easily accessible. Additionally, because clinical endpoint parameters were obtained from national health registries, no study-specific clinical follow-up was needed.

The study received widespread international attention. Many observers were astonished that such a large study could be conducted and published in just a few years as a randomised study including nearly all current patients in Sweden. And all at a fraction of the normal cost for a study of that size.

"Thanks to our public registries, the study was conducted with the highest possible quality at a marginal cost compared to a conventional clinical research study. This type of study opens up opportunities for the evaluation of established therapies that are important to patients, but have no commercial interest. To use Registry - Based Randomized Clinical Trials as a complement to regular clinical trials for the documentation of new medicines or medical devices is another opportunity worthy of exploring."

Stefan James, Senior Consultant and Professor at Uppsala Clinical Research Center, Uppsala University.

[15] The Lancet, Volume 383, Issue 9925, Pages 1305 - 1312, 12 April 2014.

* The registries displayed in the diagram represent the most relevant registries handled by the Swedish the National Board of Health and Welfare.

** LifeGene is a prospective cohort study collecting information and biobank samples from healthy individuals. EpiHealth is a longitudinal cohort study focusing on collecting information and biological samples from individuals between the ages of 45 and 75 years.

TAP INTO OUR RESEARCH ENVIRONMENTS

COLLABORATE WITH ACADEMIA

The research environment in Sweden within the life sciences has an open culture that actively fosters teamwork, cross-disciplinary collaboration and innovation. Professor Kenneth Chien is just one of an increasing number of leading international researchers choosing to transfer his research activities to Sweden.

"For me with long-lasting experience from San Diego and Boston, the team-oriented, collaborative culture in combination with excellent science, world-class research infrastructure and access to patients really makes a difference. This is the place where we are already seeing tomorrow's therapies being developed".

Kenneth Chien, Professor at Karolinska Institutet and Co-founder Moderna Therapeutics

OPEN INNOVATION

The AstraZeneca BioVentureHub in Mölndal is a new approach to open innovation. The company opens up its offices, laboratory space and facilities to academic groups and biotech companies that could gain competitive advantage by tapping into the company's resources and expertise. The setup is a win-win situation for all parties involved: the company/academic group, its investors and AstraZeneca. Companies and academic groups can operate at a lower cost base, utilise the AstraZeneca capabilities, know-how and infrastructure. AstraZeneca will request value recognition for its contribution only on the success of the program.

CLINICAL STUDIES SWEDEN

The Swedish government has launched an extensive national initiative to further strengthen the infrastructure for high-quality clinical studies: A strong national infrastructure for clinical studies of high quality with the aim to establish a clear path for access to all national resources for clinical studies. Clinical Studies Sweden involves all six healthcare regions in Sweden and is coordinated by the Swedish Research Council.

The first version of a national website for clinical studies will be launched 2016. It will constitute the central point of contact for access to study centres and clinics, regulatory and other expertise as well as relevant networks.

This will provide clear competitive advantages:

- High standards in clinical studies and experienced researchers.
- Accessible patient populations and a stable healthcare system.
- Extensive use of high-quality electronic medical records.
- Well-recognised regulatory authority, able to provide advice.
- Well-functioning system for national ethical approval.
- Highly-predictable clinical trials environment with minimal risk.
- Registries, databases and biobanks that provide excellent opportunities for feasibility and registry studies, real-world evidence data collection and long-term follow-up.

Sweden produces the 2nd highest number of scientific articles per capita in the world[16].

[16] The SCImago Journal & Country Rank, http://www.scimagojr.com/index.php

PHOTO: © ADVANCED MR ANALYTICS AB.

With AMRA's technology, MR images are transformed into precise fat and muscle volume measurements.

CASES

1

NOVEL WAYS OF PROGRESSING PERSONALISED MEDICINE

Swedish AMRA and one of the world's largest pharmaceutical companies have begun a collaboration to assess fat and muscle measurements in magnetic resonance (MR) images of 7,000 subjects registered in the UK Biobank. The collaboration aims to help provide a better understanding of the relationship between body composition and risks for obesity-related diseases, as well as a broader understanding of conditions linked to body composition. AMRA's body composition measurements are acquired via a 6-minute MRI scan, and translated via AMRA® Profiler, a cloud-based, computer-aided service. The results provide precise measurements of various fat and muscle group volumes significantly faster than other alternatives. By using AMRA's detailed body composition measurements for advanced phenotyping of participants in a clinical trial, a better stratification of participants can be achieved. The advantages are smaller test groups, better results, less adverse effects, and reduced costs. Within clinical trials, the early detection of small changes in fat and muscle volumes enables earlier and better decision-making.

