

Kerecis[®]

Annual & Sustainability Report



2020

Kerecis Annual & Sustainability Report



Foreword

The objective of this report is to inform stakeholders about the Company's economic, environmental and social developments based on the United Nations Sustainable Development Goals. This is the first time that Kerecis has issued an annual report of this type. We expect that over the coming years the report will evolve and more thoroughly document the Company's products and strategy, as well as track its progress towards the goals set.

Thirty miles south of the Arctic Circle, from the pristine waters of the North Atlantic Ocean, the Kerecis laboratory processes implants derived from fish to repair human-tissue defects. Every year millions of patients develop complications and undergo operations where our technology can help. Patient populations that our current on-market products address include sufferers of diabetes, melanoma, surgical dehiscence and more.

For example, 420 million people around the world have diabetes—a number that is growing rapidly. By 2050 the World Health Organization estimates that one out of every three Americans will have the disease. Every year, five percent of diabetics develop hard-to-heal wounds on the lower extremities and one percent require amputation. Annually at least 21 million diabetes-related wounds are treated around the world.

The Kerecis mission is to harness nature's own remedies to extend life by supporting the body's own ability to defend itself and regenerate tissues. We want to do this in a sustainable manner with respect for the environment and humanity.

The Kerecis product development strategy is to expand the reach of our technology to address markets of increasing technical sophistication and regulatory complexity, with the end goal being the ability to repair complex human organs.

This report covers the financial and non-financial performance of Kerecis and its subsidiaries (the Kerecis group) for the financial year October 1, 2019, through September 30, 2020.

In 2015 the United Nations General Assembly identified seventeen Sustainable Development Goals designed to be a “blueprint to achieve a better and more sustainable future for all.”

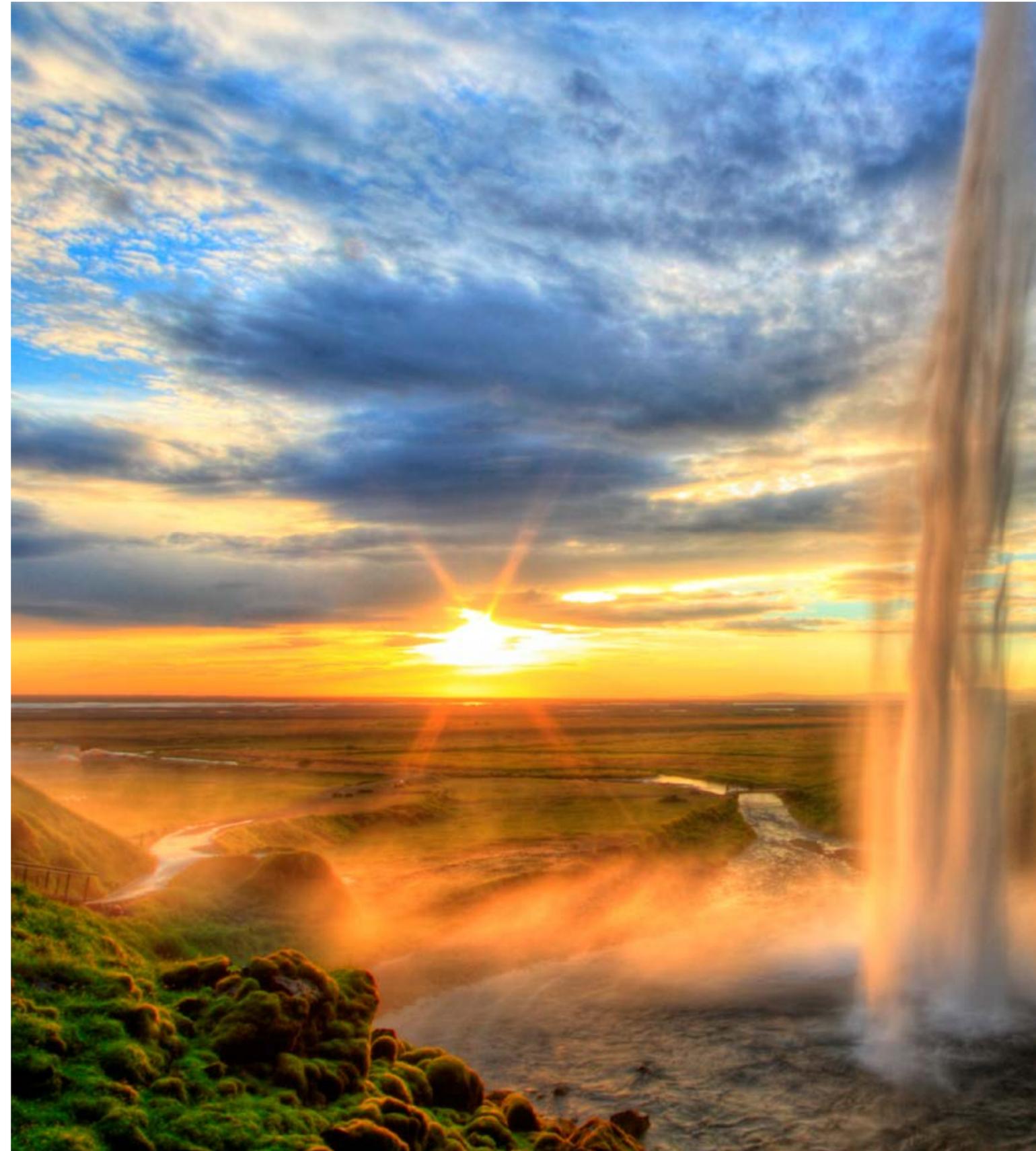
The Board of Directors and the management of Kerecis have analyzed those seventeen Sustainable Development Goals and implemented a sustainable business model using the International Integrated Reporting Council Framework and the Nasdaq Environmental, Social and Governance reporting guide. Of the seventeen goals offered by the United Nations, Kerecis has chosen six through which our management believes the Company will have the most significant impact.

The Kerecis Board of Directors have reviewed the Annual and Sustainability report and believe it is a fair representation of the Company’s performance, impact, strategy and growth prospects.

Throughout this report:

“ESG” means Environmental, Social and Governance and refers to the three central factors in measuring the sustainability and societal impact of a business investment.

“SDG” means the Sustainable Development Goals adopted by all United Nations Member States.



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1. Message from the Chairman

G. Fertram Sigurjonsson
Founder & Chairman



Thirty miles south of the Arctic Circle in Iceland's Westfjords, Kerecis was founded with the simple objective of sustainably harnessing nature's own remedies to extend life. With operations in four countries and sales in multiple international markets, we are emerging as an internationally recognized innovator in biotechnology.

Kerecis is committed to the United Nations Sustainable Development Goals that include economic, environmental and social impact factors. The purpose of this Annual and Sustainability Report is to update our stakeholders on our progress across those three impact factors.

Our fiscal year 2020 was another year of tremendous growth for Kerecis seeing tens of thousands of patients treated with our sustainably sourced, fish-derived implant. The increased number of patients treated is reflected in the Company's revenue growth from USD 8 million to USD 17 million.

Skin is the body's largest organ and thousands of patients suffering from skin wounds have been treated with our original FDA-approved product. Our principal focus has been on diabetic wounds, but many other hard-to-heal and acute types of wounds have been treated.

The Company's objectives are:

- The primary objective is sales execution and the build-up of our sales force and sales support staff in the U.S. wound-care market.
- The secondary objective is the development of new markets and products for our fish-derived technology to diversify the Company's revenue.

Our current business is focused principally on treating diabetic wounds and preventing amputations. Our geographical focus is on the U.S. market, where 94 percent of our revenue is created and where we are experiencing most of our growth. We foresee continued, accelerated growth in the United States and a rapid increase of market share.

In fiscal year 2020, we had planned to hire 30 new sales employees, but with the onset of the Covid-19 pandemic we could not predict the effect it would have on our business. To prepare for the worst, we immediately froze all recruitment and made substantial reductions to the salaries of the executive staff and lesser reductions to the salaries of other staff. Some employees were furloughed in each of the four countries where Kerecis has employees: The United States, Iceland, Switzerland and Germany.

At the same time, we continued to pursue our strategy of expanding research and development with our proprietary technology to address markets of increasing technical sophistication and regulatory complexity.

As we increase our footprint in hard-to-heal wounds, we are working to diversify our revenue stream. For example, we are working closely with the U.S. Department of Defense, as our Omega3-rich fish tissue can be used in the treatment of blast injuries as well as the treatment of gun and burn wounds.

We are also working to develop other products for surgical use in, for example, oral surgery, body wall reconstruction, hernia repair, breast reconstruction, brain surgery, and obesity stomach reduction. These additional applications are expected to diversify our revenue stream, create an even stronger value proposition for Kerecis, and serve as a platform for significant future growth.

Key developments for the year included:

- Named Iceland's fastest growing company in 2020 (We also held that title in 2017.)
- Listed as "Top 10 Surgical Solution Provider 2020"
- Launched Kerecis Omega3 OR (Operating Room) and Kerecis Omega3 Burn product options (focusing on larger 250 cm² sizes for the burn option)

- Due to Covid-19, converted our marketing efforts from physical tradeshows to webinars. We have in the past years become a leader among our competitors in the use of webinars to engage current and prospective customers
- Launched the Kerecis Telemedicine App to make it easier for customers to get product advice, to submit benefit investigations and to order products
- Expanded internal reimbursement evaluation capacity while reducing our reliance on outside contractors
- Expanded Kerecis VET product line for animals
- Received additional grant awards from the U.S. Department of Defense, raising the amount of committed grants to more than USD 3 million

As part of our policy to provide products for humanitarian efforts around the world, Kerecis supplied products to several disaster-stricken areas during the year. Those included burn victims of the White Island volcanic eruption in New Zealand, Western U.S. wildfires and the Nagorno-Karabagh conflict.

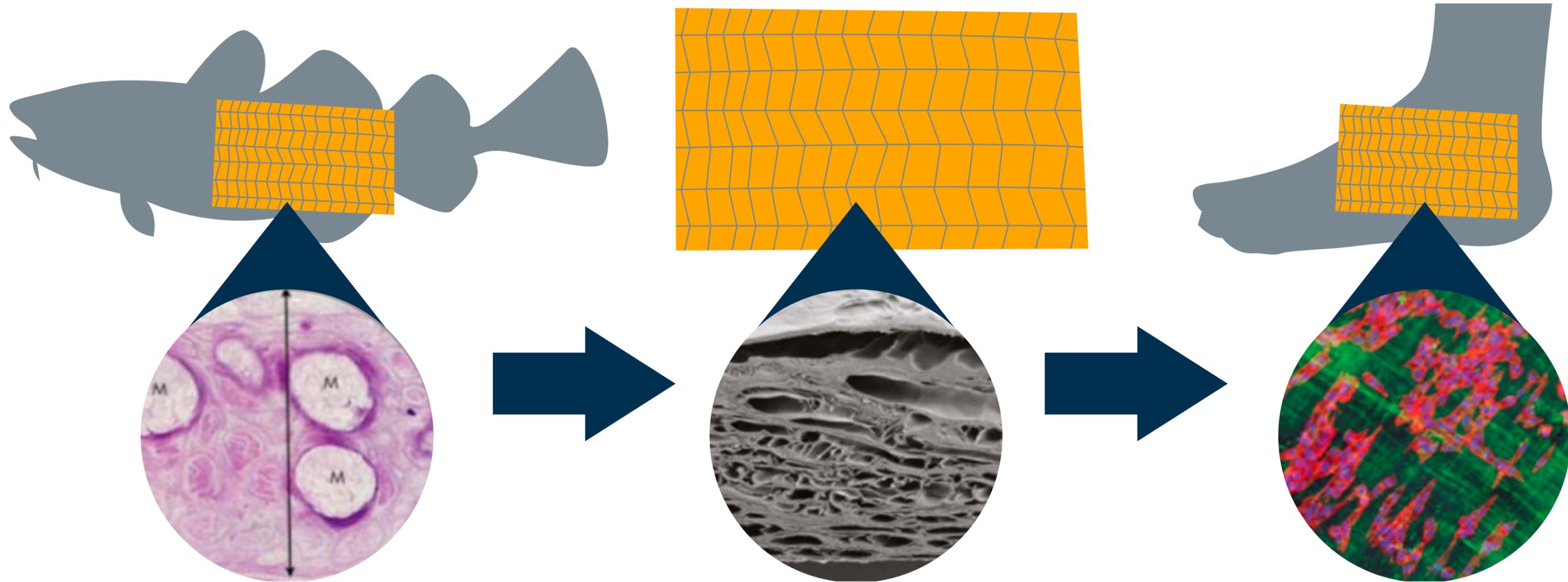
Kerecis has achieved all of this while at the same time integrating sustainability into our strategies and operations. Our core values of compassion, curiosity and integrity are based on sustainability as a founding principle.

