

corline
biomedical

September 2021

Solutions for life

Advancing regenerative medicine through CHC™ coating technology

Proprietary CHC™ technology

- Proprietary heparin conjugate technology that reduces bleeding risks associated with systemic administration of heparin
- Reduces coagulation, complement cascade activation and inflammation
- Used for surface modification of medical devices, cells and vasculature of solid organs

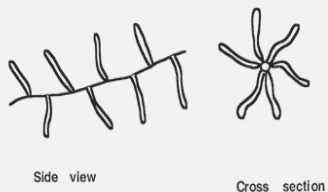
Renaparin® for kidney transplantation

- Preventing ischemia/reperfusion injury through ex vivo treatment for improved kidney transplantation outcomes
- Protection from innate immune response and improved immediate kidney function, demonstrated through proof-of-concept studies in animals
- Phase I trial presented favourable safety and tolerability profile
- Phase II trial currently being planned

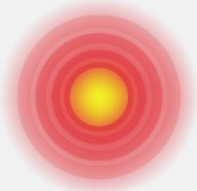
CHS™ as medical device coating

- CHS™ – validated potential in medical device coating with two pivotal customer contracts signed H2 2020, and a 3rd Term Sheet in mid 2021
- Prospect of building a near-term revenue stream with high margins

CHC™ – proprietary heparin conjugate technology



- **Corline Heparin Conjugate (CHC™)** is a proteoglycan-like conjugate of covalently bound heparin
- Heparin is a naturally occurring biomolecule routinely used in surgery as a systemic anticoagulant
- CHC™ is used to locally increase concentration of heparin without the bleeding risks associated with systemic administration



- **CHC™** modification makes surfaces blood compatible, mimicking the inner lining of a blood vessel, and
- reduces coagulation, complement cascade activation and inflammation, thus **attenuating immune thrombosis**



- **CHC™** technology can be used to modify surfaces of medical devices, cells and vasculature of solid organs

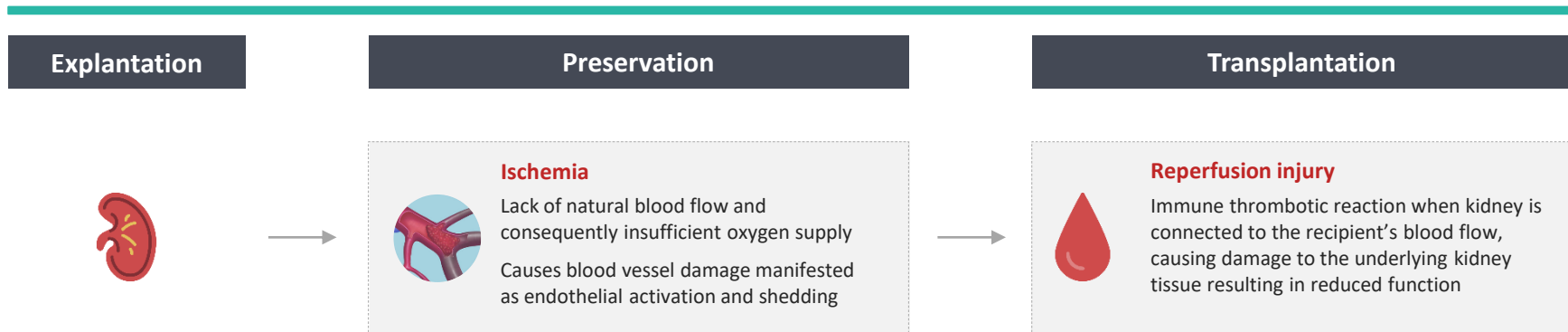
Renaparin®

> Improving the outcome of kidney transplantation

CHS™ Medical Devices

Opportunities & validation

Ischemia/reperfusion injury – no drug approved for prevention



Ischemia/reperfusion injury (IRI) reduces clinical efficacy of kidney transplantation

- IRI leads to delayed graft function
- IRI is associated with decreased graft function and survival
- **No drug approved for prevention of IRI**

