



CytoSorbents Corporation  
Third Quarter 2021 Earnings Conference Call  
November 4, 2021

**CytoSorbents**<sup>TM</sup>

WORKING TO SAVE LIVES

# Conference Call Participants

Moderator: Terri Anne Powers  
CytoSorbents Corporation



Phillip Chan, MD, PhD – Chief Executive Officer



Vincent Capponi, MS – President and Chief Operating Officer



Kathleen Bloch, MBA, CPA – Chief Financial Officer



Efthymios “Makis” Deliargyris, MD, FACC, FESC, FSCAI – Chief Medical Officer



Christian Steiner, MD – Executive Vice President of Sales and Marketing and  
Managing Director – CytoSorbents Europe GmbH



Christopher Cramer, MS, MBA – Vice President of Business Development

# Safe Harbor Statement

---

Statements in this presentation regarding CytoSorbents Corporation and its operating subsidiaries CytoSorbents Medical, Inc and CytoSorbents Europe GmbH that are not historical facts are forward-looking statements and are subject to risks and uncertainties that could cause actual future events or results to differ materially from such statements. Any such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. It is routine for our internal projections and expectations to change. Although these expectations may change, we are under no obligation to inform you if they do. Actual events or results may differ materially from those contained in the projections or forward-looking statements. The following factors, among others, could cause our actual results to differ materially from those described in a forward-looking statement: our history of losses; potential fluctuations in our quarterly and annual results; competition, inability to achieve regulatory approval for our device, technology systems beyond our control and technology-related defects that could affect the companies' products or reputation; risks related to adverse business conditions; our dependence on key employees; competition for qualified personnel; the possible unavailability of financing as and if needed; and risks related to protecting our intellectual property rights or potential infringement of the intellectual property rights of third parties. This list is intended to identify only certain of the principal factors that could cause actual results to differ from those discussed in the forward-looking statements. Readers are referred to a discussion of important risk factors detailed in the Company's Form 10-K filed with the Securities and Exchange Commission on March 9, 2021, and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).

# Q3 2021 Operational Update

Phillip Chan, MD, PhD  
Chief Executive Officer

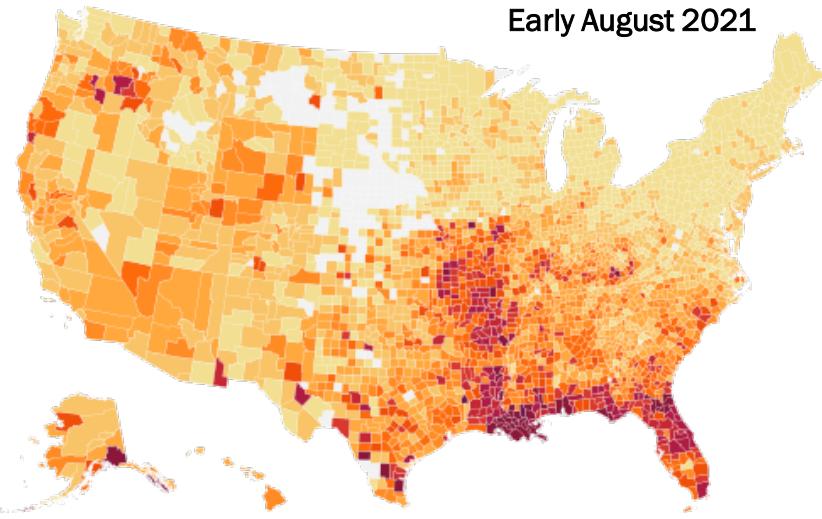
# Q3 2021 and Recent Operational Highlights

- Q3 2021 total revenue was \$9.8M, including product sales of \$8.9M, and blended product gross margins were 82%. Balance sheet is solid with \$61.0M in cash (9/30/21) and no debt
- The U.S. STAR-T pivotal trial has begun with first patient enrolled in October
- DrugSorb-ATR received Breakthrough Device Designation to remove the DOACs apixaban and rivaroxaban in CT surgery and received full FDA IDE approval to begin the U.S. STAR-D pivotal trial for this application in only three months
- Topline results from the multicenter U.S. CTC Registry demonstrated high survival using CytoSorb and ECMO in critically ill COVID-19 patients
- Preliminary REMOVE study results evaluating the use of CytoSorb in infective endocarditis were neutral, but showed a favorable adverse event profile and validated CytoSorb's mechanism of action
- CytoSorb is now distributed in more than 70 countries, including the recent addition of Thailand and the Ukraine
- More than 152,000 cumulative CytoSorb devices utilized to date, up 38% Y-Y