We have selected the following from the list of United Nations Sustainable Development goals (SDGs) to be our focus:

- Good Health and Well-being
- Gender Equality
- Reduced Inequalities
- Industry Innovation and Infrastructure
- Responsible Consumption and Production
- Life below Water

This report discusses the above goals and how we intend to achieve them.

Kerecis Products Feature Intact, Gently Processed Fish Skin Used to Heal Wounds and Tissue Damage



Cells are removed from the fish tissue in a gentle process.

All fish-tissue components (proteins, glycans and fats, including Omega3 fatty acids) are preserved while keeping the tissue intact.

Graft is applied to damaged human tissue. The fish graft recruits cells (including stem cells) and facilitates tissue regeneration and healing.

2. Operations & Strategies



Kerecis is a biotechnology company that was founded to develop sustainable, science-driven treatments to address global health issues. Kerecis is domiciled in Iceland but most of its operations are in the United States. The Company employs personnel in the United States, Iceland, Switzerland and Germany.

Driven by its core values of compassion, curiosity and integrity, the Company is pioneering the use of fish tissue and fatty acids in the cellular-therapy and regenerative-tissue markets. Kerecis products are based on patented technologies that protect the body's own tissues, provide an infection barrier, and enable the body to regenerate its own tissues.

The Kerecis mission is to sustainably harness nature's own remedies to extend life by supporting the body's own ability to defend itself and regenerate, and our vision is to become the world leader in tissue regeneration by sustainably harnessing nature's own remedies.

Sustainability at our core

Kerecis creates life-saving medical products from the waste product of Iceland’s fishing industry, which itself processes only sustainably sourced fish.

Kerecis manufacturing facilities are located on the edge of the North Atlantic fishing grounds. The Company is deeply rooted in Icelandic culture, which has long held sustainable fisheries as a central pillar of the nation’s economy. Strong stewardship has evolved over centuries such that Iceland has created and imposed long-term quotas for fishing companies as a means to treat its fish stocks with respect and care. Iceland aggressively promotes strong certification standards. Kerecis relies on these certifications to ensure the sustainability of the source material for its products.

The primary supplier of fish for Kerecis products has been certified as meeting the sustainability requirements of the Marine Stewardship Council. The supplier is also a member of Fisheries Iceland, which was certified as sustainable through the Iceland Responsible Fisheries Certification Program.

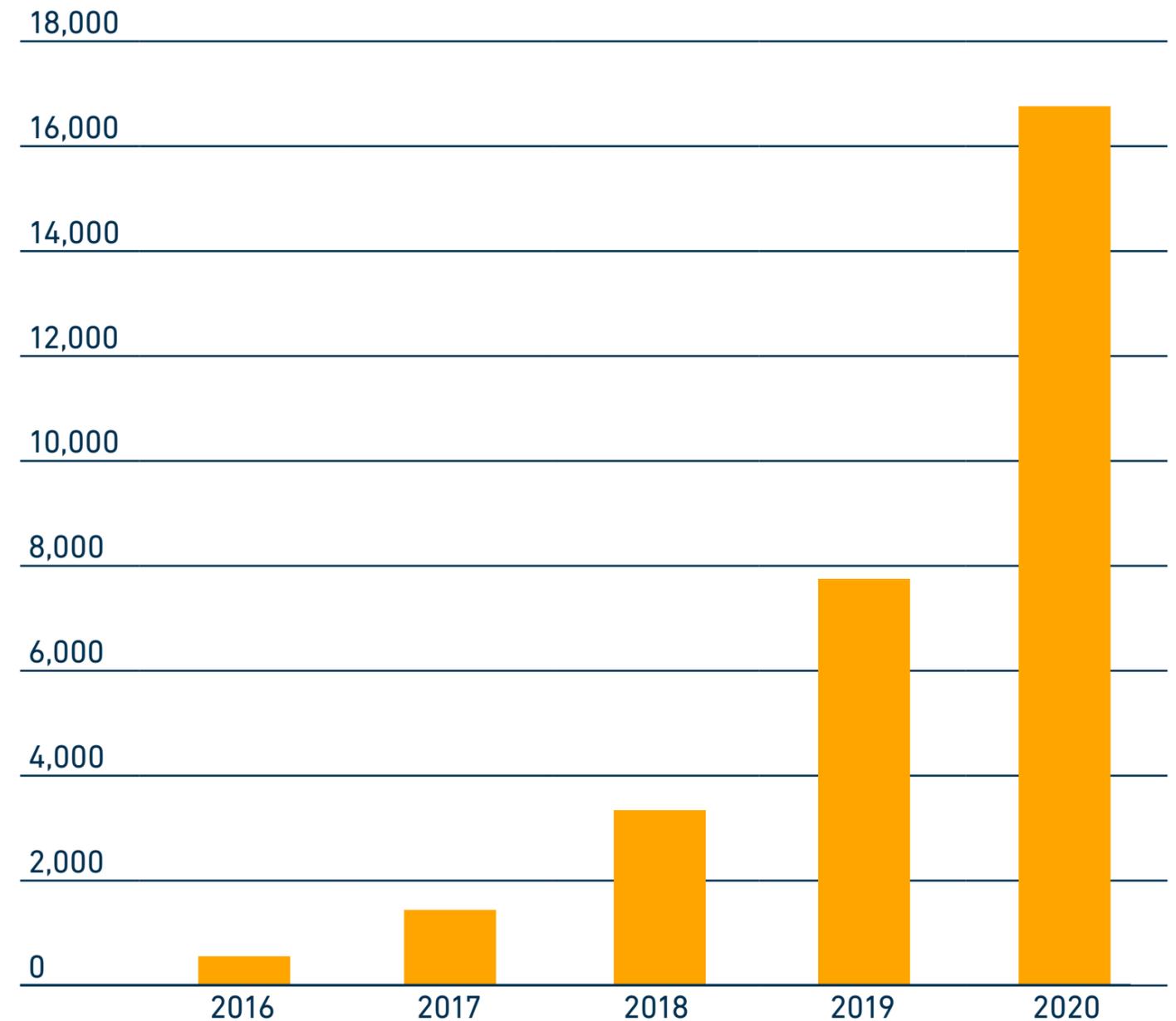
The Kerecis manufacturing facility is powered exclusively by renewable energy.



Business Performance

Kerecis Omega3 Wound has been well received on the market and sales have more than doubled year on year since its commercialization in 2015.

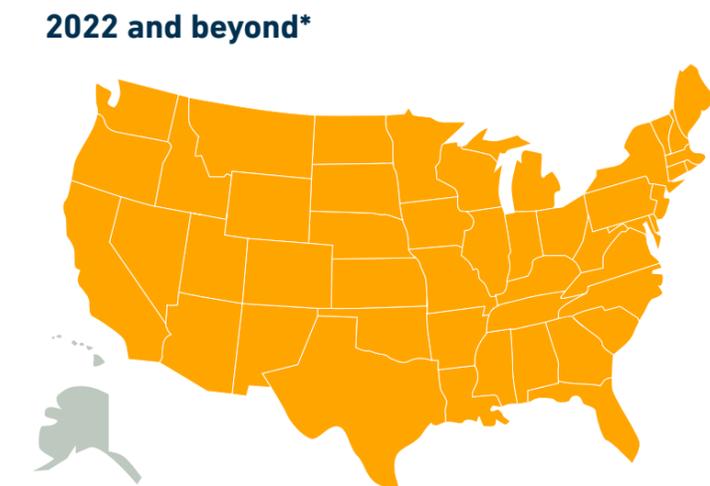
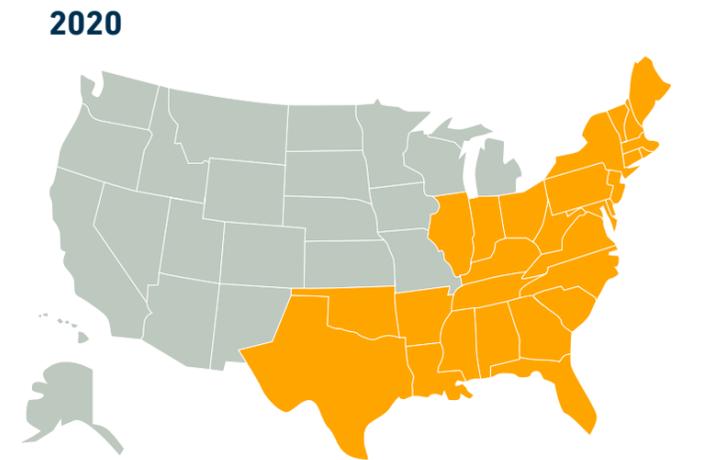
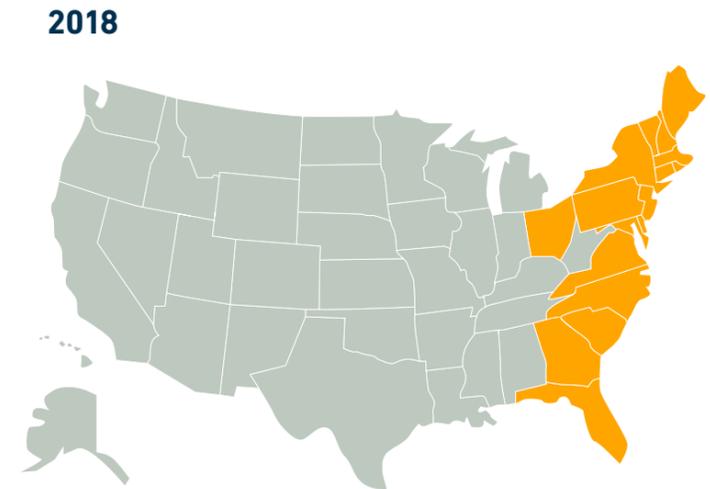
USD thousand



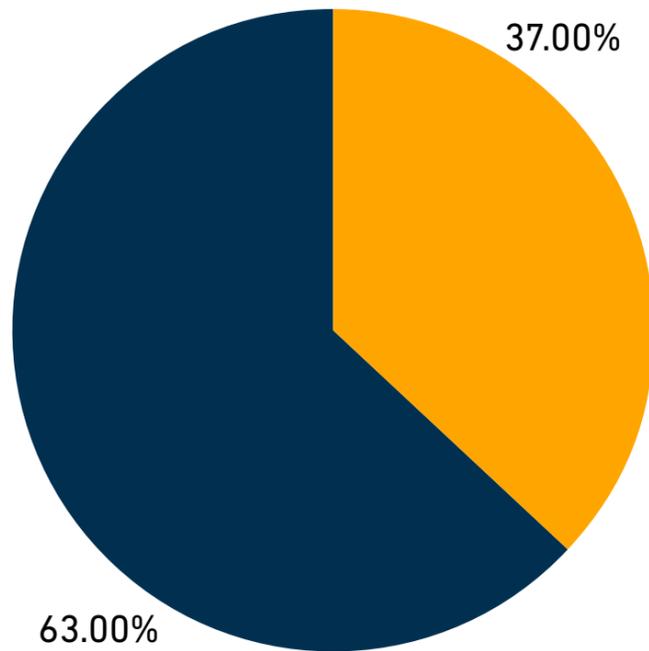
Sales growth year on year generally has resulted from an increased emphasis on direct sales by Company employees (rather than through independent sales agents) and the growth of the Company's strong sales force in the United States. Kerecis relied primarily on agents until 2017, when the Company decided to focus on hiring its own team. That decision proved successful, as sales have grown rapidly these past two years.

