

CytoSorbents Corporation Fourth Quarter and Full Year 2021 Earnings Conference Call March 8, 2022

## **Conference Call Participants**





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 forwardlooking 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 2021 Form 10-K filed on March 9, 2021, our 2022 Form 10-K to be subsequently filed with the Securities and Exchange Commission, and other reports and documents filed from time to time by us, which are available online at <u>www.sec.gov</u>.



# **Operational Update**

Phillip Chan, MD, PhD Chief Executive Officer



## 2021 Executive Summary

- Despite pandemic headwinds, 2021 was a good year with sales growth driven by increased CytoSorb utilization and advancement of key objectives
- Total revenue grew 5%, product gross margins improved to 80%, and balance sheet remains strong with ~\$54M in cash (12/31/21) and no debt
- Made significant progress on U.S. antithrombotic removal clinical program with the launch of two pivotal RCTs evaluating the intraoperative use of DrugSorb-ATR during urgent cardiothoracic surgery under two FDA Breakthrough Device Designations
- Invested in people and processes to ensure focus on critical care and cardiac surgery applications to position the Company for sustained revenue growth
- Continued to drive awareness of CytoSorb via Company and investigator-initiated presentations and publications
- >162,000 cumulative CytoSorb devices utilized as of 12/31/21, up 34% year over year
- Focused capital allocation on priority clinical programs, sales and marketing, and new manufacturing facility build-out



## Worldwide COVID-19 and Vaccination Status

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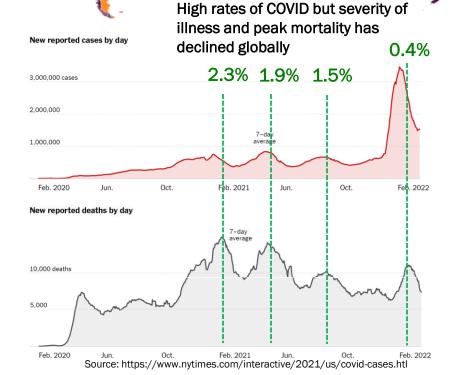
#### Early November 2021

Early March 2022

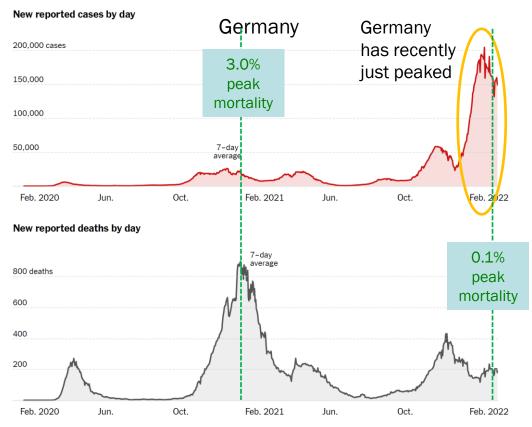
65% of the world population has now had at least 1 vaccine dose and 58% fully vaccinated vs 28% with 1 dose and 14% fully vaccinated in November 2021

Country	Fully Vaccinated	Partially Vaccinated
U.S.	65%	76%
Germany	76%	76%
Italy	79%	84%
France	78%	80%
Spain	83%	87%
U.K.	73%	79%
Worldwide	58%	65%