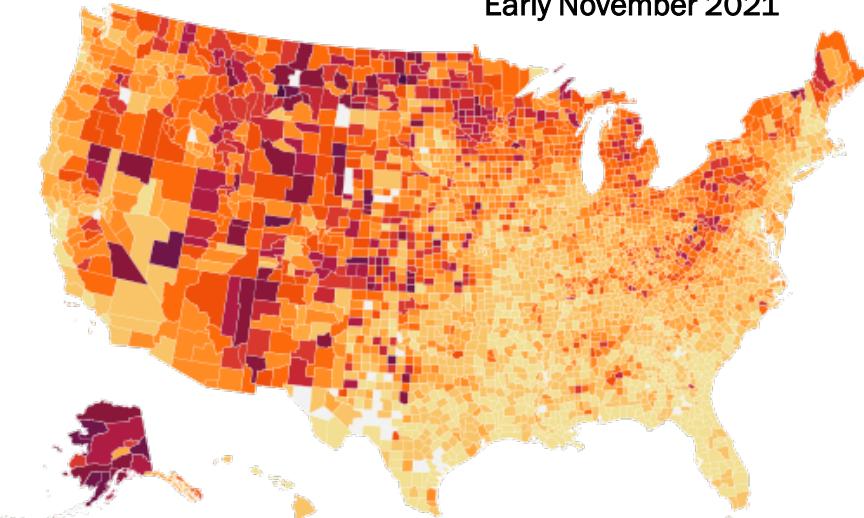


# U.S. COVID-19 Status

Early August 2021



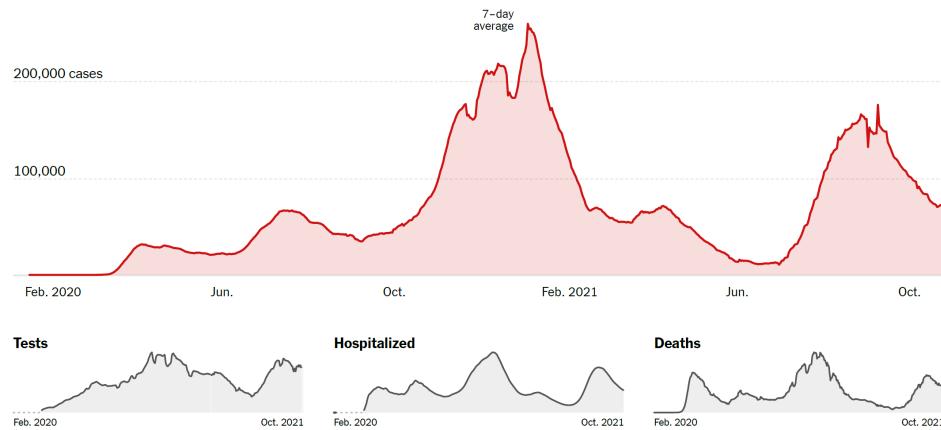
Early November 2021



**CytoSorbents**<sup>TM</sup>

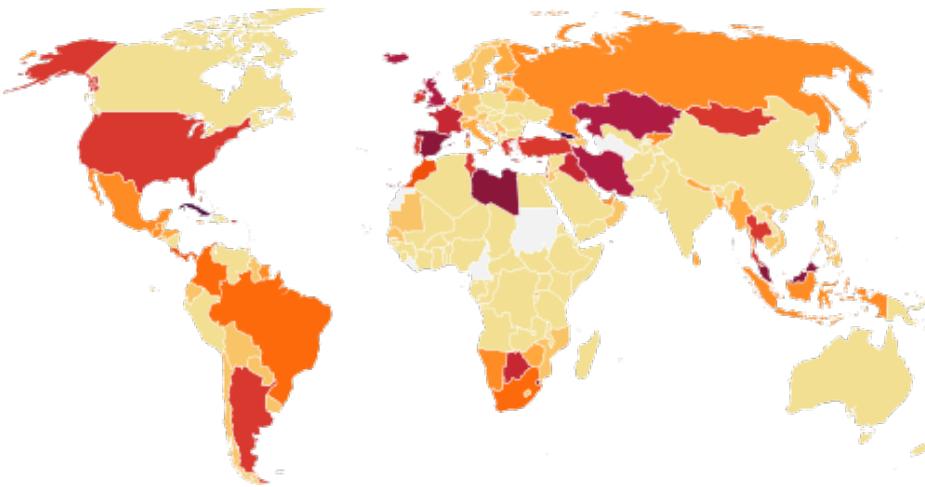
WORKING TO SAVE LIVES

- Migrated to Western US and increasing in the Northeast
- 68% of eligible people (12+ yo) are fully vaccinated with 78% with at least 1 dose. 58% of entire population is vaccinated
- Highly contagious Delta variant responsible for 99% of new U.S. infections