At year end 2022 Kerecis has the goal of selling directly in most of the United States. Agents will service rural markets.

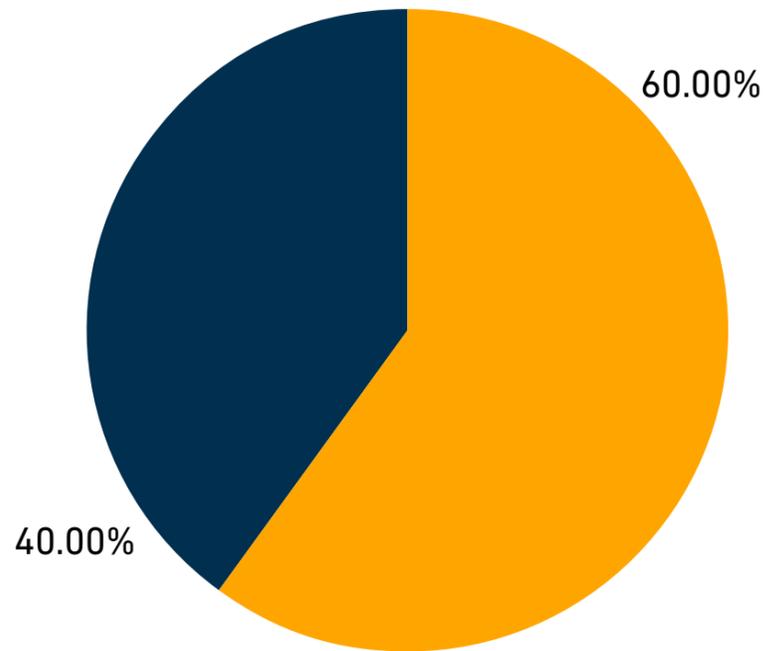
- Agent / Distributors
- Own sales force



Revenue split in 2020



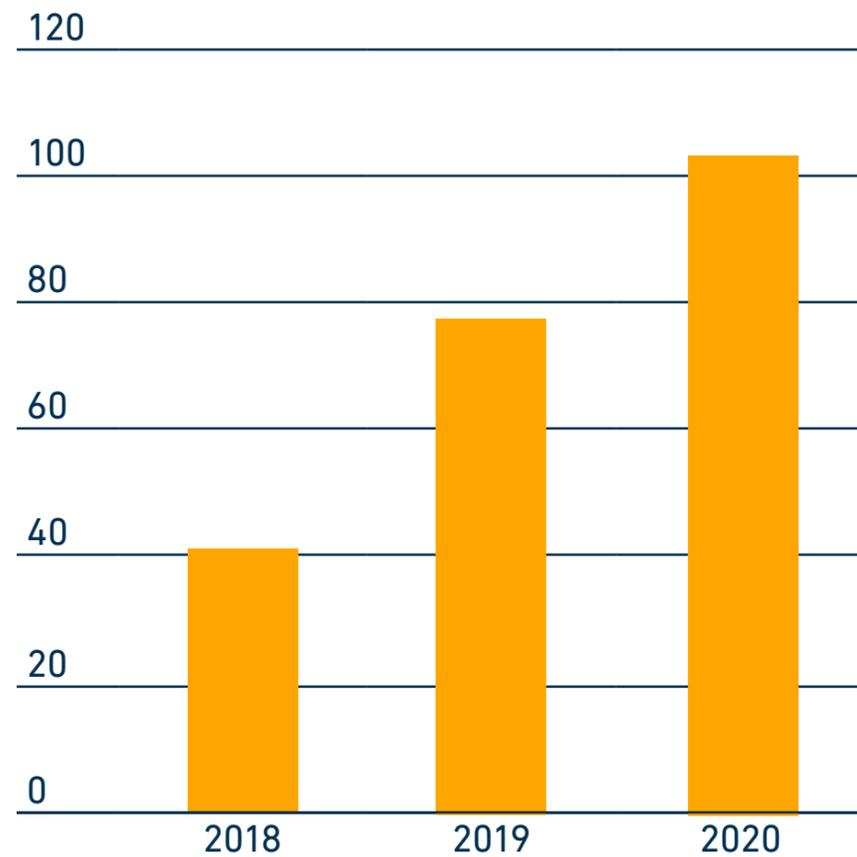
Revenue split in 2018



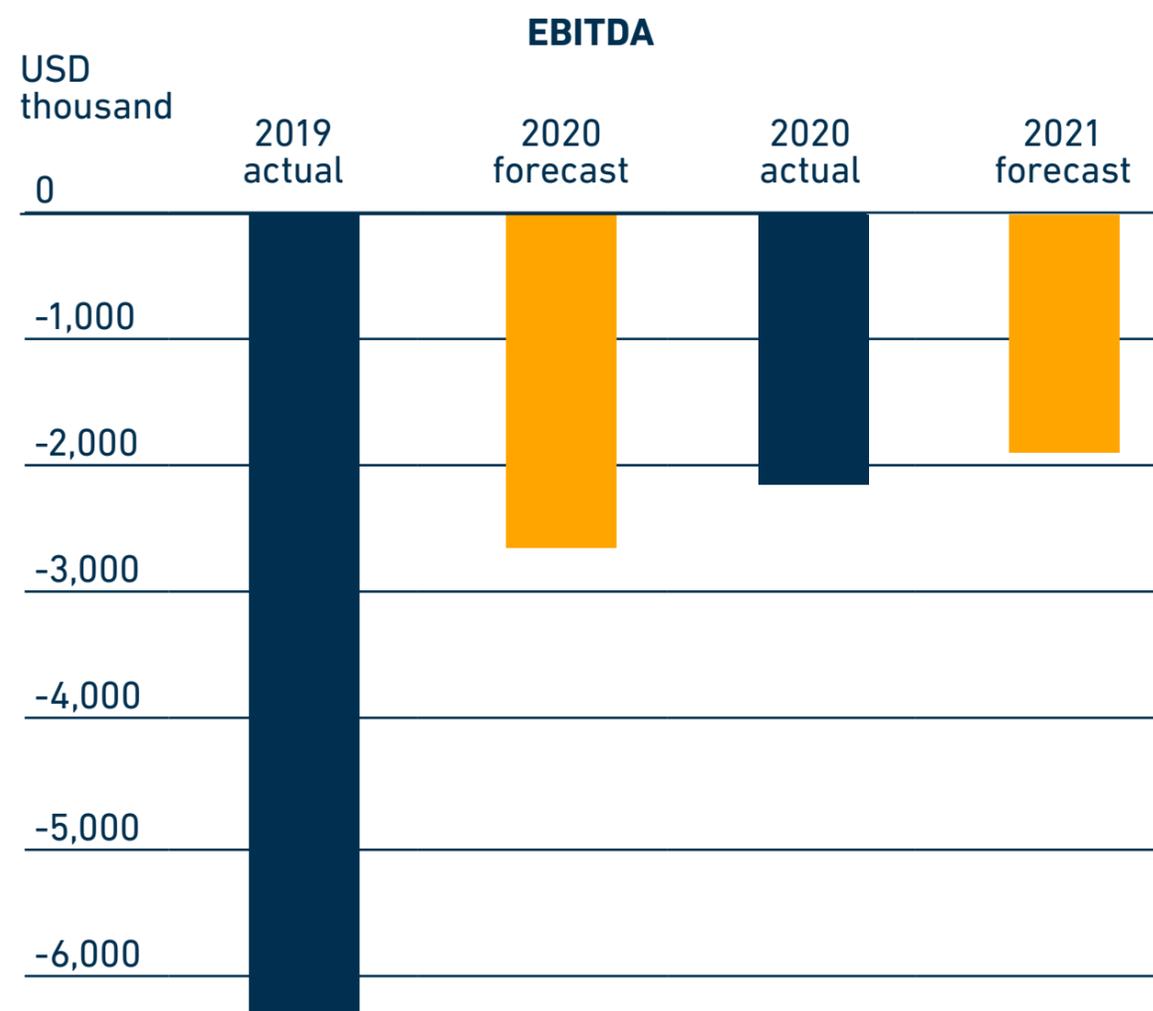
- Direct U.S.
- Agents U.S.

In 2020 Kerecis installed new manufacturing equipment on its production line with increased automatization of the production processes. This has substantially increased production capacity. The Company expects these additions to allow production capacity to quadruple, which will be more than adequate to service projected sales volumes until the next scheduled factory update in 2022.

Total square meters produced



Converting to an employee sales model and phasing out the independent sales agent model has been a time-consuming and expensive project. New sales employees can be unproductive for several months before they are able to establish a sufficient network and connections to begin to deliver sales, but the future profits of the model are obvious. This approach resulted in higher operating losses in fiscal year 2019 than in prior years but more favorable results in fiscal year 2020. Operating results in fiscal year 2020 are better than forecast, as the global pandemic prevented the Company from hiring all of the sales employees we had planned. In fiscal year 2021, however, Kerecis plans to more than double the number of direct sales employees, which we expect to impact the Company’s profitability for the year.



Fulfilling unmet clinical need with innovative, patented technology

Every year millions of patients develop complications, undergo operations and suffer trauma that result in severe tissue damage. Patient populations include sufferers of diabetes, melanoma, burns, trauma ruptured sutures (dehiscence) and many other ailments.

Kerecis is committed to developing new treatment options for the rapidly growing number of patients who suffer from diabetic wounds. Today at least 21 million such wounds are treated annually around the world. In the United States alone, one third of the population is expected to suffer from diabetes by 2050, an estimated five percent of which will develop hard-to-heal wounds on their lower extremities and one percent of those will likely require amputation.

Because there is no risk of disease transfer between cold-water fish and humans, the fish tissue in Kerecis products is only gently processed and retains its similarity to human tissue, making it an ideal substitute for human skin. When grafted onto human tissue, the fish skin recruits the body’s own cells and is ultimately converted into human skin. Mammalian-derived materials, on the other hand, need to be harshly processed to remove the risk of disease transfer, as viruses can pass between different mammalian species. The harsh treatment reduces these products’ similarity to human skin.

Kerecis is the only company in the world that uses intact fish tissue in medicine. The Company’s waste-to-value proposition is significant, as Kerecis uses fish skin that was previously considered a waste product of fish processing. The Kerecis fish tissue is rich in natural Omega lipids and comes from fish stocks that are certified as being sustainably harvested.

More than 50 studies have been conducted on the Kerecis technology. Multiple principal studies have been published on the product. One, for example, expands on the effects of Omega3 fatty acids in the wound environment, and another examines the costs and benefits of using the Kerecis graft as compared to the current standard of care. The studies help expand the scientific foundation for our technology and have developed evidence to speed up hospital purchasing cycles.

Historically, Kerecis has concentrated its research and development efforts in the biologic wound-care market. In 2015, the Company undertook the commercialization of Kerecis Omega3 Wound with a primary focus on hospital outpatient and physician office use. We have expanded FDA approvals for the wound product by, for example, making products available in larger sizes and in packaging tailored to the surgical wound market. Surgical wounds include trauma, burn and plastic surgery wounds, as opposed to hard-to-heal wounds that result from diabetes or other conditions.

Kerecis continues to expand its product portfolio, primarily through the deeper penetration of the proprietary fish-tissue products into the wound-care market and through the expansion of its advanced surgical uses as evidenced by new FDA approvals. To advance within wound care, Kerecis is conducting several clinical trials, including two large multicenter randomized controlled trials—the LEG Study and the Odinn Study, for the U.S. and E.U. markets, respectively—that the Company expects to provide crucial support for increased insurance coverage of the underlying product. The first study already has shown favorable interim analysis with 71 percent healing in the Kerecis group vs 36 percent in the Control group.



