2020 Annual Report

ENZYMATICA AB (PUBL)

enzymatica

History of Enzymatica

The science of the barrier function in the body

The history of scientific progress is marked by many achievements, large and small, step by step and, eventually, real breakthroughs.

They all contribute to the development of improvements for humans in various ways, but the common denominator for human progress is constant curiosity.

This trait is shared by Newton, Pasteur, Fleming, and many others who have contributed their knowledge to change and improve the world we live in today.

Enzymatica's history has followed its own path of successive discoveries, which has led to the company's growing importance in protecting consumers and their families from viruses.

It was Enzymatica's persistent curiosity that culminated in the discovery of a unique marine enzyme, trypsin, and the role it could play in the body's barrier function to protect against the cold virus.

One important explanation for Enzymatica's success is that management has ensured that the right regulatory and scientific expertise has been in place for development of new products. These unique products help people to improve or take care of their health and quality of life.

This ability and opportunity to help people to protect their health created our vision for the business moving forward.

Our future focus is on strengthening our growth and position in the global market, while providing consumers with more innovative products.

Enzymatica's milestones for continued growth

From curiosity to discovery

From originally having been the answer to a question about skin care, Enzymatica has grown from discovery and development of enzyme technology to offering unique solutions that address growing health problems around the world.

From ambition to vision

The reason for Enzymatica's existence is the "science of the barrier function of the body" and the role enzymes play for stronger protection against viruses, bacteria and other external health risks.

With this ambition, our vision is to contribute to a healthier world – where people in daily life do not need to worry about coming into contact with viruses and other health risks.

From innovation to growth

Through the inherent power of our research and development of enzyme technology, Enzymatica has developed products that can protect everyone. These unique self-care products have been shown to be able to protect against the cold virus and to contribute to good health.

In order to realize this ambition globally, Enzymatica is now working intensively to accelerate the launch of products so that people can receive help faster. This drive has led to partnerships with leading pharmaceutical and self-care companies such as Sanofi, STADA and others, to be able to meet demand in more international markets.

Through the partner agreements that Enzymatica signed in 2019 and 2020, the company is positioned for global growth, making it possible to protect people against the cold virus and other threats to health through the unique barrier technology.

Enzymatica uses a unique marine enzyme, a cold-adapted trypsin that forms in the pancreas of cod. The enzyme is extracted as a byproduct of fish processing (from fish waste) and therefore leaves no negative ecological footprint.

The year in brief

2020 was an eventful year for Enzymatica. The company's ColdZyme® mouth spray was recertified to class III for medical devices within the EU. Enzymatica was granted an EU patent that protects ColdZyme until 2035. During the year Enzymatica signed an agreement with leading international pharmaceutical companies and sales of ColdZyme in about 50 markets.

Q1

- ✓ January: Enzymatica's partner Evergreen Health Ltd launched ColdZyme in Hong Kong & Macau.
- ✓ January: Enzymatica enters into an exclusive 7-year distribution agreement with Keyuan Xinhai (Beijing) Medical Products Trade Co., Ltd., a subsidiary of China's second largest pharmaceutical company, Shanghai Pharma, for sales of ColdZyme in China.
- ✓ February: A user survey conducted by IPSOS on 50 children in Sweden shows shorter colds and milder cold symptoms when using ColdZyme.
- ✓ March: A report based on four user surveys between 2015 and 2019 shows that preventive use of ColdZyme leads to fewer colds, as well as milder colds and fewer days with common cold symptoms when participants used ColdZyme for colds.
- ✓ March: Enzymatica enters into a distribution agreement with the leading pharmaceutical distributor Chemipal for the sale of ColdZyme in Israel.
- ✓ March: Because of the coronavirus outbreak, Enzymatica reports strong demand for ColdZyme in March, with the trend expected to continue during the coming months.

Q2

- ✓ April: ColdZyme is granted class III approval for medical devices within the EU. After the notified body Eurofins Product Testing reviewed the complete documentation for the mouth spray, including safety, efficacy and product claims, ColdZyme receives class III CE marking for sales within the EU.
- ✓ May: The European Patent Office grants Enzymatica's patent for the cod enzyme, which is one of the key components in ColdZyme, for the European market. The patent is valid until 2035.
- ✓ May: Enzymatica and STADA expand their agreement for the ViruProtect® (ColdZyme) mouth spray to cover an additional 19 countries in Europe.
- ✓ June: A British study initiated by researchers in which endurance athletes used ColdZyme shows significantly shorter duration of colds and milder cold symptoms with upper respiratory tract infections compared with endurance athletes in the untreated group.

Q3

- ✓ July: The results from Enzymatica's *in vitro* study showed that ColdZyme inactivates the SARS-CoV-2 virus (the cause of the COVID-19 pandemic) by over 98%. The results indicate that ColdZyme can offer a protective barrier against harmful viruses such as SARS-CoV-2 by locally inactivating the virus in the mouth and throat. This hypothesis must be clinically confirmed with continued studies.
- ✓ August: The final results from Enzymatica's double-blind, randomized placebo-controlled study in Germany show additional clinical evidence for use of ColdZyme for colds as well as excellent safety data for the product.
- ✓ September: New patents approved for ColdZyme in Japan and Russia.
- ✓ September: The Journal of Medical Virology reviews, approves and publishes the findings from Enzymatica's *in vitro* study on SARS-CoV-2.

Q4

- ✓ October: Enzymatica and STADA expand the agreement for ViruProtect to apply to Russia, Poland, Ukraine and 11 other CIS countries (Commonwealth of Independent States – former Soviet republics), as well as Central Asia.
- ✓ October: Enzymatica enters into an agreement with Sanofi – one of the world's largest pharmaceutical companies in consumer health care – for sales of ColdZyme in France and Italy.
- ✓ November: Enzymatica enters into an agreement with MS Pharma, with headquarters in Amman, Jordan, for sales of ColdZyme in ten selected markets within MENA – the Middle East and North Africa.
- ✓ December: Enzymatica and STADA expand the agreement for ColdZyme to apply to the Nordic region excluding Sweden – i.e., Denmark, Norway, Finland and Iceland.

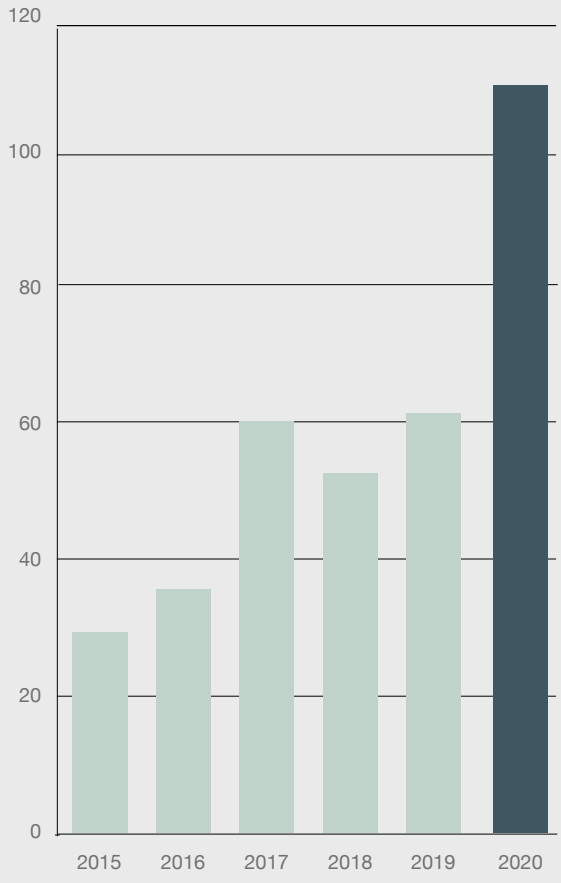
Significant events after the end of financial year 2020

- ✓ Enzymatica recruits Malin Richter as Director of Operations and Kristoffer Ahlerup as Commercial Director – both with extensive experience from the international pharmaceutical industry.
- ✓ Enzymatica announced on March 22 that the turnover for 2021 might be lower than for 2020, which amounted to SEK 111 million, due to the effects of the pandemic on the common cold markets. The Board of Directors has therefore decided, by exercising the authorization from the 2020 Annual General Meeting, to carry out a new rights issue of about SEK 60 million to safeguard the company's long-term investments including geographical expansion, and meet the need for working capital for 2021.

GROUP

SEK m	2020	2019
Net sales	111.2	61.3
Gross margin, %	68	73
Operating profit/loss	-12.1	-41.7
Cash flow for the year, operating activities	-10.7	-37.6
Average number of employees	18	19

SALES TREND (SEK M)



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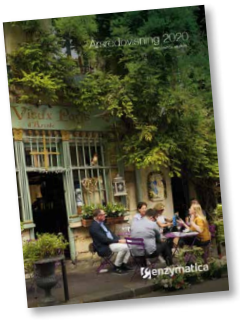

On the cover:

In 2020, the French pharmaceutical company Sanofi, one of the world's largest pharmaceutical companies in consumer health care, launched Enzymatica's ColdZyme mouth spray in France.

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Enzymatica in brief

Enzymatica AB is a life science company that is listed on the Nasdaq First North Growth Market. The company develops and sells products mainly to address diseases and symptoms in the ear, nose and throat region. The products are based on a barrier technology that includes marine enzymes. In 2020 ColdZyme was recertified, which means that the mouth spray is now sold as a class III medical device within the EU. During the year the company also continued to pursue its international expansion. At the beginning of the year Enzymatica signed an agreement with Keyuan Trade, a subsidiary of China's second largest pharmaceutical company, Shanghai Pharma, for the Chinese market. The agreement with German STADA was expanded on three occasions and now covers a total of 40 markets. Enzymatica also signed an agreement with Sanofi – one of the world's largest pharmaceutical companies in consumer health care – for sales of ColdZyme in France and Italy, as well as with MS Pharma for the sale of ColdZyme on ten selected markets within MENA – the Middle East and North Africa. Enzymatica also entered into an agreement with Chemipal, one of the leading pharmaceutical distributors in Israel.

Vision
A Life Free From Viruses: We wish to be part of creating a world where daily life is free from the uncertainties of viral contact and their risk to health.

Mission
Create self-care solutions that protect people and help them to defend their health and way of life.

Business concept
Enzymatica's special barrier technology uniquely protects the health of people, by providing a shield from viruses, microbes and irritants that can cause people infections and colds. We pursue global expansion through open innovation, branded and co-marketing collaborations and partnerships.

Goals
Enzymatica's goal is to work with partners to establish ColdZyme as a leading global product within the cold category, and by extension, to leverage the company's platform technology to develop new health-promoting self-care products.

The people we turn to
People are more aware than ever – of their health and of the need to protect their loved ones. They are also more aware of the impact they have on the world in which they live.

The outside world is uncertain. People think and act differently than previously. Proactive and preventive health care will be the new norm. People will take greater responsibility for their own well-being and search for solutions that best protect them and their way of life.

Enzyme-based platform technology
Enzymatica uses a unique marine enzyme, a cold-adapted trypsin that forms in the pancreas of cod. The enzyme is extracted as a byproduct of fish processing (from fish waste) and therefore leaves no negative ecological footprint. The unique properties of the enzyme make it super-active at body temperature, about 37 °C (98.6 °F), at which point its enzymatic activity is more than 20 times higher than the corresponding enzyme in mammals. These properties make the enzyme highly effective in protecting against disease-related microorganisms such as viruses.