"This collaboration holds the potential to better understand the relationship between fat and muscle distribution and obesity-related conditions such as diabetes, NASH, and cardiovascular disease. As more data becomes available via collaborations such as ours, the research and medical community will be better equipped to make decisions on how to improve and personalise treatments for individuals with obesity-related diseases."

Tommy Johansson, Chief Executive Officer at AMRA.

2

ACCELERATED TESTING OF NEW BIOMARKERS

The Swedish company Biovica has developed a blood test (DiviTum™) that provides accurate measures of cell-division rates in blood. Testing and validation were accelerated by ready access to blood samples from Karolinska University Hospital's biobank. These had been collected during a clinical study including 287 women with breast cancer undergoing two different kinds of chemotherapy.

"In this retrospective study, the test, based on biobank-stored blood taken from patients before treatment started, predicted which groups of patients would respond to treatment or not. Thus, patients with tumors expressing a low value lived significantly longer than those with high values. We are now keen to examine whether the new test can also be used more widely to monitor the effect of a chosen treatment, thereby constituting a tool for documenting new drugs in clinical trials. The fact that it only takes a blood sample is a distinct advantage, as other methods require tumor tissue".

Thomas Hatschek, Associate Professor at Karolinska Institutet and lead investigator for the study performed at Karolinska University Hospital

THE UNIVERSITY HOSPITAL OF THE FUTURE

New Karolinska Solna (NKS) is the project name for the state-of-the-art hospital currently under construction next to Karolinska University Hospital in Solna. The assignment for the new university hospital, which will open its doors to the first patients at the end of 2016, is to provide highly-specialised healthcare to the 2.5 million population in the region, and to conduct basic research, patient-focused clinical research, and education. Greater collaboration between healthcare and research will contribute to new research findings being turned into new treatment methods and medicines more quickly.

ILLUSTRATION: NYA KAROLINSKA SOLNA, WHITE TENGBOM TEAM

INVESTMENTS IN HEALTHCARE AND CLUSTERS

A 1.5 BILLION EURO INVESTMENT IN A NEW HOSPITAL COMPLEX

Adjacent to the existing Karolinska University Hospital, Solna, a new state-of-the-art hospital complex will open its doors to its first patients at the end of 2016. The new hospital will take a patient-centric approach to healthcare, and develop new care pathways by integrating patient care, clinical research and education.

STOCKHOLM LIFE – A HUB FOR LIFE SCIENCE IN CENTRAL STOCKHOLM

Located in central Stockholm, the city's largest ever development project, Hagastaden, is well underway. The area is devoted to life science and encompasses all the elements required to become a true international hub. Karolinska Institutet, KTH Royal Institute of Technology, Stockholm University, SciLifeLab, Stockholm School of Economics and the existing and new Karolinska University Hospital are all within walking distance. This means that within a radius of two kilometres, there are four major universities, some of the world's best clinical research facilities, leading healthcare providers, and one of Europe's highest concentrations of life science companies, organisations and institutes.

For an overview of Sweden's life science clusters, see page 7.

OTHER CLUSTERS

Major investments in clusters, life science and healthcare facilities are also underway in other cities in Sweden. Examples include:

- The Skandion Clinic in Uppsala; the first clinic for proton therapy in Scandinavia. The first patient was treated in 2015.
- Re-building and expansion of Uppsala University Hospital, planned to be ready by 2022. A major investment of approximately 600 million euros.
- A new Centre for Imaging and Intervention at Sahlgrenska University Hospital in Gothenburg; a 200 million euro investment, due for completion in 2016.
- A new hub for biomedical translational research (Sahlgrenska Life) at Northern Europe's largest hospital, in central Gothenburg. At an early stage of development, the core concept is to create an environment for seamless collaboration between industry, healthcare, research and education.
- In Lund, the Max IV and ESS investments in physical research infrastructure for use in several scientific branches exceed 2 billion euros.
- A new Medical Biology Centre (MBC) at Umeå University enabling the Faculty of Medicine to co-locate its activities and gather its medical cutting edge research under one roof. An investment of almost 30 million euros.

EMBRACING INNOVATION IN MEDTECH

THE SWEDISH MEDTECH INDUSTRY

Sweden's technology-driven environment, characterised as it is by close collaboration between academia, healthcare and industry, has produced many notable medtech innovations that have saved lives and alleviated symptoms for millions of patients globally. The pacemaker, the gamma knife and renal dialysis are just a few examples. Swedish medtech companies are represented across the whole spectrum of the industry, from radiotherapy and imaging, through biomaterials, implantable devices, stents and minimal invasive surgery products, to haemodialysis, disposables and assistive technology. A couple of areas in particular where Sweden can rightfully claim a world-leading position are radiotherapy and imaging.

DIGITALISATION-DRIVEN INNOVATION

Digital solutions are increasingly important for the medtech industry. This is not only because they enable the development of new and better monitoring and other devices, but digitalised add-on services are also becoming essential staying competitive.

