HELPING TO TREAT LIFE-THREATENING CONDITIONS IN THE ICU AND CARDIAC SURGERY AROUND THE WORLD

# CytoSorbents™

WORKING TO SAVE LIVES

## NASDAQ: CTSO

Jefferies Healthcare Conference

June 8, 2022

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# CytoSorbents

Leading the Prevention or Treatment of
**Life-Threatening Inflammation**
**and other Deadly Conditions**
in the ICU and Cardiac Surgery using
CytoSorb® Blood Purification

# CytoSorbents At a Glance (NASDAQ: CTSO)

- U.S.-based international medical device company commercializing our E.U. approved CytoSorb® blood purification cartridge in more than 70 countries worldwide
  - $40.1M in 2021 product sales
  - 80% product gross margins
  - $44.7M in cash (3/31/22)
  - >230 employees worldwide

- Celebrating 10 years of commercialization with >170,000 cumulative CytoSorb devices utilized (3/31/22)
  - Treating cytokine storm and massive uncontrolled inflammation in life-threatening conditions such as sepsis, COVID-19, shock, lung failure, pancreatitis, and many others
  - Reducing other toxins such as bilirubin (liver disease), myoglobin (trauma)
  - Removing “blood thinners” or antithrombotic drugs during cardiac surgery that cause bleeding

- Partnered with leading multi-national corporations:

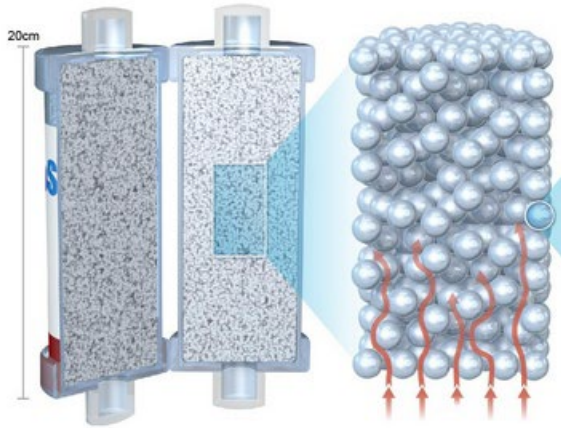
FRESENIUS MEDICAL CARE · B BRAUN SHARING EXPERTISE · TERUMO CARDIOVASCULAR · Biocon · NIKKISO

- Seeking dual U.S. FDA approvals for DrugSorb-ATR, an equivalent polymer technology to CytoSorb, to reduce perioperative bleeding during cardiac surgery by removing the leading blood thinners, Eliquis, Xarelto, and Brilinta under FDA Breakthrough Device Designation
  - U.S. pivotal STAR-T and STAR-D RCTs are underway with both expected to complete in 2023
  - Targets a $1B total addressable market opportunity in the U.S. alone

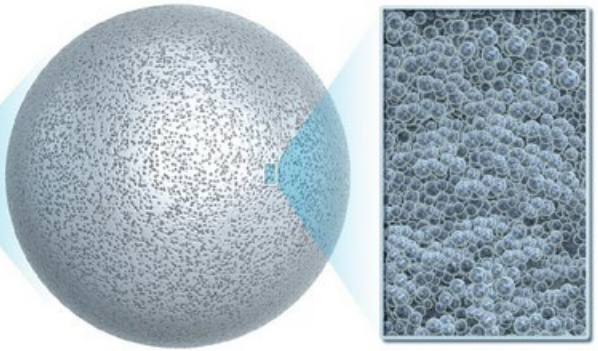
# What does CytoSorb do and How does it work??

# The CytoSorb Adsorber

The underlying blood purification technology is based on biocompatible, highly porous polymer beads that act like tiny sponges to remove harmful substances from blood



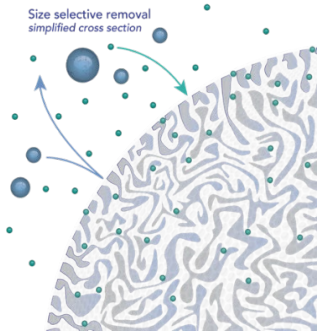

Section through an adsorber



Adsorber bead



Internal structure




- Massive surface area: 7 football fields in a single cartridge

- 21 issued U.S. patents and multiple patents issued and pending worldwide

- Manufactured at our ISO 13485 certified facility in New Jersey



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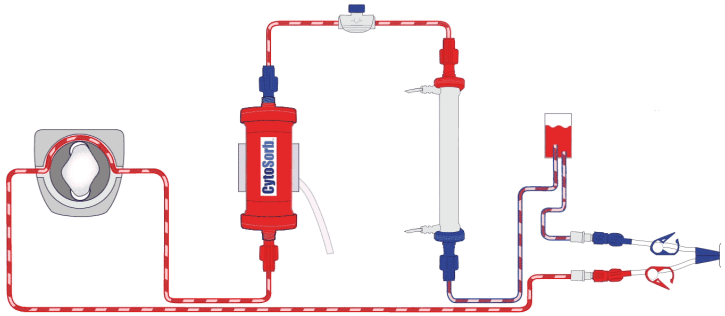
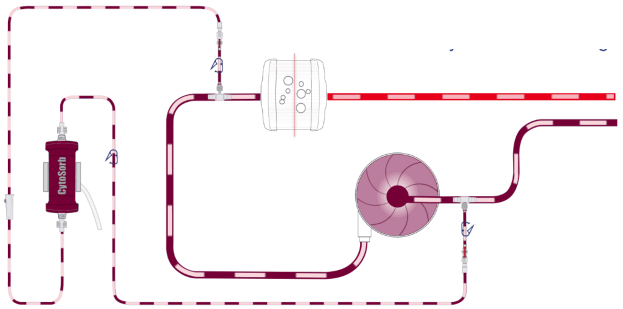
# CytoSorb is “Plug and Play” Compatible

## Compatible with Existing Blood Pump Infrastructure In Hospitals Today

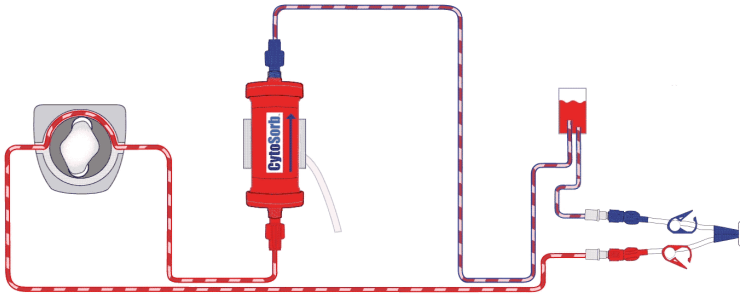
### Dialysis or CRRT
(Continuous Renal Replacement Therapy)