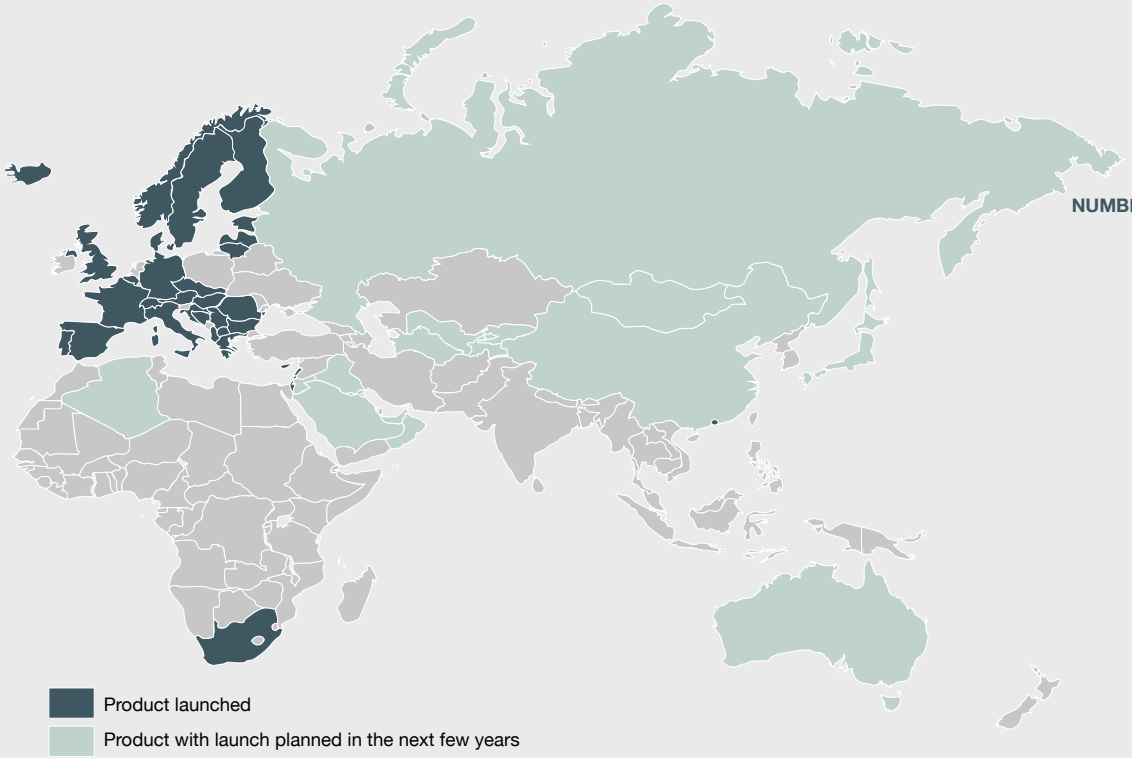
Why should you invest in Enzymatica?

- ✓ A solid scientific base and knowledge, verified via *in vitro* and clinical studies of the ColdZyme Mouth Spray.
- ✓ Unique patented product that addresses the cause of colds, while most other cold products only provide symptomatic relief.
- ✓ Proven success on the Swedish home market through continual growth since the launch in 2013.
- ✓ Scalable business model based on partnerships with successful international distributors with strong market prescence.

ColdZyme treats the cause – not just the symptoms

In our opinion, ColdZyme is unique in the market since it treats the cause of the cold, the actual cold virus. Most cold products on the market mainly focus on treating the symptoms by alleviating the effects of the cold. ColdZyme is easy to use and works immediately by forming a protective barrier in the mouth and throat.

ColdZyme captures and inactivates the cold virus, thereby protecting the throat. When the viral load decreases, there is less risk of coming down with a cold and the course of disease can be shortened if a cold has already begun. The product is most effective when used to protect against the cold virus, or at an early stage of infection. ColdZyme can also alleviate cold symptoms and improve quality of life. ColdZyme also alleviates throat problems associated with colds.



18
AVERAGE NUMBER OF EMPLOYEES

111
SEKM NET SALES

30
LAUNCHED MARKETS

Growth strategy

The growth strategy has three pillars: strengthening the company's position in existing markets, expanding into more geographic markets and developing more unique products.

We have chosen three models for sales of our products: Mouth spray as a medical device product, mouth spray as a cosmetic product and an enzyme formulation that is included in our customers' skin care products. We have thereby created opportunities for the company to broaden its product portfolio. We are now able to adapt our product offering to the different regulatory conditions found in each market.

Business model

For the cold product ColdZyme the company is working with two different business models, adapted based on opportunity and risk. In both cases the product is sold to consumers via the pharmacy and health chains under its own brand or a combined brand, known as co-branding.

In Sweden, Denmark and Norway Enzymatica has its own industry-experienced sales force. This model provides Enzymatica with high margins and better control, but also with higher risk since the company is responsible for the fixed costs for both the sales organization and for market investments.

In markets outside Sweden, Denmark and Norway, Enzymatica sells via distributors who contribute to the market investment. The model provides lower margins, but also entails lower costs and risk. In the UK a combination of the two models is currently applied, where Enzymatica is responsible for the market investment, but distributors handle sales.

In some markets, ColdZyme is sold under combined brands, known as co-branding. These include PreCold® (Iceland), ViruProtect® (a large number of markets including in Europe and Central Asia), ColdGuard® (South Africa), Zerinol Virus Defense (Italy) and Psysiomer Stop Virus (France).

Distributor network

In recent years, Enzymatica has built up a network of international distributors. Collaboration with well-known partners is the foundation for implementing Enzymatica's growth strategy. In 2020 the company continued to pursue its international expansion. The agreement with STADA was expanded on three occasions and now covers a total of 40 markets, mainly in Europe, but also in Russia, Ukraine and Poland, as well as CIS (Commonwealth of Independent States – former Soviet republics). Enzymatica also signed an agreement with Sanofi – one of the world's largest pharmaceutical companies in consumer health care – for sales of ColdZyme in France and Italy, as well as with MS Pharma for the sale of ColdZyme on ten selected markets within MENA – the Middle East and North Africa. Enzymatica also entered into an agreement with Chemipal, one of the leading pharmaceutical distributors in Israel, where the product was launched in the fall of 2020.

Product portfolio

ColdZyme class III certified within the EU

In May 2020, ColdZyme was recertified according Medical Devices Directive 93/42/EEC (MDD) by the notified body Eurofins Product Testing. ColdZyme may thereby be sold as a class III medical device within the EU. ColdZyme and its documentation have been reviewed by Eurofins, an approved notified body for medical devices designated by the competent authority within the EU. Eurofins reviewed the complete documentation, including safety and efficacy data, as well as product claims.

Medical devices

- ColdZyme, a mouth spray against common cold - 20 ml and 7 ml. ColdZyme treats and alleviates common cold symptoms:
  - protects against common cold virus
  - reduces duration of illness when used at an early stage
  - alleviates common cold symptoms and soothes sore throats

- ColdZyme® Strawberry 20 ml – in the late summer of 2019 we expanded our product range with a strawberry flavor for ColdZyme – which appeals to consumers of all ages.

Cosmetic products

- STADAProtect – a new mouth spray for problems in the mouth that was launched by our partner STADA on the German market in early 2020.

Enzyme formulations

- Enzymatica delivers enzyme formulations for other companies' products. In 2019 we signed an agreement with the German company Maren to sell an enzyme formulation for their cosmetic products; we signed a similar agreement with the Dr Bragi Company for the Chinese skin care market.

ColdZyme is available in both menthol and strawberry flavors.

COMMENTS FROM CLAUS EGSTRAND, CHIEF OPERATING OFFICER (COO) AND SENIOR DIRECTOR OF GROWTH

From a small company with big growth ambitions to a company with high growth

2020 was a successful year for Enzymatica. We transitioned from being a small company with big growth ambitions to truly becoming a company with strong growth. One important milestone was recertification of our ColdZyme® mouth spray to class III. With the approval of the EU patent for one of the key components in ColdZyme, we have protection until 2035. ColdZyme also took market share in the Swedish home market. Finally, we entered into agreements for marketing and sales of ColdZyme in about 50 new markets with high-quality international pharmaceutical companies such as Sanofi, Keyuan Trade, a subsidiary of Shanghai Parma, Chemipal and MS Pharma; we also expanded the agreement with German STADA. The agreements are confirmation of the significance of an effective product and recertification to class III, while setting the stage for continued strong growth. In light of what we achieved in 2020, I would like to extend my warmest thanks to all employees for their outstanding contributions during the year.

In 2020, we increased our sales by 81%, from just over SEK 61 million to SEK 111 million. It was mainly sales in new markets, primarily in Europe, that contributed to the growth, as well as sales in the UK which almost doubled during the first quarter. The company's strong growth was generated despite the decline in established and more mature markets because of the pandemic, which also had a negative impact on our sales in these countries.

Recertification a stamp of quality

In 2020 ColdZyme was approved and received CE marking as a class III product according to the MDD – the EU medical device directive. The notified body EuroFins reviewed Enzymatica's procedures and the complete documentation for the product regarding safety, efficacy and product claims. It is truly an indicator of quality and helps to make the product even more attractive in discussions with highly reputable international distributors. There is no doubt that recertification opened doors for the agreements with pharma companies such as Sanofi and MS Pharma.

New patents strengthen protection for ColdZyme

Additional patent approvals also strengthened confidence in our cold spray and the company. First, an EU patent for one of the key components was approved, providing the product with protection until 2035, and then additional patents for indications other than colds were granted in Japan, Russia and Australia.

New distributor agreements – in all, we have agreements for about 60 countries

Over the past year, Enzymatica entered into several strategic distributor agreements for marketing and sales of ColdZyme. At the beginning of the year we entered into an agreement with Keyuan Trade for China. The agreement gives us access to one of the world's largest healthcare markets, with a population of about 1.3 billion and a cold remedy market with annual sales of about SEK 37 billion. During the year we expanded our distribution agreement with our German partner STADA three times, first with 19 countries in Europe, primarily in Eastern Europe, and then with 14 countries including Russia, Poland, Ukraine and the CIS countries (former Soviet republics), and finally with four Nordic countries. In total, the agreement with STADA covers about 40 markets. We also signed agreements with French Sanofi – one of the world's largest pharmaceutical companies in consumer health care – for France and Italy, as well as with MS Pharma for MENA – Middle East and North Africa. We also entered into an agreement with one of the leading pharmaceutical companies in Israel, Chemipal, which launched ColdZyme during the year. In all, we now cover over 60 markets with ColdZyme and the product has been launched in about 30 of these markets.

Ensure resources for continued expansion

In order to handle our growth we expanded the agreement with our contract manufacturer Recipharm, which ensures a significantly increased production capacity at two of their facilities in Spain and Italy. We also invested in the production facility on Iceland, and purchased and are in the process of deploying a new ERP system. In early 2021 we also carried out two strategic new hires: Malin Richter as Director of Operations and Kristoffer Ahlerup as Commercial Director. Both have extensive experience of the international consumer and pharmaceutical industry and are therefore important additions to strengthen our expertise and organization. We also strengthened our organization in 2020 with several new hires in areas such as Quality Affairs and Supply Chain.

Successful studies with ColdZyme

In 2020 we also conducted several successful studies with ColdZyme. At the beginning of the summer the European Journal of Sport Science published the findings of a British study on ColdZyme and endurance athletes. The findings showed that endurance athletes who used Enzymatica's ColdZyme® mouth spray had a significantly shorter duration of colds and milder cold symptoms with upper respiratory tract infections compared with endurance athletes who were not treated with ColdZyme. But the study that drew the greatest attention was an *in vitro* study, which showed that ColdZyme reduced the presence of the SARS-CoV-2 virus by over 98%.

Impact of the pandemic on business

The coronavirus pandemic had both a negative and a positive impact on Enzymatica's sales. At the beginning of the pandemic, ColdZyme sales surged. But, the implementation of social distancing and the increased focus on hand hygiene as a result of the pandemic led to fewer and milder colds – which reduced demand for ColdZyme and other cold products, especially in established markets like Sweden and Denmark. In addition, fewer consumers visited pharmacies to avoid contact with other people. Due to the pandemic the common cold market in both Sweden and abroad was in principle halved during the first two months of 2021. The downturn resulted also in decreased sales of ColdZyme, and we therefore believe today that Enzymatica's financial performance for 2021 may be worse than 2020.