# Worldwide COVID-19 Status

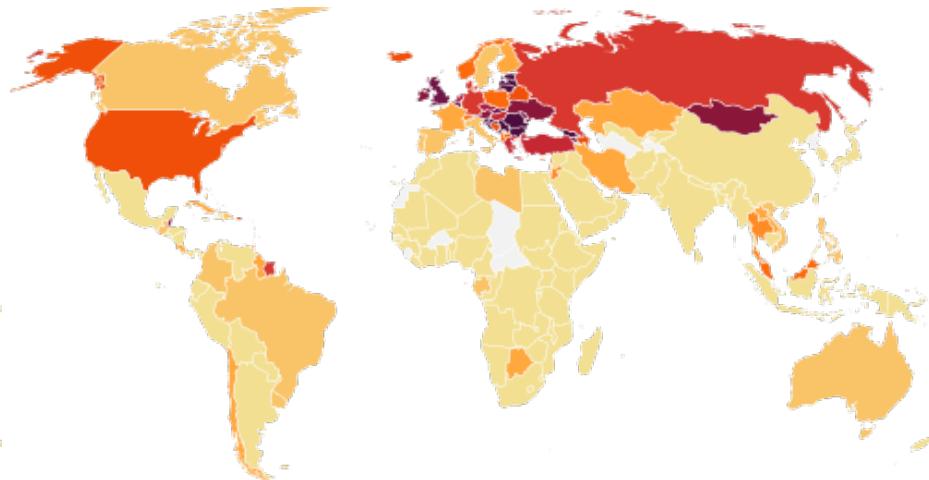
Early August 2021



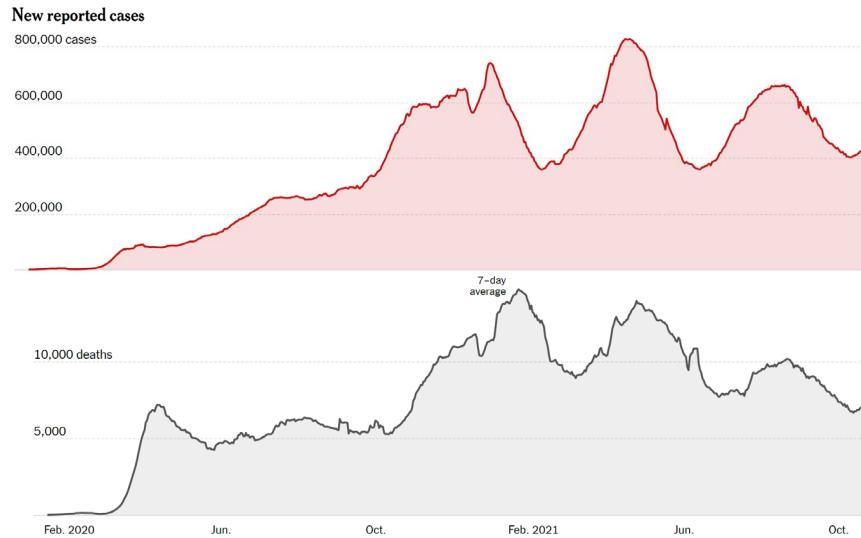
Major increases in vaccinated populations, esp. Europe.  
U.S. lagging other major countries, despite head-start

Country	Fully Vaccinated	Partially Vaccinated
U.S.	58%	67%
Germany	67%	69%
Italy	71%	77%
France	68%	76%
Spain	79%	81%
U.K.	68%	75%
Worldwide	14%	28%