40%
transplants affected

+10-14 days
added to ICU stay

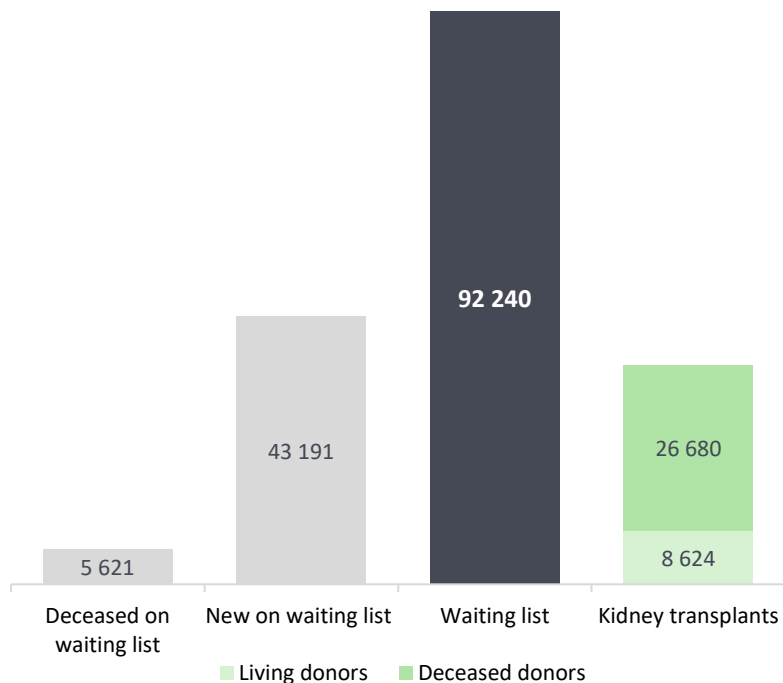
USD 100k
transplant cost

USD 2.5k/day
ICU cost

Organ shortage – a multi-faceted challenge for kidney transplantation

Significant organ shortage gap remains...

US & EU5 Kidney transplants¹ (2017)