Focus 2021 – take advantage of all good market opportunities

In 2021 we will build on the momentum from 2020 by taking advantage of all good market opportunities. We will work with our partners to register, prepare and launch ColdZyme in many of the new markets for which Enzymatica entered into agreements in 2020. One important aspect of this work will be to prepare for the new MDR legislation for medical devices within the EU. We will also continue with our international expansion strategy, with the aim of signing more distributor agreements, while continuing efforts to broaden our product claims and lay the foundation for the next generation of new products based on our successful barrier technology.

Lund, March 2021
Claus Egstrand

INTERVIEW WITH BENGT BARON, CHAIRMAN OF THE BOARD OF ENZYMATICA:

A fabulous year – solid foundation laid to become an international player

How would you summarize 2020 for Enzymatica?

The company has achieved a variety of accomplishments in 2020. We increased sales by over 80% during the year. Our international expansion really gained momentum through many new distributor agreements and the launch of ColdZyme in several markets. We achieved a milestone in that ColdZyme was recertified and was approved as a class III medical device within the EU. In addition, an EU patent was granted that provides ColdZyme with protection for the product until 2035. We strengthened the organization with new employees and increased our production capacity. Finally, the company conducted several successful *in vitro* and clinical studies on ColdZyme. We achieved all of this despite the uncertainty related to the coronavirus pandemic. In this context I would like to warmly thank all of our wonderful employees. Considering that the organization is relatively small, with only 20 employees, the year has gone incredibly well. I am truly impressed by how the team advanced the positions in all important areas.

Using Enzymatica's growth strategy as a starting point – what has the company delivered?

Our growth strategy has three cornerstones. Firstly, strengthen the position in existing markets – in Sweden, ColdZyme increased its market share from 6.5% to 7.1% in 2020. Secondly, geographical expansion – we expanded our collaborative efforts with existing partners, while entering into agreements with new distributors. In all, we entered into agreements for about 50 new markets during the year. Finally, develop new products and applications – here we achieved good results in our preparatory work with new patents for ColdZyme and successful studies on ColdZyme, both the *in vitro* study and clinical studies. For natural reasons, we now have the greatest focus on the first two pillars to accelerate our growth, but our barrier technology will give us great opportunities when it comes to developing products in new areas.

What impact has the coronavirus pandemic had on operations in 2020?

We've seen a "jerky" development in sales between the quarters. When the pandemic broke out at the beginning of the year, we had a strong surge in sales in the first quarter when our customers built up large inventories. In both Q2 and Q4, sales were negatively impacted by social distancing and an increased focus on hand hygiene in response to COVID-19. In addition, consumers were less mobile, which resulted in fewer visits to stores.

How do you view Enzymatica's financial position, given the positive economic development in 2020?

Considering that the common cold markets in Sweden and abroad in principle have been halved during the first months of 2021 also sales of ColdZyme decreased. The Board therefore believes that the turnover of 2021 can be lower than 2020's turnover, which amounted to SEK 111 million. The Board has therefore decided, using the authorization from the Annual General Meeting 2020, to carry out a new rights issue of about SEK 60 million to safeguard long-term investments in geographical expansion, clinical studies, organization and supply chain, and in addition meet the need for working capital for 2021. As it looks today the pandemic will postpone Enzymatica's development for 12 to 18 months, but we are still convinced that we can realize our international expansion.

What issues has the Board of Directors focused on in 2020?

We continued to dig in our heels, focusing on the same core issues as last year. This includes entering into agreements with the right partners for our international expansion, strengthening our position in existing markets, maintaining reliable delivery capacity and ensuring that we have sufficient resources for our expansion. Other issues addressed include the MDD certification of ColdZyme, new patents, governance and control, as well as ensuring that the company is well-organized and running smoothly.

What resources and skills are needed for Enzymatica to be able to continue with its strong expansion strategy?

We actually have all of the necessary skills within the company, but we will ensure that the company can scale up quickly enough to handle the various projects when we transition from being a local and regional player to become an international life science company.

Where will the company be in three years?

In three years, we will have launched the product for consumers in many markets where we currently have entered into agreements with distributors. We will be a much larger, broader and even more stable company. We will have a broad geographic presence and focus even more on increasing sales in markets where we already have a presence. I can also see that we will have the MDR certification in place; we will have conducted several clinical studies that will guide us toward our vision in which we contribute to a healthier world and where our products can protect people when they come in contact with viruses and other health risks. Last, but not least, we will have specific projects in new applications of our barrier technology.

What are factors for success for Enzymatica?

Attracting the right partners who can successfully launch our products in new markets, primarily ColdZyme at this time. Supply chain with production planning and logistics are also absolutely crucial. We also need to successfully develop our organization, with a focus on delivery in line with our growth strategy. While our progress has been more evolutionary over the past few years, the focus is now on implementation and making things happen. A successful MDR certification is also necessary for our continued success. And I just have to mention all the exciting opportunities that lie ahead in the new applications for our barrier technology.

What expectations do you have for 2021?

From a sales point of view 2021 can be a challenging year considering the pandemic's effects on the common cold market. At the same time, we have received a positive response from the launch of ColdZyme in new markets, such as France and Italy, and we are having discussions about agreements for further markets, that we hope to finalize in 2021. Despite the challenges of the pandemic it is most important that we continue to build our long-term base and implement our strategy. The planned new rights issue will safeguard resources for this purpose.

Lund, March 2021
Bengt Baron, Executive Chairman of the Board

Three pillars of Enzymatica's international expansion

Enzymatica's growth strategy has three pillars: strengthening the company's position in existing markets, expanding into more geographic markets and developing more unique products. In 2020 ColdZyme® strengthened its position on the Swedish market by capturing market share. Enzymatica signed new distributor agreements with leading international pharmaceutical companies and we now have agreements for ColdZyme in about 60 markets. Finally, we continued our work on line extensions, or new product variants, of ColdZyme, as well as on developing products based on barrier technology.

GROWTH STRATEGY

The growth strategy is based on three pillars

1 STRONG POSITION ON EXISTING MARKETS

In Scandinavia, where the company has its own sales organization, the company will strengthen its market position, while maintaining its margin.

ColdZyme is now an established product on the Swedish market and is among the top-selling cold products in Swedish pharmacies. The Danish market follows the Swedish development curve.

2 GEOGRAPHIC EXPANSION

The company currently has agreements with established partners regarding distribution of ColdZyme on about 60 markets. At year-end 2020 the product was launched in about 30 of these markets. The agreements largely cover

- Majority of Europe, incl. Eastern Europe
- Russia, Ukraine and Poland
- CIS – (Commonwealth of Independent States – former Soviet republics) and Central Asia.
- MENA – Middle East and North Africa
- Israel
- South Africa
- Japan
- Hong Kong & Macau
- China
- Australia and New Zealand

Enzymatica intends to reach out with ColdZyme on more markets and continue its international expansion. In 2020, ColdZyme was granted class III approval according to the MDD (Medical Device Directive). Recertification to class III is a stamp of quality for the product and simplifies expansion to more markets.

3 MORE UNIQUE PRODUCTS

The company's enzyme-based product portfolio will grow as a result of our own research and development. The strategy is to identify medical needs, primarily related to upper respiratory tract.

The strategy moving forward includes strengthening the company's technology platform with more products and continuing to pursue research in barrier technology. In 2020, we continued our work on developing new product variants of ColdZyme, as well as on future products based on barrier technology.

Our platform for growth is now global, with a broader product offering

Enzymatica has chosen three models for sales of its products: Mouth spray for colds registered as a medical device product, mouth spray registered as a cosmetic and an enzyme formulation that is included in our customers' skin care products. Each model is based on collaboration with partners on different consumer markets around the world. We are now able to adapt our product offering to the different regulatory conditions found in each market.

Enzymatica's three models

Medical device for common colds

Continue to commercialize the enzyme technology as a medical device under its own brand, our partners' brands, or by combining our brands with our partners' brands.

The product and the brand's claims are based on Enzymatica's barrier technology, supported by clinical findings. In 2020, Enzymatica signed an array of agreements with international pharmaceutical companies covering about 50 markets for ColdZyme. By year-end 2020, the mouth spray had been launched in about 30 of these markets.

Mouth spray as a cosmetic product

At the same time, Enzymatica will undergo rapid commercialization on markets where there are opportunities to sell products that are subject to regulations for cosmetics. This model will leverage the advantages of Enzymatica's enzyme technology and consumer interest in improved quality of life, affected by the air we breathe and the environment in which we live. In this type of market, such as Germany where STADA launched a new mouth spray in early 2020, the appeal of the product with its physical barrier is being tested through development on the market or through consumer surveys.

Enzyme formulations for skin care products

Through the third model, Enzymatica will have opportunities for global collaborations regarding additional areas in which the company's patented enzyme technology can be used, exemplified through the agreements that Enzymatica has signed with international cosmetic companies for delivery of enzyme formulations.

STADA sells ColdZyme under the ViruProtect brand

Diversified growth strategy for success

In summary, by being able to work with both medical device and cosmetic products, alongside bulk deliveries of enzyme formulations, Enzymatica can fully leverage business opportunities in both the short and long term, supported by confirmed consumer needs and demand. This diversified strategy creates the best conditions for successfully entering markets on a global basis, penetrating them and capturing market share.

Sustainable growth potential

Enzymatica's growth strategy is supported by recurrent surveys which clearly show that once consumers begin to use the product, a high repeat repurchase rate is generated along with loyalty that contributes to the volume growth of the product – which creates conditions for successful long-term growth and profitability. In 2020, Enzymatica announced the findings of several such studies – including preventive use of ColdZyme against the cold virus, as well as shorter colds and milder symptoms among children who use ColdZyme.

ENZYMATICA'S COLLABORATIVE PARTNERS

Strong growth in 2020 with several strategic distributor agreements

In recent years, Enzymatica has built up a network of international distributors. Collaboration with well-known partners is the foundation for implementing Enzymatica's growth strategy. At the beginning of 2020, Enzymatica signed an agreement with Keyuan Trade, a subsidiary of China's second largest pharmaceutical company, Shanghai Pharma, for ColdZyme® for the Chinese market. In 2020, the agreement for ViruProtect® (ColdZyme) was expanded with our German partner STADA on three occasions and now covers about 40 markets. Enzymatica also signed agreements with the French company Sanofi – one of the world's largest pharmaceutical companies in consumer health care – for France and Italy, as well as an agreement with MS Pharma for MENA – the Middle East and North Africa.