Early November 2021

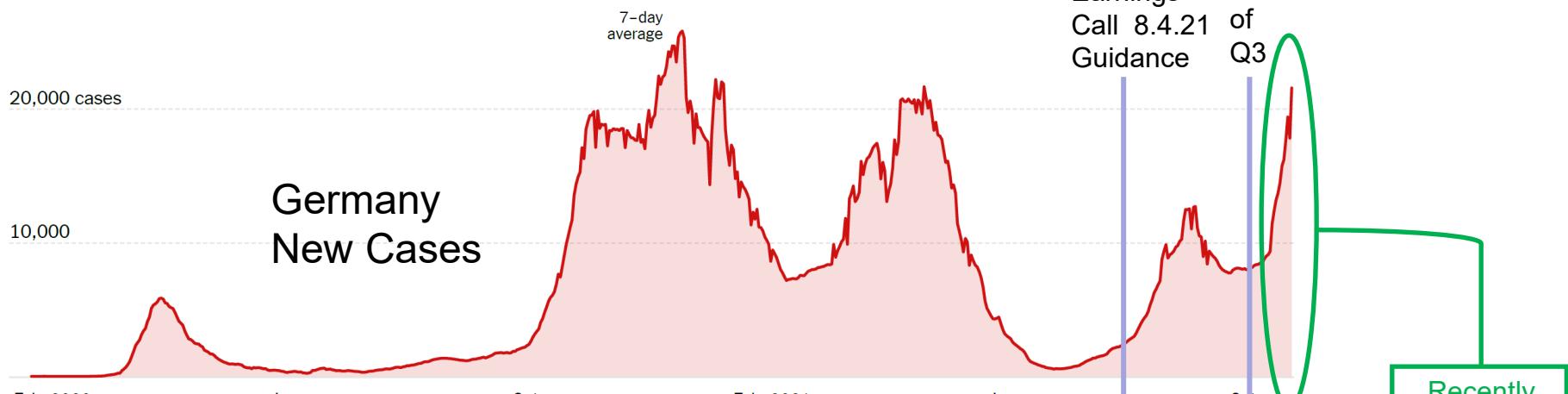


Worsening in the UK and Germany but mortality is low. High in Eastern Europe and Russia

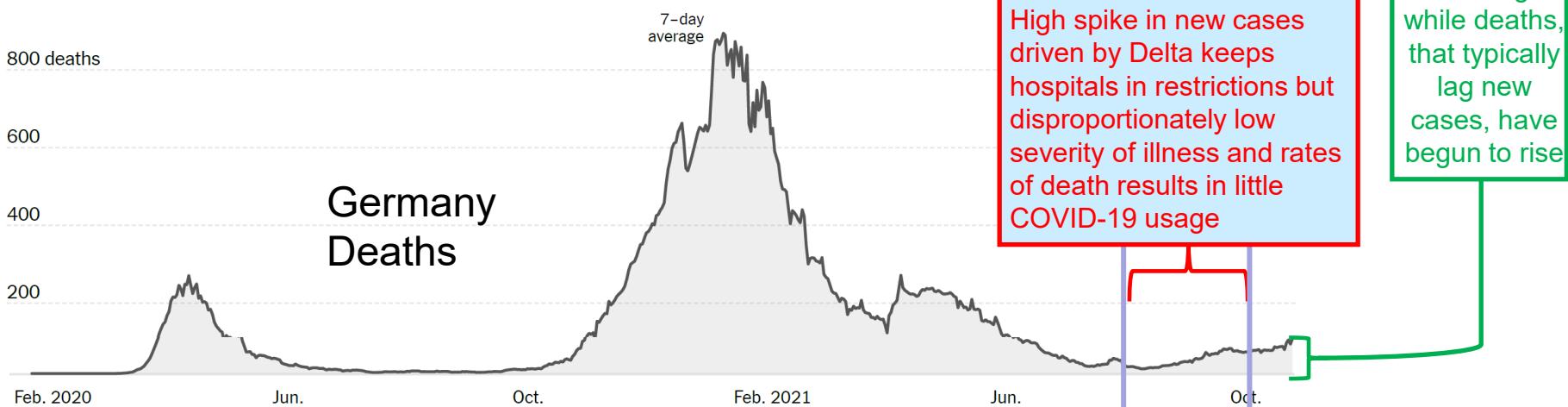


# Germany COVID-19 Status

New reported cases by day



New reported deaths by day



**CytoSorbents**<sup>TM</sup>

WORKING TO SAVE LIVES

# Commercialization Update

Christian Steiner, MD

Executive Vice President of Sales and Marketing

Managing Director – CytoSorbents Europe GmbH

**CytoSorbents**<sup>TM</sup>

WORKING TO SAVE LIVES

# COVID Situation Reversed During 3Q21

---

- A fourth wave in new COVID-19 cases in Europe, including Germany, accelerated in August through the end of Q3. We observed:
  - Many hospitals reduced elective surgical procedures, reserved ICU beds and either maintained or reinstated visitation restrictions
  - Lower rates of severe COVID-19 illness requiring ICU care were observed, with lower death rates partially attributable to increased vaccination rates
- Our critical care and cardiac surgery businesses were impacted by:
  - Fewer critically ill COVID-19 patients and fewer core non-COVID-19 patients
  - Increased hospital restrictions resulting in decreased sales access
  - Continued reduced ICU capacity, compounded by staffing shortages and implementation of strict patient to nursing ratios
  - Reduced ability to visit and gain new customers
- Quarterly results also impacted by greater-than-normal Q3 seasonality

