

biovitrum.



Corporate Responsibility Report 2009

Responsibility, Commitment and Sustainable Development

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Glossary – see www.biovitrum.com/glossary

This is Biovitrum's Corporate Responsibility Report 2009

Biovitrum is an international pharmaceutical company that markets specialist pharmaceuticals in several regions globally. The company head office is located in Sweden. Using its expertise and experience Biovitrum takes scientific innovation to patients with significant medical need. Research expertise and capabilities are focused on development and production of biotechnology therapeutics within our prioritized areas of hemophilia, inflammation/autoimmune diseases and malabsorption. The company has revenues of approximately SEK 1.3 billion and around 400 employees. It is listed on the OMX Nordic Exchange in Stockholm. For more information go to www.biovitrum.com.

To further emphasize our commitment to financial, social and environmental accountability we present our corporate responsibility report this year as a document detached from our Annual Report. The report depicts our vision, mission and business model. It outlines our business strategy and how we take responsibility for our employees, the environment and our products. We are committed to the UN Global Compact (GC) principles but are not members and our report is not fully in accordance with the Global Reporting Initiative (GRI) guidelines. However, our goal is to reach reporting standards that fulfill the highest level of GRI recommendations and to join the GC initiative.

Biovitrum is a Swedish corporation governed by Swedish laws. All financial values are expressed in Swedish kronor. Million kronor is abbreviated SEK M. Numerical data within parenthesis refer to 2008 if not stated otherwise.

We make great efforts to be an attractive and accountable company in order to create sustained value for both patients and shareholders. Our ambition and mandate, to make life better for many patients, permeates the entire operation – from providing the market with innovative drugs to supporting the Arosenius fund, Save the Children, SOS Children's Villages, and research in the field of pediatric cardiology. We approach our work with pride, convinced that we make a difference.

In addition to developing and marketing medications that meet significant medical needs, our responsibility is also to safeguard the interests of our employees and the society around us. It is very important to maintain good working conditions for our employees. We also actively promote and strengthen our values through internal platforms for discussions on corporate cultures, and we place great emphasis on ethical, safety and environmental concerns both in our daily work and in strategic work for the future.

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» Biovitrum develops and sells specialist pharmaceuticals that give people a better life «

Yesterday, Today, Tomorrow

Our History

Biovitrum AB (publ) commenced independent operations in August 2001. We were formed from various business units within Pharmacia (now Pfizer) that were based in Sweden, including its metabolic diseases research group, biopharmaceutical development unit and its plasma products business. The history of Biovitrum extends back to Vitrum, the first pharmaceutical company to be established in Sweden in 1877. Vitrum was involved in the development of insulin in the 1930's and became one of the first companies in the world to manufacture insulin. In 1972, Vitrum merged with Kabi, a Swedish pharmaceutical company that pioneered the development of pituitary-derived human growth hormone.

In 1978, the merged entity, Kabi Vitrum, signed an agreement with Genentech to produce human growth hormone based on recombinant DNA technology using the bacteria *E. coli* as the host organism. Kabi Vitrum later founded its own biotechnology company named KabiGen, which focused on research in the recombinant biotechnology field. Our biopharmaceutical competences and certain basic pharmaceutical technologies that we still use today have their roots in KabiGen. In 1990 KabiGen was integrated into KabiPharmacia's operations following the merger of Kabi-Vitrum and Pharmacia. Following the merger of Pharmacia and Upjohn in 1996, a metabolic disease research group was formed within the combined entity.

In July 2001, Nordic Capital and MPM led a syndicate of investors that acquired Biovitrum from Pharmacia. Since the acquisition, we progressively rationalize our operations with the aim of building an integrated and focused business for sustainability and growth.

Biovitrum in 2009

During 2009 Biovitrum has developed, manufactured, distributed and sold specialty pharmaceuticals internationally within five specialist areas: hemophilia, rheumatoid arthritis, supportive cancer care, hormonal disorders and fat malabsorption. Biovitrum had at the end of 2009 revenues of approximately SEK 1.3 billion and around 400 employees.

Biovitrum's portfolio of marketed products within the above-mentioned specialist areas consist of ReFacto AF[®]/Xyntha[®], BeneFIX[®], Novastan[®], Kineret[®], Kepivance[®], Stemgen[®], Aloxi[®] and Mimpara[®]. For further product information see www.biovitrum.com.

Biovitrum's research and development is focused on new pharmaceuticals in areas with high unmet medical needs and attractive commercial potential. For further information on product development see www.biovitrum.com.

Through the acquisition of three unique biotechnological products in 2008, Biovitrum developed into an international product company. In addition to successful operations in the Nordic countries, the company now also has a product presence in Europe, North America and Australia/New Zealand.

Swedish Orphan Biovitrum

On January 14, 2010 Biovitrum completed the acquisition of Swedish Orphan International forming Swedish Orphan Biovitrum. The mission of the new company is to develop and make available orphan drugs and niche specialty pharmaceuticals for patients with rare diseases and with high unmet medical needs. Swedish Orphan Biovitrum has a pan-European commercial organization and representation in North America and Australia/New Zealand, a strong business development track-record and compelling product development and manufacturing capabilities. The company has access to about 60 orphan or niche specialty products. Several late stage development programs within rare diseases provides exciting future business value.