Access to the Chinese market with 1.3 billion people

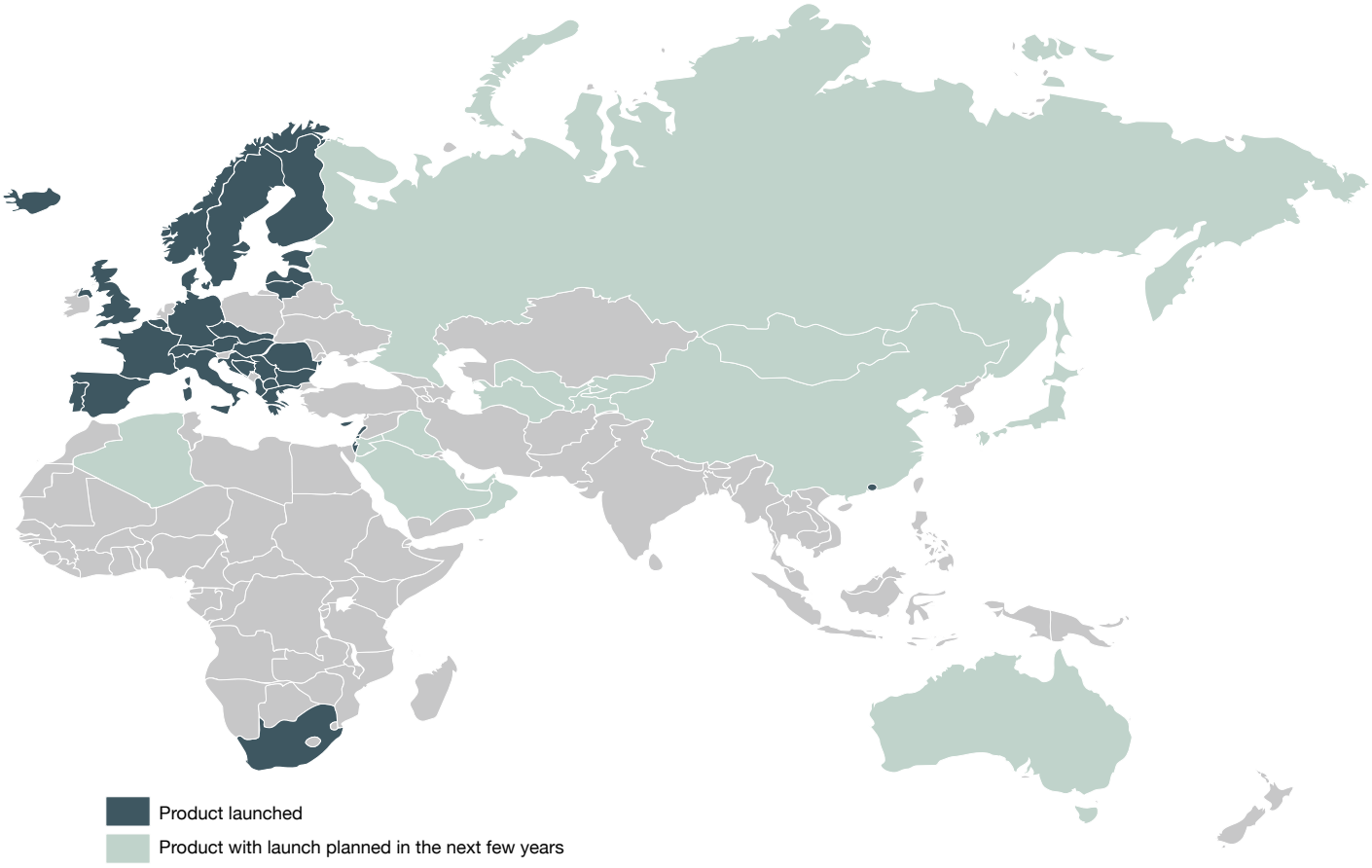
At the beginning of the year Enzymatica signed an exclusive 7-year distribution agreement with Keyuan Xinhai (Beijing) Medical Products Trade Co., Ltd., a subsidiary of China's second largest pharmaceutical company, Shanghai Pharma, for marketing and sales of ColdZyme mouth spray in China. The contract provides Enzymatica with access to one of the world's largest healthcare markets, with a population of about 1.3 billion and a cold remedy market with annual sales of about CNY 27 billion[1], corresponding to SEK 37 billion, with an annual growth rate of about 8%. The product is expected to be launched on the Chinese market in 2022.

The agreement with STADA for ViruProtect now covers 40 markets

Enzymatica and STADA have had an agreement for sales and distribution of ViruProtect in Belgium and Austria since 2017. In May 2020 the agreement was expanded to cover an additional 19 countries in Europe. Most of the countries are in Eastern Europe, but a few Western European markets are also included. The OTC market for cold and flu medications in these countries amounts to a total of SEK 23.6 billion[2]. The launch in many of these markets took place in the autumn of 2020.

In October the agreement was expanded with an additional 14 countries for marketing and sales of ViruProtect in Russia, Poland, Ukraine and 11 other CIS countries (Commonwealth of Independent States – former Soviet republics), as well as Central Asia. Russia, Poland, Ukraine and the other CIS countries represent a large and growing consumer health market, in which STADA has extensive commercial operations, including sales and marketing resources. The Russian cold remedy market is estimated at approximately EUR 2 billion and in Poland, the cold remedy market at the consumer level amounted to just over EUR 600 million during the 12-month period ending June 30, 2020, all according to IQVIA OCTIM market data. The launch through STADA's local organization in the 14 countries is planned for 2021-2022.

In December the agreement was expanded once again to include the Nordic countries with the exception of Sweden – i.e., Denmark, Norway, Finland and Iceland. The cold remedy market for Denmark, Norway, Finland and Iceland is estimated at just under DKK 1.5 million[3]. The launch of ViruProtect in these markets is expected in 2021.



Agreement with one of the leading pharmaceutical companies in consumer health care – Sanofi

Enzymatica also signed an agreement with Sanofi Health Care, which is part of the French pharmaceutical group Sanofi, for marketing, distribution and sales of ColdZyme in France and Italy. In late 2020 Sanofi launched ColdZyme in France and Italy under its established cold remedy brands Physiomer® Stop Virus and Zerinol® Virus Defense. These two countries are among the largest Over-the-Counter (OTC) markets in Europe, with a total population of almost 130 million. Sanofi has strong market positions on the French and Italian cold remedy markets. The French cold remedy market has an estimated value of EUR 0.8 billion[4]. Sanofi has the leading market position in this segment, with a market share of about 15%. The Italian cold remedy market has an estimated value of EUR 1.1 billion[4], and Sanofi is the fourth largest player in this market.

Agreement for MENA

Finally, Enzymatica entered into an agreement with MS Pharma, with headquarters in Amman, Jordan, for marketing, distribution and sales of ColdZyme in ten countries within MENA – the Middle East and North Africa. The total population of MENA is estimated at 347 million[5], including 160 million in the ten countries covered by the agreement[6]. In 2019, the cold and allergy market within MENA was valued at more than USD 430 million in producer prices, according to IQVIA and the regional drug data analysis company, AMS. MS Pharma expects to launch ColdZyme under its registered brands in 2021-2022.

1. MENET, 2018
2. Sale to wholesaler, Nicholas Hall, 2018.
3. Norsk Apotekerforening Total 2019, Dansk Aptekerforening Total 2019, Tamro MAT2019, Vistor, IDM – Icelandic Drug Market, 2019
4. IQVIA MAT 7/2019.
5. United Nations, Department of Economic and Social Affairs, Population Division, 2019. World Population Prospects 2019.
6. World Population Review, MENA countries 2020

Enzymatica's distributor partners

Market	Partner	Contract	Preliminary launch of ColdZyme
Albania	STADA	2020	2021
Algeria	MS Pharma	2020	2021
Armenia, Azerbaijan	STADA	2020	2022
Australia and New Zealand	Symbion/EBOS	2016	Not yet launched
Bahrain	MS Pharma	2020	2022
Belarus	STADA	2020	2022
Belgium	STADA	2017	2017
Bulgaria	STADA	2020	2021
Denmark	STADA	2020	2021
United Arab Emirates	MS Pharma	2020	2022
Georgia	STADA	2020	2022
Greece and Cyprus	STADA	2020	2021
Hong Kong & Macau	Evergreen Health	2018	2019
Finland	Tamro/STADA	2015	2015/2021
France	Sanofi	2020	2020/2021
Estonia, Latvia, Lithuania	STADA	2020	2021
Iraq	MS Pharma	2020	2022
Iceland	Vistor/STADA	2014/2020	2015/2021
Israel	Chemipal	2020	2020
Italy	Sanofi, STADA	2020	2020
Japan	One of the largest pharmaceutical companies in Japan	2018	Prelim. 2021
Jordan	MS Pharma	2020	2022
Kazakhstan, Kyrgyzstan	STADA	2020	2022
China	Keyuan Xinhai (Beijing) Medical Products Trade	2019	Prelim. 2022
Croatia	STADA	2020	2021
Kuwait	MS Pharma	2020	2022
Lebanon	MS Pharma	2020	2022
Luxembourg	STADA	2020	2021
Moldova, Mongolia	STADA	2020	2022
Netherlands	STADA	2020	2021
Norway	STADA	2020	2021
Oman	MS Pharma	2020	2022
Poland	STADA	2020	2021
Qatar	MS Pharma	2020	2022
Romania	STADA	2020	2021
Russia	STADA	2020	2021
Saudi Arabia	MS Pharma	2020	2021
Switzerland	STADA	2020	2021
Serbia, Montenegro, Bosnia	STADA	2020	2021
Slovenia	STADA	2020	2021
United Kingdom	Boots, Amazon	2014	2014
South Africa	ABEX Pharmaceutica	2018	2019
Tajikistan, Turkmenistan	STADA	2020	2022
Czech Republic	STADA	2020	2021
Germany	STADA – new mouth spray	2019	2020
Hungary	STADA	2020	2021
Ukraine	STADA	2020	2021
Uzbekistan	STADA	2020	2022
Austria	STADA	2017	2017

Market	Partner	Contract	Launch Enzyme formulation
Germany	Maren Cosmetics	2019	2019
China	Dr Bragi Company	2019	2020

Enzymatica's partner Sanofi launched Physiomer Stop Virus (ColdZyme) on the French market in late 2020.

REGULATORY AFFAIRS AND QUALITY ASSURANCE

Recertification of ColdZyme and updating of procedures for future regulatory requirements

In early 2020, ColdZyme® obtained recertification according to class III (MDD). In this recertification process, Eurofins reviewed the complete documentation and manufacturing processes for ColdZyme, and confirmed that the product meets the applicable regulatory requirements. During the year Enzymatica also focused considerable attention on updating processes in order to meet the stringent requirements for the new European regulatory requirements, the medical device regulation (MDR – 2017/745), which will come into force in May 2021. A significant component of the work within the scope of the quality management system was dedicated to preparing documentation to ensure that the medical device has the correct labeling and complies with national requirements in the new European markets that were added during the year.

Enzymatica develops products in an environment that is regulated by laws, directives and standards. The company's quality management system is designed in compliance with applicable regulatory requirements. The promised performance of the product is guaranteed by correctly monitoring the entire life cycle. Our products maintain a high level of quality because we take responsibility to ensure that they are safe and meet performance requirements.

Changed regulatory requirements for medical devices

Regulatory requirements for Enzymatica's products and processes depend on both the intended use of the products and on stipulated requirements in each global market. Enzymatica markets self-care products, which are regulated through legislation for either medical devices or cosmetics.

The EU has changed and strengthened the requirements for medical devices in recent years. CE marking of medical devices has been regulated within the EU by the Medical Device Directive – MDD 93/42/EEC. In 2021 MDD will be replaced by new regulatory requirements, medical device regulation, MDR 2017/745, which entails significant changes for market access within the EU.

Enzymatica has designated Eurofins Product Testing as its notified body, which means that they review and certify Enzymatica's medical devices and processes in accordance with the CE marking requirements of the directive/regulation.

In early 2020, ColdZyme® obtained recertification according to class III (MDD). In this recertification process, Eurofins reviewed the complete documentation and manufacturing processes for ColdZyme. This review includes data for safety, performance and health claims/advantages. The certification process included reclassification of ColdZyme from class I to class III. The reason for the reclassification was due in part to a change in interpretation of the substance trypsin, which is a natural enzyme from cod (Gadus morhua), and in part to an intentional strategy to approach the higher requirements of the MDR. By achieving the stringent requirements for a class III product in the current medical device directive (MDD), the company is one step closer to achieving the requirement in the upcoming regulation for medical devices (MDR) in June 2024, see the "Medical Device Regulation" fact box on the next page.