# Current Situation in Q4

---

- The macro environment remains challenging in Germany
  - Significant rise in new cases of COVID
  - Continued ICU capacity constraints due to staff shortages and resource allocation
  - Higher vaccination rates not yet reflected in decreased restrictions
  - But unlike Q3, ICUs are beginning to fill and we are starting to see an increase in COVID-19 related orders
  - Ongoing debate in health politics to address how to break 4th wave
- Similar situation in many markets, but impact on business most relevant in Germany
- We expect the environment to improve over time, but the pace is difficult to predict
- Sales trends to date, including Germany, suggest we are on track to meet fourth quarter product revenue guidance

# Increasing Marketing and Promotion



# Increasing Marketing and Promotion



Setup of broadcasting studio of the 8th International CytoSorb Users Meeting

# Priorities for Driving Worldwide Growth

---

- CytoSorbents is applying a parallel strategy to drive sales
  - New CytoSorb-in-COVID campaign – clinical results, best practice in treating patients with a focus on patient selection / timing / dosing
  - Continued promotion of core indications
    - » Critical Care – Septic Shock, Trauma, Acute Pancreatitis etc.
    - » Cardiovascular – Antithrombotic removal (ATR), Infective Endocarditis, others
    - » Liver Support Therapy
- Increasing marketing and promotion efforts given access and travel restrictions
  - New hybrid conferences and symposia
  - In-person customer meetings where possible
  - Additional educational and training meetings (virtually and in-person)
- Priorities to drive medium-term and longer-term growth
  - Sales force optimization
  - Maximizing existing clinical applications and launching new ones
  - Expanding direct territories

# Clinical Update

Efthymios N. Deliargyris, MD, FACC, FESC, FSCAI  
Chief Medical Officer

**CytoSorbents**<sup>TM</sup>

WORKING TO SAVE LIVES

# Path to FDA Marketing Approval

STUDY	Status
<b>STAR-T</b> (NCT04976530)	<ul style="list-style-type: none"><li>July - Full FDA IDE approval</li><li>August – Study start-up activities ramp up</li><li>September – Site activations begin</li><li>October – Enrollment begins (FPI - University of Maryland)</li><li>November 4<sup>th</sup>, 2021 – 6 sites activated</li><li>STAR-T methods manuscript accepted for publication (AHJ)</li><li><u>Next Steps</u> – Site activations continue; Ongoing enrollment</li></ul>
<b>STAR-D</b> (NCT05093504)	<ul style="list-style-type: none"><li>July – FDA Breakthrough Designation application</li><li>August – FDA Breakthrough Designation granted</li><li>September – FDA IDE submission</li><li>October – Full FDA IDE approval + WIRB approval received</li><li>November 4<sup>th</sup> 2021 – Study start-up activities ramp up</li><li><u>Next steps:</u> Site activation and FPI</li></ul>
<b>REFRESH-2 AKI</b> (NCT03384875)	<ul style="list-style-type: none"><li>15 sites activated</li><li>Nov 4<sup>th</sup>, 2021 - 178 patients enrolled; 111 randomized</li><li>Significant COVID-19 headwinds as elective surgeries postponed</li><li><u>Next steps:</u> continued enrollment to interim analysis</li></ul>

# Other Company Clinical Programs

PROGRAM	Latest Update & Status		Next	Target Completion
PROCYSS RCT Septic Shock	GER	Recruiting (1 active site) – Ongoing site activation	Enrollment	2023*
CYTATION Ticagrelor Removal	GER	Enrolling (4 sites active; 3 in GER and 1 in LUX)	Enrollment	2022*
Hep-On-Fire Liver Failure	GER	Ethics approval received – Site activations begin	Enrollment	2023*
CTC Registry COVID-19	US	Topline results presented - Ongoing data analyses	Publications	2021
STAR Registry Antithrombotic Removal	EU	Enrolling – UK + GER active; Next target countries: Austria, Belgium, Netherlands, Sweden	Enrollment	Ongoing
COSMOS Registry All inclusive Critical Care	EU	Protocol finalized – Start up operational activities	EC submission	Ongoing

\*COVID-19 continues to create challenges:

- “Acute” effects: Elective procedures delayed/deferred; Patients not screened; Research personnel visit restrictions; Fewer ICU beds
- “Long” effects: Staff fatigue & turnover; Hiring challenges/shortages