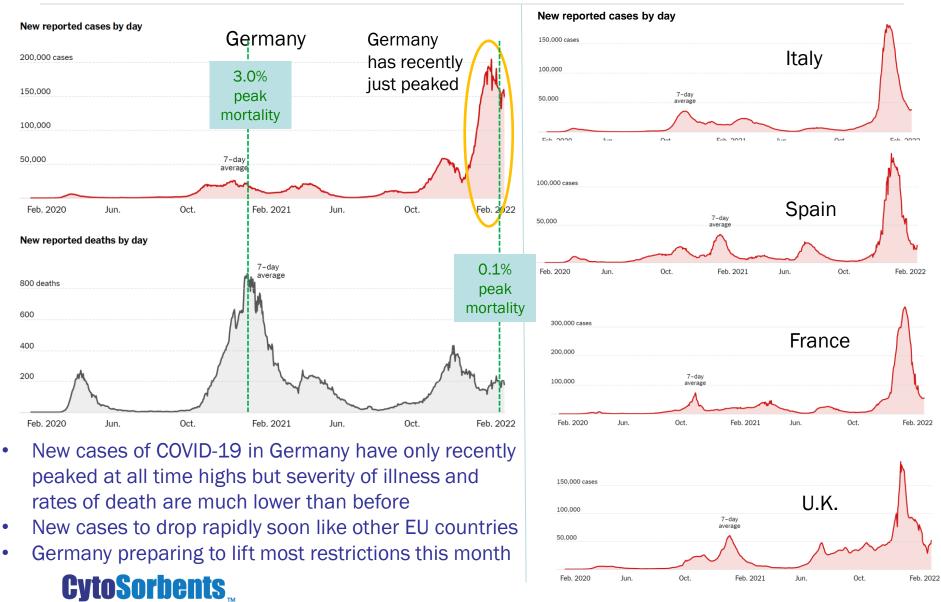
## Germany COVID-19 Status (3/8/22)



- New cases of COVID-19 in Germany have only recently peaked at all time highs but severity of illness and rates of death are much lower than before
- New cases to drop rapidly soon like other EU countries
- Germany preparing to lift most restrictions this month

#### **CytoSorbents**<sub>...</sub>

## Germany COVID-19 Status (3/8/22)



## Navigating through Global Uncertainty

- We expect the COVID-19 pandemic will likely burn out in 2022
  - Likely will see minor spikes in COVID-19 as restrictions like masks are lifted
  - But pandemic is likely coming to an end this year, due to natural history of viral pandemics, the very high rates of vaccinations and natural immunity, and the decreased severity of illness, globally
  - There will be other COVID-19 variants, but will likely be more like seasonal flu, some worse than others
- We believe we currently have limited exposure from the Russia-Ukraine war, with less than 4% of our 2021 product revenue coming from the region
- We expect continued and progressive improvement throughout the year in our core non-COVID-19 business with 20% or more growth over \$33.8M in core non-COVID-19 sales which assumes:
  - Recovery of normalized hospital activity and sales access in Germany and other key countries
  - No major economic slowdowns caused by new variants of COVID-19
  - Little to no sales from Russia, Ukraine, and neighboring countries
- We expect limited COVID-19 related sales in 2022 as the severity of COVID-19-related illness, hospitalizations, critical illness, and deaths have dropped significantly



## We Remain Focused on 2022 Strategic Priorities

- 1) Advance the high priority STAR-T and STAR-D U.S. clinical trials in pursuit of U.S. FDA marketing approval
- 2) Targeting 20% or more growth in core CytoSorb sales in 2022
- 3) Complete the buildout and begin commercial CytoSorb production out of our new manufacturing facility in New Jersey by the second half of 2022, to increase production capacity to support annual product sales of up to \$400M and to improve product gross margins
- 4) Expand both new and existing strategic partnerships to maximize the synergy between our technology and those of our partners, while creating new opportunities for global growth