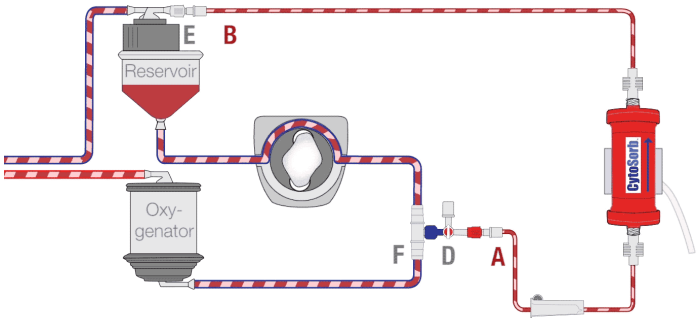

### ECMO
(Extracorporeal Membrane Oxygenation)




### Hemoperfusion
(Standalone Treatment)




### CPB
(Cardiopulmonary Bypass)



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# Targets Deadly Conditions that Afflict Millions of People

## Critical Care

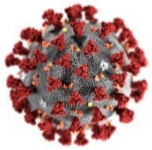
Removes the "fuel to the fire" of massive uncontrolled inflammation that is often associated with organ failure and death

Sepsis

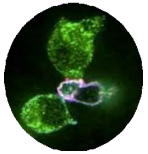
Surgical Complications

Influenza

Burn Injury



COVID-19



Cytokine Release Syndrome

Lung Injury

Liver Failure

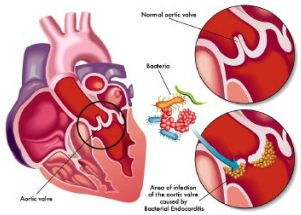
Trauma

Pancreatitis

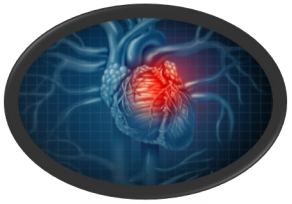
## Cardiothoracic Surgery

Reduces inflammation and blood thinners, targeting reduction in complications of cardiac surgery like sepsis, bleeding, shock, and others

Life-threatening bleeding due to anti-thrombotic "blood thinners"



Infective Endocarditis



High Risk Procedures



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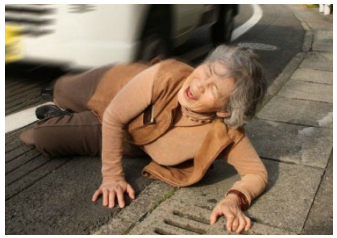
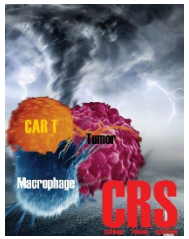
# Riding Many Macro Trends in Healthcare

## Aging Population is Getting Older

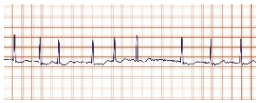
>1 billion over 60

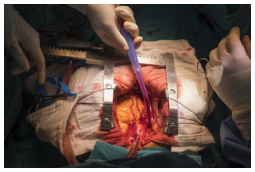




## The Use of Blood Thinners

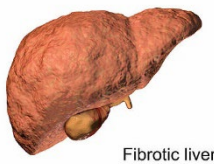
Millions worldwide are on blood thinners to reduce risk of stroke and heart attack



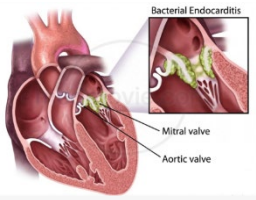


## Chronic Liver Disease

Afflicts 1 in 11 worldwide



## Opiate Crisis & Endocarditis



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# What is the Company's Business model and Financial performance?

# CytoSorbents Has a Strong Hybrid Sales Model

More than 70 Countries Worldwide and >170,000 devices utilized

Critical Care and Cardiac Surgery

Direct Sales ⟺ Distributor and Partner Sales

Direct sales in 12 countries:

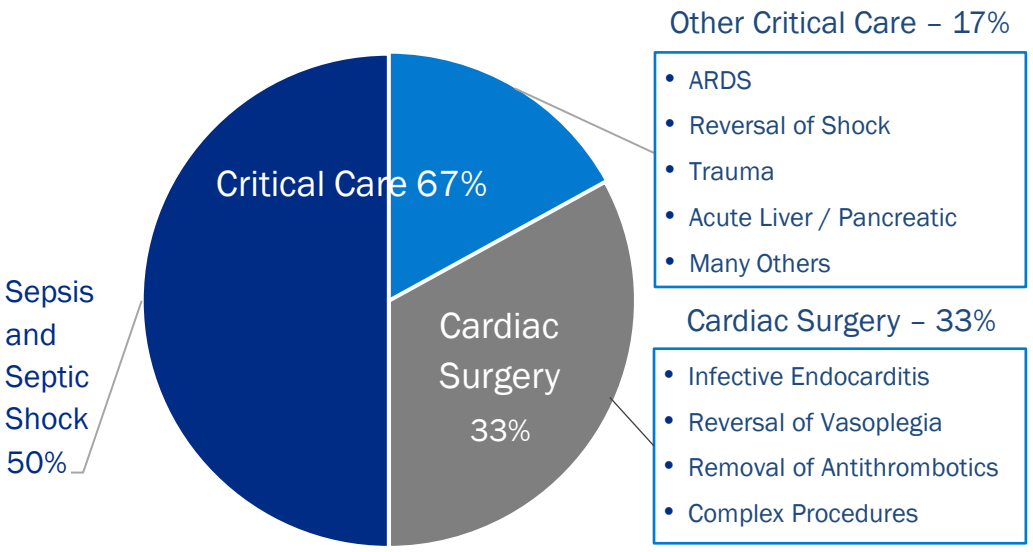
Germany, Austria, Switzerland, Belgium, Poland, Netherlands, Denmark, Norway, Sweden, Luxembourg, U.K, Ireland

