



XVIVO PERFUSION ACQUISITION OF ORGAN ASSIST B.V.

September, 2020

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Today's presenters



**DAG
ANDERSSON**
CEO | 2020

Selected experience

- CEO at Diaverum AB
- Various positions at Mölnlycke Health Care
- Controlling & Logistics at SKF



**CHRISTOFFER
ROSENBLAD**
CFO | 2012

Selected experience

- Head of Business Planning and Analysis at Ciba Vision
- Various positions at LG Electronics



**“NOBODY SHOULD
DIE WAITING FOR A
NEW ORGAN”**



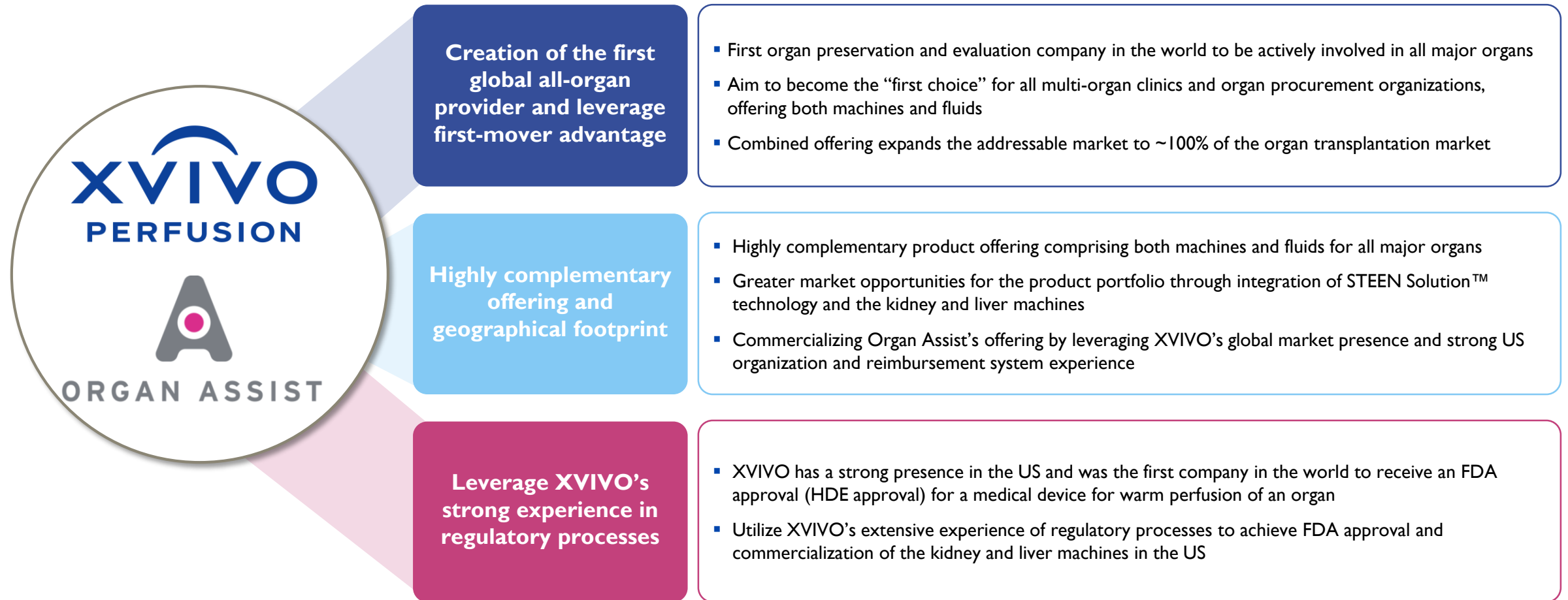
TODAY'S AGENDA

1. Acquisition of Organ Assist

2. Supplementary materials

3. Risk factors

Highly compelling strategic rationale forming a global all-organ provider



Note: All-organ provider refers to solid organs: lungs, heart, kidney and liver.

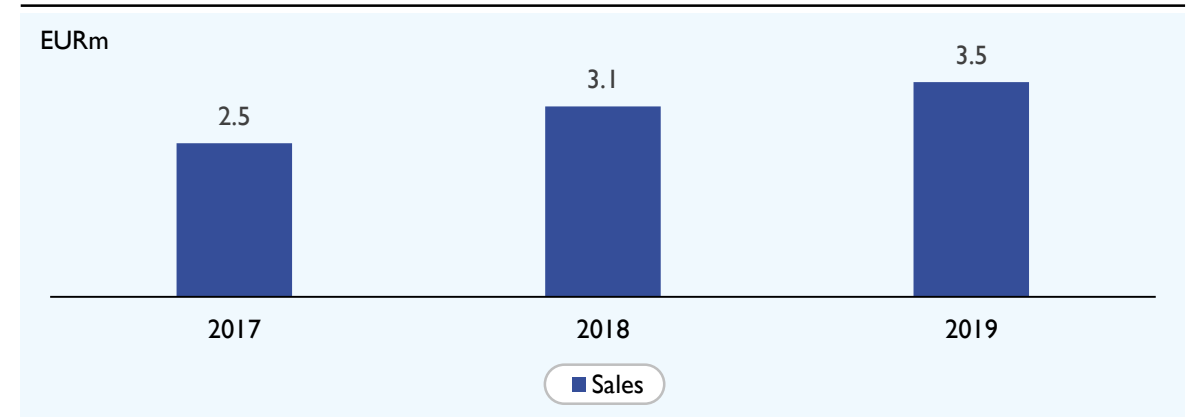
Source: Company information.

Organ Assist is a provider of proprietary perfusion solutions

Organ Assist overview

- History dates back to 2005 when Organ Assist B.V. was founded by two medical scientists who, after six years of dedicated academic research, had developed and refined a liver perfusion pump
- Headquartered in Groningen, the Netherlands with 18 employees
- All the perfusion machines consist of at least one (or more) pump unit(s), for most devices a thermo unit and a work bench/trolley
- The most important feature of all devices is that they allow for true oxygenated perfusion
- Key devices clinically proven by randomized clinical trials