# **Financial Highlights**

Kathleen Bloch, MBA, CPA Chief Financial Officer



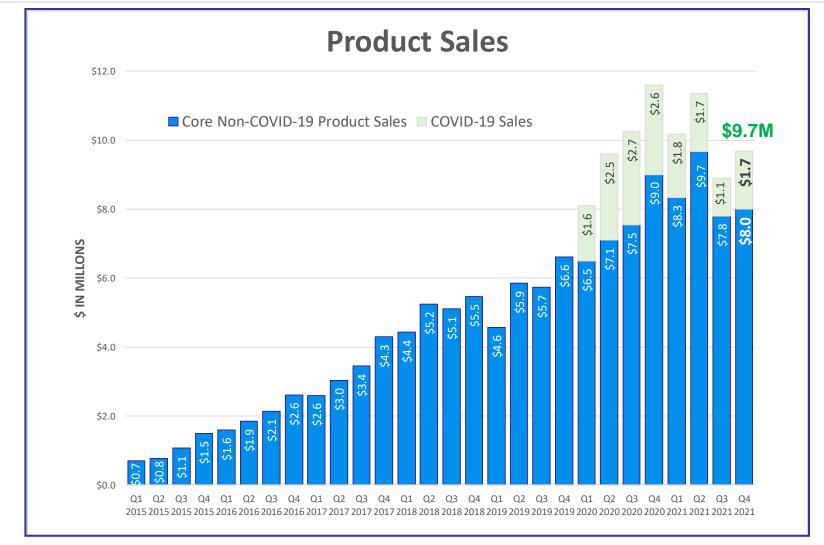
## Q4 2021 Comparative Revenue Results

	Quarter Ended Dec. 31, 2021	Quarter Ended Dec. 31, 2020	% Incr.
Product sales	\$ 9,697,876	\$ 11,530,563	-16%
Grant income	1,084,320	425,214	155%
Total revenue	\$ 10,782,196	\$ 11,955,777	-10%

- Total revenue in Q4 2021, which includes both product sales and grant revenue, decreased 10% to approximately \$10.8M, compared to approximately \$12M in Q4 2020
- Q4 2021 product sales were \$9.7M, a 16% decline over \$11.5M in Q4 2020
  - Q4 2021 product sales of \$5.3M in Germany increased 45% from Q3 2021
- Grant revenue in the fourth quarter was \$1.1M compared to \$0.4M in Q4 2020
- Gross profit margins on product sales were 78% for Q4 2021, versus 81% for Q4 2020



#### **Quarterly Product Sales**



2021 COVID-19 sales are estimated to be \$6.3M



## 2021 Comparative Revenue Results

	Year Ended Dec. 31, 2021	Year Ended Dec. 31, 2020	% Incr.
Product sales	\$40,108,567	\$39,452,502	2%
Grant income	\$3,056,960	\$1,552,099	97%
Total revenue	\$43,165,527	\$41,004,601	5%

- Total 2021 revenue, which includes both product sales and grant revenue, was \$43M as compared to \$41M in 2020, an increase of 5%
- 2021 Product sales were \$40.1M, a 2% increase over 2020 product sales of \$39.5M
  - Core, non-COVID 19 product sales increased 13% to \$33.8M vs. \$30.1M in 2020
- 2021 Grant revenue was \$3.1M, as compared to 2020 grant revenue of \$1.6M
- Product gross margin was 80% in 2021 compared to 76% in 2020



#### Annual Product Sales & Blended GM%



**CytoSorbents** 

## Working Capital and Cap Table (\$M)

Working Capital as of			
	12/31/2021	12/31/2020	12/31/2019
Current Assets:			
Cash and short-term investments	\$52,138	\$71,422	\$12,232
Grants and accounts receivable, net	4,523	5,159	4,467
Inventories	4,766	2,674	2,114
Prepaid expenses and other current assets	2,872	3,198	2,088
Total current assets	64,299	82,453	20,902
Current Liabilities:			
Accounts payable	2,805	1,835	2,039
Accrued expenses and other current liabilities	9,145	7,871	5 <i>,</i> 802
Current maturities of long-term debt	-	-	1,667
Lease liability - current portion	571	447	428
Total current liabilities	12,521	10,153	9,936
Net Working Capital	\$ 51,778	\$ 72,300	\$ 10,966

#### Cap Table 12/31/2021

	Fully Diluted Common Shares
Common Stock	43,478,487
Options	6,885,978
Restricted Stock Unit Awards	304,962
	50,669,427



## Focus on Financial Discipline and Flexibility

- Core product sales are expected to grow 20% or more, over last year
- We remain focused on tight control of expenses and prioritization of capital use
- Our spend is fully aligned with our strategic priorities
  - Key Clinical trials
  - Sales & Marketing
  - Manufacturing facility
- We expect to fund our operating needs and capex with cash on hand and have financial flexibility if needed
  - \$15M Loan commitment from Bridge Bank
  - Sale of 2020 NJ tax and R&D NOLs of \$0.7M expected in first half 2022