Distributor and Partner sales in >60 other countries

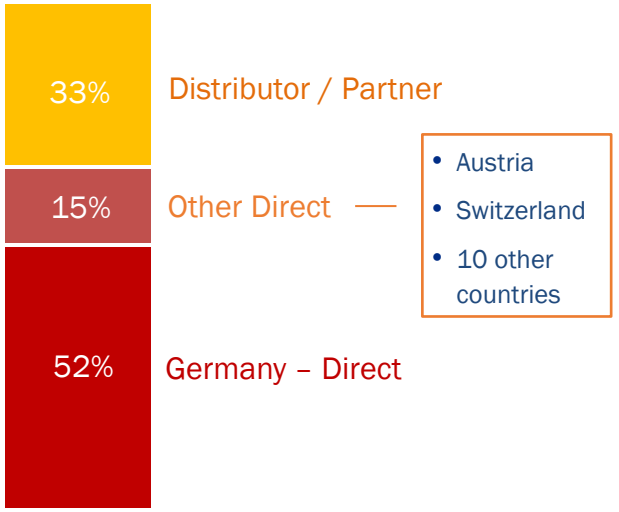
Entered U.S. under FDA EUA, expanded to Latin America, the Middle East, South Korea, and many others

# CytoSorb Commercialization Focus

## By Market




## By Geography



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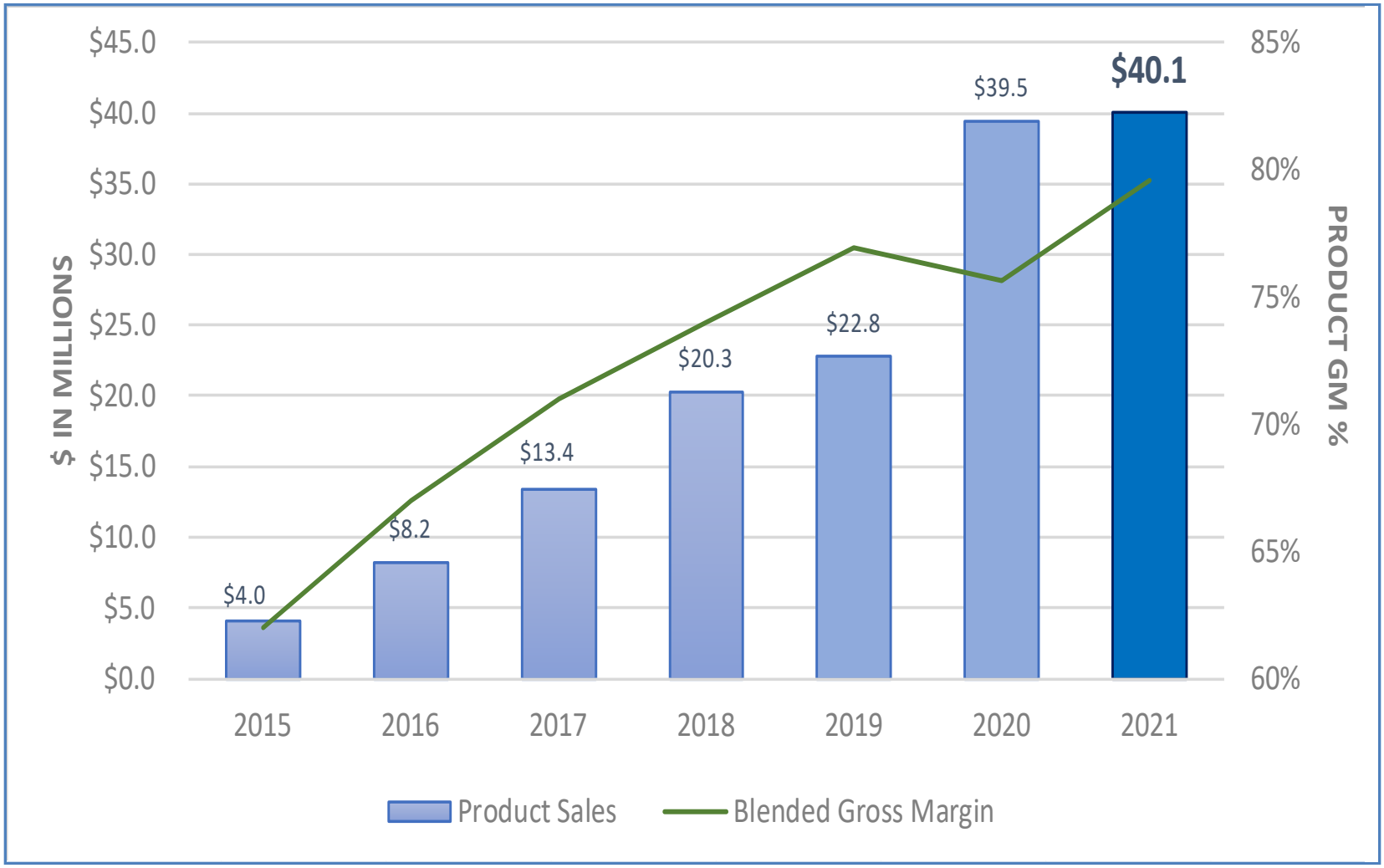
# CytoSorb Is a High Margin "Razorblade"

- High margin "razorblade" fully compatible with existing installed base of "razor" blood pumps: Dialysis, CRRT, and ECMO machines (ICU), and heart-lung machines (OR)
- Blended gross margins were 80% in Q1 2022, driven by volume production from our current manufacturing facility and manufacturing efficiencies.
- Average Direct Selling Price is approximately $1,000 per cartridge
- ~1 - 5 cartridges are typically used per patient depending on the course of treatment
  - Open heart surgery: 1-2 cartridges
  - Sepsis: 3-5 cartridges (or the cost of roughly 1 day in the ICU)
  - ARDS and ECMO: 5+ cartridges
- In Germany, 400 hospitals have >400 beds. Each hospital typically sees 300-600 sepsis patients per year. At 3-5 cartridges per patient:
  - Revenue per patient = ~$3,000-5,000
  - Potential revenue per hospital = $1-3M for sepsis alone
- Previously disclosed one German hospital with sales >$1M, broadly adopting the use of CytoSorb in critical care and cardiac surgery, validating revenue model. Other hospitals are tracking along same path, giving us visibility on future growth