Revenue development (EURm)⁽¹⁾



Solutions offering based on proprietary technology



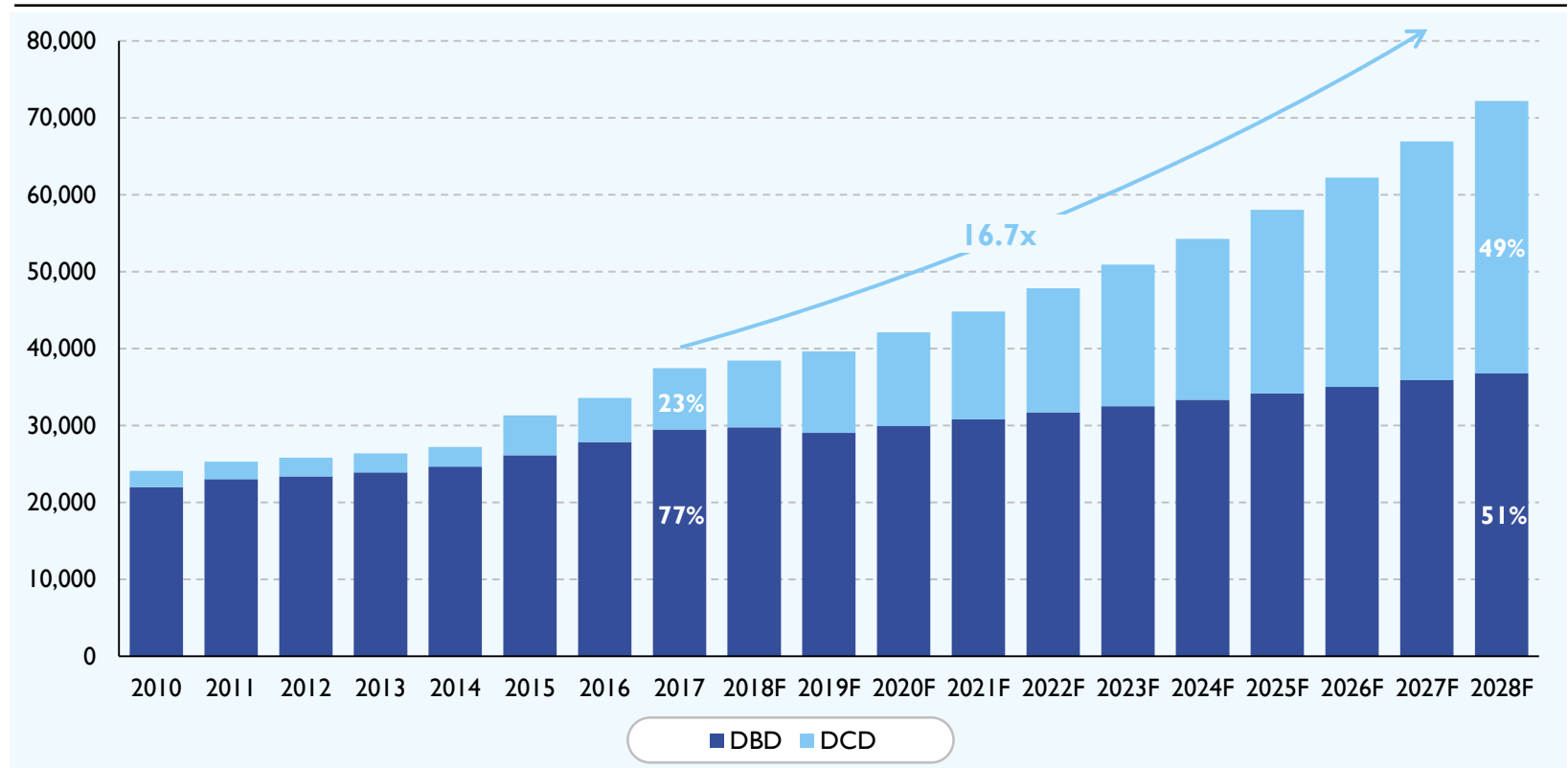
1) According to Dutch GAAP.

Donation trends support the rationale of acquiring machine knowledge

Main trends

- Main trends 2010 – 2017
 - In 2017: ~35,000 donations
 - Overall donation growth: ~5% p.a.
 - Donation after Circulatory Death growing ~19% p.a.
 - Donation after Brain Death +3% p.a.
- Main trends estimated until 2028
 - Donation after Brain Death estimated to grow ~3% p.a.
 - Donation after Circulatory Death estimated to grow ~14% p.a.

Source of donation development (2010 – 2028F)



An increased DCD portion expected to lead to an **increased need of machine perfusion and warm evaluation** of donated organs

1) DCD: Donation after Circulatory (=Cardiac) Death.

Data is number of dead donations. Source: 2010 – 2017 GODT and 2018 – 2028F Company analysis.

Best in class products to meet the DCD increase in donations

Warm perfusion – New technology



XPS™
The flexible comprehensive EVLP platform



XVIVO LS™ & XVIVO DISPOSABLE LUNG SET™
Provides a method for evaluating lungs by EVLP



XPS DISPOSABLE LUNG KIT™
Convenient, reliable, sterile accessories

Accessories



STEEN SOLUTION™
For reliable objective assessment of “marginal” and rejected lungs

Unique and patented product




XVIVO ORGAN CHAMBER™
Single use, sterile disposable container




XVIVO LUNG CANNULA SET™
Single use, sterile disposable product

Cold perfusion – Traditional technology



PERFADEX PLUS®
The gold standard in lung preservation made ready-to-use


Unique and patented product



XVIVO SILICONE TUBING SET™
For perfusion and donor lung procurement


Organ Assist's offering






KIDNEY TRANSPORT
First generation Kidney Transport device is CE-marked


Newly developed Kidney Transport device pending CE-mark and 510k regulatory file to be submitted