Digital solutions enable specialised care to move out of hospitals and into the patient's own home. Digitalisation can also facilitate decision-making for healthcare professionals by creating decision making support systems utilising data from both healthcare itself and/or from other sources. Sweden is a country with high levels of digital development[17], ranking 2nd in the world in the Digital Economy and Society Index (DESI)[18] and 3rd out of 144 countries in the World Economic Forum's Network Readiness Index 2013[19]. Taking advantage of this, a number of initiatives implementing digital solutions as a way to improve healthcare are underway. Augmenting the existing infrastructure by further developing patient registries is just one investment by the government. In a drive to encourage Swedish citizens to take an active role in preventive measures and treatments, personal health records are being made accessible online 24/7. Currently, this has been implemented in a third of the counties, with the rest soon to follow.

NOVEL WAYS TO BOOST INNOVATION

In Sweden, all healthcare stakeholders are increasingly embracing the notion that progress can only be made by devising collaborations where different capabilities contribute to the whole. For example, when Stockholm County Council looked to procure imaging and operational equipment for the new hospital, they took the bold decision not to copy and paste from previous procedures, but to take a whole new approach. Read about the process on the opposite page.

Sweden has already made major progress in digitalising healthcare, and has ambitious programs to advance this position even further.

- 100% of all hospitals and primary care facilities use Electronic Health Record systems.
- Over 80% of all drug prescriptions are performed electronically.
- Close to 90% of all x-ray and laboratory test results are disseminated electronically.
- All hospitals have switched to digital radiology solutions with digital archives.
- All Swedes can make doctor's appointments and renew prescriptions online.

PHOTO: OSKAR LÜREN

Cutting-edge development in action at the Center for Medical Image Science and Visualization (CMIV), a multidisciplinary research centre at Linköping University.

CASES

1

ASSESSMENT OF CARDIOVASCULAR BLOOD FLOW USING 4D (TIME + RD) FLOW MRI

Despite the primary role of blood flow measurement for assessing function, cardiovascular diagnostics still rely almost exclusively on tools focused on morphological assessment. Flow characteristics are often assumed rather than measured directly, as reliable, non-invasive tools for characterising and measuring flow dynamics are lacking. A new method for studying cardiovascular blood flow dynamics in patients and healthy subjects has therefore been developed by CMIV, the Medical Image Science and Visualization Unit at Linköping University.

"The method will potentially improve cardiac diagnostics and offer novel ways to assess pharmaceutical, interventional, and surgical therapies. We are now working on optimising the accuracy, measurement time, and robustness of 4D flow MRI, and are confident of bringing the technique into clinical use in the near future"

Tino Ebbers, Professor in Cardiovascular Physiology at Linköping University, Department of Medical and Health Sciences.

2

A NOVEL APPROACH TO PROCUREMENT

Instead of tendering for certain pre-specified imaging equipment, Stockholm County Council, who carried out the procurement, asked for a long-term agreement guaranteeing access to the imaging and operational equipment functionality the new hospital will need over a defined time period. This was then awarded to Philips for an initial period of 14 years. The agreement comprises an innovation and training partnership, as part of which Philips will establish a research & innovation hub at the new hospital. The intention is to bring researchers from the medical technology industry, the hospital and academia together to forge a closer link between the delivery of care and clinical research, and ideally translate into the accelerated development of new therapeutics and treatment methods.

"With this innovative agreement, Philips, the Stockholm County Council and Karolinska University Hospital are committing themselves to working together and enabling the high pace of innovation that is necessary to address future healthcare challenges".

Dr. Diego Olego, Senior VP, Lead Technology and R&D Management, Innovation, Philips

[17] Harvard Business Review: https://hbr.org/2015/02/where-the-digital-economy-is-moving-the-fastest
[18] EU: https://ec.europa.eu/digital-agenda/en/desi
[19] World Economic Forum: http://www.weforum.org/reports/global-information-technology-report-2013

DEVELOPMENT, MANUFACTURING & EXPERT SERVICES

WHY SWEDEN?

The decisive factors on where to make new or follow-on investments in manufacturing include safeguarding product quality, meeting regulatory and healthcare body requirements, cost-effective production and guaranteed access to global distribution networks. Meeting environmental standards is another increasingly important factor. Sweden meets all of these demands, and there are numerous recent examples of global companies expanding their capacities in Sweden, including AstraZeneca, Cepheid, Fresenius Kabi, GE Healthcare, Kemwell, Octapharma and Pfizer.

"We have found the technical capability of the personnel to be outstanding, and at a cost which is less than in the US. In addition, the close proximity of institutions such as Uppsala University and Karolinska Institutet will provide an excellent personnel resource for our current and projected future growth."