# Annual Product Sales and Blended Gross Margin



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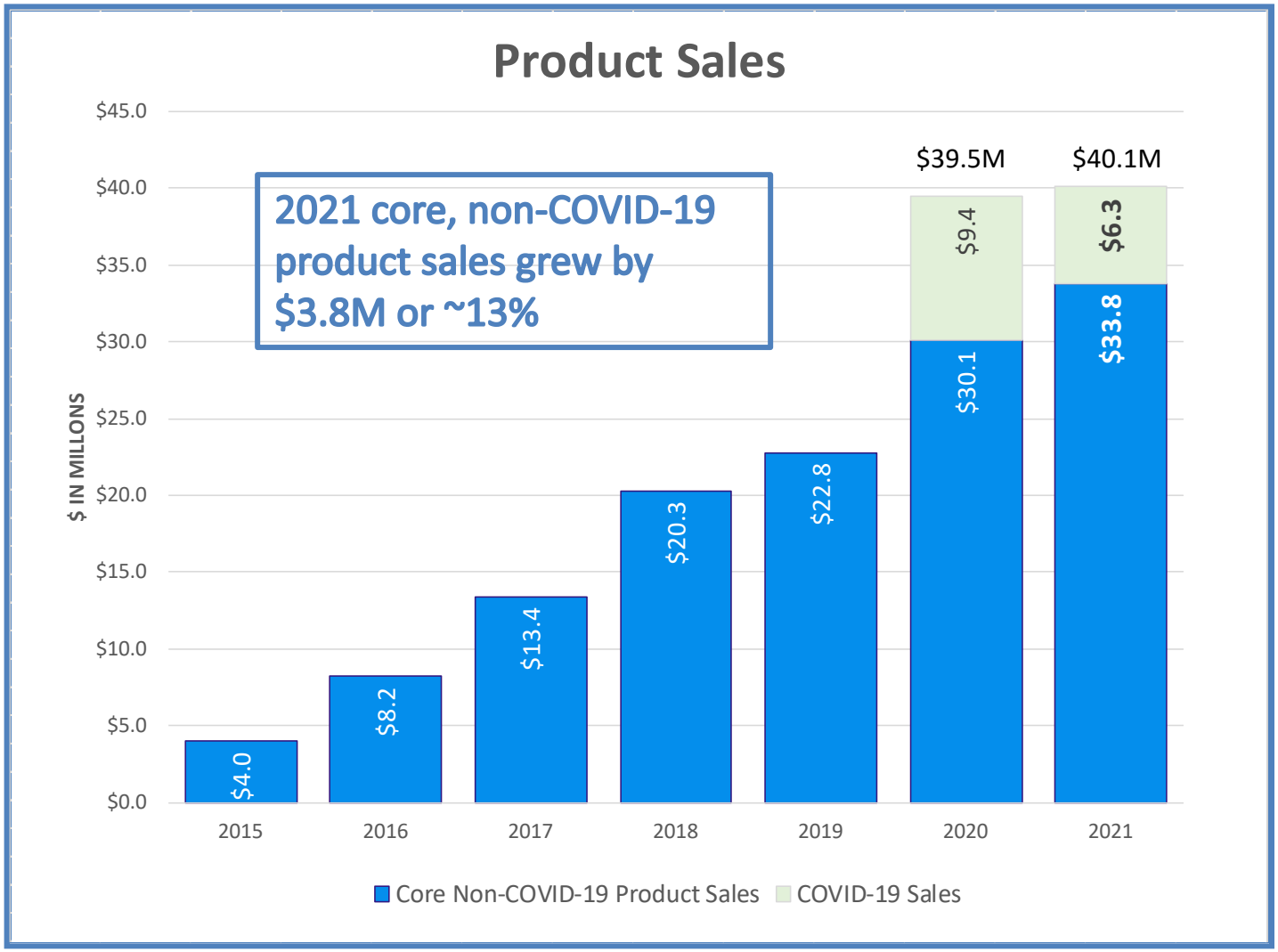
# Annual Product Sales



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# What are the catalysts for growth?

# Laser-Focused on 2022 Strategic Objectives

We are well-capitalized with $44.7M in cash and will continue investing selectively on priority programs, while taking proactive measures to significantly reduce our cash burn to end 2022 with more than $30M in cash with the flexibility to add debt if needed.

Meanwhile, we are laser-focused on the following key objectives:

- Open the U.S. market by obtaining FDA Marketing approval for DrugSorb™-ATR to remove blood thinning drugs during cardiothoracic surgery through the STAR-T and STAR-D trials
- Restore growth of core CytoSorb sales
- Transition CytoSorb production to our new manufacturing facility and headquarters in Princeton, New Jersey this year
- Forge and expand new and existing strategic partnerships to maximize the synergy between our technology and those of our partners, while creating new global opportunities for growth.

# #1

Open the U.S. Market by Targeting FDA Marketing Approval via STAR-T and –D Pivotal Trials

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# EU Approval to Remove Ticagrelor and Rivaroxaban "Blood Thinners" During Cardiothoracic Surgery

CytoSorb has received E.U. approval to remove two well-known blockbuster "blood thinners" during cardiothoracic surgery, used in millions of patients to reduce risk of stroke and heart attacks

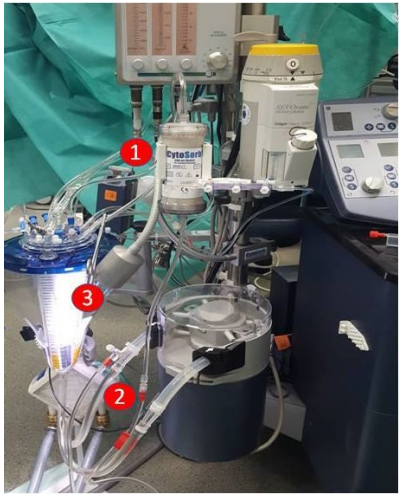
**Ticagrelor (Brilinta®, Brilique® - AstraZeneca)** is a blockbuster $P2Y_{12}$ anti-platelet agent ("blood thinner") with more than $1.6 billion in worldwide sales, used in patients with acute coronary syndrome

**Rivaroxaban (Xarelto® – Bayer, Jansenn/J&J)** is a blockbuster Factor Xa inhibitor anticoagulant ("blood thinner") with ~$7 billion in 2019 global sales used as lifelong therapy in patients with atrial fibrillation

**Problem:** Patients that require emergent or urgent cardiothoracic surgery on these blood thinners can develop serious bleeding complications