LIVER ASSIST
CE



LUNG ASSIST
CE



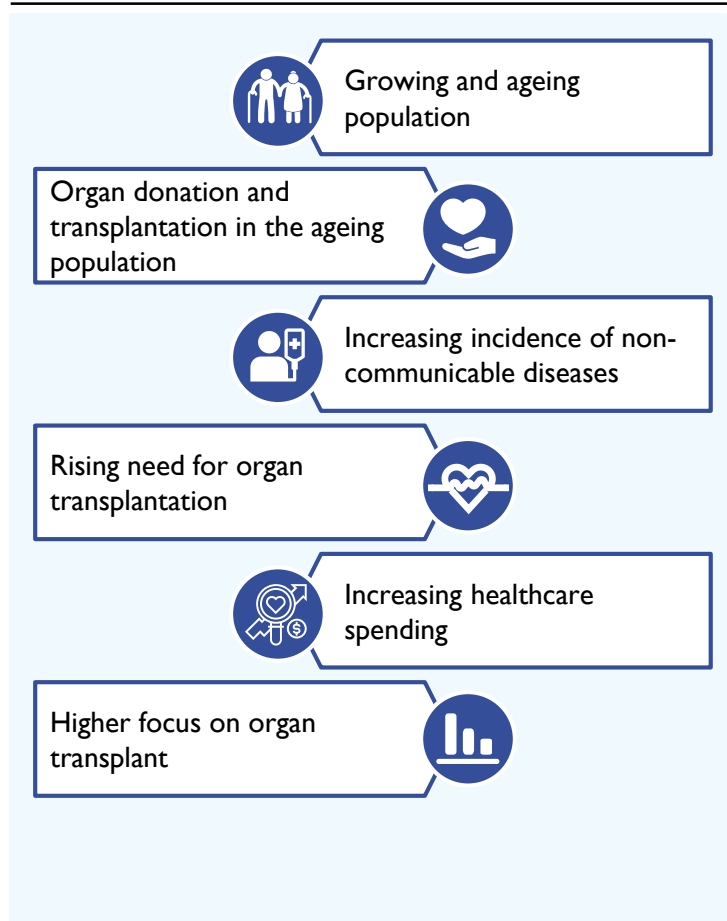
KIDNEY ASSIST
CE

The combination of XVIVO and Organ Assist technology can better preserve and evaluate organs to increase the number of organs used for transplantation

Source: Company information.

Following the acquisition XVIVO addresses ~98% of the market

Market drivers

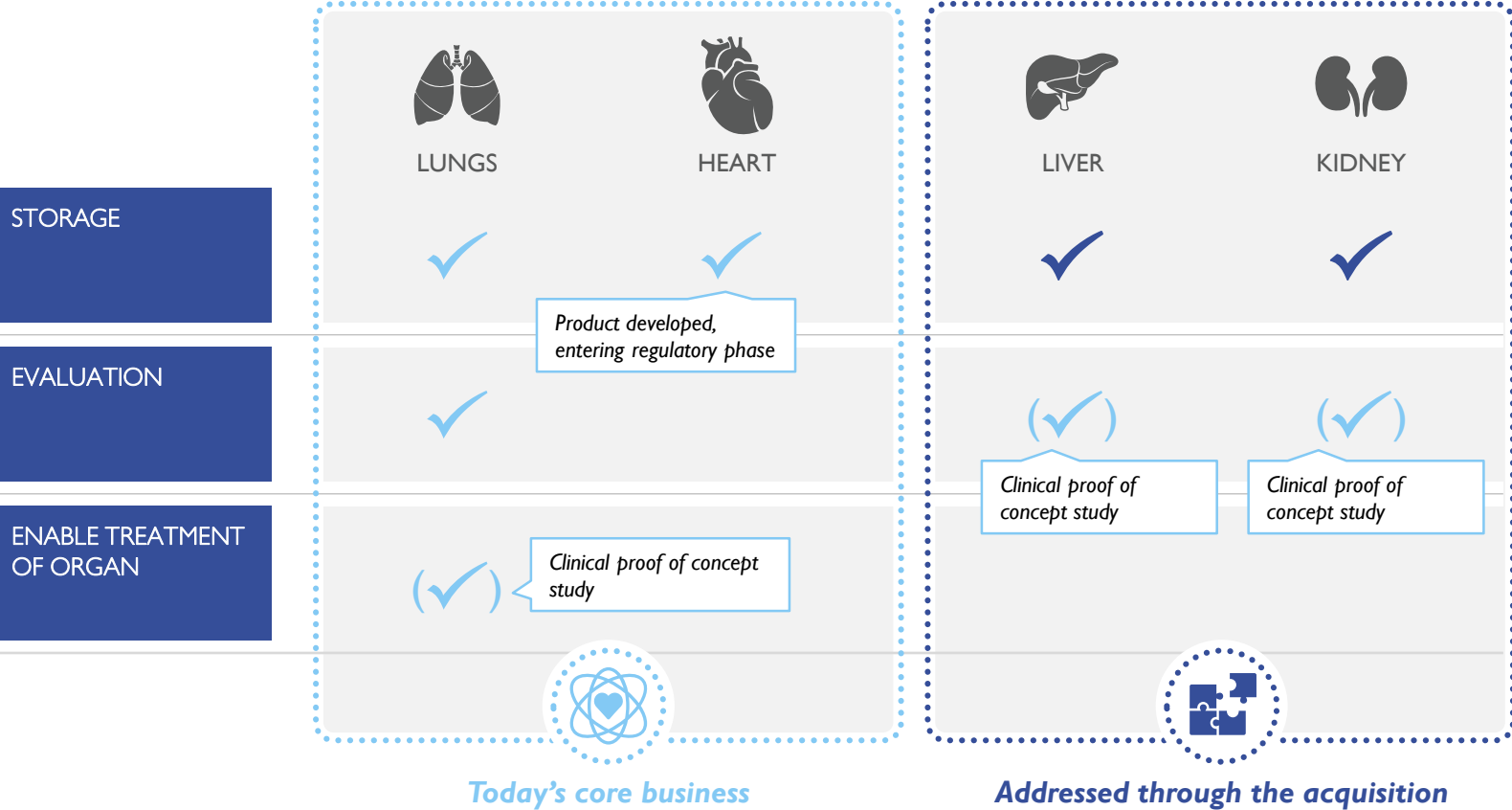


145,000 organs transplanted in 2018, and global market is expected to grow 5-7% p.a.



Source: Company information.

Unique position with presence in all major organs



Leverage strong position within lung transplantation to address the significant multi-organ opportunity

Source: Company information.

Key transaction features

Rationale	<ul style="list-style-type: none">▪ Creation of the first global all-organ provider and leverage first-mover advantage▪ Highly complementary offering and geographical footprint▪ Leverage XVIVO's strong experience in regulatory processes
Synergies	<ul style="list-style-type: none">▪ Sales synergies from bundling of the STEEN Solution™ technology and Organ Assist's liver and kidney warm perfusion machines▪ Limited cost synergies due to limited overlapping business within the field of thorax transplantations (lungs and heart)
Structure considerations	<ul style="list-style-type: none">▪ XVIVO Perfusion AB (publ) ("XVIVO") intends to enter into an agreement to acquire 100% of the shares in Organ Assist B.V. ("Organ Assist") (the "Transaction")▪ The purchase price amounts to up to EUR 24 million (Enterprise value)
Acquisition considerations and financing	<ul style="list-style-type: none">▪ Cash consideration of up to EUR 24 million, divided into upfront consideration of EUR 20 million, and milestone payments of up to EUR 4 million related to sales and regulatory approvals in the US▪ To be financed through directed share issue of primary shares to institutional investors
Conditions	<ul style="list-style-type: none">▪ Closing of the transaction is conditional upon financing
Timetable	<ul style="list-style-type: none">▪ Signing of SPA tentatively planned September 23, 2020▪ Closing expected in October 2020

Note: All-organ provider refers to solid organs: lungs, heart, kidney and liver.