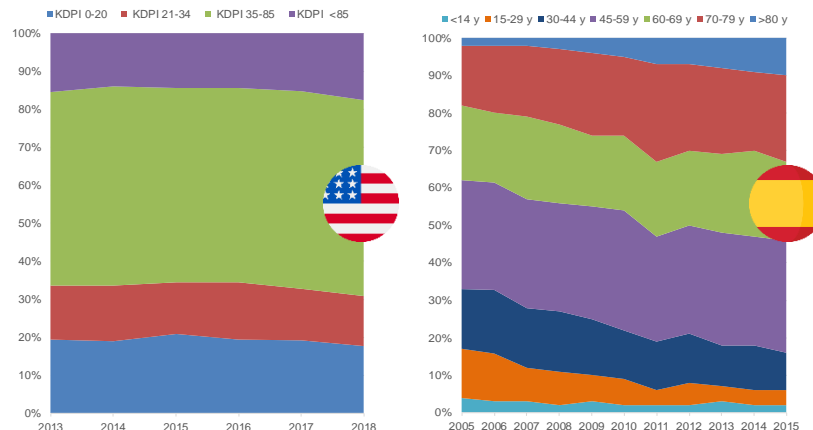


...driving acceptance of marginal donors

Deceased donor kidney transplants CAGR 2012-17²

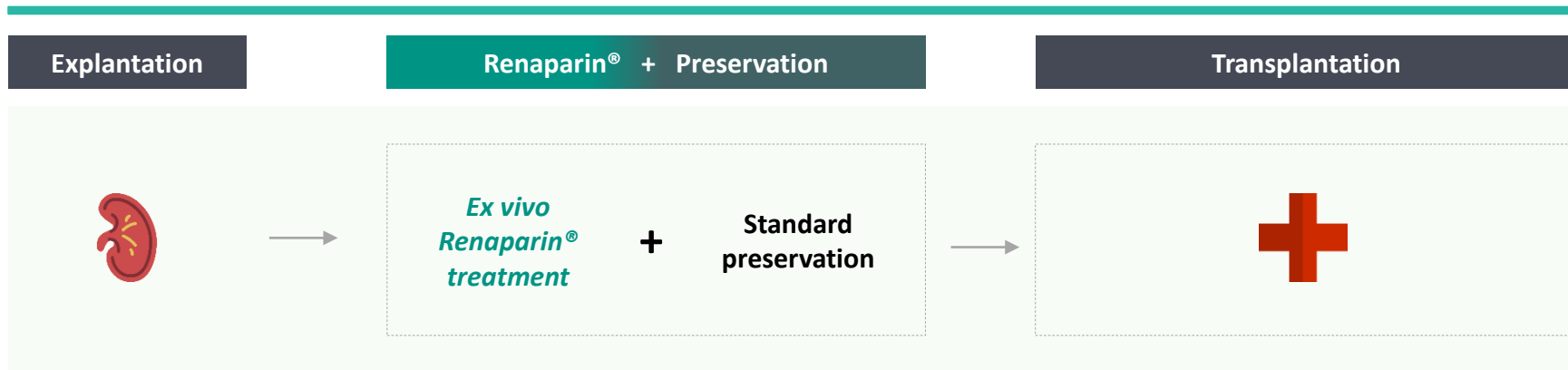
4.9% US
3.1% EU5

Increase in high KDPI and ECD donors³



> Marginal donors are more susceptible to IRI/DGF

Renaparin® – reducing risk of marginal donor kidney transplantation



Renaparin® helps avoid delayed graft function -> reduced need for dialysis, duration of hospital stay and improved kidney function/survival

- ✓ Restores/repairs vessels in the kidney (endothelial repair), emulating a coherent vascular glycocalyx
- ✓ Prevents Ischemia/Reperfusion injury in kidney transplantation by presenting a repaired endothelium and attenuating the reperfusion injuries
- ✓ Compatible with all standard perfusion solutions, cold storage and machine perfusion

**Phase I
Completed**

With a good
safety profile

**Phase II Design
Underway**

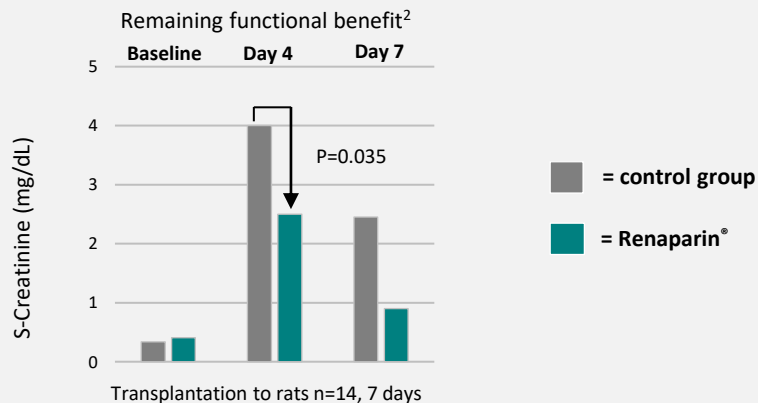
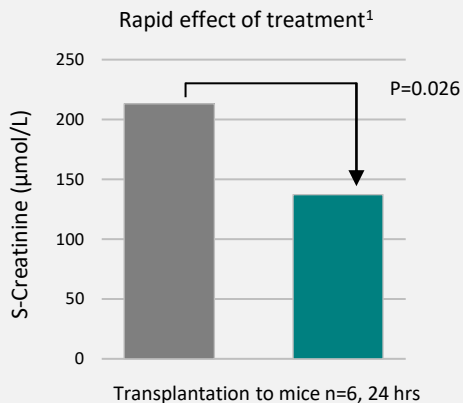
Primary end-point is
eGFR at 3 months

**Orphan Drug
Designation**

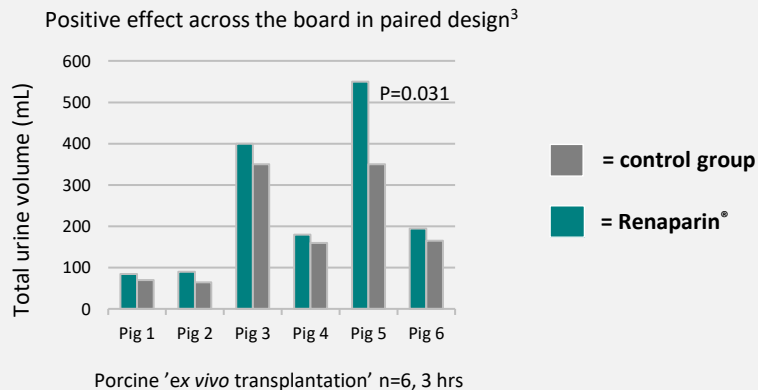
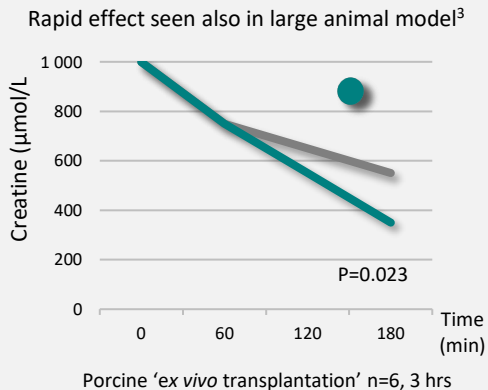
Obtained for both
US and EU