CytoSorb installs easily into a heart-lung machine or cardiopulmonary bypass machine and as blood flows through the cartridge, removes these drugs rapidly during surgery and >90% from whole blood in CPB simulations to reverse their anticoagulant effect

We believe CytoSorb can quickly become a cost-effective standard of care to prevent bleeding due to antithrombotic drugs, helping to drive sales growth



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# By Removing Drug, CytoSorb Reduces Bleeding Complications

| 43 patients emergency surgery **with ticagrelor** | | 55 patients | 12 patients emergency surgery **with rivaroxaban** | |
|---|---|---|---|---|
| **32 patients** with intra-operative CytoSorb | **11 patients** control without CytoSorb | | **7 patients** with intra-operative CytoSorb | **5 patients** control without CytoSorb |
| CPB + CytoSorb *(n=32)* | CPB alone *(n=11)* | | CPB + CytoSorb *(n=7)* | CPB alone *(n=5)* |
| 288 ± 63 | 353 ± 84 | Procedure duration** (min; mean ± SD) | 184 ± 97 | 309 ± 50 |
| 21.9% *(n=7)* | 45.5% *(n=5)* | Red blood cell transfusion | 14.3% *(n=1)* | 100% *(n=5)* |
| 34.4% *(n=11)* | 100% *(n=11)* | Platelet transfusion | 28.6% *(n=2)* | 100% *(n=5)* |
| 350 *[300 - 450]* | 890 *[630 - 1025]* | Chest tube drainage remove volume/24hrs (ml; median [IQR]) | 390 *[310 - 430]* | 600 *[590 - 1000]* |
| 0% *(n=0)* | 36.4% *(n=4)* | Re-thoracotomy | 0% *(n=0)* | 40% *(n=2)* |
| 2 *[1 - 3]* | 3 *[2 - 4]* | Days in intensive care (median [IQR]) | 2 *[2 - 3]* | 6 *[5 - 6]* |
| 11 *[9 - 12]* | 14 *[10 - 16]* | Total length of stay (days; median [IQR]) | 11 *[10 - 13]* | 18 *[18 - 20]* |

**In a separate analysis done in the U.K., this has translated into a projected cost savings to the hospital of approximately $5,000 per patient, including the cost of CytoSorb**


- Hassan K, et al. Ann Thor Surg. 2019; 1:45-51.
- Javanbakht, M, et al. Pharmacoecon Open. 2020 Jun; 4(2):307-319.




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# Targeting U.S. FDA Marketing Approval

DrugSorb™ ATR — Breakthrough Device Status

- We seek U.S. FDA marketing approval of the DrugSorb™-ATR antithrombotic removal system to remove the blood thinners, Brilinta®, and Xarelto® and Eliquis® during open heart surgery, to reduce potentially fatal bleeding complications
- We were awarded two FDA Breakthrough Device Designations for this application - a “fast track” path for devices addressing major unmet clinical needs
- In 2021, we began dual pivotal U.S. randomized controlled trials, called STAR-T (to remove Brilinta) and STAR-D (to remove Xarelto and Eliquis), each designed to separately support U.S. FDA marketing approval of DrugSorb™-ATR
  - Each trial is expected to enroll 120 patients across 30 sites
  - The primary endpoint is a reduction in peri-operative bleeding vs standard of care alone
  - STAR-T is expected to achieve its first milestone of 40 patients enrolled this summer and complete enrollment by March 2023, and STAR-D 6-months behind
  - FDA marketing approval submission is expected within 3-6 months of completing enrollment
  - If successful, we seek to establish DrugSorb-ATR as the new global standard to reduce a broad range of blood thinners during cardiothoracic surgery



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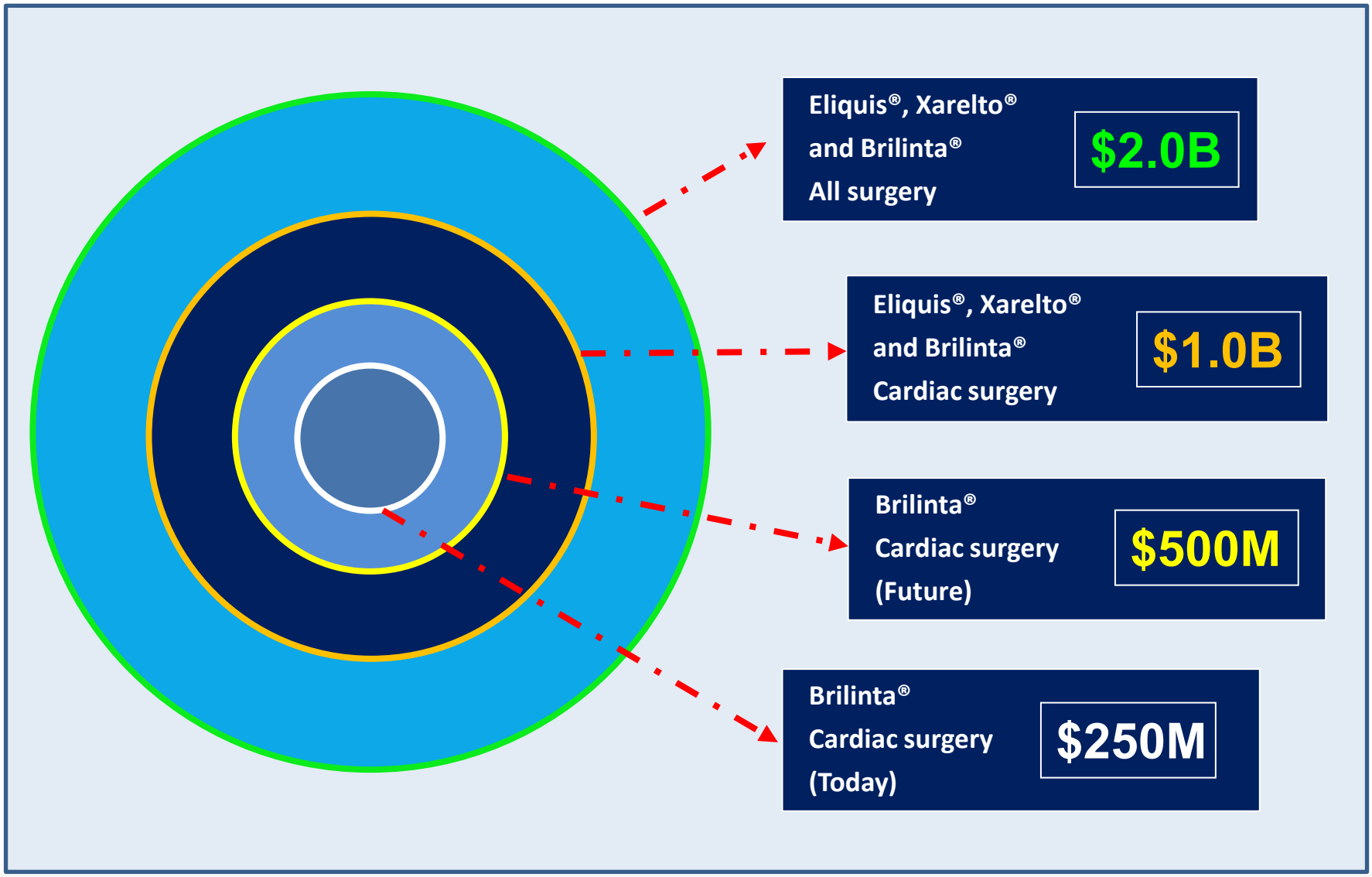
# Addressable U.S. Market For Current and Potential Future Indications for Antithrombotic Removal by DrugSorb-ATR