Use of proceeds

- financing of the acquisition of Organ Assist B.V.;
- funding the FDA (US Food and Drug Administration) 510k⁽¹⁾ regulatory approval process in the US of Organ Assist's Kidney Assist Transport device;
- funding the regulatory approval processes of the Liver Assist in combination with the STEEN Solution™ technology in the US and other key markets; and
- continue to build and strengthen the organization to support the Company's growth strategy and for general corporate purposes

1) A 510k is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, equivalent, to a legally marketed device.

FDA: Food and Drug Administration; CFDA: the China Food and Drug Administration; TGA: Therapeutic Goods Administration; PMA: Premarket Approval Application.

Key investment highlights



1. World leading in lung transplantation with established network in thoracic surgery

→ XVIVO Perfusion is a strong global brand in lung transplantation and market leader in both cold preservation and warm perfusion of donated lungs



2. Focus on becoming a global all-organ provider

→ With the acquisition of Organ Assist, XVIVO takes the first step of becoming a global all-organ provider



3. Experts in advanced solutions for transplantation

→ Together with Igelösa Life Science and Professor Stig Steen XVIVO has for more than 20 years developed unique solutions to take care of organs outside the body



4. Profitable growth

→ Consistent growth and positive EBITDA every quarter since the share was listed in October 2012, apart from Q2 2020 due to extraordinary Covid-19 pandemic



5. Enhanced commercialization focus based on successful track-record of innovations

→ New organization to drive commercialization and time to market

Note: All-organ provider refers to solid organs: lungs, heart, kidney and liver.

Source: Company information.

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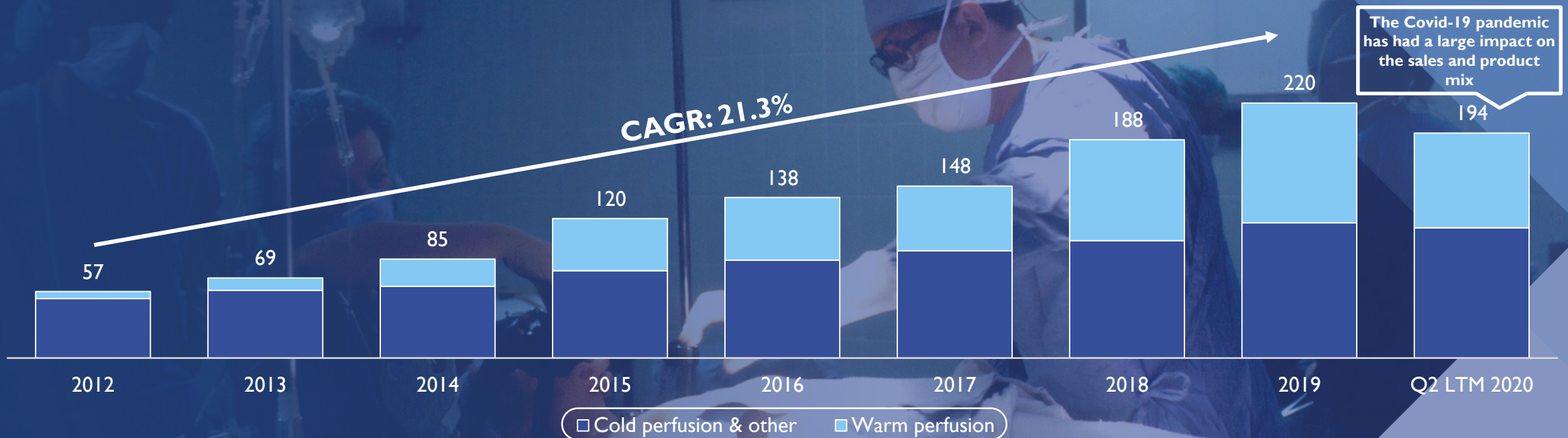
3. Risk factors

Proven platform ready for transformation

Building XVIVO and global regulatory approval on the warm perfusion product pipeline

Strengthen the product pipeline and build key account management, technical advisors / product specialists in the US and EU

Develop the next generation solution for warm perfusion and broaden the use of STEEN Solution™ to evaluation of livers and kidneys

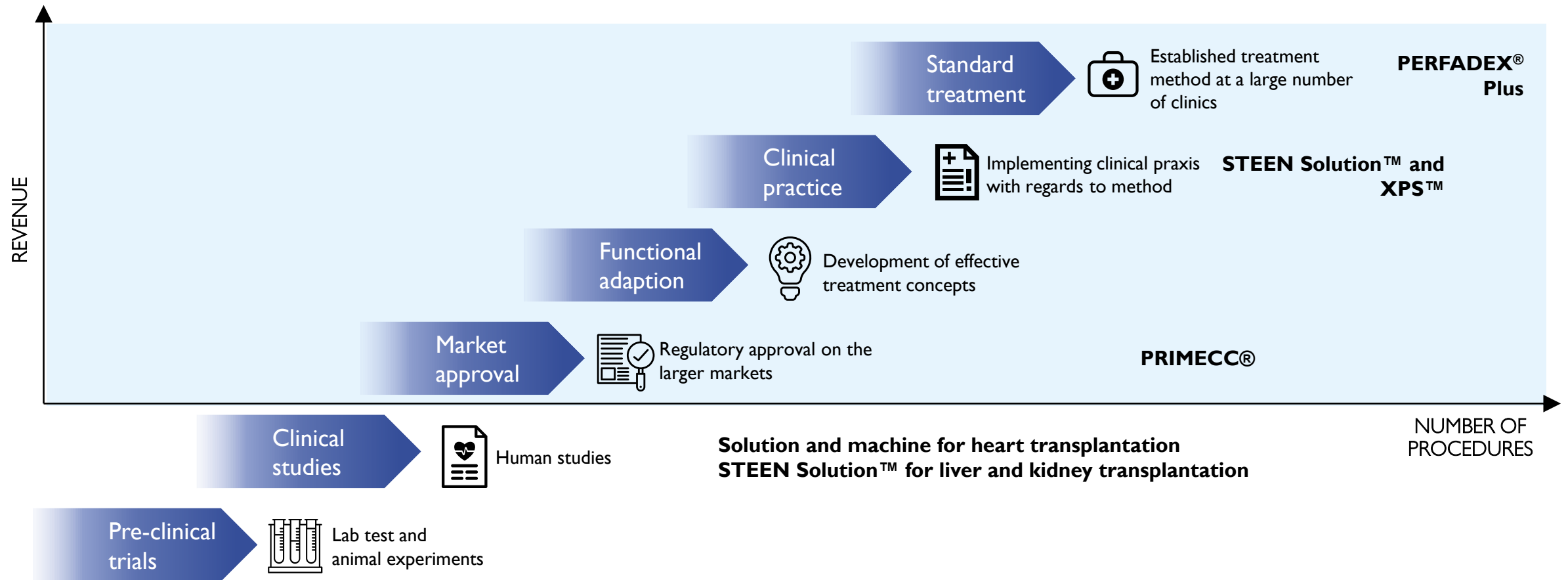


Close relationship with Igelösa Life Science has generated breakthrough solutions

Net sales in SEKm.