Promising results from proof-of-concept studies in small and large animals

Small animals



Large animals



Clinical safety and tolerability demonstrated in recent Phase I study

Description

- Phase I interventional, double-blind, randomized, controlled study of kidney transplantation after ex vivo treatment with Renaparin® of kidneys from deceased donors
- Multi-center in Sweden, at 3 sites: Uppsala, Stockholm and Gothenburg

Endpoints

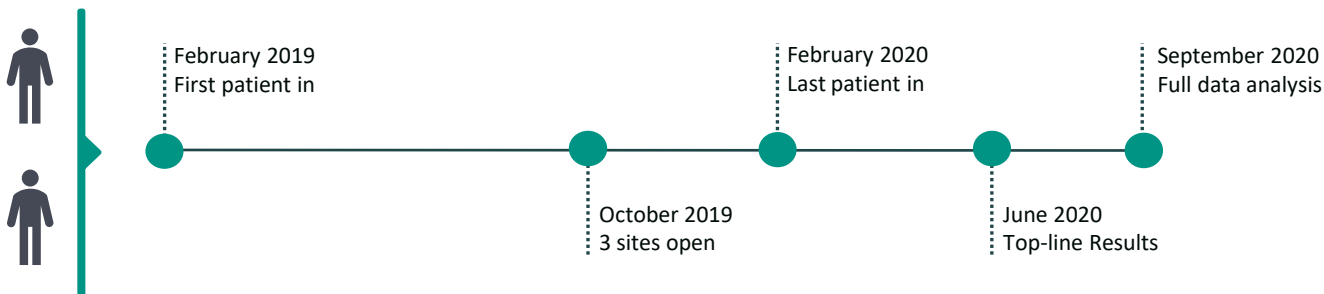
- Number and severity grade of Serious Adverse Events and Adverse Events including description of their associated MedDRA terms during the first 30 days after transplantation

Conclusions

- **Primary and secondary safety endpoints were successfully evaluated – it was concluded that Renaparin® administration is safe and tolerable for this indication and dose**

8 patients
Renaparin®
30 days follow-up

8 patients
Placebo
30 days follow-up



Phase II study design

Description

- Phase II interventional, single-blind, randomized, controlled study of kidney transplantation after ex vivo treatment with Renaparin® of kidneys from deceased donors
- Multi-center in EU, at 4-10 sites in 2 countries

Objectives

- Primary objective: assess efficacy of donor kidney pre-treatment with Renaparin® in renal transplant patients with a high risk of IRI/DGF
- Secondary objectives: assess incidence of DGF, DGF severity, rejection and safety evaluation

Endpoints

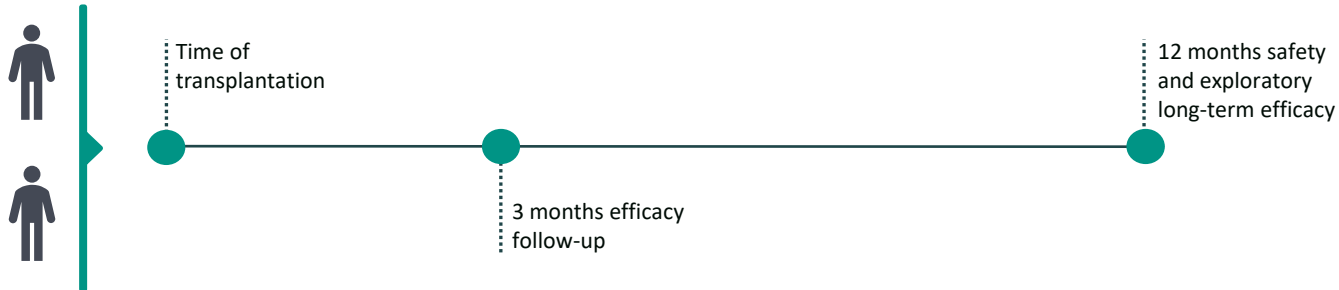
- Primary end-point: eGFR (MDRD7) at 3 months
- Secondary endpoints: creatinine, incidence and severity of DGF, BPAR proven rejection and assessment of AE/SAEs