The acquisition is a logical consequence of Biovitrum's business strategy which was adopted in 2007. The decision then was to focus on the attractive niche specialist pharmaceuticals market and on rare diseases, and at the same time seek to generate profitable and stable growth derived from product sales to a greater extent than in the past. The new strategy has significantly changed Biovitrum's business over the past two years, on both the revenue and the cost side – a change that will now accelerate.

Swedish Orphan Biovitrum is a company with a strong cash flow and good growth potential. Our vision is to be a market-leading European specialty pharmaceutical company. Our business concept is to develop, market and sell orphan drugs and niche specialty pharmaceuticals for patients with rare diseases and with high unmet medical needs. These pharmaceuticals may be co-marketed, in-licensed, acquired or developed in house.

MARTIN NICKLASSON, CEO:

Our Agenda for Sustainability

In 2009 we have successfully continued our transformation of Biovitrum into a leading European pharmaceutical company within rare diseases. Our revenues before licensing revenues grew strongly, and I am pleased that the operating profit was according to our guidance, demonstrating a turnaround into a future profitable business. The positive progression of many of our clinical programs is also exciting. We have continued to divest non-core projects and, at the same time, strengthened the infrastructure needed for our key products. Going forward, we intend to grow both organically and through strategic acquisitions.

The acquisition of Swedish Orphan, completed in January this year, was a significant achievement. The new company, Swedish Orphan Biovitrum, has a diverse product portfolio and an interesting late stage project pipe-line within rare diseases. The company has a strong and profitable growth potential.

Our citizenship involves social responsibility, management systems for environmental protection, policies for patient responsibilities, ethical handling of experimental animals and risk management.

The merger was a logical consequence of the business strategy Biovitrum established in 2007. We then decided to focus on the attractive market for specialist care pharmaceuticals and rare diseases, and at the same time seek a profitable and stable growth that, to a larger extent than earlier, would emanate from sales of products. This new strategy has implied a considerable change in Biovitrum's business during the past two years, both on the revenue and cost sides – a change that now is accelerated through the merger with Swedish Orphan.

Our agenda for sustainability is foremost focused on delivering results in line with our business strategy. Our citizenship involves social responsibility, management systems for environmental protection, policies for customer responsibilities, ethical handling of experimental animals and risk management.

Several key initiatives have been implemented during 2009.

- Our R&D department has been restructured. Our clinical programs are progressing well and we have decided to move one of them into registrational trials. We are thus getting nearer one of our most important goals; to launch in-house developed pharmaceuticals on the market.
- Sales & Marketing have expanded and taken on a series of new work assignments. Sales of the new products Kineret® and Kepivance® are according to plan, strongly contributing to the increase in our revenues.
 - The protein for ReFacto AF® is now being produced in our production facility using a new, more efficient process. ReFacto AF was launched by Biovitrum in the Nordic region, and through that, has satisfied the desires of both patients and professional caregivers for safer treatment.
 - The Business Development function has successfully closed many out-licensing deals and delivered a restructured collaboration agreement with Biogen Idec in the hemophilia area.

The evolvement from a research based company into a pharmaceutical company requires a corresponding change in how we take on every day challenges, to ensure a sustained growth in the short and long run. A strong corporate culture will assist our efforts to become a successful and profitable company selling our own specialist pharmaceuticals internationally. During spring 2009, our Senior Management, Extended Management Team and Leaders Forum



initiated discussions around cultural issues with the aim to define what kind of behavior and culture that are essential in creating a successful company. Our success rests on the common desire to solve medical problems, and to help people achieve a better life. The endeavor to attain these ambitious objectives is based on ethical decisions and actions in accordance with the core values that exist within the company.

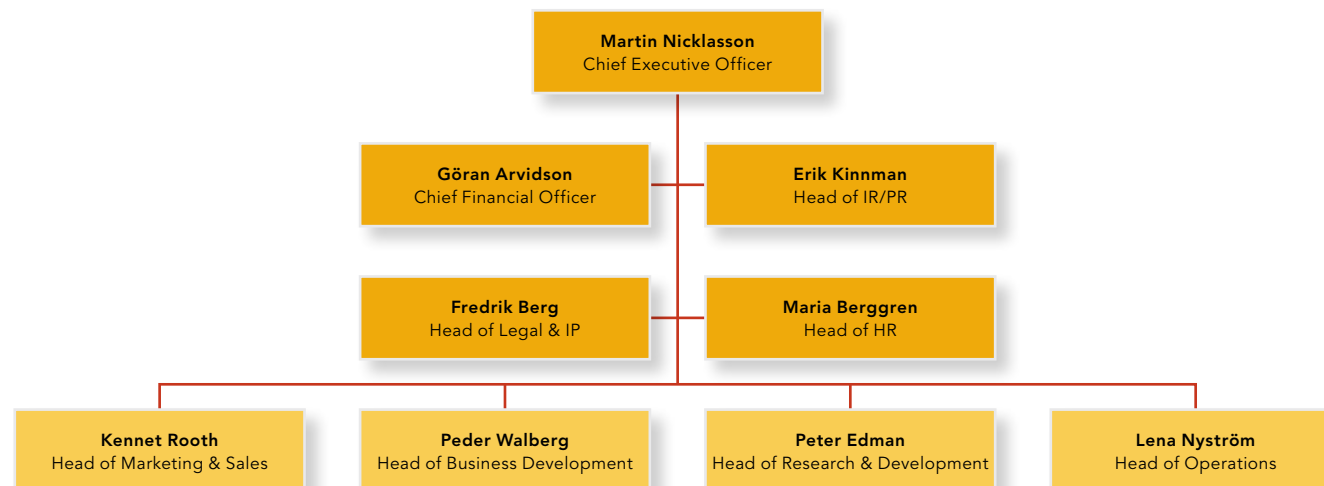
Martin Nicklasson, CEO

Corporate Structure, Senior Management and Board of Directors

Biovitrum's organizational structure is based on functions such as sales and marketing, business development, research and development as well as product supply being joint functions. The diagrams below show the Company's operational structure.