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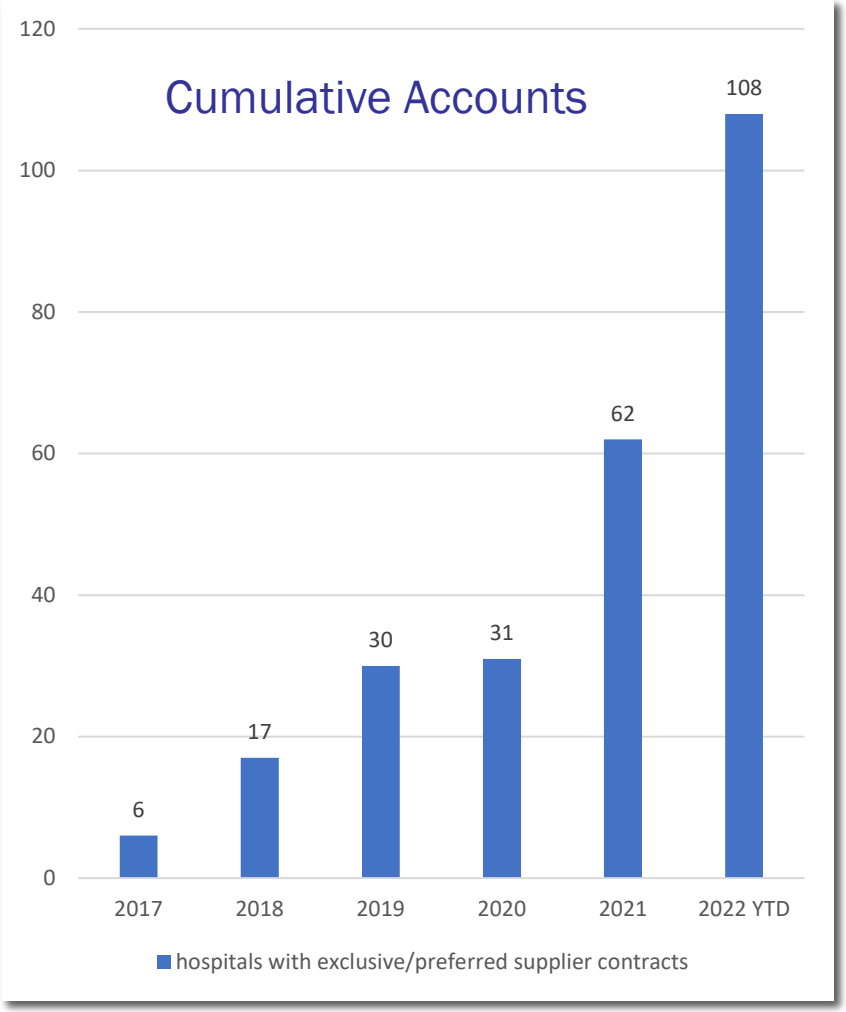
# #2

## Resume Growth of CytoSorb Sales

# Exclusive/Preferred Supplier Contracts in Germany




- Customer loyalty and satisfaction has led to a significant increase of exclusive or preferred supplier contracts of CytoSorbents
- Contracts with hospital chains or with purchasing organizations enable easier access to hospitals



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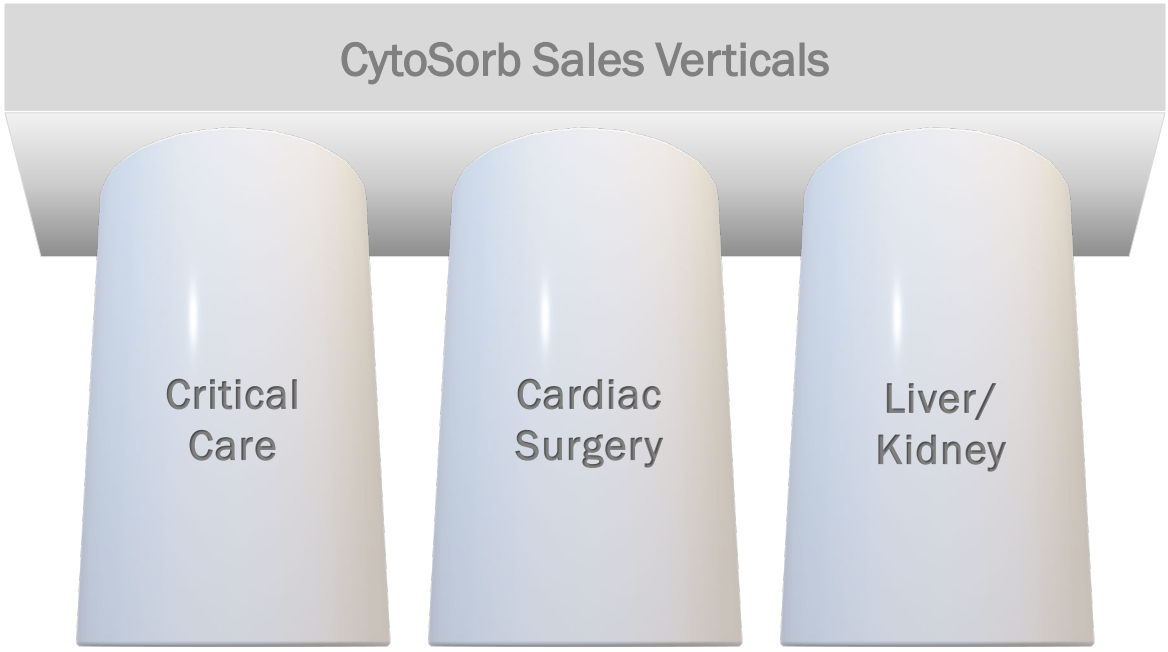
# Realignment on Therapy Area Verticals