Outlook

The Company’s primary objective is sales execution and the build-up of our sales force and sales support staff in the U.S. wound-care market. Our secondary objective is the development of new markets and products for our fish transplant technology to diversify the Company’s revenue.

Kerecis’ success to date has been in the U.S. wound-management and surgical soft-tissue repair market. In this market, we have more than doubled our revenue annually. Kerecis expects the strong growth to continue, such that our revenue from this segment will grow to more than USD 100 million within three years.

According to the analysis firm Markets and Markets Research Private Ltd., the wound-care segment of the regenerative medicine market will grow by a 25 percent compound annual growth rate (CAGR) between 2019 and 2024.

To achieve our primary objective, we plan to quintuple our sales force in the United States and have direct sales employees based throughout the nation by 2022.

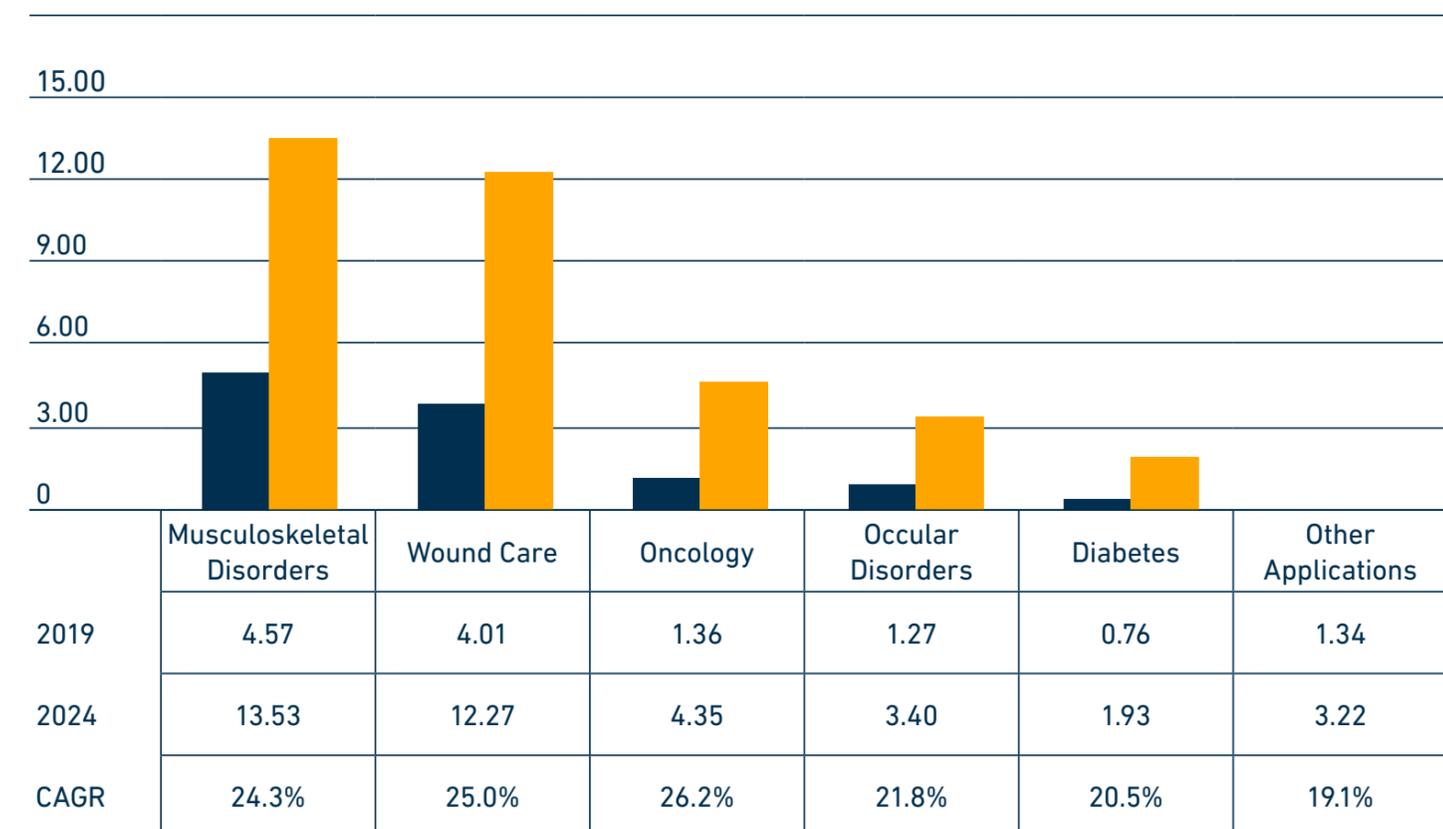
In the United States, publicly funded health care through Medicare and Medicaid is the primary payer for Kerecis products. Private insurance coverage is significantly less robust, but that is expected to change following the results of the studies described above.

In Europe Kerecis’ sales are emerging, yet growth is likely to be slower as government reimbursement and other payment mechanisms for Kerecis products and competing products are largely lacking. Kerecis is conducting a large-scale study with significant financial support from the European Union, the results of which could change this trend over the next three to four years.

To achieve our secondary objective of developing new markets, the Company plans to partner with established distribution companies to reach markets outside of Europe and the United States in lieu of hiring a direct sales force in those locations.

Regenerative medicine market, by application

2019 vs. 2024 (USD Billion)



Updates to the manufacturing facility in Isafjordur are already ongoing. These improvements will streamline processes, lead to higher volumes of production, and create more sustainable production in line with the new Kerecis sustainability strategy and key performance indicators.

The Company has sufficient funds to conduct its operations through the end of calendar year 2022. Our plans are to become cash-flow positive in year 2023 under the current expansion plans. This may change based on the Board focus on growth strategy versus profitability.

Resources

Kerecis sells products through three channels:

- The Company's own sales employees market Kerecis products directly to healthcare facilities in the United States, Iceland, Switzerland and Germany.
- Independent sales agents source orders for the Company's products at U.S. healthcare facilities, which the Company then fulfills. These agents are located in areas where Kerecis does not currently have its own sales employees.
- The Company also sells through distributors, who buy inventory from Kerecis and sell directly to customers at prices that they control.

The vast majority of the Company's sales operations are executed through its U.S. subsidiary with offices in the Washington, D.C., area. Research and Development and regulatory affairs are conducted from both the United States and Iceland. Finance, legal and other administrative functions operate from an office in Reykjavik, Iceland, and manufacturing operates entirely in Isafjordur, in the country's Westfjords region.





Key Figures

Very favorable
U.S. Medicare
reimbursement

Distribution in
12
countries

Patents in
50+
markets

Sustainable
harvesting,
eco-friendly
& low-cost
processing

Sales to
450+
US facilities

2
GPO contracts
in place

Proven faster
healing:
30 publications
2 top-tier
clinical trials

Fast revenue
growth and
rapid market
expansion

3. Business Model

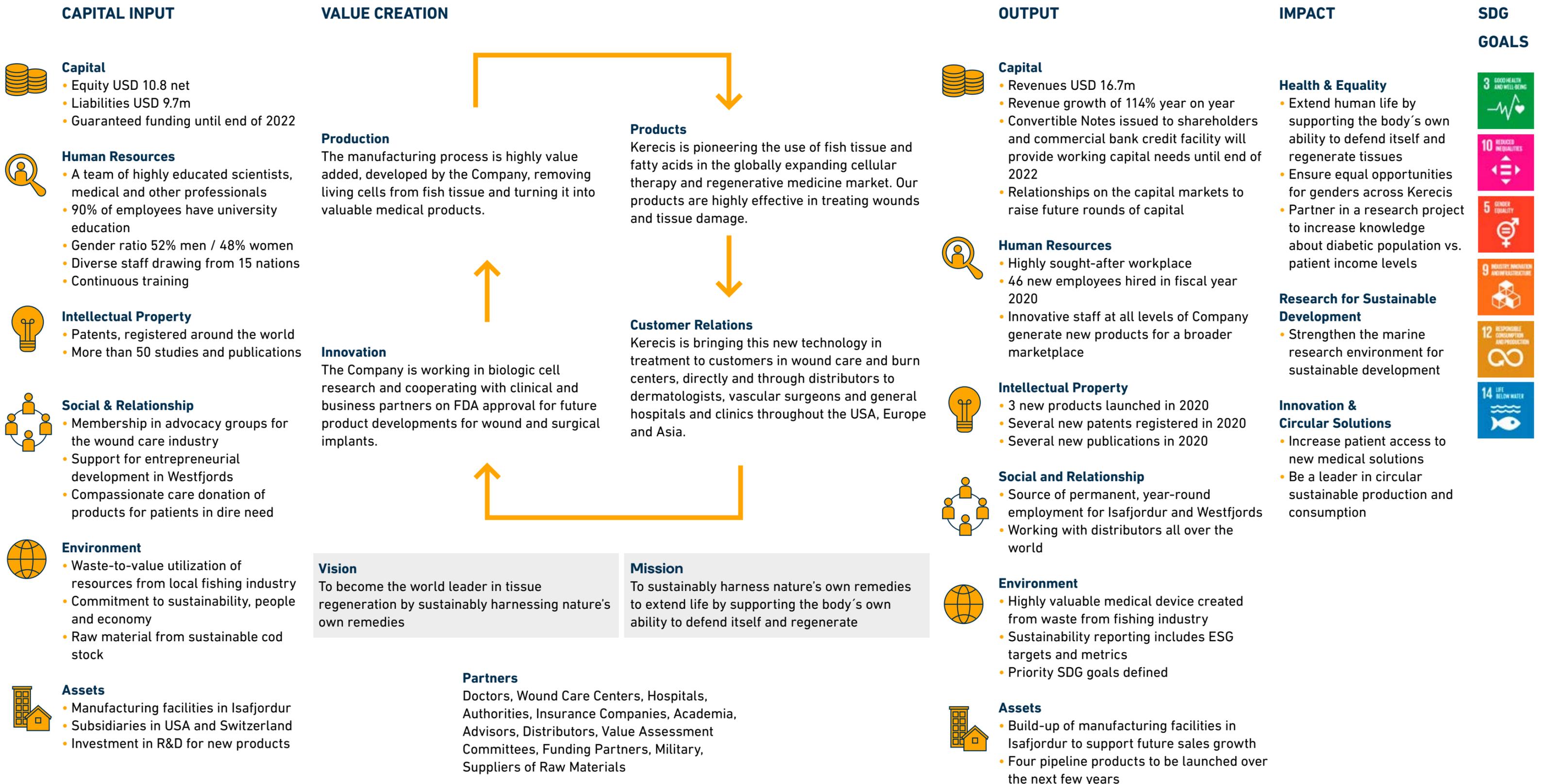


The Kerecis business model described in this Annual and Sustainability Report emphasizes sustainability and define reporting metrics that positively impact value creation and contribute beyond simple financial profit.

At Kerecis the development, manufacture and sale of a product is not the only value creation that takes place. Our business model allows the development of assets and capital that place independent value on human resources, intellectual property, social relationships, and natural resources.

The figure on the next page presents a more comprehensive overview of the resources at hand and how they are used to create value. The model encompasses more than the buying and selling of products and demonstrates in a transparent way how the business works, impacting our chosen SDGs.

Kerecis continues to optimize the Company's business model, clarifying and defining business elements such as customer engagement, activities, value propositions, partners and pricing. Each of these factors is included in our business model.



4. Corporate Social Responsibility



As with many progressive, innovative companies, Kerecis is expanding its traditional, financially focused reporting to include performance indicators that measure impact on the environmental and on social aspects.

With this addition, our stakeholder reporting is based on the following three pillars:

- Traditional economic reporting (Profit and Loss, Cash Flow and Balance Sheet)
- Environmental impact
- Social Impact

These three pillars are often referred to as “profit, people and planet,” or the “triple bottom line.”