Operational structure

The Company's operational structure and [Senior Managers](#) as of January 15, 2010



Board of Directors

As of January 15, 2010 the [Company's Board](#) consists of eight members elected by the general meeting and two employee representatives.

Chairman

Håkan Åström

Vice Chairman

Bo Jesper Hansen

Board members

Mats-Olof Ljungkvist

Wenche Rolfsen

Michael Steinmetz

Hans Glemstedt

Hans Wigzell

Peter Sellei

Board member (employee representative)

Catarina Larsson

Bo-Gunnar Rosenbrand

Our Business Model and Strategy

Biovitrum's mission is to develop and sell specialist pharmaceuticals that give people a better life.

Biovitrum's vision is to continue to be a successful and profitable company, which also has launched its own desirable specialist pharmaceuticals internationally.

Biovitrum's business model is based on research & development and the generation of revenues from production, and sales & marketing.

Biovitrum's business strategy: Our action plan for transforming Biovitrum from a strong regional player to a European leader in specialist pharmaceuticals market includes:

- Positioning ourselves as a pharmaceutical company highly focused on developing, producing and marketing biotechnology-based therapeutics for rare diseases.
- Increasing and diversifying revenue by expanding the portfolio of marketed products. Short-term, by:
 - Acquiring development and marketing rights to specialist therapeutics from selected pharmaceutical and biotech companies.
 - Tapping the capabilities of regional partners to capture opportunities in emerging markets.
- Long-term, by bringing products developed in-house or with partners to the market by leveraging our international infrastructure.
- Establishing an international presence by leveraging a marketing and sales approach already proven in the Nordic region.

Successful implementation of our strategic roadmap:

Strategic roadmap	Achievements to date
Expand commercial portfolio	Acquisition of Swedish Orphan International adds 50 new niche specialty pharmaceuticals to the portfolio
	Global rights to 3 unique biotech therapeutics acquired from Amgen
Expand geographic presence	Increased geographic presence following the Amgen agreement to USA, Canada, Europe, Australia and New Zealand
	Presence in Europe expanded as a result of acquisition of Swedish Orphan
	Distribution partner contracted in the Middle East
Develop projects all the way to market leveraging on biotech therapeutics expertise	Restructuring of R&D completed. Focus on biotech therapeutics and development projects
	Focus on the rare disease specialist pharmaceuticals market with high unmet medical need
Focus on the rare disease specialist pharmaceuticals market with high unmet medical need	Co-development agreements with Biogen Idec and Symphogen
	Discontinued small molecule discovery and primary care research
Leveraging in-house biotech process development and manufacturing expertise	ReFacto [®] supply agreement with Wyeth extended until December 31, 2015. ReFacto AF [™] approved in EU March 2009
Spinning out small molecule primary care programs	Out-licensing to Karolinska Development and Inovacia of small molecule projects, March 2009
	Cambridge Biotechnology (CBT) sold to Proximagen Neuroscience together with metabolic programs, November 2009
	AstraZeneca acquired all of Biovitrum's rights to its leptin modulator program aimed at treating obesity, December 2009

- In-house development of specialist pharmaceuticals projects from early-stage research to commercialization on a proprietary or partnered basis.
- Leveraging our in-house biotech process development and manufacturing expertise to attract partners offering breaking science and/or limited production resources or know-how.

Recent Financial Development

Total revenues before licensing and milestone revenues amounted to SEK 1,234.4 M (1,008.1) driven mainly by Kineret® and Kepivance®. Profit for the year was SEK 32.4 M (-335.4), which represents earnings per share of SEK 0.33 (-3.67).

Cash flow from operations was SEK 58.8 M (-506.5). Cash and cash equivalents and short-term investments as of December 31 amounted to SEK 306.6 M (460.1).

Research and development expenses amounted to SEK 569.4 M (670.6). The fixed in house costs have decreased significantly due to previous transformation and downsizing of the R&D organization.

Key Financials over six years

Amounts in SEK million	2009	2008	2007	2006	2005	2004
Biovitrum consolidated revenues	1,297.0	1,140.6	1,256.4	1,201.1	936.6	787.4
Cost of goods and services sold	(375.7)	(264.7)	(348.8)	(293.8)	(270.7)	(248.3)
Gross profit	921.3	875.9	907.7	907.3	665.9	539.1
EBITA	68.0	(380.3)	60.5	69.6	133.3	44.8
EBIT	16.2	(386.3)	55.1	54.6	129.9	41.4
Net interest income	16.3	20.2	23.9	39.6	47.9	51.9
Profit before tax	32.4	(366.0)	79.0	94.2	177.8	93.3
Tax	-	(30.6)	(0.0)	(1.5)	(1.6)	2.3
Net profit / Loss (profit after tax)	32.4	(335.4)	79.0	92.7	176.2	95.6

Social Responsibility

Values and culture

Biovitrum combines advanced research and commercial performance with a strong patient focus. Our operations place high demands on [our employees and our corporate culture](#).