Target Population

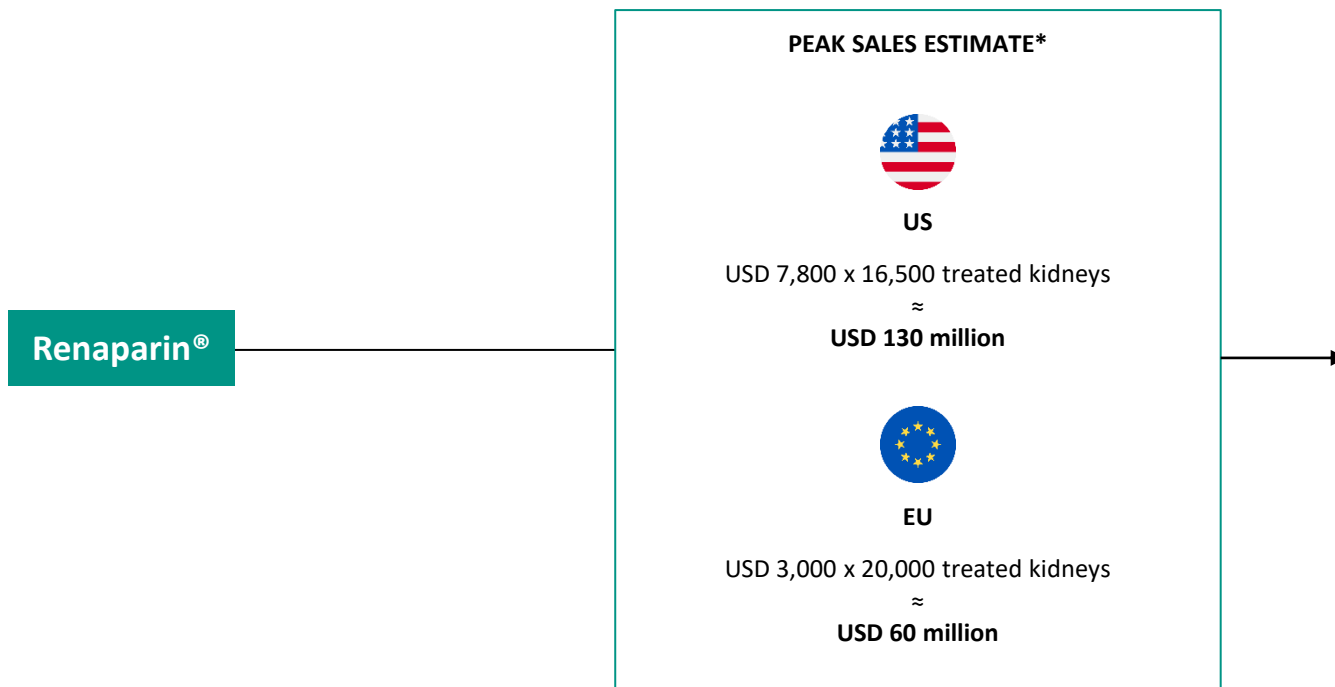
- Deceased donor kidney recipients at increased risk of developing IRI/DGF (ECD-DBD, DCD)

40 patients
Renaparin®

40 patients
Placebo



Peak Sales Estimates – US focus for pivotal study



Renaparin®

> Improving the outcome of kidney transplantation

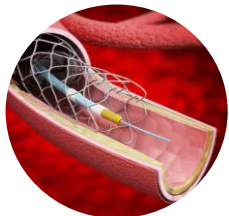
CHS™ Medical Devices

> Anti-thrombotic coating for vascular devices

Opportunities & validation

CHS™ for medical devices – prospects of near-term revenues and high margins

Thrombosis in medical device use



- Artificial surfaces can cause thrombotic reactions upon contact with blood
- Vascular stents, dialysis catheters, etc. all initiate immune thrombosis