This approach is very much symbiotic with the core purpose of Kerecis—to fully utilize natural resources in an innovative way to make products that restore the quality of life.

UN Sustainable Development Goals

United Nations Sustainability Development Goals (SDGs) help companies define and integrate sustainability into their core business. Kerecis has taken several steps in this direction, including:

- Establish the process of collecting and reporting on non-financial information, including environmental, social and corporate governance (ESG) data that are integrated into this report.
- Utilize the SDG framework to support this process, providing as it does a blueprint for industry, government and civil society to progress towards mutually sustainable goals.
- Integrating the targets and goals into its strategic operations.

Kerecis is using reporting frameworks as the guidance to publish its corporate social responsibility information and financial information in an integrated annual report.

The Company began this process in 2020 and seeks to document results and pursue new goals as it matures.



Process and framework

Kerecis utilizes the SDG framework to translate strategy to a broader sustainable development, providing priority opportunities to engage, unifying around common themes, as well as implementing measurements and indicators of progress.

Kerecis has selected six SDGs through which we believe the Company can have significant impact.

These goals are:

- Good Health and Well-being [SDG 3]
- Gender Equality [SDG 5]
- Industry Innovation and Infrastructure [SDG 9]
- Reduced Inequalities [SDG 10]
- Responsible Consumption and Production [SDG 12]
- Life Below Water [SDG 14]

These six goals have been grouped to three themes meant to characterize the area of focus and help sharpen communication around them, both inside and outside the Company. Management considers that Kerecis could contribute and support the priorities in

- Health & Equality
- Research & Sustainability
- Innovation & Circular Solutions

Kerecis recognizes that the business has impact on other SDGs, and we will continue to define targets, measurements and actions to support other SDGs.

The process is ongoing, and next steps will include introducing it to a variety of stakeholders. The intention is to seek input, conduct materiality analysis, explore what the business defines as important and listen to the stakeholder views. Materiality analysis benefits from broad input made by a group of stakeholders with diverse power and influence.

The Company recognizes that this approach requires time and constant improvement. Implementing the first SDG targets into its operations and strategic development is first step in this process.

Theme: Health & Equality

Kerecis focuses on three SDGs under the theme of Health & Equality:

- Good Health and Well-being [SDG 3]
- Gender Equality [SDG 5]
- Reduced Inequalities [SDG 10]

The Company's leadership is confident that it can have a significant positive impact on Good Health and Well-being [SDG 3]. The Kerecis mission, "To sustainably harness nature's own remedies to extend life by supporting the body's own ability to defend itself and regenerate," is closely interwoven with this SDG. Kerecis has an activity plan that establishes a number of targets and measurements to be more clearly refined by 2021. The activities will focus on increasing the number of wounds treated, the number of lives covered by insurance, and the number of regulatory applications submitted and approved. Even though these activities are already the core business areas of Kerecis, the goals and targets are going to be monitored and reported in a more transparent way than before.

The goal "Ensure equal opportunities for genders across Kerecis" supports SDG goal Gender Equality [SDG 5]. The objective is to define policies and drive initiatives that ensure equal opportunities for everyone affiliated with the Company regardless of gender. These include measures to ensure gender pay ratio per role and gender diversity at all levels.



Kerecis is in a strong position to make a positive impact on the Reduced Inequalities goal [SDG 10] by partnering with health-disparity groups to help make advanced technologies such as the Company’s products available to patients of all income levels. Kerecis products are used to a great extent to treat patients suffering from diabetic wounds, and the prevalence of diabetes is higher in African American communities than in many other population groups in the United States. Untreated, diabetic wounds can lead to amputations, which are known to shorten life span and therefore contribute directly to the lower life expectancy for this minority group. Kerecis seeks to help develop knowledge in this area so that more expansive use of its products may reduce this inequality.

PILLARS	KERECIS GOALS	KERECIS TARGETS	MEASURES	ACTION	SDG IMPACT
Health & Equality	<ul style="list-style-type: none"> The Kerecis mission is to sustainably harness nature’s own remedies to extend life by supporting the body’s own ability to defend itself and regenerate tissues 	<ul style="list-style-type: none"> Increase number of wounds treated Increase number of people that have access to Kerecis products Increase number of Regulatory approvals 	<ul style="list-style-type: none"> Wounds treated Lives covered Approved applications 	<ul style="list-style-type: none"> Activity plan 2021 Internal & external Training Enroll products on U.S. insurance schedules Run clinical trials in Europe supporting European insurance coverage Regulatory application efforts 	
Health & Equality	<ul style="list-style-type: none"> Ensure equal opportunities for genders across Kerecis 	<ul style="list-style-type: none"> Define policy for equal gender opportunities 	<ul style="list-style-type: none"> Per role gender pay ratio Gender diversity 	<ul style="list-style-type: none"> Equal pay certification Yearly policy review and communication to employees Gender training 	
Health & Equality	<ul style="list-style-type: none"> Partner with health-disparity groups to make advanced technologies available to patients of all income levels 	<ul style="list-style-type: none"> Define project structure, tasks and responsibilities 	<ul style="list-style-type: none"> Roll-out 	<ul style="list-style-type: none"> Project realization 2023 	

Theme: Research and Sustainability

Kerecis focuses on one SDG under the theme of Research for Sustainable Development:

- Life below Waters [SDG 14]

The Kerecis manufacturing facility sits in the Westfjords of Iceland, just 30 miles from the Arctic Circle. Its production relies on raw materials brought directly to shore by the fishing industry, on which life in the coastal villages of Iceland largely depends. The sustainable sourcing and use of resources are essential for the entire nation’s economy.

The goal “Strengthen the marine research environment for sustainable development,” will contribute to the SDG Life below Water through participation in cooperative marine impact groups such as the Arctic Circle and the Ocean Cluster.

PILLARS	KERECIS GOALS	KERECIS TARGETS	MEASURES	ACTION	SDG IMPACT
Research for Sustainable Development	<ul style="list-style-type: none"> • Strengthen the marine environment for sustainable development 	<ul style="list-style-type: none"> • Create awareness of marine health 	<ul style="list-style-type: none"> • Participation in marine impact groups 	<ul style="list-style-type: none"> • Track progress • By June 2022 identify relevant academic research partnerships, e.g. through the Arctic Circle and the Ocean Cluster 	



Theme: Innovation & Circular Solutions

Kerecis focuses on two SDGs under the theme Innovation & Circular Solutions:

- Industry, Innovation and Infrastructure [SDG 9]
- Responsible Consumption and Production [SDG 12]

The second Kerecis goal under the theme of Innovation & Circular Solutions is to “Be a leader in circular sustainable products and consumption.” The objective is to reduce waste and comply with sustainability standards by identifying opportunities to reduce the carbon footprint of its products. The Company has defined a specific pathway to develop procedures for waste measurement and disposal recycling in manufacturing by the close of fiscal year 2021.

PILLARS	KERECIS GOALS	KERECIS TARGETS	MEASURES	ACTION	SDG IMPACT
Innovation & Circular Solutions	<ul style="list-style-type: none"> • Increase patient access to new medical solutions 	<ul style="list-style-type: none"> • Introduce new products 	<ul style="list-style-type: none"> • New products added to portfolio 	<ul style="list-style-type: none"> • Product development and definition of opportunity ongoing 	
Innovation & Circular Solutions	<ul style="list-style-type: none"> • Be a leader in circular sustainable production and consumption 	<ul style="list-style-type: none"> • Reduce waste and comply to sustainable production standards • Identify opportunities in reducing footprint of the products • Certification on sustainable production 	<ul style="list-style-type: none"> • Improvement in waste management with positive impact 	<ul style="list-style-type: none"> • By 2021 develop procedures for waste measurement and disposal including recycling in factories and offices, 	

Stakeholder Engagement

Integrating sustainability into Kerecis strategy is, among other things, a means to add a new set of key performance indicators (KPIs) to its strategy. These indicators are mostly of a non-financial in nature, such as transparent governance, diversity, employee development and positive environmental impact. Integrating sustainability into corporate strategy has emerged as an accelerating trend in recent years, driven significantly by global warming, international political developments, and investor agendas. The term “stakeholder” has gained more clout as these expanded areas of value creation are influenced by more stakeholder groups than only the shareholders, owners and management.

Kerecis recognizes that responding to the needs of its stakeholders will determine its long-term success. With this in mind, the Company has identified its key internal and external stakeholders to build stronger relationships with both groups.

As the Company plans its next steps toward documenting, expanding and reinforcing sustainability, we will include conversations with employees, exploring their views towards the SDGs prioritized by the management team, and a comprehensive materiality analysis.

Environmental, Social and Governance Responsibility

Sustainability and social responsibility can influence a company’s long-term financial performance. Therefore, it is vital to provide necessary tools to integrate specific Environmental, Social and Governance (ESG) risks and opportunities into strategic plans and operational policies and procedures.

Since its inception, Kerecis has always respected social responsibility and sought to have a positive impact on the environment and society as a whole.

Kerecis is implementing policies, targets and measurements to further strengthen its responsibilities. This Annual and Sustainability Report presents the initial ESG aspects of the business.

Recognizing that integrating ESG throughout the core business takes time, Kerecis is dedicated to improving its data collection and reporting, using transparent and trusted information to enhance sustainability.

Kerecis Contribution to Environmental, Social and Governance Responsibility and the United Nations Sustainable Development Goals

The United Nations SDGs can be reviewed in the context of Kerecis through the themes of

- I. Environmental
- II. Social
- III. Governance

I. Environmental

Kerecis operates its production in the Westfjords region of Iceland, an area known for its commitment to environmental protection.

One of the Company's goals is to eliminate the production of its greenhouse gas (GHG) emissions. In this effort, we are establishing a structure to collect data related to the environmental aspects of its operations for future reporting on GHG emission and related KPIs.

The Greenhouse Gas Protocol (GHG Protocol) is the most widely used international accounting tool for quantifying GHG emissions. GHG Protocol Scope 1 includes direct emission from sources that are owned or controlled by a company, for example buildings and vehicles. Kerecis leases all of its vehicles and buildings, and its buildings in Iceland exclusively utilize geothermal and hydroelectric energy, which has zero direct emission. The Company is in the process of collecting data to be able to report further on direct emission from the production and indirect emission according to Scope 2 and Scope 3 of the GHG Protocol for all locations.

Kerecis has implemented the following Environmental Policy, which formulates the Company's future environmental strategy and supports the United Nations SDGs.

Environmental



- Kerecis has started the process of collecting data to be able to report on emission and related indicators
- Kerecis has implemented an Environmental Policy
- The managers of Kerecis are responsible for Climate Oversight
- The core of the business is focused on sustainability, and sustainability aspects are considered in all investments

This table shows the impact on the SDGs after analyzing the ESG Environmental indicators.



Kerecis Environmental Policy

Kerecis strives to become the world leader in tissue regeneration by sustainably harnessing nature's own remedies. In its pursuit of this mission, the Company creates life-saving value from waste as medical devices are produced from sustainably sourced fish.

Product Lifecycle

- Kerecis seeks to minimize and further reduce the environmental impact of its products throughout their lifecycle.
- The Company selects suppliers of its fish stock that carry the certification of the Marine Stewardship Council and/or Fisheries Iceland's Responsible Fisheries.
- Kerecis processes all materials in its products using 100% renewable energy.
- Clean waters are essential to the core mission of Kerecis and the success of its products. The Company complies with all applicable environmental laws in all countries in which operations take place.
- Kerecis promotes recycling at its manufacturing facilities and offices to reduce waste.
- For its products Kerecis seeks environmentally friendly packaging that also meets medical standards of sterilization, preserves shelf life and reduces waste.

Engagement

- Kerecis seeks to educate, train and motivate its employees to work and live in an environmentally responsible manner.
- Kerecis supports and participates in discussions about environmental issues and in particular about sustainability in the Arctic region.