# **Commercialization Update**

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



## Q4 2021 Sales Improvement from Q3

- Q4 product sales improved compared to Q3 2022 due to:
  - Improving macro-environment allowed increase of visit frequency and attendance of congresses and events
  - Germany started to regain lost business (product sales +45% vs. Q3)
  - Historically best result of International Direct Sales
  - Solid US EUA COVID business
  - Good business volume of the most important distributor partners
- Clear correlation of improved customer access and normalization of ICU environment with CytoSorb usage
- Delta strain of the CoV-SARS-2 caused 4<sup>th</sup> wave of COVID-19 in Europe/ Germany
- Declined to the end of the year and was followed by the Omicron wave:
  - Again reduced elective surgery, blocked ICU beds and visit restrictions
  - Lower COVID-19 severity, less ICU cases, lower death rates
  - Favorable data of CytoSorbents' CTC registry, rising consumption during the delta wave and the fear of the Omicron wave triggered total COVID-19 sales of \$1.7M including the EUA business in the United States



## Current Situation in Q1

- The macro environment remains challenging in Europe and Germany
  - COVID-related sales continue to decline (lower severity of illness)
  - Pandemic-related access restrictions, cancelled congresses and events, reserved ICU beds, limited elective surgeries and high number of infected HCPs
  - Ukraine/Russia conflict creates difficult situation in several markets
- But we anticipate conditions to improve throughout the year, and an increasing number of positive developments keep us cautiously optimistic, for example:
  - Our recently initiated KOL & key account programs in Cardiovascular is helping to jumpstart our post-pandemic business
    - Better access and higher level of relationships through key hires and new collaborations
    - Increasing penetration and adoption in major indications
    - Currently focused on Germany; Roll out International starting in Q2
    - New data and publications for important indications in the Cardiovascular field expected
  - Strong progress with comparable initiatives in Critical Care and other therapeutic areas



#### CytoSorb World Users'

Meeting

CytoSorb<sup>®</sup> Therapy

**EARS** 



Radisson Collection Hotel

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PB

PanAm Lounge

It is our special pleasure to personally invite you to the CytoSorb World Users' Meeting in Berlin on July 2nd, 2022.

JULY 1.3, 2022 | BERLIN, GERMAN

2022 marks the 10<sup>th</sup> anniversary of CytoSorb Therapy and we want to celebrate this milestone together with you.

Look forward to an exciting, top-class scientific program in a unique ambience and use the trip to Berlin for personal conversations and interesting networking.

Follow the link below for details on the Get Together in the heart of Berlin, the CytoSorb World Users' Meeting in the historical cinema BABYLON and the Anniversary Party at the legendary PamAm Lounge.

We are very much looking forward to welcoming you to Berlin!

Your CytoSorbents Europe Team



**USERS' MEETING** Saturday, July 2 | Day **Babylon Berlin** 



#### **PROGRAM**& REGISTRATION

cyto.news/WUM2022

**ARRIVAL & GET TOGETHER** Friday, July 1 | Evening

9 **ANNIVERSARY PARTY** Saturday, July 2 | Evening

CytoSorb<sup>®</sup>



## Priorities for Driving Worldwide Growth

- CytoSorbents is focusing on replacing the COVID business with core growth
  - Increased firepower through expanded commercial/medical teams
    - » Critical Care Septic Shock, Non-infective vasoplegic shock, Trauma etc.
    - » Cardiovascular Antithrombotic removal (ATR), Infective Endocarditis, others
    - » Other indications
- Expanding and strengthening of sales forces
  - Sales force optimization in Germany; focus on key account and KOL management
  - Strengthening and expanding international direct territories
  - Focus on high priority distributor markets
- Increasing marketing and medical efforts given access and travel restrictions
  - New hybrid conferences and symposia
  - Additional educational and training meetings (virtually and in-person)
  - Increased manpower for KOL relationship management

We are starting to see positive developments which fuel our optimism and confidence in our ability to return to the sustained growth path we were on before COVID



## **Clinical Update**

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



## **Execution and Focus**

Our updated and streamlined global clinical plan comprises of:

- 7 Programs (3 RCT, 3 Registries, 1 Pilot study)
  - <u>US (3)</u>: 2 FDA RCT: STAR-T; STAR-D + CTC Registry (EUA)
  - <u>EU (4)</u>: RCT (PROCYSS); Pilot (HepOnFire); Registries (STAR + COSMOS)
- Although institutions around the world continue to struggle with personnel shortages and fatigue in the aftermath of the pandemic, we continue to see high levels of interest and participation in our trials
- Data readouts and international conference presentations in 2022 include:
  - <u>COVID-19</u>: Accepted abstracts from CTC at ISICEM (3/22) and EuroELSO (5/22); final results (n=100) to be submitted for publication
  - <u>Antithrombotic Removal</u> First ever *in vivo* antithrombotic removal data (to be submitted for ESC 8/22), potential early readouts from the STAR Registry