Our values – **commitment, new mindsets, accountability, and focus on results** – are important premises for achieving our objectives. [These values](#) are expressed in our leadership and are reflected, for example, in the evaluation of our employees' efforts. We work according to the Performance Management Process, a specific process for management by objectives and follow-up. Together, managers and employees set individual goals for the year based on the company's overarching objectives. Each employee must understand the company's mission and objectives and how their personal performance contributes to achieving them. At the end of the year employee efforts are assessed and they receive an individual performance evaluation.

Our culture is characterized by high-performing teams that are committed to helping patients with rare diseases. In order to promote our values, increase the overall awareness of the implications of our business strategy and support those behaviors that help us to achieve our business goals an internal program for improved communication and performance was introduced in the beginning of 2009. Two new, reoccurring meetings for dialog on cultural matters and behavior in relation to corporate objectives was formed; Extended Management Team and Leader Forum. Furthermore, 80 percent of all employees participated in one of eight seminars emphasizing our mission, vision and business goals and what to focus on to achieve these. Consensus was reached on attitudes that would help us to focus on behaviors leading to success while acting according to our values. In summary, the three words Dare-Choose-Grow describe a mind-set that will guide us in the further development of our company culture.

Skills development and innovation

Biovitrum is a knowledge-intensive company. Staff members' professional skills development is crucial, not only to improve our project portfolio, strengthen the production process and the launch of products, but also to strengthen, develop and inspire the individuals who comprise Biovitrum. Professional skills development is linked to individual objectives based on the needs of the operation and the projects. Many employees actively participate in academic networks with advantages such as access to new research findings, which positively contributes to the operation.

Salaries and benefits

Favorable terms of employment are essential for Biovitrum to be able to recruit and retain talented employees. Consequently, our goal is to offer competitive salaries and benefits. The company works according to the principle that salaries are set on an individual basis and differentiated; moreover, salary structuring is based on locally agreed salary criteria. We supplement parental salary for our employees.

Work climate

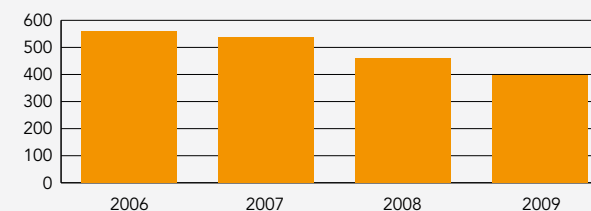
We are convinced that a good work climate provides job satisfaction, low sickness absence and good relationships, which leads to a strong sense of engagement and motivation and a will to stay at Biovitrum. Employee surveys are carried out on a regular basis to ensure a positive work climate. Results from the survey are brought back to the managers in the organization and each manager reviews the information together with the employees. Company management and managers place great emphasis on the information from the employee survey and work on making changes based on the opinions of our staff. We therefore continuously develop the dialog between senior management and the rest of the organization

(cf. above under Values and culture). As judged by the results of the 2009 employee survey this work is successful; an 88 percent employee satisfaction index (ESI) was obtained.

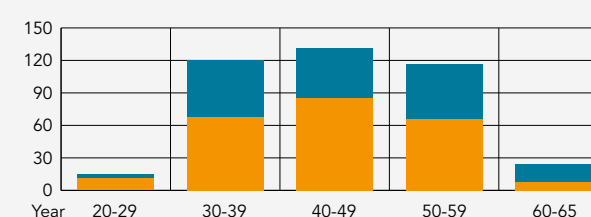
Diversity and gender equality

Biovitrum has operations in Sweden, Norway, Denmark and Finland, and, up to November 2009, we also had an operation in the UK. As of December 31, 2009 Biovitrum had 397 employees. 46 percent of our employees worked in research and development, 33 percent in manufacturing, 14 percent in staff functions, 6 percent in sales and

Average number of employees by December 31 2006 – 2009



Age structure 2009



marketing and 1 percent in business development. Of our employees, 58 percent were women. In 2007 a salary review was made showing that no significant differences in the salary level between men and women existed. This review is since then carried out annually with corresponding results.

For us, it goes without saying that everyone will be offered the same opportunities and be treated the same way, irrespective of age, gender, religion, sexual orientation, physical disabilities or ethnic affiliation. We have for some time addressed diversity issues and during 2009 this work has been formalized to adhere to the Equal Opportunities Act and the other Swedish Acts against Discrimination in the Workplace.

We will also be a company where working life and parenthood should be able to coexist within the framework of our operations. We have a policy on parenthood aiming at facilitating planning before and during as well as after a parental leave. We also supply extra payment in addition to the compensation provided by the Regional Social Insurance Office (Försäkringskassan) at parental leave. Employees at parental leave are also included in the annual salary revision unless something else has been agreed.

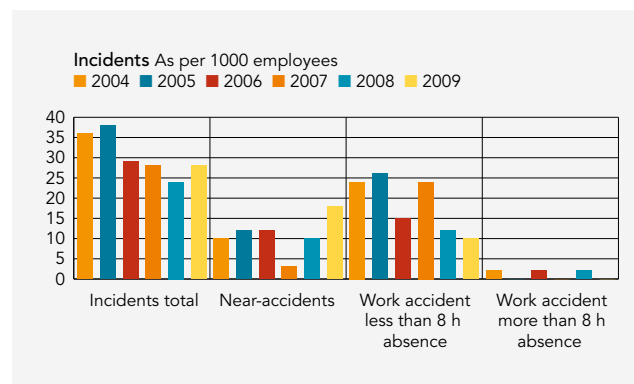
Health and wellness programs

Biovitrum aims to offer a work environment that promotes good health and well-being. In 2009 sickness absence at the company was two percent. Our employees are offered a healthcare program on favorable terms through an agreement with The Feelgood Group, where our employees can receive both preventive healthcare and certain medical services.