Regulatory requirements for medical devices products

Enzymatica is in an internationalization phase with launches in Europe and a number of additional markets, with extensive registration and documentation requirements. Enzymatica is continually working on regulatory matters and is compiling the documentation required to register a product in selected markets. From May 2021, new legislation, MDR 2017/745, must be applied to new product registrations and quality management systems. Products that have a valid product registration under the previous regulation, MDD 93/42 EEC before May 2021, may continue to have this product registration until the product's certification expires, though no later than May 2024. Efforts to meet the requirements of the new regulatory framework are ongoing and have been assigned high priority.

Enzymatica's quality and regulatory work focuses on the following:

- Quality assurance and control of the various steps in the value chain, from raw material to finished product purchased by the consumer.
- Continually work to ensure that the quality management system meets the increased external requirements and facilitates a long-term, efficient and structured initiative.
- Continually strengthen the documentation for the main product, ColdZyme, based on the requirements of different countries. This documentation includes data such as the quality, safety, function and clinical benefits of the product.

The quality management system covers all essential processes

Enzymatica's quality management system is certified to ISO 13485:2016, which provides a framework for covering all essential processes required in the regulatory requirements of the different markets. These impose a unique property with respect to the quality management system processes. The quality management system is monitored and challenged annually by the certifying body British Standards Institution (BSI), which ensures that regulatory requirements for the quality management system are maintained and certifies the quality management system to ISO 13485:2016. The quality management system is also reviewed in relation to MDD 93/42/EEC requirements by the notified body that certified the class III medical device.

From a risk-based perspective, essential processes in the quality management system are monitored to ensure product quality from the early development stage to monitoring of products on the market. Internal audits are carried out to review quality management system processes. In addition, management regularly assesses the performance of the quality management system by reviewing predetermined quality-related parameters.

In 2020 the certifying body BSI, which certifies the quality management system to ISO 13485, conducted an annual inspection that resulted in a minor comment, which could easily be remedied for the next annual inspection. Over the past year, Enzymatica also focused considerable attention on updating processes in order to meet the stringent requirements for the new European regulatory requirements, the medical device regulation – MDR 2017/745. Examples of processes that were updated include those that control clinical activities, as well as the post-market surveillance process for monitoring the product on the market. A significant component of the work within the scope of the quality management system was dedicated to updating documentation for new labeling in accordance with the new classification of the product and to prepare documentation so that all of the new markets added during the year have the correct labeling. The expansion in new markets was noticeable in the quality work since the number of production batches approved for sale in 2020 increased three times, compared with the number of released batches in 2019.

PRODUCT DESCRIPTION

ColdZyme treats the cause of common colds

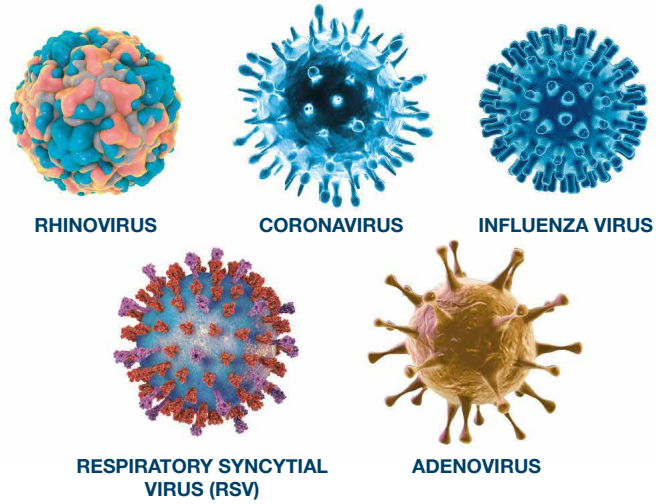
ColdZyme® is unique because it treats the cause of the cold, the actual cold virus. ColdZyme protects against the cold virus by reducing viral load by up to 99%. ColdZyme can also shorten the duration of colds among people who already have a cold by up to 3.5 days. ColdZyme alleviates cold symptoms and soothes sore throat, is easy to use and works immediately by forming a protective barrier in the mouth and throat.

ColdZyme serves as an active virus barrier

When ColdZyme is sprayed, a barrier forms on the mucous membrane of the oral cavity. The barrier works through osmosis – it captures the cold virus and inactivates the ability of the virus to infect cells so that the body can get rid off the virus naturally. ColdZyme treats colds and alleviates cold symptoms by protecting against the cold virus, shortening the duration of colds and providing symptomatic relief if it is used at an early phase of infection.

ColdZyme is effective against the majority of cold viruses

In vitro studies have shown that ColdZyme inactivates the majority of known viruses that cause colds, while *in vivo* (clinically controlled) studies have subsequently shown that ColdZyme is effective against the viruses found in colds during cold season.



ColdZyme and COVID-19

Note that in the *in vitro* study above achieved a viral load reduction of up to 99.9%. The coronavirus in the study, coronavirus 229e, causes colds and is a milder variant than SARS-CoV-2, which causes COVID-19. During the year, Enzymatica conducted the same type of standardized and validated *in vitro* study on SARS-CoV-2. ColdZyme has been shown to be able to inactivate 98.3% of the virus within 20 minutes. The study was published in September 2020 in the Journal of Medical Virology. Even though *in vitro* findings cannot be directly translated to clinical efficacy, they indicate that ColdZyme could help to offer a protective barrier and possibly reduce the risk of spread of infection.

ColdZyme - a class III medical device

In 2020 ColdZyme was recertified from class I to class III, which is the highest classification for medical devices. This means that ColdZyme has been reviewed and certified by a “notified body,” Eurofins, which includes processes, documentation, efficacy, safety, intended use, indications and clinical benefits.

ColdZyme’s intended use, indication & clinical benefits

ColdZyme’s intended use is to treat and relieve colds. The indications state that ColdZyme may be used on exposure to the cold virus, or at an early stage when cold symptoms arise. ColdZyme can be used by adults and children over the age of 4 years. The clinical benefits are many: ColdZyme protects against the cold virus. ColdZyme can reduce the duration of colds. ColdZyme alleviates cold symptoms and soothes sore throats.

Clinically proven efficacy

Data from several randomized, controlled clinical trials demonstrate clinically proven efficacy; for example, use of ColdZyme can reduce the duration of a cold (by up to 3.5 days) and cold symptoms and a sore throat can be relieved. Clinical trials have also shown that ColdZyme is a safe product to use, that the viral load in the mouth and throat decreases (by up to 99%) and that endurance athletes can reduce the number of lost training days when using ColdZyme. Read more about the positive effects of ColdZyme on colds in the section ColdZyme studies.

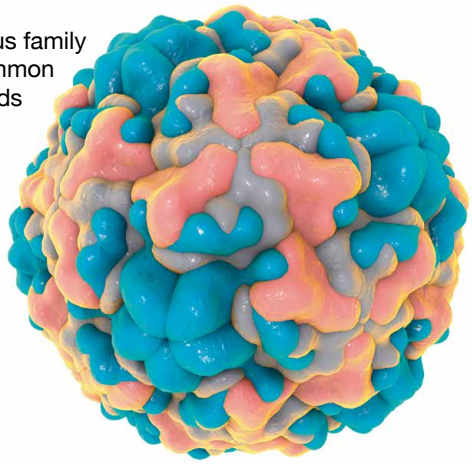
Socioeconomic benefits

Colds are the single biggest cause of sickness absence, corresponding to just over 30 percent of all sick leave according to occupational health company Previa. According to a survey[1] carried out by Nordeg and commissioned by Enzymatica, major socioeconomic benefits can be achieved by reducing the number of sick days due to colds. The report shows that a reduction of a single sick day in Sweden would result in an annual savings of SEK 1.4 billion for society, based on 10 percent of all 4.7 million full-time employed individuals.

1) A study of the socioeconomic effect for the Swedish population when using ColdZyme Mouth Spray, Nordic Evaluation Group AB (Nordeg) on behalf of Enzymatica 2013.

The common cold – one of the most common infectious diseases

The common cold is an infection of the upper respiratory tract and one of the most common infectious diseases. It is highly contagious, especially during the first days of the disease.



The rhinovirus family is the most common cause of colds

Colds are caused by viruses that enter the mucosal cells, primarily in the mouth, nose and throat. When someone with a cold coughs or sneezes, the virus can spread up to 16 feet. In addition to direct contact and airborne transmission, the cold virus can also be transmitted by touching door handles, bus seats and other surfaces. A virus particle can survive outside the body for up to seven hours. People can also be carriers of the virus for some time without becoming ill. When the immune system weakens for some reason, the cold can develop.

More than two hundred different viruses are associated with colds, the most common of which is the rhinovirus. After a cold some protection remains against a new infection by the same type of virus, but there is a big risk of encountering new types of the cold virus.

Adults suffer from colds caused by viruses an average of two to four times per year, and sometimes more. Children in preschool and school comprise the group that have the most colds, but the frequency decreases with age as immunity builds up against more strains and as direct contact with other children declines.

Disease-causing viruses are tiny biological particles that cannot be seen with the naked eye. Unlike bacteria, viruses can only reproduce in living tissue, but they can survive longer even on inhospitable surfaces. Viruses consist of genetic material and a protective protein coat with anchoring proteins that allow the virus to attach to body cells and penetrate them. Once inside, their genetic material uses the body cells to produce new viruses.

Viruses cause many diseases, such as the common cold and the flu. Viruses have the ability to replace the proteins on the protein coat that the body's immune system learns to recognize so it can destroy the virus. Once these proteins are modified, the body's immune system has difficulty protecting the body against a new infection.

Infection with the common cold, step by step

1. The cold virus is deposited on, for example, the front portion of the nasal passages either via contaminated fingers or airborne droplets from someone who has coughed or sneezed. Small doses of virus are sufficient to cause infection.
2. Next the virus is transported to the throat where it binds to the mucosal cells.
3. After binding to surface proteins on the cells of the mucous membrane, the virus enters the host cell* and the infection begins. Once inside, new virus particles are produced and ultimately the host cell dies and releases newly made viruses that can infect new host cells. This process, from initial infection until the first release of newly produced viruses, takes about ten hours, and is called the incubation period.
4. After approximately ten more hours the infected person begins to experience cold symptoms such as sore throat, fatigue and sneezing. As a countermeasure the mucous membranes of the nose and throat swell and produce fluid, causing a runny nose and mucous discharge. The cold usually reaches its maximum intensity 36-72 hours after initial infection and generally lasts 7-10 days.

* Host cell: Cell that harbors a virus or foreign microorganism.

http://sv.wikipedia.org/w/index.php?title=Förkylning&oldid=27366039
Läkemedelsverket, Behandling av rinosinuit (förkylning, inflammation i näsa och bihålor). [Medical Products Agency, Treatment of rhinositis (cold, rhinitis and sinusitis)

RESEARCH & DEVELOPMENT

Research & Development – focus on reclassification and introduction on new markets

Enzymatica primarily develops medical devices in the colds therapeutic area and is continually working on compiling and improving the documentation required to register a product in selected markets. In 2020, development efforts focused on recertification of ColdZyme® to class III according to the MDD, as well as formulating the necessary documentation and packaging design for the introduction on new markets. The work on additional product variants (line extensions) also continued.

Enzymatica focuses on research and development based on the tested and patented barrier technology used in the cold product ColdZyme. Strengthening the clinical documentation for the mouth spray ColdZyme is a key part of Enzymatica's R&D activities. The company's total research and development expenses amounted to SEK 22.5 (28.5) million in 2020, of which SEK 0 (0) million was capitalized on the balance sheet.