Thrombosis may increase patient risks – clot formation, infection, endothelial damage – and compromise device function

Coating with CHS™

- Corline Heparin Surface (CHS™) coating system can be used on any type of medical device material
- CHS™ renders high concentration of surface-bound heparin locally on the device, without any systemic heparin exposure for the patient
- CHS™ is extremely thin, in the 50-100 nm range and does not alter the properties or functionality of the coated device
- Coagulation and infection risk is reduced at the source, and the risk of bleeding associated with IV-heparin or other anti-thrombotic treatments is mitigated

Competitive landscape & profitability benchmark

- **In head-to-head comparisons:** CHS™ functionality is on par or better than industry gold standard CBAS® (Carmeda/Gore Medical)
- **Business model advantage:** CHS™ can easily be outsourced to customers – simple CHC™ based design – whereas CBAS® cannot

- Medical device coating business has **prospects of high margins**

Competitor EBITDA-margin (%)			
2016	2017	2018	2019
69%	64%	74%	66%

Establishing a track-record within device coating

Current status

>100,000

patients in EU have received coronary stents coated with CHS™

SEK 35m

expected annual income on full roll-out of CHS™ treated stroke care product – more in pipe-line

SEK 50m

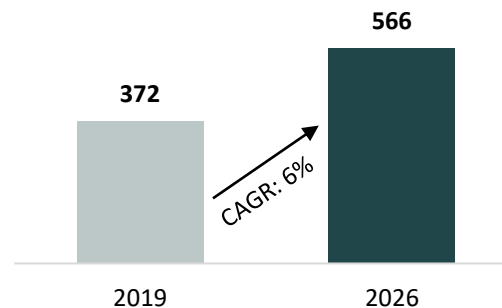
expected annual income on full roll-out of CHS™ treated ablation catheters

SEK 50m

Non-disclosed customer representing potential of annual income on full roll-out of CHS™ treated implants for venous insufficiency

Future potential

Global medical device coatings market¹ (USDm)

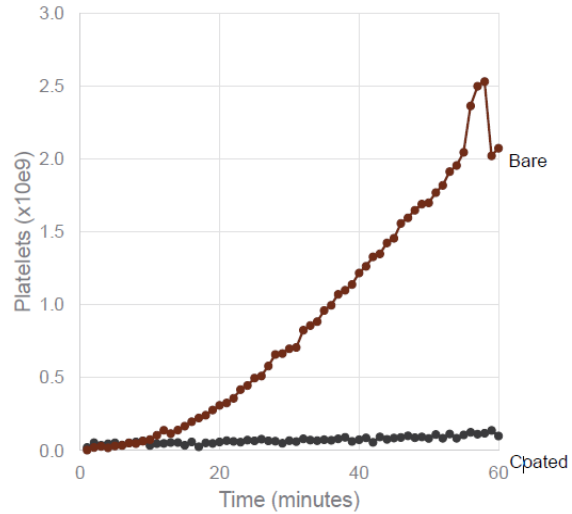


Anti-thrombotic coatings are estimated to have represented **>USD 100m** of the 2019 medical device coatings market²

Corline currently works with 5-7 customers in feasibility evaluations to leverage future market opportunity and build pipe-line

CHS™ equals best-in-class performance

Primate model platelet adherence



Visual inspection



Coating Service model

- ✓ CHS™ is applied to device in Corline Biomedical's clean room facility in Uppsala, Sweden
- ✓ Corline invests in developing and maintaining coating process
- ✓ Corline ships CHS™ coated products to customer
- ✓ Full control over technology
- ✓ Target EBITDA margins of 60 %

Small geometries, medium volumes

Out-licensing model

- ✓ CHS™ is applied by customer at customer site or 3rd party
- ✓ Customer invests in developing and maintaining coating process
- ✓ Corline sells and ships CHC™ and priming reagent to customer
- ✓ Full control over critical technology, however low tech part is outsourced to customer
- ✓ Target EBITDA margins of 80 %. All things equal - lower sales volumes than Coating Service model