# Update on Recent Data Releases

---

## COVID-19 - Topline U.S. multicenter CTC Registry ECMO results

- 90-day survival of 73.1% (n=52, 5 centers). For context, 90-day survival in the North American cohort of the ELSO Registry is 50% (n=5,264, Oct 30, 2021)
- CTC data well-received and are expected to drive COVID-19 + ECMO usage worldwide
- Future CTC analyses will aim at better defining the optimal use of CytoSorb with ECMO and identify potential additional clinical and economic benefits

## ENDOCARDITIS - European Association of Cardio-Thoracic Surgery

- The REMOVE randomized study (n=282) did not meet the primary endpoint of change in SOFA score with the use of CytoSorb in an all-comer population
- Observational study from Nuremberg, Germany (n=195) showed reduction in sepsis related mortality with CytoSorb in patients with left sided endocarditis
- Both studies declared intraoperative use of the device as safe with the same adverse event rates as the standard of care (i.e. control arm without device)
- We intend to work closely with the investigators of both studies to further analyze the data and potentially inform future endocarditis studies

# Global Clinical Program is Accelerating

---

- Clinical capabilities scaled up significantly in the past 12 months to support our global clinical plan comprised of 9 Company-sponsored clinical studies
- Path to US marketing approval focused on the antithrombotic removal opportunity with the 2 IDE-approved RCTs (STAR-T, STAR-D)
- Outside the US, we are focused on generating data in several critical care applications including sepsis and liver failure, among others
- By the end of 2021 we expect to have 7 programs actively recruiting, and all 9 programs active by the end of Q1 2022

# Q3 2021 Financial Highlights

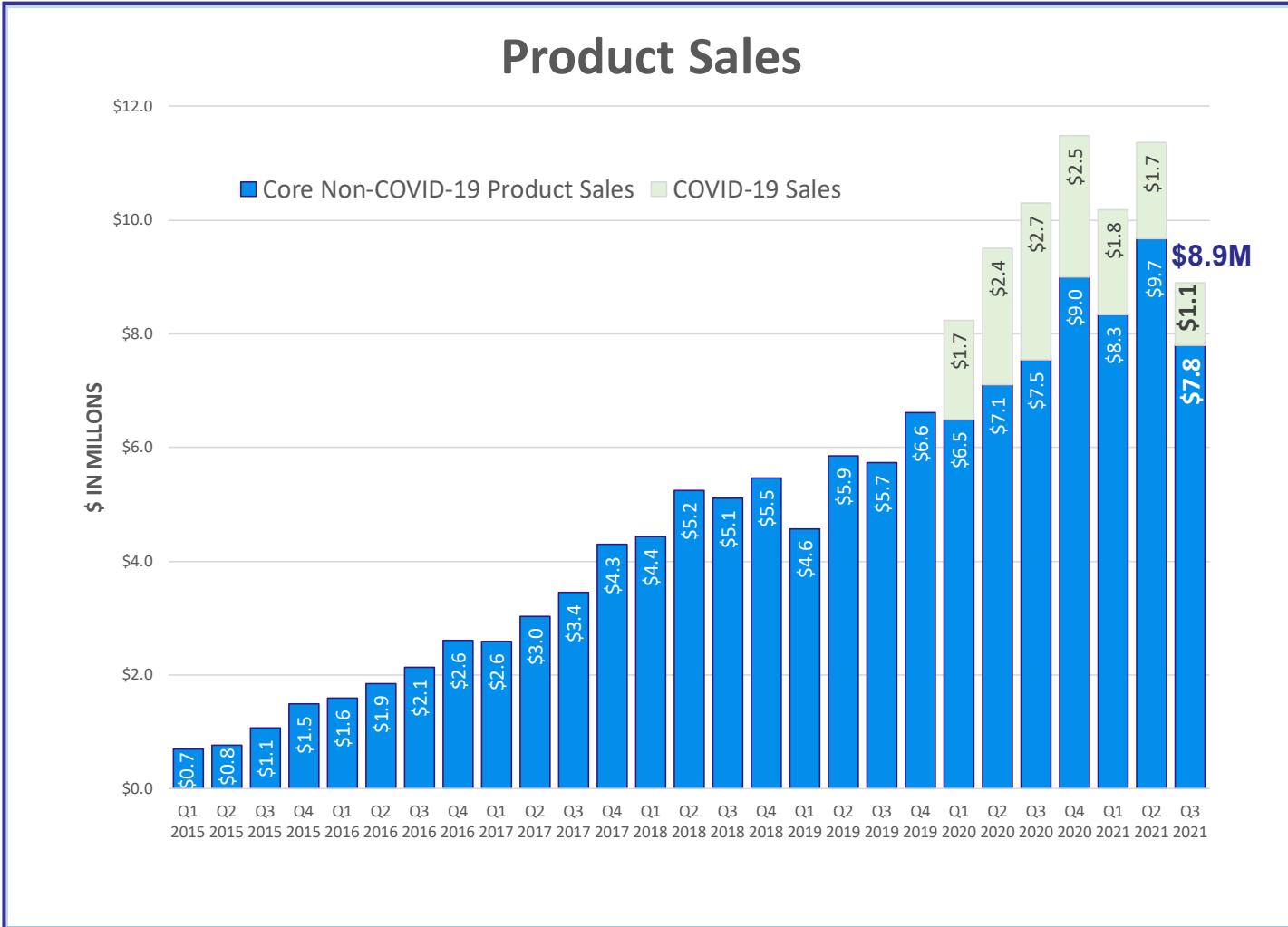
Kathleen Bloch, MBA, CPA  
Chief Financial Officer