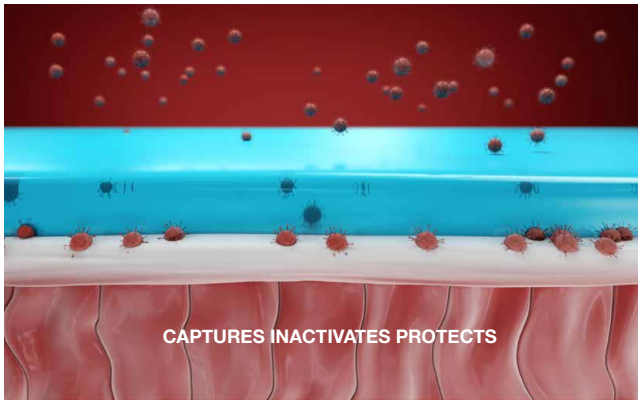
In 2020 Enzymatica worked on further strengthening the product documentation and completing the recertification of the product, which was approved in March. In addition, the product was introduced in about 15 new markets, which in some cases requires updated documentation and the development of consumer packaging for these markets.

Research continued on the enzyme technology that is the basis for the patent granted in the EU in 2020.

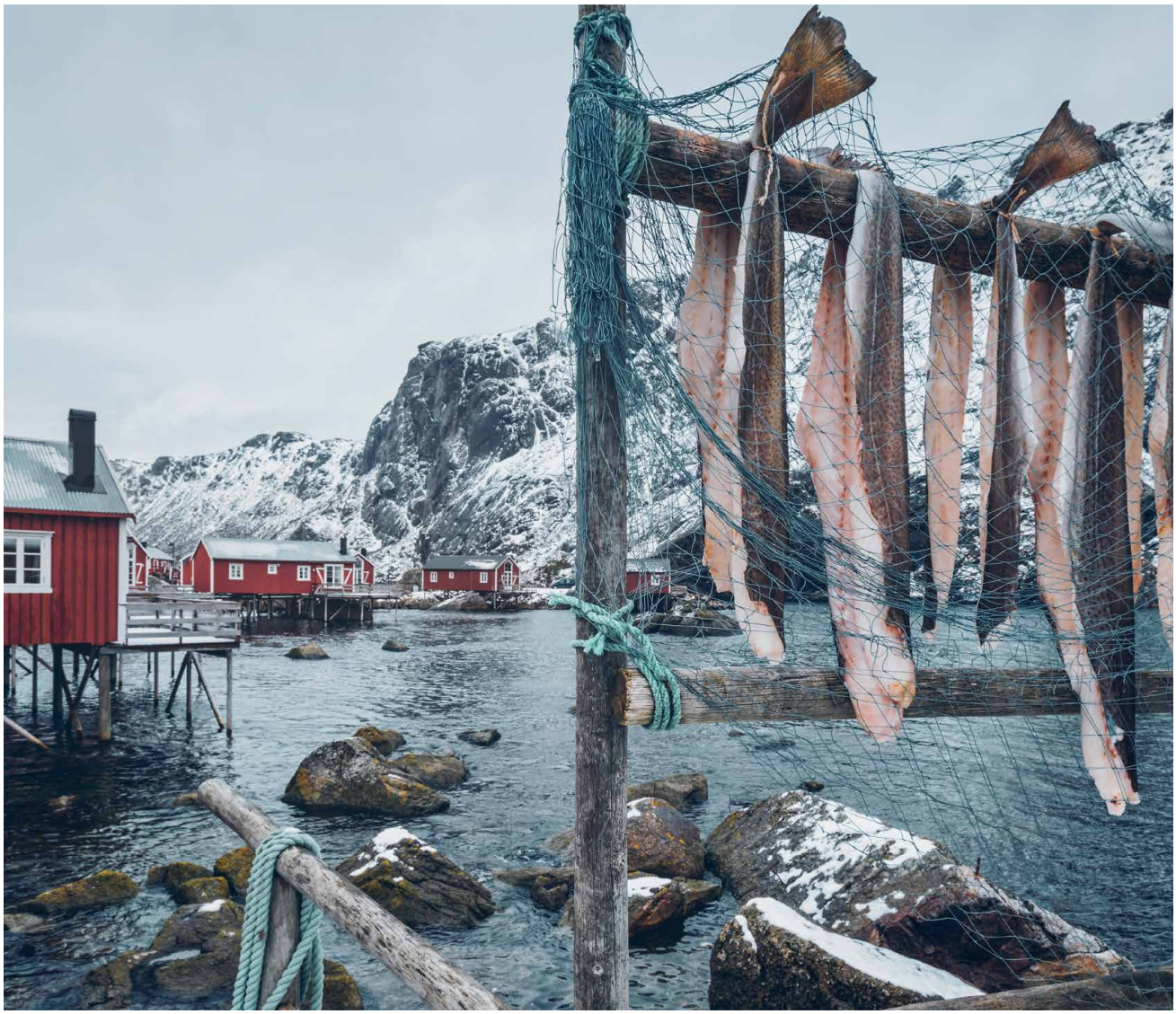
Over the next few years the company aims to expand the range of enzyme-based products for colds. Examples include development of additional line extensions that will complement the existing flavors, Menthol and Strawberry. The purpose is to attract new consumer groups, as well as to increase exposure of the products in stores.

Barrier technology

The barrier in ColdZyme consists of a transparent hypertonic solution that includes glycerol and enzymes. The main mechanism of action of the barrier is based on its ability to generate an osmotic barrier on the mucous membrane in the mouth/throat that draws fluid out of the mucous membrane. This fluid contains viruses. When applied to the mouth/throat, as in the case of ColdZyme, the presence of virus declines, thereby facilitating a faster natural recovery from the common cold. ColdZyme can protect against the cold virus, reduce the duration of colds, soothe sore throats and relieve cold symptoms.



The barrier in ColdZyme, which works through osmosis, captures the cold virus and inactivates the ability of the virus to infect cells, which protects the mouth and throat.



Enzyme from deep-sea cod

A key sub-component of the barrier is an enzyme. The enzyme from deep-sea cod is a cold-adapted trypsin that has evolved to be active at a temperature of around four degrees C. As a result of this adaptation to the cold, this type of enzyme has become extremely effective at higher temperatures, as in humans.

Product development strategy

Enzymatica's product development strategy has the following priorities:

1. Optimize ColdZyme (production, technical documentation, market access outside the EU, clinical studies, new patents, etc.).
2. Strengthen and expand existing claims through additional studies.
3. Formulate new ColdZyme versions ("line extensions") to expand the product offering and to increase shelf exposure at the sales location.
4. Explore new indications with the same formulation and function, which requires minimal lead time for product development (existing storage studies, toxicity tests, etc., can be used).
5. Develop new product formulations for use within the file of ear, nose and throat (ENT).
6. Develop new products for completely new indications.

COLDZYME STUDIES

British study shows shorter duration of colds for endurance athletes with ColdZyme

In early summer 2020, the findings of the first researcher-initiated study were published in the article "ColdZyme® Mouth Spray reduces duration of upper respiratory tract infection symptoms in endurance athletes under free living conditions" in the European Journal of Sport Science. The British researcher-initiated study is the first randomized and controlled study investigating the effect of ColdZyme in endurance athletes. The results show that endurance athletes who used ColdZyme had significantly shorter duration of colds and milder cold symptoms with upper respiratory tract infections compared with endurance athletes in the untreated group.

The study was conducted at the School of Sport and Exercise Sciences at the University of Kent, with Dr. Glen Davison as principal investigator for the study. In all, 123 endurance athletes who participate in endurance sports such as triathlons, marathons, and bicycling, were randomized to the ColdZyme group or to the control group. The study was conducted during two cold seasons, beginning in December 2017 and December 2018, respectively. The participants logged their symptoms according to the Jackson cold scale over a three-month period during training.

Shorter colds and milder cold symptoms

The findings show that the duration of colds was reduced by 26%. The athletes who also used ColdZyme according to the instructions achieved statistically significant better results, with a 34% shorter duration of colds, compared with the endurance athletes who were not treated with ColdZyme. A statistically significant difference was also seen regarding cold symptoms, which were milder in the group treated with ColdZyme. The control group also had more than twice as many lost training days, compared with the ColdZyme group.

Efficacy is important for endurance athletes

Endurance athletes as a group are of particular interest to study because high training loads lower immunity and make the athletes more susceptible to upper respiratory tract infections, causing them to lose training and competition days.

> "Treatment strategies to reduce illness episodes are especially beneficial for athletes by reducing the number of training days lost. This study indicates that ColdZyme can reduce the duration of naturally acquired colds reported by endurance athletes and result in fewer lost training days due to cold symptoms, especially when ColdZyme is used correctly," says Dr. Glen Davison.

Reference: Glen Davison, Eleanor Perkins, Arwel W. Jones, Gabriella M. Swart, Alex R. Jenkins, Hayley Robinson & Kimberly Dargan (2020) ColdZyme® Mouth Spray reduces duration of upper respiratory tract infection symptoms in endurance athletes under free living conditions, European Journal of Sport Science, DOI: 10.1080/17461391.2020.1771429

Laboratory study shows that ColdZyme inactivates the SARS-CoV-2 coronavirus

In July 2020, preliminary findings were announced from an *in vitro* study demonstrating that ColdZyme® inactivates SARS-CoV-2, the virus that causes COVID-19. The study, which was published in September in the article "Inactivation of SARS-CoV-2 and HCoV-229E *in vitro* by a medical device mouth spray" in the Journal of Medical Virology, demonstrates that ColdZyme inactivates the SARS-CoV-2 virus and the HCoV-229E virus by 98.3% and 99.9%, respectively. HCoV-229E is one of the viruses that causes the common cold, but does not belong to the same subgroup of the coronavirus family as SARS-CoV-2.

The *in vitro* study is based on the international standard ASTM E1052: "Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension." The study was carried out by the US-based independent accredited and certified laboratory, Microbac Laboratories Inc.

Protective barrier against several coronaviruses

The overall results indicate that ColdZyme should be able to offer a protective barrier against two different types of coronavirus by locally inactivating the virus in the mouth and throat. SARS-CoV-2 replicates in the pharyngeal region and high viral concentrations have been found even with mild symptoms. The relevant findings indicate that application of ColdZyme to the mouth and throat may reduce the risk of infection and reduce viral load locally. A lower viral load can reduce the virus concentration, thereby minimizing the spread of SARS-CoV-2.

"Although the current *in vitro* results cannot be translated into clinical efficacy, it is extremely interesting that ColdZyme has the ability to effectively inactivate SARS-CoV-2 *in vitro*, since this provides a solid basis that can be used for clinical trials. Thus the results suggest that ColdZyme could create a protective barrier against SARS-CoV-2," says Claus Egstrand, Chief Operating Officer at Enzymatica.

Reference: Gudmundsdottir, Á, Scheving, R, Lindberg, F, Stefansson, B. Inactivation of SARS-CoV-2 and HCoV-229E *in vitro* by ColdZyme® a medical device mouth spray against the common cold. J Med Virol. 2020; 1- 4. https://doi.org/10.1002/jmv.26554

COLDZYME STUDIES

Results from placebo-controlled study confirm earlier study findings

The final results from Enzymatica's double-blind, randomized placebo-controlled study show additional clinical evidence for use of ColdZyme® for colds. The results show a statistically significant beneficial effect, as well as somewhat shorter duration of colds, among participants in the ColdZyme group compared with the placebo group. The study results also confirmed the excellent safety data of the mouth spray from earlier studies, but this time in a larger population.

In the spring of 2019, Enzymatica's largest clinical study to date was conducted at ten study centers in Germany. The aim of the double-blind, randomized and placebo-controlled study was to evaluate the efficacy of ColdZyme for colds, with the hypothesis that treatment with ColdZyme is superior to placebo in naturally acquired colds. A total of 701 men and women participated in the study, of whom 438 developed cold symptoms and were randomly treated with either ColdZyme or placebo, beginning at the first sign of cold symptoms. Unfortunately, the results showed that the primary goal of significantly improving quality of life for people with colds was not achieved. However, the evaluation, which was carried out using the Wisconsin Upper Respiratory Symptom Survey (WURSS-21) Quality of Life (QoL) domain and Jackson score, shows somewhat more rapid recovery with ColdZyme; in other words, the duration of symptoms and associated problems that affect quality of life was shortened. The beneficial effect of ColdZyme was especially apparent on the fifth day of the cold. The shorter duration of the cold confirms earlier study results[1-3]. The actual difference, however, was less pronounced in the study under consideration.