Source: Company information.

Pipeline targeting multiples organs⁽¹⁾

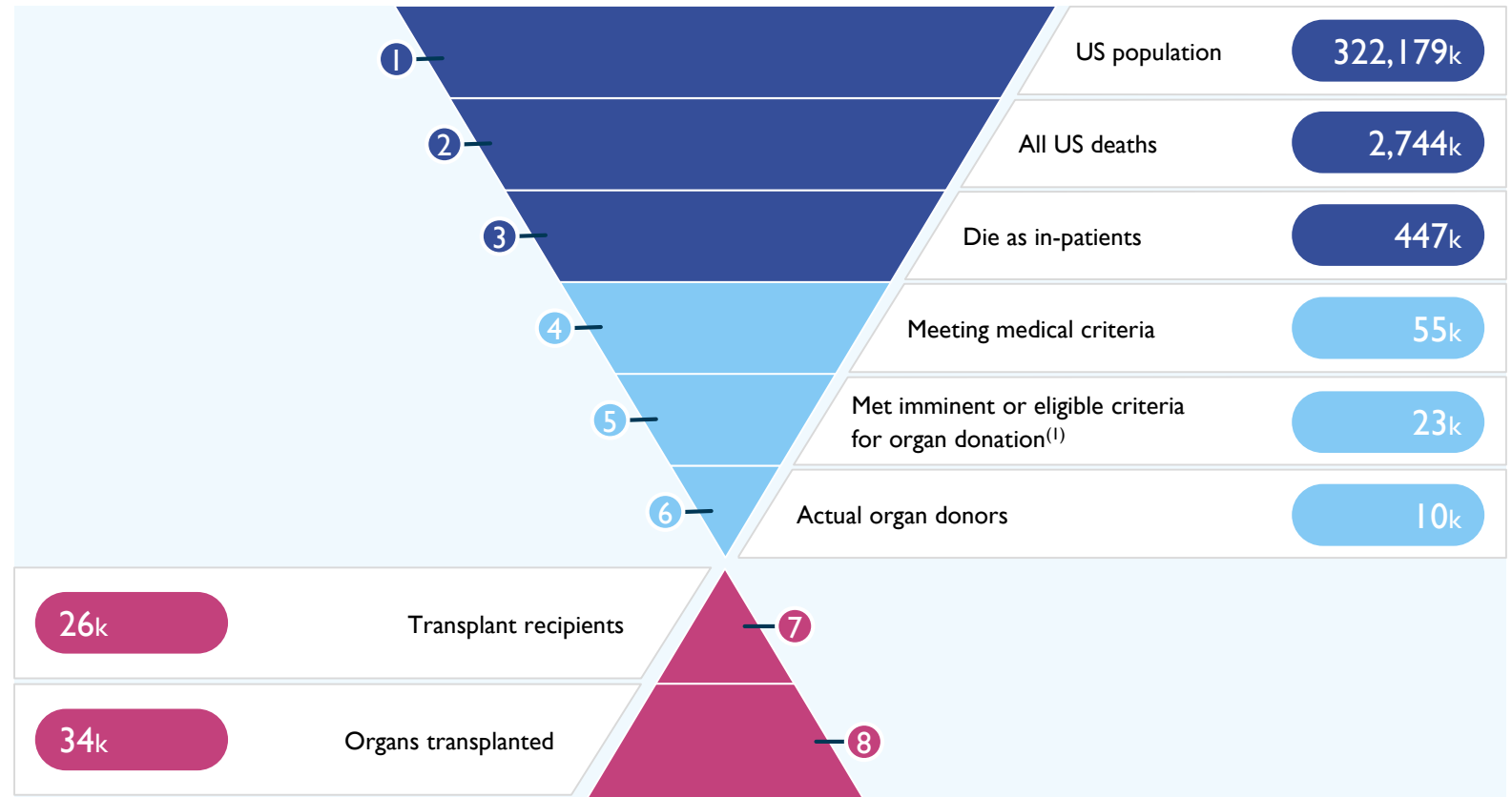
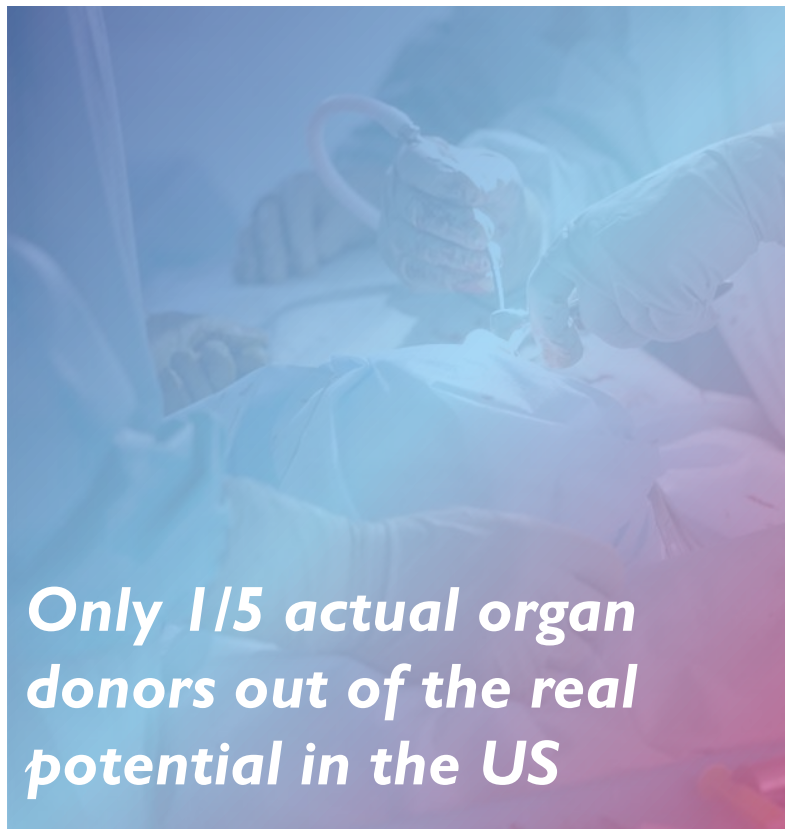


Compelling market position with promising late stage pipeline

¹⁾ Medical Device Class III.