During 2008 we introduced a wellness portal where all employees have the opportunity to use an annual wellness subsidy for various activities. This portal has become very popular and we can see that the subsidy is being used to a greater extent and in a more individual way.

Workplace environment

Biovitrum has a work environment management system that is integrated with its quality environmental management systems (more information on [page 12](#)).



In 2009 the comprehensive procedures for environmental management and incident reporting were updated. Incident reporting is an important tool for improving occupational health and safety, and all incidents and accidents are followed up. No accidents in the workplace were reported to the Swedish Work Environment Authority during 2009.

Respect for rules in the labor market

Biovitrum complies with and respects the rules that apply in the labor market and the agreements that have been signed by its various parties. We continuously follow developments and changes to be able to adopt our activities to new laws and rules, but also to good praxis within the market where we act. We have a very good, constructive collaborative relationship with our local trade unions and solve issues that occur through talks, information and local

negotiations. We hold regular meetings with trade unions and senior management in a CEO Council as well as with trade unions and management teams in Unit Councils (Enhetsråd) within major functions, the aim being to have a preventive and positive cooperation. Employee membership in trade unions amounts to 65 percent.

Biovitrum is a member of the Confederation of Swedish Enterprise, the Swedish Employers' Federation and the Swedish Industrial and Chemical Employers Association

Biovitrum's values

Biovitrum's conduct, products, and services affect and influence people. Consequently decisions and actions are based on ethical behavior and a sense of responsibility in accordance with the company's common fundamental values. These values guide how we develop, produce, and provide medications, as well as our communication, collaborations, and business agreements.

Commitment – Accountability – Innovation – Results

We are driven by the common desire to build a company, the success of which rests on the ability to solve medical problems and help people attain a better life. We accept our responsibility and are accountable for our words and deeds. Biovitrum strives to achieve dynamic cooperation based on participation, initiative and drive. Respect for one another, and for the environment, is essential. We dare to think differently and have the courage to try new paths. We value an open dialogue and nurture diversity in experience, expertise and personality. With this approach, we strive to achieve common objectives, where results and accomplishments are rewarded.

Customer Responsibility



Clinical studies

[Drug development](#) is governed by the needs of the patient and society. It is therefore vital for us to have good contacts with patients, patient organizations and regulatory authorities. As a key component in our social commitment, we participate in the debate about long-term prospects for clinical research and help to influence public opinion. Conversations with doctors, patients and patient organizations help us gain greater understanding of the problems that individuals, large patient groups and society consider to be important to address.

Biovitrum's project portfolio mainly consists of projects in clinical phase. The clinical studies are carried out according to Good Clinical Practice and in cooperation with highly-respected clinical contract organizations. These undergo extensive evaluation before their services are purchased to ensure that the studies are carried out according to best practices and that legal and regulatory requirements are followed. Biovitrum follows Standard Operation Procedures formulated together with and maintained by our own [Quality Assurance/ Quality Control \(QA/QC\) department](#) to regulate how it purchases and carries out clinical trials.

Patient safety

Continuous assessment of the benefit/risk balance is the most important consideration in Biovitrum's research and development phase. During clinical trials, the focus is always on patient safety and consideration of human rights. Our Pharmacovigilance unit ensures compliance with internal and external rules with respect to Biovitrum-sponsored clinical trials. The unit reviews the study protocol before the study begins, monitor the conduct of the study and reports potential side effects to regulatory authorities and ethics review committees in compliance with existing regulations.

Handling of adverse event reports from products on the market

Biovitrum is the marketing authorization holder for a number of [products in several markets](#). We therefore have the responsibility to gather and process safety information and report adverse events to Drug Regulatory Agencies in compliance with international regulations and guidelines. This responsibility includes discovery, assessment, understanding and prevention of adverse drug events and other drug-related problems. Now that we hold marketing authorization, we will receive more reports of rare side effects

because we reach many more patients than in the past. Our medications are also prescribed to patients with varied health conditions and diseases. Our Pharmacovigilance unit is responsible for capturing and analyzing signals to benefit patient safety and well-being. It is therefore crucial that Biovitrum has an effective system and network for gathering, marketing and communication of side effects.

We receive signals about adverse drug events from patients, medical personnel, regulatory authorities, consumer reports, matters pertaining to product quality, scientific publications, business partners, and drug information and marketing functions. Our employees are also required to report any adverse drug events from Biovitrum products that come to their knowledge.

Safe production of pharmaceutical proteins

Biovitrum [manufactures](#) the active ingredient in ReFacto AF® to meet global needs, as well as research material for all phases of clinical trials. Our Quality Assurance/ Quality Control department takes an active and goal-oriented approach to ensure quality and safety throughout the complex biotech production process. The department guarantees cGMP standard on pharmaceutical substances provided for clinical and commercial use. Our results also help to constantly improve operations in order to achieve sufficient quality and delivery reliability. The production facilities are regularly inspected by European (EMA) and American (FDA) drug regulatory authorities, as well as by other regulatory authorities.

Customer contacts

[Marketing and sales](#) are handled in Europe via our own organization with a clear customer focus. In the rest of the world where Biovitrum's products are marketed, contract organizations handle sales and distribution. In addition to our code of conduct, Biovitrum's values are also applied in all contacts with different types of customers.