# Q3 2021 Comparative Revenue Results

	Quarter Ended Sept. 30, 2021		Quarter Ended Sept. 30, 2020		Y-Y % Trend
Product revenue	\$8.9M		\$10.2M		(13%)
Grant income	\$0.9M		\$0.3M		185%
Total revenue	\$ 9.8M		\$ 10.5M		(7%)

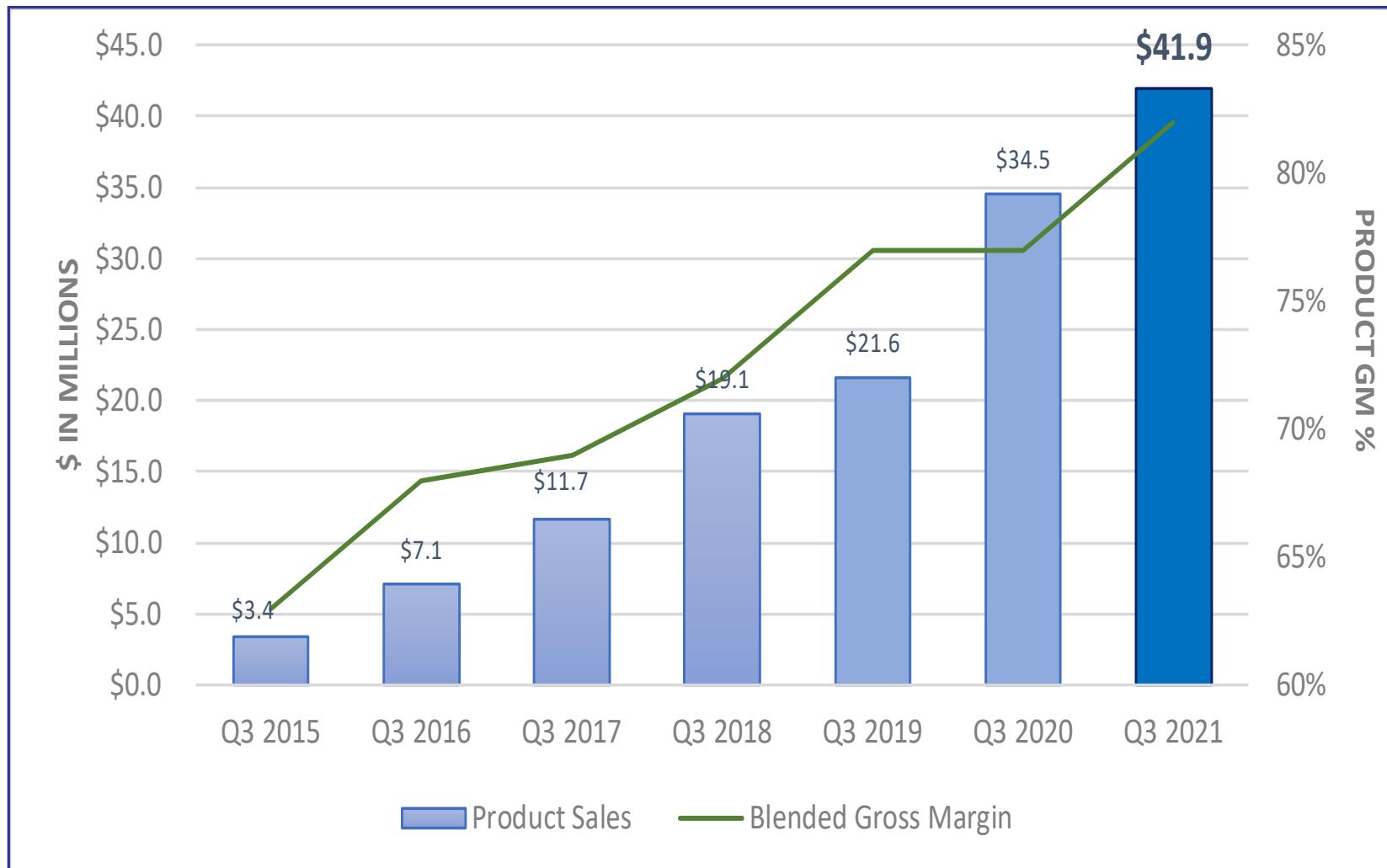
- Q3 2021 product sales were \$8.9M, down 13% compared to \$10.2M in Q3 2020, driven by lower COVID-19 related sales and slower Y-Y growth in core non-COVID-19 sales of 3%
- Q3 2021 grant revenues were \$859K, up from Q3 2020 grant revenues of \$301K
- Total revenue, which includes both product sales and grant revenue, decreased 7% to \$9.8M in Q3 2021, compared to \$10.5M in Q3 2020
- Q3 2021 product gross margins were 82%, compared to 74% for Q3 2020