Source: Company information.

Transplantation is a supply-constrained market



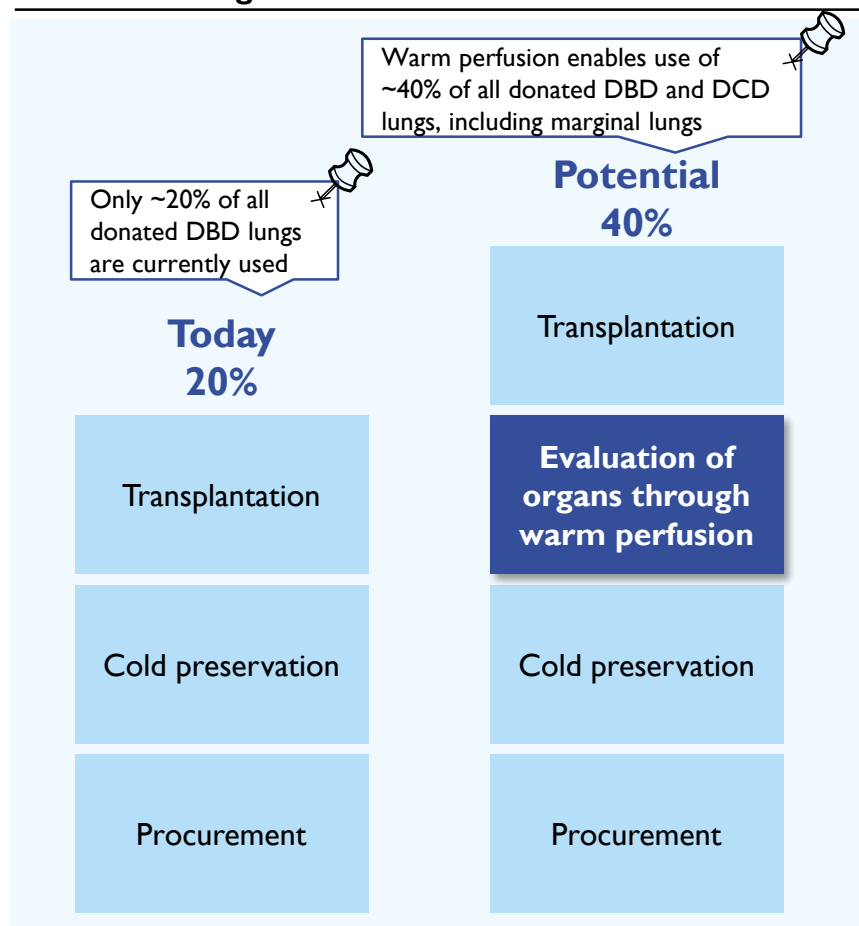
There are changes related to policy, regulatory and practice to encourage organ procurement and transplantation of a broader population

1) Imminent deaths are a subset of potential donors for whom brain death has not been declared, but the patient shows signs consistent with brain death. Eligible deaths represent patients who have been declared dead in accordance with state and local laws and have no exclusionary criteria as defined in current OPTN Policy.

Source: OPTN Annual Report; The OPTN Deceased Donor Potential Study: Implications for Policy and Practice, *Am J Transplant*. 2016 Jun, 16 (6); Scientific Registry of Transplant Recipients; Washington Post.

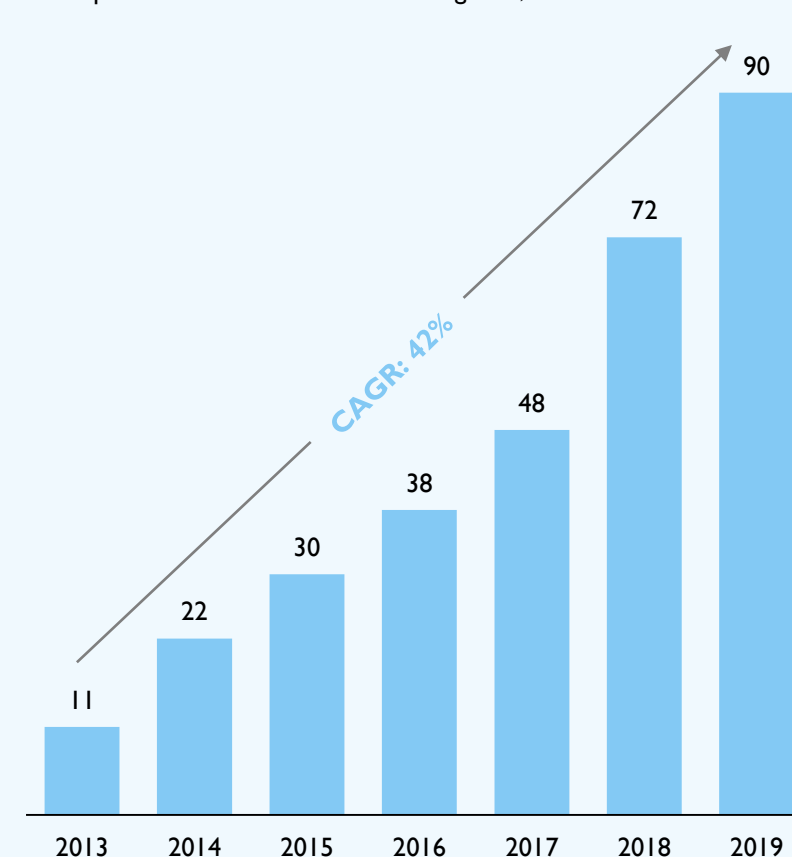
XVIVO's warm perfusion technology increases number of available lungs

Warm perfusion has the potential to double the number of available lungs⁽¹⁾



Strong development in XVIVO warm perfusion sales

Warm perfusion sales excl. non-durable goods, SEKm⁽¹⁾



DBD: Donation after Brain Death; DCD: Donation after Circulatory (or Cardiac) Death; Marginal lungs: Lungs that were initially considered not to be possible to transplant.

1) According to the Company's assessment; (2) Warm perfusion sales excluding non-durable goods are STEEN Solution™ and other sterile input goods used in each lung evaluation. Source: Company information.