Anita Herrström-Sjöberg, Vice President and Managing Director, Cepheid AB

CDMOs, CROs AND EXPERT SERVICES

Swedish-based Contract Development, Manufacturing Organizations (CDMOs), Contract Research Organizations (CROs) and other life science experts are increasingly finding their services in demand on the global market. This results from their reputation for delivering expert services and manufacturing products of the highest quality. Able to offer expertise along the entire value chain, they typically work seamlessly with clients to drive constant improvements, guarantee quality and deliver services and finished products often above expectations.

An increasing number of innovative international companies are tapping into Sweden's well-established pool of life science consultants who are able to offer expertise along the entire value chain. A major competitive advantage is the ability of these consultants to understand big pharmas' or international medtech companies' mindsets and requirements, as since the majority have either previously worked in managerial positions within such companies or acted as consultants. In addition, Sweden's large number of experts within patent law, legal and financial services, industrial design, etc., should also be seen as a major contributing factor to an innovative life science environment.

INCUBATORS, CLUSTERS AND SCIENCE PARKS

All major sites with universities and university hospitals (see map on page 7) are home to incubators, cluster organisations and science parks. There is a range of services for local scientists and companies, including expertise in IP protection, business development and other types of advice, as well as access to financing and local networks.

PHOTO: LIPKA

Sobi has been involved in the development and manufacturing of re-combinant protein drugs since the technology was first developed more than 30 years ago.

CASES

1

INDEPTH UNDERSTANDING OF BIG PHARMA'S NEEDS

SP Process Development (SPPD), formed in 2013, offers services within drug development and manufacturing, but is far from being a new kid in the block. SPPD assimilated decades of experience and state of the art equipment when it acquired parts of former AZ Process and Pharmaceutical R&D unit in Södertälje. 2/3 of the employees are PhDs, and services cover the entire value chain from raw material to clinical trial material according to GMP. Thanks to the AstraZeneca heritage, the quality level of equipment for drug formulation, synthesis and chemical engineering, analysis etc. as well as the competence pool, is on par with any similar facility within big pharma.

2

A KEY ROLE IN NEW EU ANTIBIOTICS PROGRAM

SPPD is to join forces with over 30 European universities, research institutes, and companies in a 6-year, 85 million euro European program (ENABLE) to develop novel antibiotics. SPPD's resources and expertise will be applied throughout the process, from the formulation stage to candidate selection.

3

MAJOR INVESTMENT BY ASTRAZENECA

A new 255 million euro hightech facility for the manufacture of biological medicines is to be built in Södertälje. The new plant will focus on the filling and packaging of protein therapeutics. AstraZeneca's largest global tablets and capsules manufacturing facility and launch platform site is also located in Södertälje. By locating the new manufacturing plant in Södertälje, the company will combine its expertise in biologics with the well-established culture of operational excellence that exists within the Sweden Operations unit.

"This is a strategically important investment for AstraZeneca to support the accelerating development of biotech medicines, which now make up around half of our pipeline. We expect to bring a significantly increased number of new specialty care medicines to patients in the coming years, driven in large part by biologics. This new plant will give us greater capacity and flexibility to handle clinical trials, and will also play an important role in our future commercial production."

Pascal Soriot, Chief Executive Officer, AstraZeneca

INNOVATION THROUGH COLLABORATION

Sweden is a world leader in innovation. We have been very successful to date. Millions of hearts around the world beat with the help of the pacemaker – just to mention one of many examples of successful Swedish inventions that have made a difference.

A key factor to this success is the close collaboration between academia, research institutions and the private and public sector, a system which lays the foundation for global Swedish companies such as Elekta, Getinge and Sobi. Through collaboration, we will be able to meet the needs of the healthcare system for more efficient equipment, medical procedures and smarter healthcare chains, providing improved outcomes and safer care at a lower cost.

Innovation is closely linked to research and development. Sweden is one of Europe's top investors in this area. The country is ranked second in the world in terms of number of patents produced per capita. This also proves that our long track record of investing heavily in research and development has borne fruit – and is another reason to look at Sweden for business development, licensing, partnership or direct investment.

Business Sweden helps international companies expand their business in Sweden, through entering strategic partnerships or investing in Swedish companies. We connect global companies with business opportunities in Sweden, and provide them with the information, guidance, solutions and network required to invest in Sweden. With in-depth knowledge of Sweden's leading industries, as well as established contacts with key decision makers, we will help you succeed and make your business grow.

Business Sweden is your best partner for your future business investment in our country, and we look forward to supporting you. Together, let us pave the way for future innovations!

Ylva Berg
CEO, Business Sweden

PHOTO: OLOF HOLDAR

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PHOTO: MONA LOOSE/IMAGEBANK.SWEDEN.SE

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