# Quarterly Product Sales



Q3 2021 COVID-19 product sales were approximately \$1.1M

# Trailing Twelve Month Product Sales



# 2021 Product Revenue Guidance

---

- We expect Q4 2021 product revenue to be similar to Q3 2021 product revenue of \$8.9M
- Full year 2021 product revenue is expected to be at least \$39.3M, roughly flat compared to 2020 product revenue of \$39.5M
- While difficult to predict, 2021 core non-COVID-19 product revenue is expected to be approximately \$33M to \$34M for the year versus \$30.1M in 2020

# Working Capital and Cap Table (\$M)

Working Capital as of						
	9/30/2021	6/30/2021	3/31/2021	12/31/2020	12/31/2019	12/31/2018
<b>Current Assets:</b>						
Cash and short-term investments	\$ 61.1	\$ 65.6	\$ 68.5	\$ 71.4	\$ 12.2	\$ 22.4
Grants and accounts receivable, net	5.2	5.8	5.0	5.2	4.5	3.9
Inventories	4.6	3.7	3.1	2.7	2.1	0.8
Prepaid expenses and other current assets	1.9	2.0	3.0	3.0	2.1	1.1
<b>Total current assets</b>	<b>72.8</b>	<b>77.1</b>	<b>79.6</b>	<b>82.3</b>	<b>20.9</b>	<b>28.2</b>
<b>Current Liabilities:</b>						
Accounts payable	3.4	2.2	1.7	1.8	2.0	1.5
Accrued expenses and other current liabilities	7.4	8.4	7.6	7.9	5.8	4.4
Current maturities of long-term debt	0.0	0.0	0.0	0.0	1.7	0.6
Lease liability - current portion	0.3	0.3	0.4	0.4	0.4	0.0
<b>Total current liabilities</b>	<b>11.1</b>	<b>10.9</b>	<b>9.7</b>	<b>10.1</b>	<b>9.9</b>	<b>6.5</b>
<b>Net Working Capital</b>	<b>\$ 61.7</b>	<b>\$ 66.2</b>	<b>\$ 69.9</b>	<b>\$ 72.2</b>	<b>\$ 11.0</b>	<b>\$ 21.7</b>

## Cap Table 9/30/2021

Fully Diluted Common Shares	
Common Stock	43,475,648
Options	6,864,854
Restricted Stock Unit Awards	301,212
	<b>50,641,714</b>

# Concluding Remarks

Phillip Chan, MD, PhD  
Chief Executive Officer

# Well-Positioned for Long-Term Growth

---

- Despite the complexities of COVID-19 on our business, we remain confident in our therapies that have been utilized in more than 152,000 treatments, the core business both in Germany and internationally, and our excellent business model and strong product gross margins
- Pursuing parallel strategy to drive utilization in COVID-19 patients and in our core applications to return the German business to growth and drive longer-term worldwide growth potential
- Strong cash balance that we are directing towards key investments in growth (e.g. clinical studies, sales & marketing, manufacturing capacity expansion)
- We are accelerating our U.S. clinical program focused on the antithrombotic removal opportunity – a potential major future growth catalyst

# Q&A Session

---

## CytoSorbents Corporation

NASDAQ: CTSO

Investor Relations Contact

Terri Anne Powers

[tpowers@cytosorbents.com](mailto:tpowers@cytosorbents.com)



**CytoSorbents**<sup>TM</sup>

WORKING TO SAVE LIVES