TODAY'S AGENDA

1. Acquisition of Organ Assist

2. Supplementary materials

3. Risk factors

Risk factors (1/4)

Risks relating to the Company's business, -industry and markets

Product liability and inadequate insurance coverage	The Company develops and sells medical devices and conducts clinical trials. Consequently, the Company is exposed to liability risks. Such risks encompass, among other things, product liability risks that may arise in connection with manufacturing, clinical studies, improper handling, marketing and sales of the Company's products. The Company faces the risk of substantial liability for damages if its products were to cause patients illness, bodily injury, death or any other damage. There is a risk that the Company's insurance policies would not provide sufficient coverage in the event of a product liability claim. There is also a risk that the Company fails to obtain or maintain adequate insurance coverage on acceptable terms in the future. Any product liability claims could be time consuming and costly, cause harm to the Company's reputation if the market perceives its products to be unsafe or ineffective and may limit or prevent the sales or further development or commercialisation of the Company's products and products candidates.
Limited capacity at intensive care units	Following an organ transplantation, the patient must spend several days in a hospital's intensive care unit. Accordingly, if the hospitals' intensive care units have limited capacity to treat organ translation patients, for example due to the covid-19 pandemic or any other circumstances or events, there is a risk that the number of organ donations and organ transplantations, and thus the Company's sales, will decrease significantly.
Inability to protect intellectual property rights	The patent positions for companies within the medical device industry, including the Company, are generally uncertain and involve complex medical, legal and technical assessments that may give rise to uncertainty as to the validity, scope and priority of a particular patent. There is a risk that the Company will fail to develop products that are patentable, that patents will not be granted under pending or future applications, that patents will not be of sufficient breadth to provide adequate protection against competitors with similar technologies or products, or that patents granted to the Company are successfully challenged. Oppositions, appeals and challenges of the Company's patents could cause considerable legal costs, result in the diversion of management's time and efforts and require the Company to pay damages. If the Company does not obtain patents in respect of its technologies or if its patents are cancelled, third parties may use the technologies without payment to the Company. Additionally, if the combination of patents, trade secrets and contractual provisions that the Company relies upon to protect its intellectual property is inadequate, its ability to commercialise its products successfully will be harmed, and it may not be able to operate its business profitably.
Unlawful disposal of know-how and trade secrets	In addition to registered intellectual property rights, the Company has developed substantial know-how and trade secrets which are not protected by registration in the same way as other intellectual property rights. There is a risk that obligations to maintain the confidentiality of the Company's or its collaborators' trade secrets or know-how is breached, not enforceable or that such trade secrets or know-how otherwise become known to the Company's competitors or other third parties, which in turn could result in the Company's competitors or others gaining benefits at the Company's expense
Dependency on certain suppliers	The Company is dependent on certain suppliers, including the suppliers that produce Perfadex Plus, STEEN Solution and certain raw materials that are used in Perfadex Plus and STEEN Solution. There is always a risk that suppliers, for various reasons, do not perform their services to the satisfaction of the Company, do not meet agreed or required quantitative or quality standards or are not able to manufacture on a timely basis. If such risks would occur, continued production could incur additional costs, be delayed or even be interrupted and the Company may have to contract other suppliers to perform such services, which could be time consuming and costly. If the Company needs to engage a new supplier of business critical products or raw material, or exchange existing suppliers, such a process could take more than two years. To reduce the risk of shortage of products, the Company must maintain sufficient storage levels, which in turn results in the Company being exposed to the risk that stored products are subject to contamination or quality reduction or that the storage levels do not meet the Company's needs and its customers' demands.
Unsuccessful or lack of research and development partnerships	The Company conducts research and development projects in cooperation with several clinics, universities and scientists around the world (including Professor Stig Steen and Igelösa Life Science), which the Company is dependent on to conduct and further advance its business and products. Should any such projects fail or such research and development institutions cease to provide the Company with their facilities and expertise, or if the Company would fail to attract and initiate new such research and development projects, it could lead to interruptions and disturbances in the Company's business and growth.
Expensive, time consuming and unpredictable clearance and approval processes	The Company's products are subject to regulatory assessment, clearance or approval before they are marketed in various jurisdictions. The regulatory approval process is often expensive and time consuming and the timing and outcome of the approval process is difficult to predict. Each competent regulatory authority may impose its own requirements and may refuse to grant or may require additional data before granting clearance or marketing approval even if clearance or marketing approval have been granted by authorities in other jurisdictions. The regulatory pathway for future clearances or approvals may also change due to new- or reinterpretations of applicable regulations as well as amended approval processes. Such changes or reassessments could lead to increased costs and require more clinical studies, changes to manufacturing methods and increased documentation requirements. Any increased costs or extensive requirements at some stage of the process may delay market access of future products and negatively impact the Company's operations.

Risk factors (2/4)