We therefore strive to be sensitive, accountable and solution-oriented, while being clear and honest in everything we do.

Information for patients and families

Finding out that a child has a chronic illness is overwhelming for the child and its family. In addition, care is often complicated. Parents who learn that their son has hemophilia often have an enormous thirst for knowledge. Thanks to more effective and safer treatment methods, people with hemophilia can now live longer. Consequently, there is a great need to improve information aimed at older hemophiliacs. Biovitrum has initiated an extensive campaign to offer courses and materials aimed at healthcare personnel, patients and their families. This initiative is just one example of how we help to improve patient care, while meeting a need for information that can vary over time and from person to person. Patients and their families should be able to live “an inordinately ordinary life,” the slogan we use in our patient information.

Education for the healthcare team

In 2007 Biovitrum launched not only the medication Aloxi® to prevent nausea and a training program for the healthcare team that works with the nausea issue in cancer care. Many patients perceive nausea and vomiting to be among the most difficult side effects during cancer treatment. We worked with a Swedish expert group to design an extensive training program, which is now certified by the healthcare system. For Biovitrum, the initiative brings us closer to our customers, allowing us to listen to their daily needs.

External involvement and networking

Biovitrum takes a long-term approach to continued development of new medications. For example, Biovitrum participates in Combine, a national joint venture in chronic inflammatory diseases. Combine involves a unique program that focuses on the patient perspective, both when designing studies and evaluating treatment results. The goal of this program is to establish a new model for patient participation in research.

The patient is at the center of everything Biovitrum does. Through active participation in the World Federation of Hemophilia and good contacts with patient organizations such as the Swedish Hemophilia Society and the Swedish Rheumatism Association, we keep our focus on the patient.

Biovitrum also supports the networks that contribute to continued development of medicines in Sweden. Sweden’s Biotechnology Industry Organization, SwedenBIO, is a trade association tasked with successfully establishing and developing internationally competitive biotech companies in Sweden. Biovitrum was among the initiators and has played an active role in the organization since its formation. Biovitrum is also a member of the Swedish Association of the Pharmaceutical Industry (LIF). LIF’s task is to create good conditions for research and development of drugs. LIF also advocates good access to medications and fosters understanding of the importance of medications for quality of life. Biovitrum is also a member of European Biopharmaceutical Enterprises (EBE). EBE represents biopharma companies in Europe and supports innovation and new opportunities in biotechnology. EBE also contributes industrial expertise for developing new regulatory requirements, regulations and standards that are relevant for biologics.

Environmental Responsibility

Proactive environmental management

Biovitrum's environmental management system is based on the ISO14001 standard. The system also incorporates Swedish work environment regulations, thus creating an environment, health and safety (EHS) management system. Currently we are not certified according to any EHS related standard.

At Biovitrum respect for the environment, and for one another, are essential and an important part of our values. The EHS management system is integrated in the overall activities and operational control and formal responsibility is delegated in the line organization. Biovitrum's top management establishes an EHS policy to further emphasize the importance of EHS management. The policy is available at the Biovitrum website www.biovitrum.com.

Applicable regulatory requirements are managed in an electronic system where they are linked to internal control documents/routines. All operations are systematically reviewed regarding compliance to the regulations on a yearly basis and any changes to operations are subjected to an evaluation regarding if other regulations might become applicable.

Our production facilities at Kungsholmen have permission for environmentally hazardous operations in accordance with the Swedish Environmental Code stipulating conditions for discharge into wastewater. Compliance with the conditions of the permit is reviewed annually in an environmental report to local regulatory authorities. In 2009 no violations of the conditions were reported. Operations that are notifiable according to the same regulations are carried out at a number of smaller facilities.

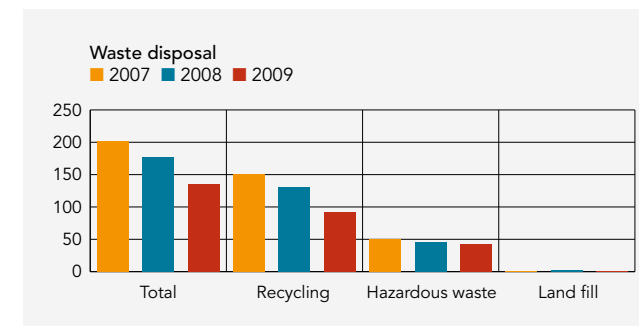
Regulatory requirements are also an issue on the agenda of the Biovitrum "EHS day", which occur quarterly and involves representatives from the whole organization. These representatives (18 in 2009) also work with the responsible line managers, health and safety representatives and other employees to formulate action

plans for EHS initiatives. Systematic risk assessments, inspection tours, surveys, EHS meetings, internal audits and other investigations are used to establish EHS objectives, targets and programs. These are usually handled at department level. The subjects concerned in risk assessments, inspection tours and surveys vary depending on the operation, but can for example be handling of chemicals, waste, electricity and ergonomic issues like noise and lighting. Issues that cannot be resolved immediately are included in an action plan, which is followed-up quarterly. Management review is performed at least once yearly according to the agenda required by ISO14001.

Awareness of environmental issues by all personnel is crucial for our successful environmental program. At the time that this annual report was written, 76 percent of all employees had completed a general environmental training program. The company provides continuing EHS education and important EHS educations are included in the annual action plans. Education within EHS is also considered during the Performance Management Process, a specific process for management by objectives and follow-up.