- Team based approach combining sales, marketing, and medical affairs
- Focused market development expected to drive more rapid adoption and usage
- Due to specific area expertise, best suited to launch new applications



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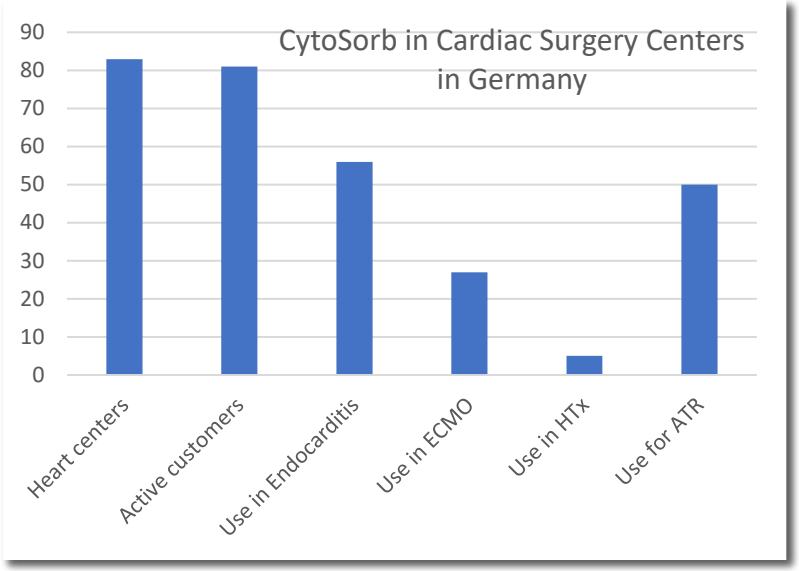
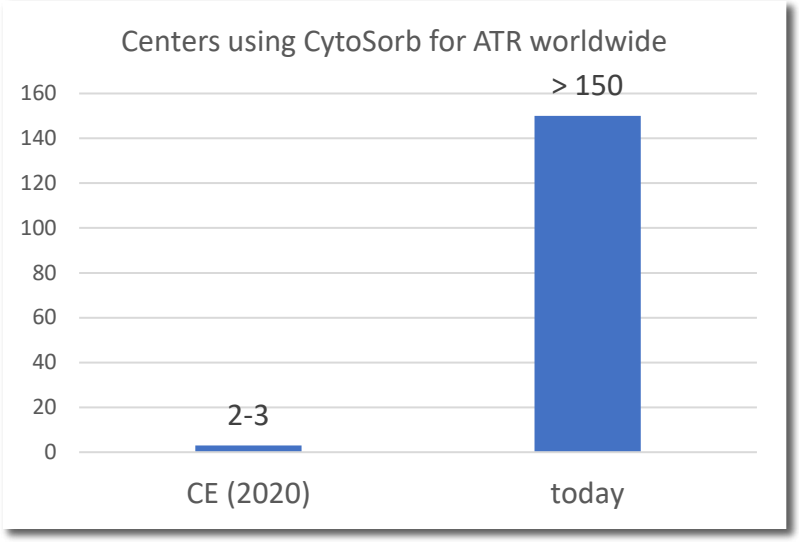
# Therapeutic Area - Cardiovascular

- Therapeutic Area team led by an experienced marketing executive and a cardiac surgeon
- Establishing and extending robust KOL network
- German Heart Center roadshow started; International planned
- A number of relevant peer-reviewed publications expected within the next months
- Increasing adoption of CytoSorb in several cardiovascular application fields



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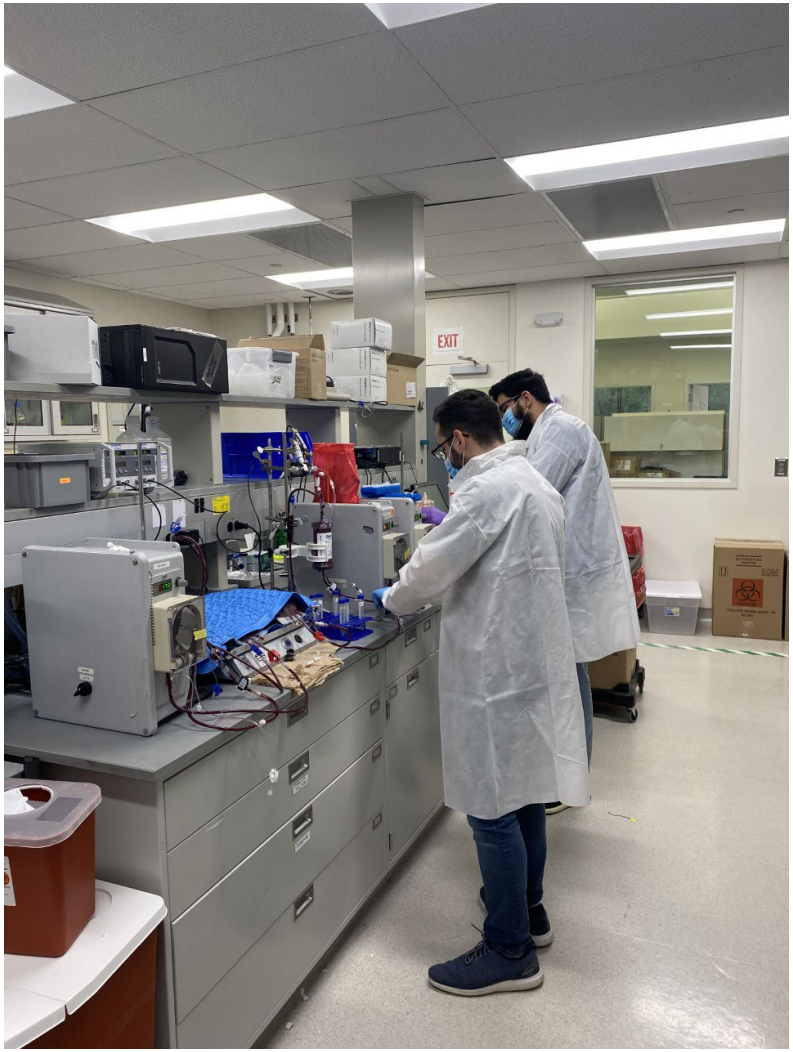
# #3