Expensive, time consuming and unpredictable clinical trials	<p>The Company conducts clinical studies on its products, among other things, to support regulatory approvals for market access or to generate evidence relating to clinical benefits and cost benefits of using its products. Clinical studies are costly and time consuming and associated with risks such as finding trial sites, recruitment of suitable patients, the actual cost per patient exceeding budget and inadequacies in the execution of the trials. There is also a risk of delays in the performance of clinical studies. If delays persist, there is a risk that studies eventually are suspended or terminated prematurely if the delays occur due to circumstances that the Company has difficulties controlling, or is unable to control, or if the measures required for conducting the studies further are deemed too costly or extensive in relation to the scope and goals of the studies. Clinical studies may also be suspended or terminated if participating subjects are exposed to unacceptable health risks or undesired side effects. Furthermore, clinical studies may not demonstrate the required clinical benefit for the prospective indication the trial is aimed at. Failure in clinical studies could lead to market clearance or approvals not being obtained which could delay or jeopardise the Company's ability to develop, market and sell the product being studied.</p>
Inability to retain and recruit members of the executive management and other key personnel	<p>The Company's operations and future success are dependent on a number of senior executives and key employees and other personnel with specialised expertise. These senior executives and employees have good relationships with different market players, an in-depth understanding of the environment within which the Company operates and a central role in maintaining the Company's corporate culture. Should any key employee fail or cease to provide the Company with his or her expertise, it could lead to interruptions and disturbance in the Company's business</p>
The market for the Company's products is subject to change	<p>Changes in the market and in customers' demand could make the Company's products obsolete. Accordingly, the Company may be required to invest significant amounts to enhance and improve its products, develop new products or acquire additional businesses or partner with other businesses to be able to offer a broader array of products in order to further adapt to the changing market and competitive environment. It is difficult to predict future changes and the cost of updating, renewing or replacing existing technologies and how this would affect the Company. Failure to anticipate and quickly adapt to changes could impact the competitiveness of the Company's products and the Company's ability to retain current customers or attract new customers. Competitive pressures could also result in pricing pressures on the Company's products and services or in loss of market shares.</p>
The regulatory environment for medical devices	<p>Medical devices are subject to extensive regulatory rules and regulations, supervised by regulatory authorities around the world, for example the U.S. Food and Drug Administration and competent national authorities in relevant European countries. The regulatory framework covers all parts of the Company's business such as research, development, manufacturing, testing, labelling, marketing, sales and distribution. In addition to these industry-specific regulations, the Company is, or may be, subject to numerous other ongoing regulatory obligations, such as data protection, environmental, health and safety laws and restrictions. The costs of compliance with applicable regulations, requirements or guidelines could be substantial. Failure to comply with regulations could result in sanctions including fines, injunctions, civil penalties, denial of applications for marketing approval of the Company's products, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase the Company's costs, restrict the sales of its current products, delay the development and commercialisation of its product.</p>
Risks related to acquisitions of companies and businesses	<p>The Company may decide to carry out acquisitions of companies or businesses in order to expand or supplement its current product offering. To be successful with acquisitions, the Company must identify suitable companies or assets to acquire, conduct adequate due diligence, negotiate favourable terms for each transaction and obtain necessary permits. Even if the Company finds suitable acquisition targets, the Company may not obtain relevant regulatory approvals for such transactions (such as clearances from competition authorities). If the Company progresses with an acquisition, there is a risk that the profitability or cash flow that the acquired business is expected to achieve will not be generated, or that advantages, including growth or expected synergies, are not realised. The Company's assessment of and assumptions regarding acquired businesses may prove to be inaccurate and actual developments may differ significantly from such expectations. In addition, the Company may experience or be exposed to unknown or unexpected liabilities or expenses, for example related to customers, employees and authorities. There is also a risk that the Company will be unable to integrate acquisitions, that such integration requires more resources than expected or that the integration process for completed or future acquisitions interfere in other ways with the Company's operations, for example due to unforeseen issues of a legal, contractual or other nature, issues with the realisation of operational synergies or failure to maintain good quality of service. Furthermore, acquisitions may divert management's attention away from daily operations.</p>

Risk factors (3/4)

Inability to obtain financing at favourable terms or at all	The Company may come to require additional financing, for example, in order to accomplish growth of its business, both organically and through acquisitions. Access to additional financing is affected by a number of factors, such as market conditions, general access to loan financing, as well as the Company's credit rating and credit capacity. Disruptions and uncertainties on the capital and credit markets may also restrict access to the capital required to conduct the Company's business. Accordingly, there is a risk that the Company is not able to obtain financing at favourable terms or at all.
Disputes, proceedings, penalties and other sanctions	The Company may become involved in disputes relating to its business activities and there is always a risk that the Company become subject to demands under a number of circumstances, such as interpretation of customer or supplier contracts or infringements of intellectual property rights. Disputes, claims, investigation and enforcement processes can be time consuming, disturb normal operations, involve large monetary amounts and cause significant costs. It can also be difficult to predict the outcome of complex disputes, claims, investigation and enforcement processes. Should the risks described above materialise, it could have a material adverse effect on the Company's business, results of operations and financial position.

Risk factors (4/4)

Risks relating to the shares in the Company

Share price volatility	The price of the Company's shares may be subject to significant fluctuation resulting from, for example, a change in the market's assessment of the Company's shares or a certain event occurring that affects the Company's business, results and development. There is also a risk that an active and liquid trading in the Company's ordinary shares will not materialise and there is therefore also a risk that shareholders will not be able to sell their shares or can only sell them at a loss
Existing shareholders' sales of shares may affect the price of the Company's shares	The price of the Company's shares could decline if there are substantial sales of shares. This could in particular be the case in the event of sales by the Company's board members, senior executives or major shareholders or when a large number of shares are being sold. Sales of large numbers of shares in the Company, or the perception that such sales might occur, may cause the market price of the ordinary shares to decline
Issuances of shares could dilute the shareholding and have an adverse effect on the share price	The Company may in the future need to raise additional capital to finance its operations or make planned investments. The Company may seek to raise additional capital by, for example, issuing shares, warrants or convertibles. An issue of additional securities or bonds could reduce the market value of the Company's shares and dilute the financial or voting rights of existing shareholders, unless existing shareholders are given preferential rights in the issue or if existing shareholders, for some reason, are unwilling or unable to exercise their preferential rights.
Inability to pay dividends	When submitting a dividend proposal to the general meeting, the board of directors of the Company shall take into consideration a number of factors, including the demands with respect to the size of the equity which are imposed by the nature, scope and risks associated with the operations of the Company and the group as well as the need to strengthen the statement of financial position, liquidity and financial position of the Company and the group. Accordingly, the Company's ability to pay dividends in the future and the size of such potential dividends are dependent upon its future earnings, financial condition, cash flows, net working capital requirements, capital expenditures and other factors. Further, pursuant to Swedish law, dividends may only be distributed to the extent that there will be full coverage for the Company's restricted equity after the dividend distribution. There is also a risk that the Company resolves to reinvest any future profit in the business or that the Company's shareholders resolve not to pay dividends in the future or that the Company will not have sufficient funds to pay any dividends at all.
Inability to exercise preferential right for non-Swedish shareholders	Under Swedish law, shareholders have preferential rights in certain new share issues unless a decision is made to deviate from the preferential right. However, securities legislation in certain jurisdictions may limit the Company's ability to allow shareholders from certain jurisdictions to exercise their preferential right in any future share issue. Accordingly, there is a risk that shareholders in, for example, the United States and certain other countries may not be able to exercise their preferential right to participate in share issues or buy-back offerings, including discount offerings, unless the Company decides to meet local criteria or if no exemption from such criteria is applicable. There is also a risk that the Company will decide to not meet local criteria for participation in issues of securities and, accordingly, that shareholders outside Sweden will not be able to exercise their preferential right in future issues of securities or participate in future buy-back offerings
Currency risk for investors with a reference currency that is not SEK	The Company's shares are listed in SEK, the Company's equity is reported in SEK and any dividend on the Company's shares is primarily paid out in SEK. Accordingly, investors whose reference currency is not SEK may be affected by a fall in the value of SEK in relation to the respective investor's reference currency. If the value of SEK falls in relation to this other currency, the value of the share investment or dividends may decline in the foreign currency, and if the value of SEK increases, the value of the share investment or dividends may increase in the foreign currency. In addition, these investors may be affected by additional transaction costs upon conversion of SEK to another currency. Investors whose reference currency is not SEK are therefore encouraged to seek financial advice.