During 2009, apart from the quarterly "EHS day", Biovitrum held altogether two safety committee meetings, two radiation safety committee meetings, two biosafety committee meetings, four emergency preparedness meetings and one management review. In addition to this there were risk assessments and inspection tours at department level. The internal control documents/routines for EHS management, delegation of EHS assignments, electrical safety and handling of chemicals were revised.

Chemical handling is a field in which Biovitrum can take part in achieving one of Sweden's 16 environmental quality objectives, A Non-Toxic Environment. All chemicals that are subject to labeling requirements and used in production are evaluated with the Swedish Chemicals Agency's PRIO database and Restricted Sub-



stances Database. Although Biovitrum is not a manufacturer or importer of chemicals according to the REACH Regulation, the company is continuously working to comply with the requirements that will be placed upon downstream users. We are actively engaged in communication with our suppliers of raw materials and during 2009 eleven employees took a one-day education in reviewing material safety data sheets.

New routines for handling of hazardous waste at our facilities at Kungsholmen were implemented and 96 employees were educated according to the dangerous goods' regulations. Both the control documents/routines for dangerous goods and for waste and sewage management were revised in connection with this.

The company has about 15 bicycles available to reduce the number of car trips between Biovitrum's facilities in Kungsholmen and Solna. Our travel policy states that travel should be replaced by tele- or video conferences whenever possible. Since 2008 our production facility and adjacent premises use only electricity produced by renewable energy sources.



New Buildings

In immediate vicinity to the Karolinska Institutet Solna campus, Akademiska Hus is building a new science park that from 2010 will host most of our activities. The new facilities are designed to support Biovitrum's values, objectives and business operations. The internal environment is designed to be functional and creative to promote discussions and interactions through openness, flexibility and possibilities for a multitude of meetings. The reason for this venture has been to co-locate and expand operations, create the best of working-places, promote the brand and our core values.

Environmental considerations have governed the choice of building materials and production methods. In order to reduce energy spending the buildings have been equipped with external sun-screens which reduces the need for air conditioning, heavy outer wall constructions gives heat inertia, stairwells are equipped with sun-protection glass and night lighting is reduced to a minimum. A modern computer hall has been built with extensive environmental concern. Green-roofs covered with sedum plants contribute to positive heating economy, air cleaning and reduce surface water discharge. All heating is water-borne including radiators and floor heating coils.

All chemical based building material has been evaluated for environmental compatibility; e. g. only water based paints have been used. Rubber mats are used for flooring instead of standard PVC containing plastic mats. Furthermore, the buildings have been designed for maximum accessibility.

IT and environmental responsibility

The Information Technology unit provides the business with tools and services that is needed for efficient work. That calls for an understanding of business needs and an ability to adjust services and solutions to those and involves a responsibility to harmonize the IT Strategy to the Business Strategy. IT operations are guided by a number of established policies and environmental considerations are essential parts of everyday work. Environmentally correct disposal of IT equipment that has served its time and common printer agreements for resource saving print outs are but some examples.

Energy savings are accomplished e. g. through the application of a small number of so called Blade Servers to drive a larger number of virtual servers. For Biovitrum this type of arrangement saves ca. 4,000 watts per hour.

Safe purchasing procedures

Raw materials, material, equipment and other services are purchased according to our procurement policy. The policy must ensure that all procurement and purchasing take place professionally, using available competition and in accordance with Biovitrum's rules and other policies. To ensure that suppliers meet Biovitrum's requirements, they must respond to a number of questions. The answers then serve as the basis for choosing suppliers. Among other things, the purchasing department focuses on environmental management practices by chemical suppliers, where compliance with the new Euchemicals legislation, REACH, is examined.

Safety and prevention of fire

Biovitrum's safety and security policy aims to protect staff, operations and property from undesirable events such as threats, theft, break-ins, and other criminal actions. The CEO has ultimate responsibility for safety and security in the company and managers have this responsibility within their respective units. The company's safety and security policy and procedures are described and available to all employees on our Intranet.

Biovitrum also conducts an active Loss Control program, mainly involving fire prevention and emergency planning. As part of its fire safety program, Biovitrum will formulate, approve, implement, and follow up on its fire safety organization, training plans, fire safety rules, fire safety description, operating and maintenance instructions, internal control and documentation & follow-up (for more information please see Risk management, [page 15](#)).

Evacuation drills, under the supervision of a total of 50 evacuation leaders, are held at least twice a year in all buildings where Biovitrum conducts operations. Internal controls are carried out twice a year as part of the company's Systematic Fire Safety work.

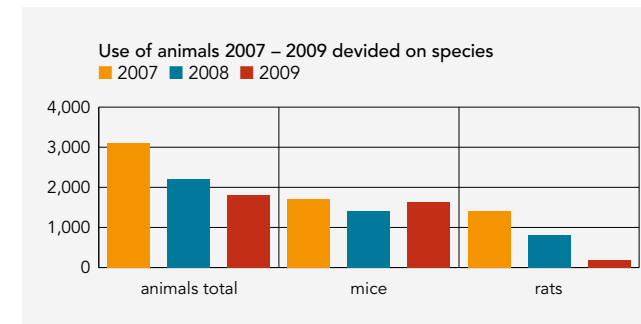
How We Handle Experimental Animals



Biovitrum strives to reduce the number of animal experiments. However, testing the effects of successful biologicals in animals is an important element of R&D operations as well as a regulatory demand (safety regulation). Therefore, we are committed to the 3Rs; Replacement, Reduction and Refinement of animal studies. We design our experiments to use the most relevant animal model and to reduce the number of animals needed to obtain necessary formation. Moreover, drug development includes a large number of methods that are not based on laboratory animals. We try to develop in vitro methods in order to replace or reduce the use of animals. These in vitro methods make it possible to test many potential biological drug candidates during a short time, allowing harmful or non-active biologicals to be eliminated at an early stage in the process. Only after biologicals/proteins have completed a host of in vitro tests the most promising ones are tested in animals to demonstrate the desired positive effects or absence of negative effects. All things considered, only a limited number of animals are used when choosing drug candidates from a large group of therapeutic proteins.