To focus our resource allocation to our top priority FDA STAR-T and STAR-D trials we have discontinued the following 3 clinical programs:

- REFRESH 2 AKI All U.S. clinical team resources now focused on the STAR trials
- TISORB and CYTATION Small, single arm studies in UK and Germany on ticagrelor removal that are now superseded by the pivotal U.S. STAR-T RCT

• <u>No safety concerns in any of the 3 studies as confirmed by each independent DSMB</u>

## FDA Programs (STAR-T & STAR-D)

- Both studies have left the station and are actively recruiting patients
- Majority of sites now selected with most (>70%) participating in both trials
- Enthusiasm is high despite pandemic fatigue, but site staff shortages are real
- STAR-D start-up moving faster by leveraging synergies to STAR-T
- Both studies have identical paths highlighted by 3 major milestones (Table)
- STAR-T: actively enrolling and projected to hit milestone #1 this summer, enrollment expected to complete within 12 months from today
- <u>STAR-D</u>: actively recruiting, but too early to project enrollment pace, enrollment expected to complete 12-18 months from first patient enrolled
- Combined STAR-T and STAR-D Investigator Summit planned for mid-March
- We will communicate study progress towards milestones during earning calls

Milestone	Enrollment target	Triggered Action	
1 <sup>st</sup>	33% (n=40)	1 <sup>st</sup> DSMB Safety review	
2 <sup>nd</sup>	67% (n=80)	2 <sup>nd</sup> DSMB + Interim analysis (IA)	
3 <sup>rd</sup>	100% (n=120)	Study completion (unless stopped at IA)	

#### **CytoSorbents**

### **Non-FDA Clinical Programs**

PROGRAM		Current Status	Next Milestone	Target
CTC Registry (n=100) COVID-19 + ECMO	US	<u>Completed</u> Database locked. Multiple readouts	Presentations Publications	2022
PROCYSS RCT (n=160) Septic Shock	GER	Enrolling at multiple sites Ongoing site activation	Interim Analysis (50% Enrollment)	2023
STAR Registry Cardiac Surgery	EU	Enrolling in UK and GER Geographic expansion	Ongoing Enrollment	Ongoing
Hep-On-Fire (n=30) Acute Liver Failure	GER	Approvals received Site activations begin	Begin Enrollment	2022
COSMOS Registry Critical Care	EU	Approvals received Site activations begin	Begin Enrollment	2022



## **Clinical Summary**

- We have focused our resources to ensure disciplined execution of our top priority STAR-T and STAR-D FDA programs
- Institutions globally are still struggling with pandemic fatigue and staffing shortages, but we continue to see high levels of excitement for our studies
- Both FDA programs are now actively recruiting at multiple sites with STAR-T in the lead and targeting 1<sup>st</sup> milestone this summer
- PROCYSS, our top priority RCT in critical care is actively enrolling at multiple sites in Germany
- CTC Registry is completed with multiple data readouts in 2022
- The international STAR and COSMOS Registries are making good progress and will serve as our real-world evidence generation platforms in cardiac surgery and critical care



# **Concluding Remarks**

Phillip Chan, MD, PhD Chief Executive Officer



## Summary

- CytoSorbents has the potential to become a highly profitable medical device company with industry-leading operating profit margins, while helping to solve some of medicine's most vexing problems
- Our business is resilient, and while macro uncertainties continue, we remain well-positioned to grow our core business in 2022 and beyond
- More focused sales and marketing to return the German business to growth and drive longer-term worldwide growth potential
- FDA marketing approval is expected to be a key catalyst for growth and the Company expects to complete enrollment of the U.S. STAR-D and STAR-T pivotal clinical trial programs for antithrombotic removal in the next 12 to 18 months
- Balance sheet remains strong with the ability to fund key investments in growth (e.g. clinical studies, sales & marketing, manufacturing capacity expansion)





## **CytoSorbents Corporation**

## NASDAQ: CTSO

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