Management reviews and introduces this environmental policy annually.



II. Social

The people of Kerecis, distributed across four countries, are the driving force behind the success of this global Company.

Established by an initially small, homogeneous group of entrepreneurs with backgrounds in the commercialization of medical devices, Kerecis has grown and evolved into a large, diverse group of employees with a wide range of specializations.

Kerecis provides a supportive and ambitious working environment that motivates its employees and encourages career development and vocational training.

The Kerecis Board of Directors and management are aware of the importance of equal opportunities and equal pay for all employees. Kerecis has taken steps to increase the proportion of women in leadership and management roles, supporting one of the priority SDG of the Company, Gender Equality.

Kerecis employed 62 men and 57 women in fiscal year 2020 across all its legal entities. At the executive level, men filled 10 positions, or 85 percent, and women filled 2 positions, or 15 percent. At the level of middle management, men hold 56 percent of entry and mid-level positions and women hold 44 percent. Kerecis defines “senior and executive level” as general manager or vice president and above. “Entry and mid-level” are defined as associate through director. Contractors and consultants are not included in these figures. Kerecis provides equal compensation for equal work and experience at every level in the Company.

Social



We mention

- Kerecis respects equal opportunities and gender diversity
- Kerecis employees are the core asset of the business with very few part time employees and few contractors and consultants
- Kerecis emphasizes employee lifelong learning
- Kerecis has a very strong anti-harassment and non-discrimination policy
- The workplace has been free of injury for over two years
- Kerecis is working on implementing Child & Forced Labor policy and Human rights policy

This table shows the impact on the SDGs after analyzing the ESG Social indicators.



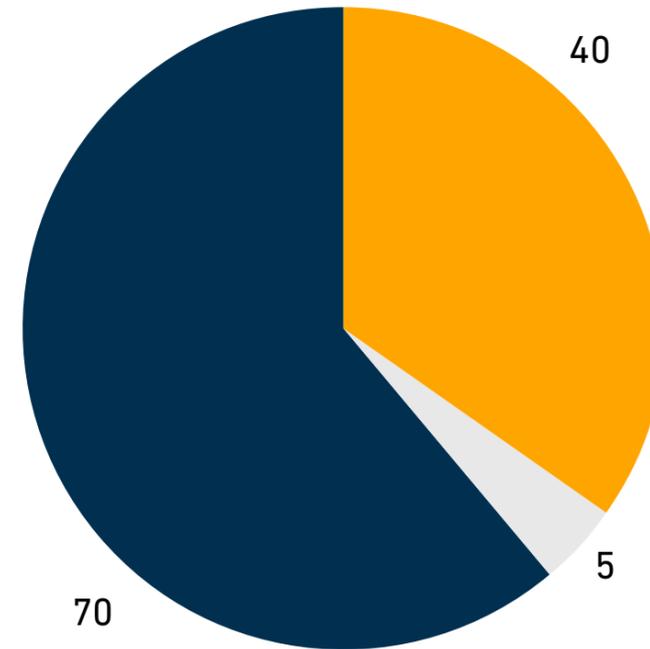
Full-time employees make up the majority of Kerecis staff, with only seventeen percent being temporary and approximately six percent working as contractors. The latter work on a project basis and do not have long-term contracts.

Kerecis offers equal opportunities to all employees and employment candidates. Kerecis does not tolerate discrimination in any form. All employment-related decisions, including those in the areas of recruitment, compensation and other terms of employment, training, advancement opportunities, and disciplinary action or termination are made without regard to color, race, ethnic or national origin, gender, age, marital status, sexual orientation, religious, political or ethical beliefs, disability or genetic information. In the United States, Kerecis adheres to standards set by the U.S. Equal Opportunity Employment Commission, a federal entity that protects workers from discrimination at work; the Americans with Disabilities Act, a law civil rights law that protects the rights of people with disabilities; and all other employment laws.

Kerecis maintains a strong anti-harassment policy that protects all its employees and prohibits harassment based on any characteristic protected by law.

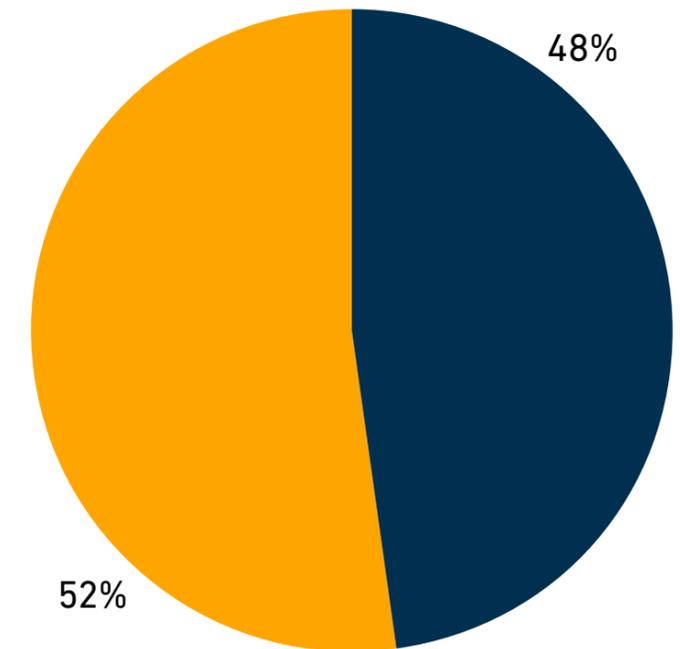


Employees by location 2020



- United States
- Iceland
- Europe

Employees by gender 2020



- Women
- Men

Employee countries of origin 2020

- | | | |
|-----------------|------------------|---------------|
| • Iceland | • Germany | • Switzerland |
| • Poland | • United Kingdom | • Iran |
| • United States | • Romania | • Portugal |
| • India | • Bosnia | • Spain |
| • Brazil | • Vietnam | • Ghana |

Global Health and Safety

Kerecis ensures that all its employees enjoy a safe and healthy workplace, whether it be in a Kerecis facility or in the field where employees travel to represent the Company. Kerecis operates in accordance with employment and labor laws in each country and in each state or local jurisdiction in which operations take place.

The Company does not tolerate child or forced labor. In the United States, the Fair Labor Standards Act, or FLSA -- a federal law -- includes child labor provisions that are designed to protect the educational opportunities of youth and prohibit their employment in jobs that are detrimental to their health and safety. Individual states also have laws covering youth employment.

In Iceland, Kerecis adheres to the employment regulations of the Act on Working Conditions, Hygiene and Safety at Work and its amendments.

In Switzerland, Kerecis adheres to the employment regulations of the Code of Obligations and the Labor Act.

Kerecis employees in the United States have access to an employee assistance program (EAP) offered by the Company through Guardian Insurance. The EAP offers a variety of services to promote well-being and help enhance the quality of life for U.S. employees and their families, at every stage of life. From family support, legal assistance, fitness, mental health resources, and work-related help, the EAP provides access to solutions and support for the challenges of daily living.

Kerecis posts monthly wellness information to all staff on topics that include flu vaccinations, diet, cardiovascular disease and the dangers of smoking.

Kerecis is aware of the risk of contractors working on its behalf or their sub-contractors not following regulation. We require contractors to adhere to the policies in our Employee Handbook, and its suppliers must comply with applicable law.

The primary supplier of fish for Kerecis products, Hradfrystihusid Gunnvor, is certified by Fisheries Iceland through the SAI Global Trust, Iceland Responsible Fisheries (IRF) Certification Program.

The anti-harassment and non-discrimination policy of Kerecis is founded on elements of human rights as protected by law and guided by the Company's core values of compassion and integrity. All employees at Kerecis are required to read and confirm receipt of the Anti-Harassment Policy and the Complaint Procedure. All employees participate in training in both the policy and the complaint procedure. In the United States, Kerecis adheres to the requirements of the U.S. Civil Rights Act of 1964 and all state laws. If there is a difference between the laws, Kerecis adheres to the more rigorous of the two. Employees in New York State, for example, participate in legally required interactive training to prevent sexual harassment.



III. Governance

The Kerecis corporate governance follows Icelandic, U.S. and Swiss corporate laws. The Company is domiciled in Iceland and all five board members are elected annually by the shareholders at the Annual General Meeting. The Board of Directors meets regularly. The Company strategy and financial plan proposed by management is discussed, revised and decided on by the Board annually. The Board monitors the Company's progress to implement the set strategy and financial plan through approximately eight board meetings during the year.

For fiscal year 2020 the board members were the following:

- G. Fertram Sigurjonsson, Founder and Chairman. Former Head of Wound Management at Össur and other medical device businesses with experience from startups and executive positions in established businesses.
 - J. Ernest Kenney,* retired patent attorney based in the Washington, D.C., area with extensive patent experience
 - Olafur Ragnar Grimsson, President of the Republic of Iceland from 1996 to 2016 and founder and Chairman of the Arctic Circle Assembly
 - Andri Sveinsson,* Partner and CFO of Novator Partners with extensive experience as board member in several listed and nonlisted companies
 - Franck Sinabian, President of Group GTF a French investment and healthcare business
- Mr. Sigurjonsson is the chairman of the board of Kerecis Limited, the Icelandic parent company. He is the “managing member” and Chief Executive Officer of Kerecis LLC, the 100 percent owned U.S. subsidiary of Kerecis Limited, where most of Kerecis operations take place. He is also the Chairman of Kerecis AG, the 100 percent owned Swiss subsidiary, and Chairman of the 100 percent owned Viruxal Ehf. subsidiary of Kerecis AG.

One member of the Board has direct ownership in the Company shares and three have indirect ownership in the Company shares. Four members of the Board are dependent board members and one is independent.

Governance



- Ethical business conduct is highly respected
- Kerecis is working on implementing formal Supplier Code of Conduct
- Formal Ethical and Anti-Corruption policy is being implemented
- Steps have been taken to implement a formal data policy and the EU GDPR rules
- Kerecis is reporting on the SDGs for the first time
- Sustainability data is worked on and provided according to international frameworks (Guidance followed: SDGs, IR, Nasdaq ESG and GHG Protocol)
- Kerecis is publishing its first annual report that contains substantial sustainability components
- Kerecis has started the journey of implementing ESG KPIs to their core business
- The Consolidated Financial Statement has external assurance

This table shows the impact on the SDGs after analyzing the ESG Governance indicators.

The Kerecis management team consists of the following:

- Chris Harte, Chief Operating Officer
- Stephen DiBiasio, Executive Vice President Commercial Operations
- Sveinn Andri Sveinsson, Chief Financial Officer
- Klara Sveinsdottir, General Manager Manufacturing & Delivery
- Gunnar Johannsson, Senior Vice President Research & Development
- Dora Hlin Gisladdottir, General Manger Viruxal
- Joseph Smith, Executive Vice President Customer Transformation

* Members of the board's subcommittee tasked with reviewing Mr. Sigurjonsson's compensation and expenses

Ethical Behavior

Kerecis expects all employees to conduct themselves and Company business in a manner that reflects the highest standards of ethical conduct, and in accordance with all federal, state and local laws and regulations. This includes avoiding real and potential conflicts of interest. Employees must take all practical steps to guard against fraud and corruption and ensure that Kerecis is, and is seen as, a company of the highest integrity. All employees are required to be honest and fair in their dealings on behalf of Kerecis and never to accept inappropriate gifts or payments or indulge in any other irregular practices.

Kerecis has implemented the related policy “Conflicts of Interest, Confidentiality & Gifts to U.S. Government Employees,” which is introduced to new hires and accessible to all employees. Failure to adhere to the terms of this policy is grounds for immediate termination. Kerecis requires participation in two training seminars on ethics: “Ethical Issues in Government Business” addresses the U.S. public (government) sector and is required for all employees—except manufacturing associates in the production facility—and “AdvaMed Compliance Training” for sales employees.

Kerecis has not yet implemented a specific Supplier and Vendor Code of Conduct.