Assessed beneficial effect of ColdZyme

At the end of the study, participants and investigators assessed the treatment effects, without knowledge concerning the treatment group. A larger proportion of participants in the ColdZyme group assessed the effectiveness of their treatment as "very good" or "good," in comparison with the placebo group, which entails a statistically significant difference in favor of the ColdZyme group. The study investigators also assessed the effect to be better among participants treated with ColdZyme. Earlier studies have shown that ColdZyme is a safe and well-tolerated medical device, a finding now also confirmed in a larger study population.

> "The results from the recently completed placebo-controlled study confirm the earlier study results on ColdZyme regarding a 0.5 to 3.5-day shorter duration of cold symptoms. The study also shows that the level of clinical documentation for ColdZyme is in line with the guidelines according to MDCG 2020-6 (Medical Device Coordination Group), published in April 2020. The results are also valuable for the long-term compliance required by the forthcoming regulatory requirements for medical devices within the EU – the Medical Device Regulation (MDR). "The fact that users themselves experience good benefit when using ColdZyme is, of course, also of great value," says Claus Egstrand, Chief Operating Officer at Enzymatica.

Follow-up of earlier study

This double-blind placebo-controlled study is a follow-up of a single-blind, prospective, controlled multicenter study of ColdZyme that Enzymatica conducted at six centers in Germany in 2018. This study included 400 participants who were randomly asked either to initiate treatment with ColdZyme at the first cold symptoms, or not to start any specific treatment at all. A total of 267 people with confirmed colds were assessed and the results showed a statistically significant advantage in the group treated with ColdZyme, such as shorter duration of colds, alleviation of cold symptoms, improved quality of life and reduced need for concurrent use of medications for symptomatic cold relief[2].

Title: Double-blind, Randomized, Parallel-group, Placebo-controlled Study to Evaluate Efficacy of CMS008618 for Common Cold

1 Clarsund, M., Fornbacke, M., Uller, L., Johnston, S.L. and Emanuelsson, C.A. (2017) A Randomized, Double-Blind, Placebo-Controlled Pilot Clinical Study on ColdZyme® Mouth Spray against Rhinovirus-Induced Common Cold. Open Journal of Respiratory Diseases, 7, 125-135. https://doi.org/10.4236/ojrd.2017.74013

2 Multi-symptom Relief and Improvement of Quality of Life – A Comparative Multicenter Trial on ColdZyme® Mouth Spray in Common Cold, Icelandic Medical Association conference, Jan 2019

3 Glen Davison, Eleanor Perkins, Arwel W. Jones, Gabriella M. Swart, Alex R. Jenkins, Hayley Robinson & Kimberly Dargan (2020) ColdZyme® Mouth Spray reduces duration of upper respiratory tract infection symptoms in endurance athletes under free living conditions, European Journal of Sport Science, DOI: 10.1080/17461391.2020.1771429

VALUE CHAIN

Investments for streamlining and increased capacity in Enzymatica's value chain

In 2020 Enzymatica made extensive investments in the Icelandic operation. The purpose of these investments is to update the production equipment with the aim of improving efficiency to ensure the capacity needed for increased production volumes of ColdZyme®. Efforts to secure production capacity for the end product were intensified through an expanded agreement with Recipharm, as well as contacts with additional contract manufacturers. In addition, a new European patent was granted for the cod enzyme that is one of the key components of ColdZyme, as well as two more patents that were granted in Russia and Japan, in accordance with the company's patent strategy.

Investments in new production equipment

The focus in 2020 was on increasing production of enzymes and finished products to meet the growing demand in existing and new markets. Investments in new equipment at Enzymatica's Reykjavik facility will increase efficiency and ensure capacity for the future. The new equipment will facilitate modular scaling up of capacity, with increased automation and improved control systems to ensure quality and a high yield in production.

In addition to producing enzymes for the ColdZyme mouth spray, Zymetech also delivers enzymes for bulk formulations that are included in customers' skin care products.

To meet the growing demand, discussions were also initiated with contract manufacturers to ensure future production capacity within both Europe and the rest of the world. These discussions culminated in a new agreement with Recipharm, which will be the foundation of the future supply platform, along with potential agreements with other contract manufacturers.

New patents approved in 2020

Enzymatica has patent protection for its own products within the EU, as well as patent applications in several markets. Since Enzymatica is the sole producer worldwide of the specific deep-water enzyme, the company also has global control of enzyme production, which could significantly delay competition in key countries where there is not full patent protection. Enzymatica thus has exclusive rights in countries with patent protection until 2035 and a technological lead of several years over the rest of the world. Enzymatica has an active patent strategy and continually submits patent applications for new applications and technical innovations. See the table on the next page for more information about the company granted patents and patent applications.

In May 2020, the European Patent Office granted a patent for the cod enzyme, which is one of the key components in Enzymatica's ColdZyme mouth spray. The patent, which will be in effect until 2035, considerably strengthens Enzymatica's patent portfolio and also strengthens the position of ColdZyme and other products on the market. Corresponding patent applications have been submitted in several large markets around the world.

Enzymatica's patents

Product	Countries/markets	Approved, year	Status	Relates to	Expires, year	Num-ber
ColdZyme	Europe	2020	Granted	enzymes from cod for medical and cosmetic use	2035	1
Unspecified	Russia	2020	Granted	Combination treatment with cod enzymes and antibiotics for streptococcal biofilm.	2036	1
Unspecified	Australia, Japan and Russia	2020	Granted	Treatment and prevention of microbial infections in individuals with immune deficiency.	2035	2
Unspecified	International applications	-	Applications	-	-	6

Value chain for Enzymatica

Enzymatica has full control over the entire value chain, from production of enzymes to the sale of medical devices. Enzymatica has the ability to offer exclusivity for the enzyme that is included in the company's product development and the company therefore has full control over enzyme production, product development and registration. Products are manufactured through contract manufacturing in accordance with Enzymatica's specifications and quality requirements. Marketing and sales are both in-house and through partners, depending on the market.

In addition, a patent was also granted in Japan and Russia for a combination treatment involving cod enzymes and antibiotics for treatment of streptococcal biofilm in the upper and lower respiratory tract This patent is valid until 2036.

Yet another patent was granted in Japan, Russia and Australia that covers the use of the cod enzyme for treatment and prevention of microbial infections in individuals with immune deficiency. This patent expires in 2035.

Design & Development

Enzymatica has refined its research and development portfolio in recent years. The focus has been on documentation, development and research related to ColdZyme.

The company has extensive knowledge in enzyme technology, applied enzyme research, and processing and formulation of the relevant enzyme, which also allows for a broadening of the areas of use for ColdZyme and facilitates development of new products based on the company's technology platform.

In 2020, Enzymatica made extensive investments in the production facility in Reykjavik, Iceland.

CORPORATE GOVERNANCE

Corporate governance

Governance of Enzymatica takes place through the Annual General Meeting, the Board of Directors, the CEO and senior management in accordance with the Swedish Companies Act, the Articles of Association, Enzymatica's internal policy documents and the rules and recommendations for companies whose shares are listed on Nasdaq First North Growth Market. In 2020 Enzymatica held 15 board meetings. Important matters addressed included strategy, growth issues, COVID-19, funding, organization, adoption of the budget and regulatory matters, such as how the company will address the new EU Medical Device Regulation.

Annual General Meeting

The Annual General Meeting (AGM) is the highest decision-making body and the forum through which shareholders exercise their influence over the company. The Annual General Meeting resolves on how to address a number of central issues, including disposition of the company's profit or loss, adoption of the income statement and balance sheet, discharge from liability for the Board of Directors and the CEO, election of the Board of Directors and the auditor, as well as fees to the Board and auditor. An Extraordinary General Meeting may be held if the Board considers that there is a need to do so, or if the company's auditors or owners of at least 10 percent of the shares should so request.

Board of Directors

In 2020, the Board of Directors consisted of six members who are elected for one year by the Annual General Meeting. According to the Articles of Association the Board of Directors shall consist of at least three and a maximum of ten members with a maximum of ten deputies. The Board of Directors elects its officers at a meeting held immediately after the Annual General Meeting. A list of the members with their respective shareholdings, attendance record, and their respective independence to the owners and the company, respectively, can be found on the next page.

Chairman of the Board

Bengt Baron is the Chairman of the Board. In addition to leading Board meetings, the Chairman of the Board is responsible for ongoing contact with the CEO, monitoring the development of the company and consulting with the CEO on strategic matters. The Chairman of the Board shall, in consultation with the CEO, be responsible for notice to attend Board meetings and the agenda, as well as for ensuring that matters are not handled in violation of regulations. Once a year, the Chairman evaluates the work of the Board with each of the members.

Committees

The Board has established an Audit Committee and a Remuneration Committee. The Audit Committee is responsible for quality assurance regarding the company's financial reporting and for work concerning internal control at Enzymatica. The Audit Committee is also responsible for the Board's ongoing communication with auditors, adoption of guidelines for what services are to be purchased from auditors in addition to auditing, evaluating the audit engagement, assisting the Nomination Committee in preparing proposals for the auditor and fees for the audit engagement. The Audit Committee consists of Board members Marianne Dicander Alexandersson and Louise Nicolin. Marianne Dicander Alexandersson is the committee chairperson.

The Remuneration Committee addresses matters concerning remuneration and benefits for senior executives, including the CEO. The committee consists of Bengt Baron, Mats Andersson and Gudmundur Palmason. Mats Andersson is Chairman of the committee.

Board meetings

During the year, Enzymatica's Board of Directors held 15 meetings at which the minutes were recorded, 4 of which were by telephone and 4 per capsulam. Four of the meetings were held in conjunction with approval of the year-end report and the interim reports. Important matters addressed during the year included strategy, growth issues, COVID-19, funding, organization, adoption of the budget and regulatory matters, such as how the company will address the new EU Medical Device Regulation. The CEO, CFO and COO of the company regularly participate

Board members' shareholdings, attendance record, and respective independence to owners and the company, respectively

Name	Number of shares	Attendance board meetings	Independence to owners and the Company, respectively
Bengt Baron, chairman (chairman beginning December 19, 2016)	996,754	15/15	Yes
Marianne Dicander Alexandersson	72,912	15/15	Yes
Gudmundur Palmason	9,360,622	15/15	Yes
Fredrik Lindberg (elected May 2020)	600,000	9/9	No
Mats Andersson	29,403,404	15/15	No
Louise Nicolin	43,000	15/15	Yes

The shareholdings shown above apply as of December 31, 2020.
Sigurgeir Gudlaugsson left the Board of Directors in conjunction with the 2020 Annual General Meeting.

at the Board meetings. Other senior executives participate at Board meetings as needed. The company's auditor attends at least one regular meeting during the year.

Audit

In 2020 Deloitte AB was elected to serve as auditor of the parent company for the period until the 2021 Annual General Meeting. In addition to the annual audit, the auditor reviews at least one interim report per year. Authorized auditor Per-Arne Pettersson is the principal auditor.

CEO and senior management

The CEO is appointed by the Board of Directors and leads the company in accordance with the guidelines and instructions adopted by the Board. The CEO appoints a management group. The management group consisted of four people in addition to the CEO during the year.

Guidelines for remuneration to senior executives

Remuneration to the Chief Executive Officer and other senior executives comprises basic salary and other benefits (relates to car allowance). The Company's senior executives, in addition to the Chief Executive Officer, include an additional four individuals. Decisions on remuneration and benefits to the Chief Executive Officer have been taken by Enzymatica's Board of Directors.