Large geometries and/or large volumes

CHS™ customer case



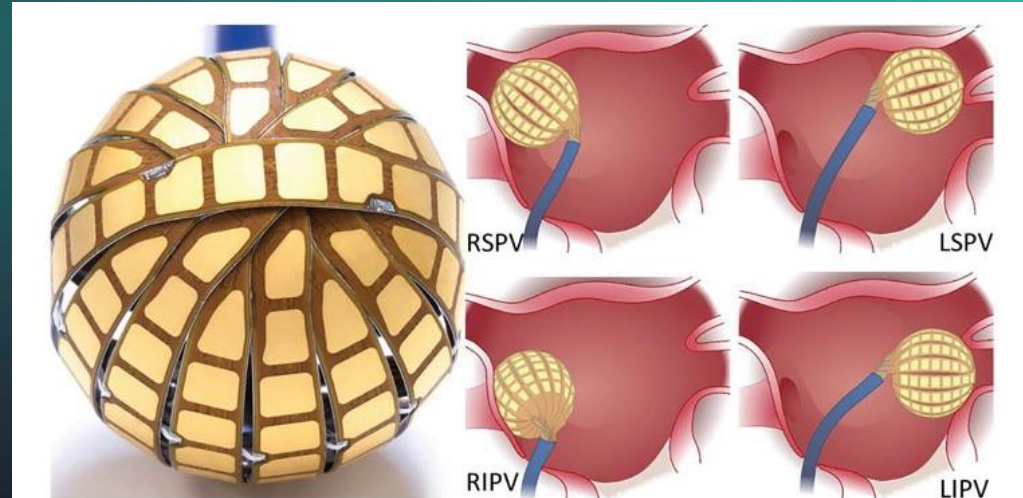
Founded in 2007 and headquartered in Vancouver, Canada, Kardium sells atrium fibrillation devices to treat heart arrhythmia.

More than 200 employees in Canada and in Dortmund, Germany, goal of 400 employees within 18 months.

CHS™ is used on the Globe Mapping System, which is an advanced AF system that combines real-time diagnostics and treatment.

Recently announced financing of 115 MUSD.

Corline expects yearly sales revenue of **50 MSEK** from this contract.



Atrial fibrillation affects 37 million people world-wide each year.

Devices for AF treatment is a 6 bn USD market, growing at a rate of almost 15 % annually. Approximately 500,000 catheter procedures are performed each year.

Approved products



Berlin Heart EXCOR® Ventricular Assist Device



GORE® PROPATEN® Vascular Graft
GORE® PROPATEN® configured for Pediatric Shunt



GORE® VIABAHN® Endoprosthesis
GORE® VIABAHN® balloon Expandable



GORE® ACUSEAL Vascular Graft

Revenue and EBIT (000' SEK)

	2018	2019	2020
Revenue	183 520	226 774	215 004
EBIT	114 239	197 966	140 615

CBAS® vs CHS™

- **Similar technology background:** Developed by same research group at Karolinska Institute in Stockholm
- **In head-to-head comparisons:** CHS™ functionality is on par or better than industry gold standard CBAS® (Carmeda/Gore Medical)
- **Business model advantage:** CHS™ can easily be outsourced to customers – simple CHC™ based design – whereas CBAS® cannot

H1 2021 financial report

**2021 H1 report
strengthens view of
Corline Biomedical
as a company with
two attractive
business segments**

- Net revenue 2 860 KSEK (792)
- Net results -3 558 KSEK (-5 082)
- Net result/share -0.18 SEK (-0.30)
- Cash, June 30: 47.7 MSEK (12.4)

Leadership team

Management



Henrik Nittmar, PhD
CEO



Gunnar Tufveson, Prof, MD
Chief Medical Officer



Åsa Holm, PhD
Regulatory & Quality Assurance Manager



Fredrik Carlsson, PhD
Research Manager



Patrizia Caldirola, PhD
Project Manager *Renaparin®*



Mats Reslow, PhD
Consultant Head of CMC

Board



Adam Dahlberg
Chairman



Lars Sunnanväder
Board Member



Gunilla Ekström
Board Member



Henrik Krook
Board Member



Magnus Nilsson
Board Member

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