5. Risk Management



The foregoing description and analysis of the Company's prospects are subject to a number of risks, some of which are foreseeable and others which are not. Below is a summary of the principal risks that the Company views as potential impediments to timely achieving its goals. There may be other material risks to the Company and its operations than those described below.

Risks Related to Liquidity and Capital Resources

- Although our financial statements have been prepared on a going concern basis, we must raise additional capital before end 2022 to fund our operations in order to continue as a going concern.
- Even if we are able timely to raise additional capital, such funds may not be adequate for our financial needs.
- We may not be able to refinance, extend, or repay our indebtedness owed to convertible note holders, which would have a material adverse effect on our financial condition.
- The borrowing base for our principal working capital line of credit is subject to certain limitations, which could result in a reduction to the amounts available under the line of credit.

Risks Related to Kerecis Business

- Operations in the United States represent a substantial portion of our existing and anticipated future revenues, and our success will largely depend on these future revenues.

- Revenues in the United States are dependent upon the performance of certain key sales personnel, the loss of whom could have a material adverse effect on our business.
- We depend on third-party suppliers for the supply of materials and processes for our products, which if disrupted, could result in a material adverse effect on our business.
- Our ability to design and manufacture new sizes and types of and indications for our products, including “fish skin version 2.0”, will be critical to the long-term success of our business.
- A material portion of our business depends on the growth of biologic wound treatment as the standard of care in the United States and the rest of the world (ROW), which if disrupted by new technology could result in a material adverse effect on our business.
- New technologies could render our existing products obsolete.
- The market for our current and future products in the ROW may never develop or may take longer to develop than anticipated, which could have a material adverse effect on our operations.
- We may not be able to identify adequate distribution partners in ROW, or those partners may not be able to market our products effectively or acceptably.
- Regulatory requirements and approvals for new products could be delayed.
- Clinical trials necessary to support governmental reimbursement in the United States and Europe for new indications and products may be subject to delays, cancellations, adverse results, or other failures.
- Governments may decide not to reimburse doctors and hospitals for the cost of our product, which could have a material adverse effect on our sales.
- Governments may change reimbursement levels to doctors and hospitals for our products, which could render the product less attractive, and we could lose sales and market share.
- We do not have experience in manufacturing the projected required volumes of product.
- Failure to meet necessary demand may have adverse financial consequences under certain supply agreements.
- We may not meet our product development and commercialization milestones, which could result in the need for additional funding and which could adversely affect our competitiveness in various markets.
- Our business may be subject to product liability claims or product recalls, which could be expensive and could result in a diversion of management’s attention.
- Our business may become subject to changing governmental regulations, which may impair our ability to market our products.
- Fluctuations in the currencies in which we transact business could have a material effect on our business and operations.
- Past acquisitions and any future acquisitions, equity investments, joint ventures, strategic alliances (upon which we may be relying for the commercialization of some of our future products) or other similar transactions may not be successful.
- We currently face and will continue to face significant competition.
- We depend on our intellectual property, and our failure adequately to protect that intellectual property could adversely affect our future growth and success.
- Our business could suffer if we fail to attract and maintain key personnel.
- While we believe we are adequately insured, existing insurance may not be sufficient for unforeseen or unanticipated future events.
- We could experience other unforeseen or unanticipated business setbacks, production problems, loss or damage to products and manufacturing or other equipment, or personnel problems.

6. Key Financials



The Kerecis fiscal year starts **October 1** and ends **September 30**. The consolidated Income Statement show continuous growth and improved operating results from the prior year.

Sales growth in recent years is driven by the growth of the direct sales team in the United States as further addressed in the Business Performance section.

As production increases, Kerecis benefits from economies of scale and is able to lower the cost of goods and services (COGS). At the same time, new equipment is installed in the factory that automate processes and contributes to lower COGS.

During fiscal year 2019 the Kerecis put more effort and investment into direct sales and marketing in the United States. This increased the loss for that year, but as the returns from direct sales have increased, and as the costs of sales and marketing have declined as a percentage of sales revenue, economies of scale have favorably affected the Company's operations in 2020. As sales continues to increase, this ratio is expected to continue to decrease, which is the basis for profitability.

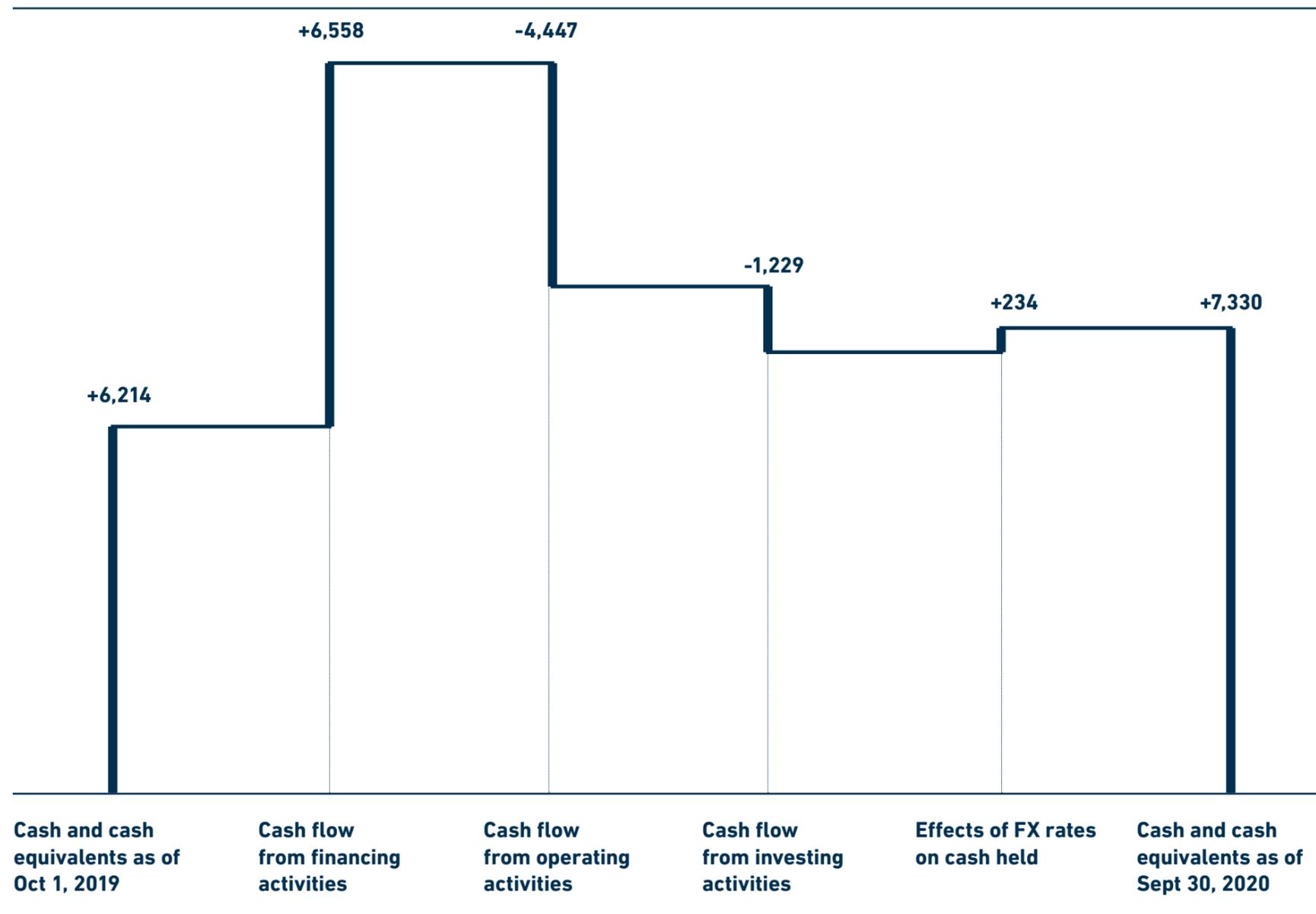
Rapid revenue growth requires working capital funding for receivables and inventories. In 2020, the Company issued convertible notes to its shareholders in the amount of USD 4.5 million, as well as securing funding from other parties. This included a credit

facility with Silicon Valley Bank in the amount of USD 10 million with an extension option of up to USD 15 million. This financing is expected to service the projected working capital of the Company until late calendar year 2022. Forecasts project cash-flow positive operations in 2023.

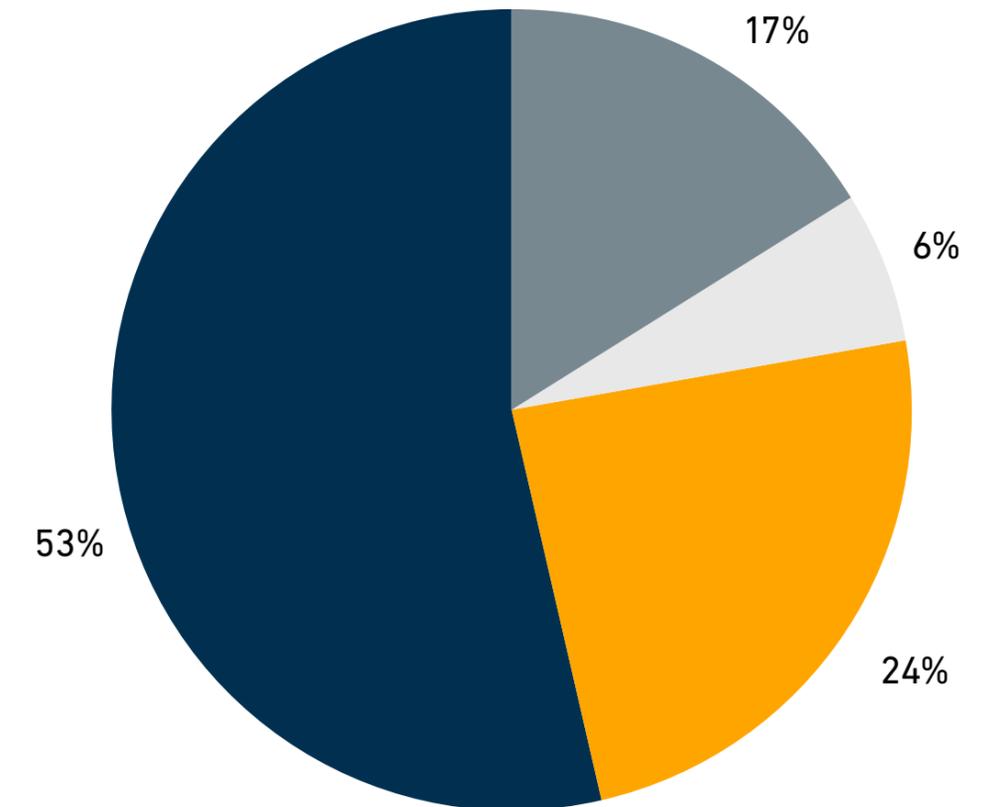
Kerecis has capitalized product development costs over the years. This includes both the Omega3 Wound development as well as development cost relating to i. extension of the wound platform for deeper penetration into the wound-care markets, as well as ii. diversification into other medical markets. The capitalized development cost is amortized from the time the product is available for sale.