During 2009 we used 1815 animals in our research. About 90 percent were mice and remaining 10 percent rats.

Biovitrum complies with the regulations that the authorities formulated for such activities and we scrutinize our working routines regularly. Biovitrum has also developed methods and procedures aimed at guaranteeing that the highest possible ethical and scientific standards of quality are upheld. These principles are summarized in an animal policy adopted by senior management. Biovitrum is also engaged in external projects aiming at developing alternative methods for experiments on animals.



The reduction in animal use during the four last years can mainly be ascribed to changes in company organization and business strategy.

Animal Handling Policy

- Those animals that we use in our drug research are treated with respect and based on the greatest possible knowledge
- All personnel who handle animals are given the theoretical and practical training necessary for all activities to have maximum quality.
- Premises and housing for animals are designed so that they promote the health of the animals and allow them to act naturally.
- Each individual experiment on animals is preceded by internal and external ethical review.
- Continual veterinary assessment ensures animal protection and quality.

Dealing with Risks

Biovitrum's core concept is to develop and sell specialist pharmaceuticals through international launches of attractive products acquired or developed in house, thereby creating long term profitability.

The company is continuously facing all kinds of uncertainties and events that positively or negatively have an impact on our business objectives and interim targets. Events with positive impact represent opportunities for the company, supporting the achievement of objectives and value creation. Events with negative impact represent risks and the processes to identify, access and manage these risks are part of everyday life.

Biovitrum continually improves processes based on initiatives within Operational Risk Management and Internal Control, following the established guidance from the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Both the Enterprise Risk Management Framework and the Internal Control/Integrated Frameworks have been implemented.

These guiding documents have been incorporated into Biovitrum's policies and guidelines to better serve the organization in its activities when moving towards established objectives. Our efforts to streamline and develop the Processes and Performance Improvement initiatives continue according to plan.

The Operational Risk Management is an ongoing process involving every level of the organization. The framework is based on the achievement of company objectives. At Biovitrum, the annual Business Performance Objectives define strategic objectives. These objectives are then divided into categories focusing on different risk aspects for both line- and project managers.

The overarching risk management structure consists of interrelated components logically following the organization and its objectives: Internal environment, Objective setting, Event identification, Risk assessment, Risk response, Control activities, Information and communication and finally Monitoring, including follow-

up and evaluation. Risk Management is part of the Legal and IP organization and the Risk Manager is appointed by the General Counsel. The Risk Manager reports to CEO and the Audit Committee quarterly.

The pharmaceutical industry is one of the most regulated and monitored of all industries. Biovitrum's risk management activities therefore also include regular follow-ups to ensure that objectives for reporting and legislative compliance are fulfilled.

The Crisis Management Routines also include areas of responsibility, activity plans and crisis communication.

Biovitrum follows an established framework for the internal control environment related to financial risk, i.e. the COSO Internal Control – Integrated Framework.

We have decided to use COSO as a starting point to develop the Enterprise Risk Management Integrated Framework (ERM), which contains basic principles and concepts, as well as consistent language. ERM builds on internal control and governance and is integrated within the framework for internal control and governance. We have implemented COSO ERM as a part our daily work. This ongoing process involves every level of the organization and is used during strategic planning.

The risk management framework is based on the company's goals and interim targets, divided into categories making it possible to focus on various aspects of risk.

The overarching risk management structure consists of eight interrelated components which following the structure of the organization and relation to its objectives:

- Internal environment
- Objective setting
- Event identification

- Risk assessment
- Risk response
- Control activities
- Information and communication
- Monitoring, including follow-up and evaluation.

This methodology makes it possible to focus on the total picture of Biovitrum's risk management with its objectives, components and the various elements and relationships of the organization.

Moving forward, Biovitrum will carry out regular risk and sensitivity analyses of relevant factors in all core functions based on the approved framework and use the results in its planning and follow-up processes.

To guarantee the delivery reliability of our products, we continually identify events that could negatively affect production reliability in our facilities. In these oversights and reviews of facilities, critical systems and equipment, we assess risks and decide on suitable actions. As a result, management can make decisions on investments and take measures to reduce risks to an acceptable level. In 2009, several investments were made in the ReFacto® production facility to further ensure the production flow.

To ensure a reliable supply of raw materials and agreed-upon inventory volumes established procurement processes with several suppliers of critical raw materials are required. The flow is ensured through repeated systematic evaluations of suppliers in order to minimize the risk of loss of production.

Like all companies, Biovitrum must comply with the Swedish Civil Protection Act and evaluating risk analyses are one aspect of upholding this responsibility. An emergency plan has been developed for this purpose and is followed up regularly.

Biovitrum has revised its Crisis Management Plan to include areas of responsibility, activity plans and crisis communication.



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