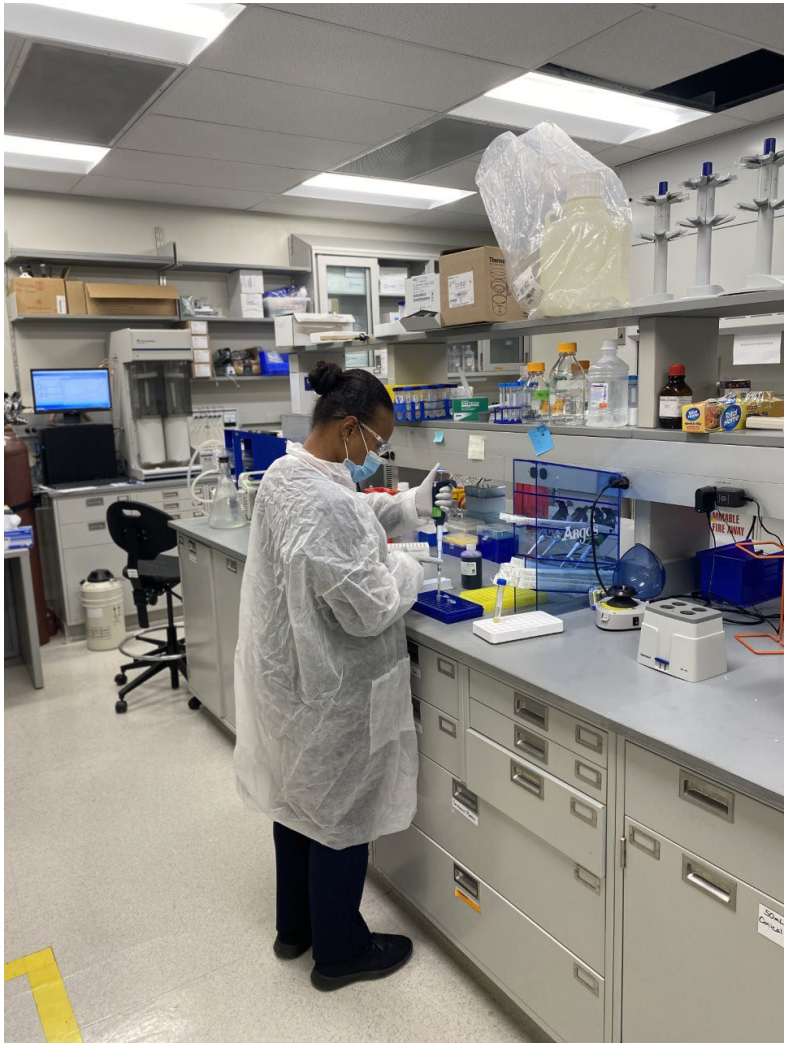
## Transition to New Manufacturing Facility

# Scaling Manufacturing Capacity to $300-$400M

- Our current manufacturing facility has capacity for ~$80M in sales
- New headquarters in Princeton, NJ houses our new manufacturing facility that is expected to increase manufacturing capacity by 5x to $300-400M in annual sales, while expanding product gross margins beyond 85% due to volume manufacturing
- Capital expenditures to build out facility are modest (<$10M), an excellent ROI
- We have completed construction, with all equipment placed and qualified
- Completed a favorable audit by our E.U. Notified body and expect final certification in the next several months, with the goal to begin manufacturing CytoSorb in 2H 2022

# New Facility – First Look





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# #4

## More Partnerships

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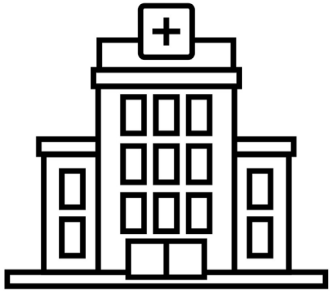
# Our Newest Partner: NIKKISO

- Nikkiso Medical is one of the world's leading manufacturers of dialysis machines and disposables for both acute and chronic blood purification therapies
- Nikkiso is also a market leader in Europe and Asia
- CTSO has executed an agreement with Nikkiso Medical to supply CTSO with its PureADJUST machines and accessories
  - 14 country reseller agreement in place
  - CTSO has the ability to provide HP machines, tubing sets and field support to customers
  - Various business models possible, can be tailored to market situation (buy, lease, etc.)

# New HP Growth Opportunity to Drive CytoSorb Adoption

Physicians want to start CytoSorb prior to CRRT, going beyond the <10% of patients in ICU that have developed kidney failure and are already on dialysis or CRRT

Access to CytoSorb can be challenging in places where CRRT is limited due to the high cost of CRRT, lack of skilled nursing, or market clearance for CRRT devices have not yet been obtained



In the future, CTSO could benefit from a low cost, easy to use blood pump to accelerate its hospital wide strategy outside of the ICU

Providing customers with **access to a low cost, easy to use extracorporeal platform** has the potential to **accelerate the adoption of CytoSorb** in our current indications and serves as a foundation for future growth

# Summary

CytoSorbents has the potential to become a highly profitable performer in the therapeutics space with superior operating profit margins

- High margin razorblade business model with excellent operating leverage and a solid track record of ex-US growth

- Strong foundation and well-funded for potential future growth, with new and existing clinical applications that address major unmet medical needs and ride major trends in healthcare

- We have extensive validation from physicians around the world, leading strategic partners, U.S. government agencies, and the media

- Focus on 4 key milestones is expected to drive our current and future success
  - U.S. FDA marketing approval based on 2 pivotal U.S. RCTs (STAR-T and STAR-D) for blood thinner removal and dual FDA Breakthrough Device Designations
  - Return to sales growth of CytoSorb as COVID fades
  - Open new manufacturing facility to increase capacity and gross margins
  - New partnerships and expansion of existing ones

# CytoSorbents™

HELPING TO TREAT INFLAMMATION AND DEADLY CONDITIONS IN INTENSIVE CARE AND CARDIAC SURGERY

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