Cash Flow in 2020

USD thousand



Financing of Kerecis as of September 30, 2020



- Equity
- Convertible bonds
- Other borrowings
- Current liabilities

Consolidated Income Statement

For the period Oct. 1, 2019 – Sept. 30, 2020

	Oct. 1, 2019 – Sept. 30, 2020	Oct. 1, 2018 – Sept. 30, 2019
Net sales	16,671,953	7,768,970
Cost of goods sold		
Manufacturing	(1,401,426)	(927,944)
Capitalized inventory increase	328,330	129,261
Gross profit	15,598,857	6,970,287
Other income	1,540,720	489,397
Sales and marketing	(14,691,934)	(10,305,230)
General & administrative	(3,070,566)	(3,071,262)
Research & development	(2,281,672)	(1,746,226)
Loss before capitalized development cost and depreciation	(2,904,595)	(7,663,034)
Capitalized development	790,719	1,311,085
EBITDA	(2,113,876)	(6,351,949)
Depreciation and amortization	(690,151)	(566,743)
Operating loss	(2,804,027)	(6,918,692)
Financial income	355,505	822,644
Financial expenses	(147,982)	(734,826)
	207,523	87,818
Loss for the period	(2,596,505)	(6,830,874)

Consolidated Balance Sheet

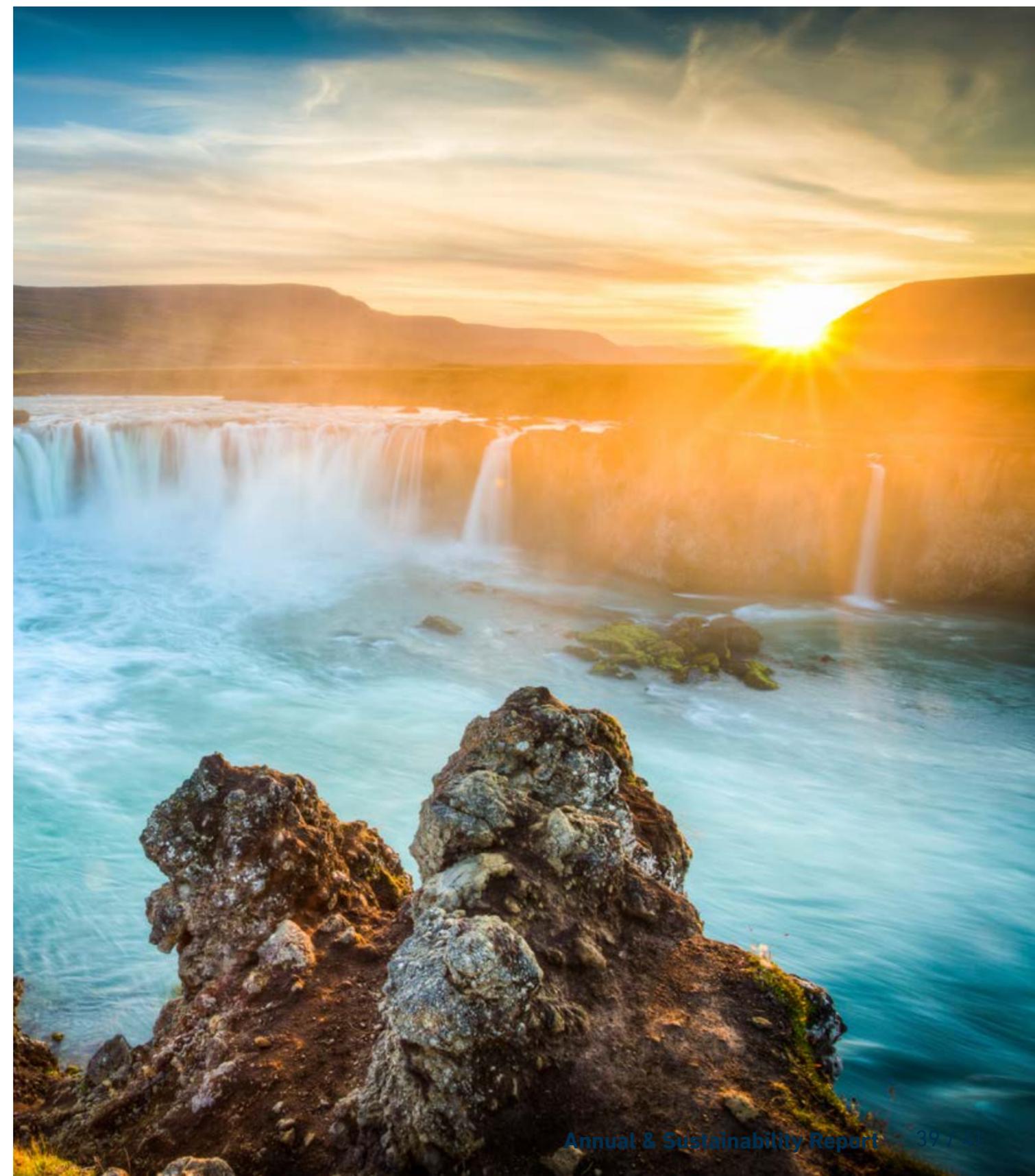
At Sept. 30, 2020

Assets	Sept. 30, 2020	Sept. 30, 2019
Non-current assets		
Goodwill	53,213	55,478
Capitalized development cost	5,041,368	5,110,162
Property, plant and equipment	673,444	350,221
	5,768,025	5,515,861
Current assets		
Inventories	1,499,431	920,118
Trade and other receivables	5,999,489	2,775,542
Cash	7,330,646	6,214,162
	14,829,566	9,909,822
Total assets	20,597,591	15,425,683
Equity and liabilities		
Equity		
Share capital	57,982	57,316
Share premium	30,472,044	30,052,513
Translation difference	(1,166,535)	(530,900)
Accumulated deficit	(18,519,797)	(15,923,292)
Total Equity	10,843,694	13,655,637
Non-current liabilities		
Borrowings	562,971	0
Convertible bonds	4,918,969	0
	5,481,940	0
Current liabilities		
Trade and other payables	3,503,069	1,770,046
Current maturities of borrowings	768,888	0
	4,271,957	1,770,046
Total liabilities	9,753,897	1,770,046
Total equity and liabilities	20,597,591	15,425,683

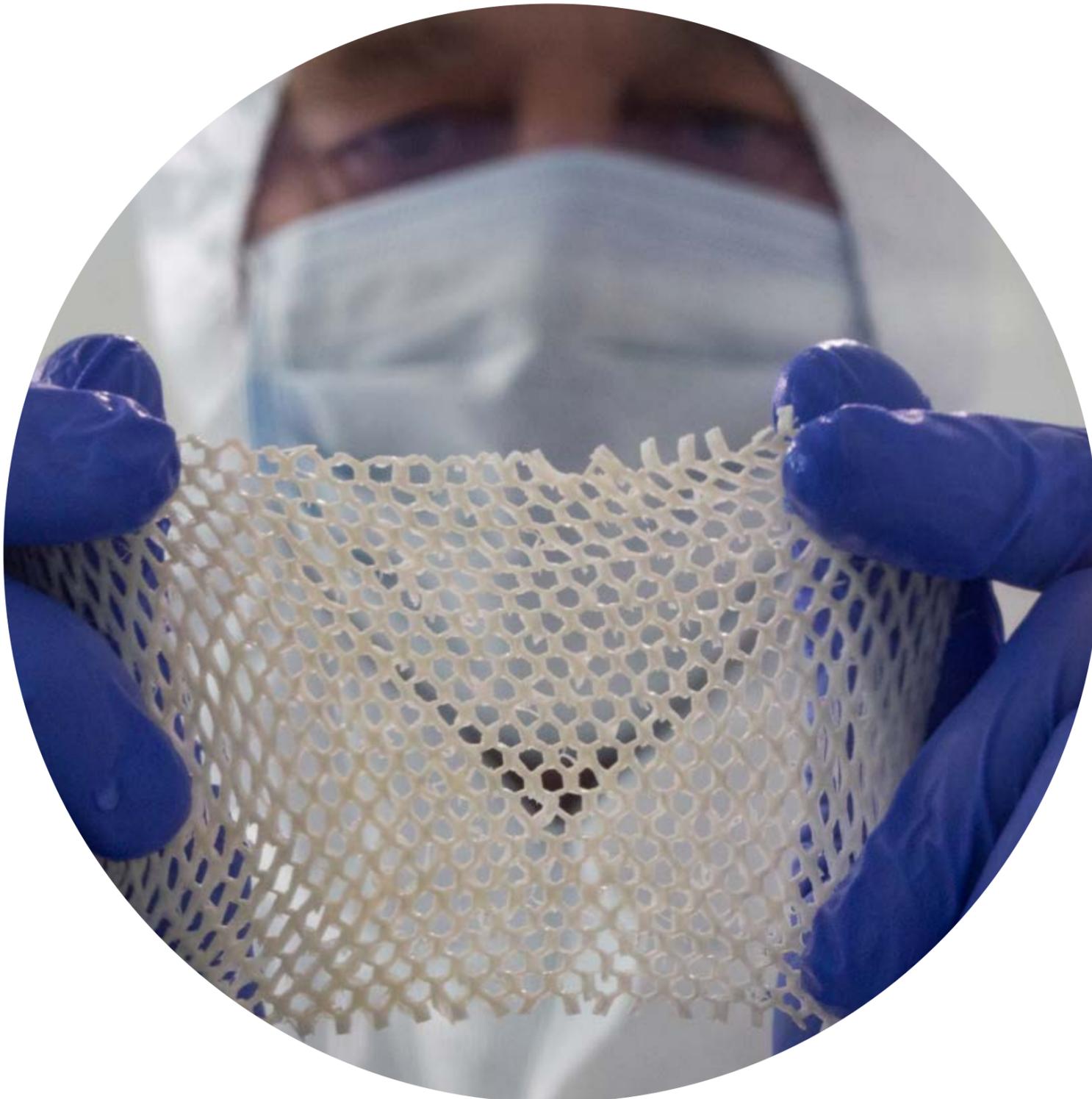
Consolidated Statement of Cash Flows

For the period Oct. 1, 2019 – Sept. 30, 2020

	Oct. 1, 2019 – Sept. 30, 2020	Oct. 1, 2018 – Sept. 30, 2019
Operating activities		
Operating loss	(2,804,027)	(6,918,692)
Depreciation and amortization	690,151	566,743
Operating cash flow before movem. in working capital	(2,113,876)	(6,351,949)
Inventories, (increase)	(579,313)	(513,136)
Operating assets, (increase)	(3,411,678)	(922,630)
Operating liabilities, increase	1,623,408	1,015,196
Cash generated to operating activities	(4,481,459)	(6,772,519)
Interest received	83,782	30,440
Interest paid	(49,224)	(53,789)
Net cash to operating activities	(4,446,901)	(6,795,868)
Investing activities		
Purchases of property, plant and equipment	(443,220)	(289,999)
Disposal of property, plant and equipment	5,008	0
Capitalized development cost	(790,719)	(1,319,609)
	(1,228,931)	(1,609,608)
Financing activities		
New borrowings	1,326,180	0
Proceeds on issuance of convertible bonds	4,811,751	0
Proceeds on issuance of new equity shares	420,197	12,028,343
	6,558,128	12,028,343
Net increase in cash	882,296	3,622,867
Cash and cash equivalents at beginning of period	6,214,162	2,665,076
Effect of foreign exchange rates on cash held	234,188	(73,781)
Cash at period-end	7,330,646	6,214,162



7. Corporate Information



Iceland

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Email: info@kerecis.com

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Email: info@kerecis.com

Switzerland

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Phone: +41 43 499 15 66
Fax: +41 43 499 15 67
Email: support@1wound.info

Kerecis Limited is registered as an hf. entity in Iceland. Kerecis LLC is a limited liability company in the United States. Kerecis AG is a company organized under the laws of Switzerland.

8. Disclaimer

This Annual & Sustainability Report includes certain statements, estimates, and projections with respect to the anticipated future performance of the Company (“Forward-looking Statements”). Such statements, estimates and projections reflect various assumptions by the Company and are subject to significant business, economic, and competitive uncertainties, and contingencies, many of which are beyond the control of the Company. The Company does not make any representations as to the accuracy or completeness of such statements, estimates, and projections or that any forecasts will be achieved. The estimates and projections presented herein and actual results will likely vary, and those variations may be material.



OUR VISION

To become the world leader
in tissue regeneration by
sustainably harnessing
nature's own remedies

KERECIS REIMBURSEMENT HOTLINE

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**FDA approved, U.S. and international
patents and trademarks granted and
pending.**

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