Decisions on remuneration and benefits to other senior executives are prepared by the Chief Executive Officer, who submits a proposal to the Board.

The Chief Executive Officer's employment agreement cites a period of notice from the company of nine months during which the level of salary and other benefits paid remains unchanged. The period of notice for the CEO is six months. No special severance package is paid. The period of notice for other senior executives is between three and six months, and the period of notice for the company is between three and twelve months. No special severance package is paid. For information on the 2020 guidelines for senior executives, please refer to the company's notice to attend the 2020 Annual General Meeting.

Internal control

Internal control in the company follows the procedures and principles established in the company using various systems, controls and ongoing reporting. The Board of Directors is responsible for compliance with these procedures and principles. Each individual entity in the company is followed up with reporting according to a set schedule and scope. Authorization guidelines and rules of procedure regulate who and how decisions are made regarding length of contract, costs or risk for the company. Signing on behalf of the parent company and subsidiaries, as well as managing cash and cash equivalents, are handled by several people to create good control. Enzymatica does not have an internal audit function because such a function is not justified by the scope and risk exposure of the company.

THE SHARE

Strong share price trend during the year

Enzymatica has been listed on Nasdaq First North Growth Market since 2015. At year-end 2020/2021 Enzymatica had 9,596 shareholders – an increase of about 237 percent compared with 2019. In 2020 the company's market capitalization increased from SEK 567 million to SEK 2.7 billion.

Shares and share capital

At the end of 2020, the share capital of Enzymatica AB was SEK 5,712,950 SEK, distributed among 142,823,696 shares, each with a par value of SEK 0.04. The company has only one class of stock. Each share entitles the holder to one vote at Enzymatica's general meeting of shareholders. Each shareholder who is entitled to vote may vote at the general meeting for the full number of shares that he or she owns and represents. Each share carries equal rights to a part of the company's assets and profit.

Warrant Plan and directed issue of warrants

The Extraordinary General Meeting resolved on May 5 to authorize the Board of Directors to implement a warrant plan and adopted a resolution on the directed issue of warrants and approval of the transfer of warrants.

Under the decision to implement the 2020/2023 Warrant Plan the plan will be offered to employees of the Company or other individuals who are affiliated with the Company by contractual agreement and who are engaged in the development of the Company (referred to below as "employees"). The Warrant Plan was offered by the Board of Directors to employees on May 20, 2020 at a price of SEK 2.38.

Warrant holders will be able to exercise allocated warrants during the period from May 15, 2023 through September 30, 2023. Each warrant entitles the holder to acquire a new share in the company at an exercise price of SEK 12.40.

If all warrants related to the 2020/2023 Warrant Plan are exercised, a total of 2,800,000 shares will be issued, corresponding with dilution of approximately 1.9 percent of the Company's share capital and votes after full dilution. If all warrants issued in the 2017/2023 Employee Warrant Plan I and the 2020/2023 Employee Warrant Plan II, as well as in the 2020/2023 Warrant Plan, are exercised, a total of 7,715,108 shares will be issued, corresponding with dilution of approximately 5.1 percent of the Company's share capital and votes after full dilution calculated based on the number of shares that will be added upon full exercise of all outstanding and proposed warrants. Upon full exercise of the warrants in the 2020/2023 Warrant Plan for subscription of new shares, the share capital will increase by SEK 112,000.04.

A maximum of 2,800,000 warrants will be issued under the 2020/2023 Warrant Plan. In all, 1,420,000 warrants have been allocated and employees have subscribed for 1,069,350 warrants as of June 30, 2020. Upon full exercise of the warrants for subscription of shares, the share capital will increase by SEK 42,774.02.

Authorization for the Board to decide on the issuance of shares from the 2020 Annual General Meeting

The 2020 Annual General Meeting of shareholders authorized the Board to resolve on the issuance of shares corresponding to a maximum of 10 percent of the total number of shares in the company, with or without deviation from preferential rights, in order to enable the company to raise working capital and to take advantage of future opportunities to acquire long-term strong owners, as well as to further finance the company's growth strategy through a non-cash issue.

Share capital trend

Since its formation, the company's share capital has changed as shown in the table below.

Enzymatica's shares were admitted for trading on Nasdaq First North Growth Market on June 15, 2015. The number of shares is 142,823,696. In 2020, average turnover per trading day was approximately 435,629 shares, equivalent to approximately SEK 5.8 million. In 2020, the share price increased by 371 percent, from SEK 3.97 to SEK 18.70. Enzymatica's market capitalization increased from SEK 567 million to SEK 2.7 billion.

Ownership structure

The number of shareholders at year-end was 9,596, an increase of 237 percent during the year. The table below shows information about ownership of the company as of Thursday, December 31, 2020.

Dividend policy

The Board of Directors does not intend to propose any dividend until the company generates a profit and a positive cash flow.

Share-based incentive programs

See earlier in this section under Warrant Plan and directed issue of warrants.

Analyses

During the year Enzymatica was analyzed by ABG Sundal Collier and Erik Penser Bank.

» Rickard Anderkrans, ABG Sundal Collier: rickard.anderkrans@abgsc.se

» Johan Löchen, Penser: johan.lochen@penser.se

The Enzymatica share

Ticker: ENZY
ISIN code: SE0003943620
Sector: Health care

Registered	Transaction	Increase in number of shares	Total number of shares	Change in share capital	Total share capital	Par value
2006	Founded	1,000	1,000	100,000	100,000	100.00
2009	Rights issue	200	1,200	20,000	120,000	100.00
2011	Rights issue	3,800	5,000	380,000	500,000	100.00
2011	Split	12,495,000	12,500,000	–	500,000	0.04
2011	Rights issue	2,220,000	14,720,000	88,800	588,800	0.04
2012	Rights issue	1,783,832	16,503,832	71,353	660,153	0.04
2012	Rights issue	1,375,319	17,879,151	55,013	715,166	0.04
2013	Rights issue	890,000	18,769,151	35,600	750,766	0.04
2014	Rights issue	4,692,287	23,461,438	187,691	938,457	0.04
2014	Rights issue	1,500,000	24,961,438	60,000	998,457	0.04
2016	Non-cash issue	20,905,942	45,867,380	836,238	1,834,695	0.04
2016	Rights issue	27,520,428	73,387,808	1,100,817	2,935,512	0.04
2016	Rights issue	17,500,000	90,887,808	700,000	3,635,512	0.04
2018	Rights issue	51,935,888	142,823,696	2,077,436	5,712,950	0.04

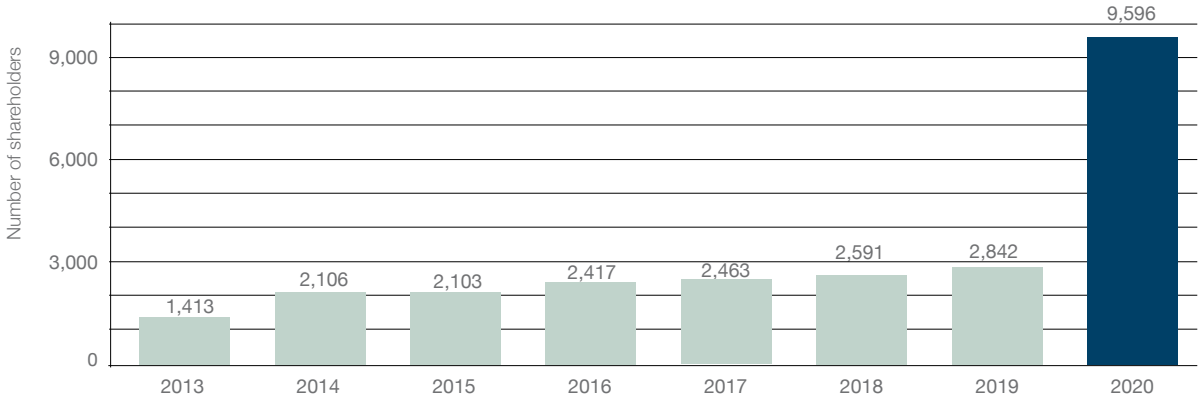
Amounts above are stated in SEK

Enzymatica's ten largest shareholders December 31, 2020

Name	Number of shares	Percentage of capital and votes (%)
Mats Andersson through Abanico Invest AB	29,403,404	20.6%
Håkan Roos through Roosgruppen AB	17,683,918	12.4%
Björn Algkvist through Fibonacci Asset Management	15,055,004	10.5%
Guðmundur Pálmason through Fortus hf.	9,360,622	6.6%
Ágústa Guðmundsdóttir	5,199,737	3.6%
Aktiebolaget Possessor	3,200,000	2.2%
Avanza Pension	2,702,160	1.9%
Nordnet Pensionsförsäkring AB	2,576,852	1.8%
Clearstream Banking, Luxembourg	2,172,493	1.5%
Ulf Winberg, privately and through company	1,968,657	1.4%
Holdings 10 largest shareholders	**89,322,847**	**62.2%**
Other	53,500,849	37.8%
Total	**142,823,696**	**100.0%**

Source: Euroclear, December 31, 2020

Shareholder trend 2013-2020



Share price trend 2020

Financial Overview

(SEK thousand)	2020	2019	2018	2017	2016
Net sales, SEK thousand	111,245	61,306	52,560	59,446	36,482
Capitalized development costs, SEK thousand	-	-	-	-	7,625
Cash flow for the period, SEK thousands	-5,056	-40,975	59,428	-24,656	27,189
Gross margin, %	68	73	70	61	61
Equity/assets ratio, %	66	81	86	83	87
Debt/equity ratio, times	0.5	0.2	0.2	0.2	0.1
Equity (SEK thousand)	106,649	119,203	159,660	110,695	142,041
Cash flow for the year, operating activities, SEK thousands	-10,652	-37,576	-28,793	-22,545	-38,434
Net investments, SEK thousands	-5,923	-866	-520	-1,265	-18,995
Average number of employees	18	19	21	21	21
Number of shares at end of period	142,823,696	142,823,696	142,823,696	90,887,808	90,887,808
Earnings per share, basic and diluted, SEK[1]	-0.09	-0.29	-0.45	-0.35	-0.69
Equity per share, SEK	0.75	0.83	1.12	1.22	1.56

[1] Based on weighted average of the number of outstanding shares.

Definitions of – Alternative performance measures

Enzymatica uses alternative performance measures to increase understanding of the information in the financial statements, both for external analysis and comparison, and for internal evaluation.

Alternative performance measures are measures that are not defined in financial statements prepared in accordance with IFRS. The following ratios are used:

Gross margin
Net sales for the period less costs for raw materials and supplies in relation to net sales. Gross margin shows earnings in relation to net sales and margin to cover other expenses, as well as profit margin.

Equity per share
Reported consolidated shareholders' equity divided by the number of outstanding shares. Shows the share of equity attributable to each share.

Earnings per share
Profit/loss for the year in relation to average number of outstanding shares. Shows the share of profit/loss for the year attributable to each share.

Earnings per share, diluted
Profit/loss for the year in relation to average weighted number of shares increased by the amount at full dilution. Shows the share of profit/loss for the year attributable to each share after taking potential shares such as warrants into account.

Debt/equity ratio
Total liabilities divided by shareholders' equity Shows the company's net debt and is used as a measure to measure debt and future financing needs.

Equity ratio
Equity as a percentage of total assets. Shows the share of equity in relation to total assets.

Net investments
Cash flow from investing activities. Shows the amount used to invest in property, plant and equipment during the year.

Enzymatica's partner Sanofi launched Zerinol Virus Defense (ColdZyme) on the Italian market in late 2020.

Enzymatica's special barrier technology uniquely protects the health of people, by providing a shield from viruses, microbes and irritants that can cause people infections and colds. We pursue global expansion through open innovation, branded and co-marketing collaborations and partnerships.

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