



# **CytoSorbents Corporation** (NASDAQ: CTSO)

A Leader in Critical Care Immunotherapy

Q2 2020 Earnings Conference Call

August 4, 2020

# Conference Call Participants

Moderator: Jeremy Feffer  
LifeSci Advisors



Phillip Chan, MD, PhD – Chief Executive Officer



Vincent Capponi, MS – Chief Operating Officer and President



Kathleen Bloch, MBA, CPA – Chief Financial Officer



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



Christian Steiner, MD – Senior Vice President of Sales and Marketing  
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 5, 2020 and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).

# Q2 2020 Operational Highlights

- Q2 2020 Total Revenue grew 58% to \$9.8M, and Product Sales grew 61% to \$9.5M over Q2 2019. Trailing 12-month Product Sales were \$30.0M
- Blended product gross margins were 70% in Q2 2020, lower than 76% a year ago, due to higher % of distributor sales and higher costs of ramped COVID-19 production
- U.S. FDA granted Emergency Use Authorization (EUA) to CytoSorb for use in adult critically-ill COVID-19 patients with imminent or confirmed respiratory failure, enabling sales to all U.S. hospitals, and generating \$667,000 in U.S. revenues
- Achieved FDA Breakthrough Designation for CytoSorb to remove ticagrelor during on-pump, urgent or emergent cardiothoracic surgery
- CytoSorb received E.U. approval to remove rivaroxaban during on-pump cardiothoracic surgery
- Appointed Dr. Efthymios Deliargyris as Chief Medical Officer
- Treated more than 1,200 COVID-19 patients in more than 30 countries, including here in the U.S.
- Received \$1.1M in non-dilutive funds from NJ Technology Business Tax Certificate Transfer Program
- Was awarded a \$2.9M Phase III STTR contract to advance HemoDefend-BGA to clinical trials
- Expanded distribution to 65 countries, adding 9 Latin American countries



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# 100,000 CytoSorb Treatments Delivered To Date!

- CytoSorbents is celebrating the delivery of more than 100,000 CytoSorb treatments cumulatively to date, with tens of thousands of patients treated in a wide variety of applications, with many publications documenting the lives that CytoSorb has helped to save



- To all of our supporters and to the broader CytoSorbents family, you have our sincerest thanks for your commitment and contributions in helping to advance CytoSorb as a therapy that is making a difference to people across the world

# Raising Growth Capital

- On July 24, 2020, we completed a landmark public offering of \$57.5M of our common stock with net proceeds to the Company of ~\$54M, raising our cash balance to ~\$89M, significantly strengthening our balance sheet
- Co-Led by Cowen and SVB Leerink, with Co-manager B. Riley FBR
- Drew a tremendous amount of interest from institutions to invest, with participation from a solid core of well-regarded, long-term, healthcare-focused institutional investors
- As part of the financing, and given our financial position, we agreed to not raise additional equity capital (e.g. ATM financing, secondary public offering, etc) for the next 90 days, and have no current plans to raise additional funds
- The funding serves multiple purposes:
  - Increases our institutional ownership with a core anchor of strong institutional investors
  - Provides growth capital to take aggressive advantage of near term growth opportunities and to strengthen worldwide sales
  - Allows us to move forward with an expansion of manufacturing that should take us to a capacity production of \$300-400M in sales, while allowing us to invest in automation and other improvements that are expected to improve product gross margins
  - Expected to fund the Company to expected GAAP profitability and provide financial stability in uncertain times
  - Enables vigorous pursuit of company-sponsored clinical studies intended to drive CytoSorb as standard of care
  - Provides additional resources, in addition to grants/contracts to fund development of our exciting pipeline
  - Importantly, enables us to expand beyond today and to unlock the U.S. opportunity

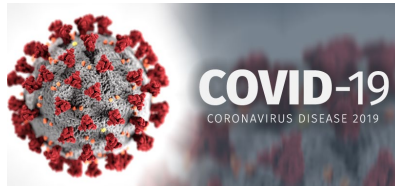


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# Expanding Beyond Today

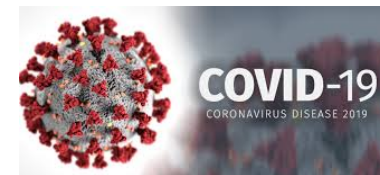
## Unlocking the U.S. Opportunity



**REFRESH 2-AKI**  
Pivotal Trial



# COVID-19 and CytoSorb



- CytoSorb has been used to treat >1,200 critically-ill COVID-19 patients in 30+ countries. Please see earnings press release for links to many COVID-19 webinars that support:
  - Reduction of cytokine storm and inflammatory mediators such as IL-6, ferritin, CRP, and others
  - Improved respiratory function in ARDS and weaning from mechanical ventilation and ECMO
  - Improved hemodynamic stability and reversal of shock
- U.S. FDA Emergency Use Authorization enables CytoSorb to be commercially sold to all hospitals in the U.S. for use in critically-ill, COVID-19+ patients, 18 years of age or older with imminent or confirmed respiratory failure.\*
  - Recorded preliminary Q2 2020 U.S. sales of ~\$667,000 through passive COVID-19 sales to U.S hospitals
  - Currently expanding U.S. commercialization efforts via distribution and internal resources to meet current surge and a potential second COVID-19 wave in winter 2020-2021
  - With U.S. leading new and overall cases of COVID-19 globally, EUA is expected to remain through Spring 2021
- COVID-19 has slowed in Western Europe, but is surging elsewhere where we continue to ship our therapy. We are preparing for a second wave and challenging flu and COVID-19 winter season
- Targeting data publication and capture via our COVID-19 “CTC” and International CytoSorb registry. Meanwhile multiple investigator initiated studies have been registered including the CYCOV, CYTOCOV-19, CytoResc, and CytoCOVID-19 trials in Europe



# Global CytoSorb COVID-19 Activity

In addition to FDA Emergency Use Authorization for COVID-19

## CytoSorb COVID-19 status in other selected countries:



CHN – Handbook of COVID-19 Prevention and Treatment



COL – Expert consensus - Colombian Journal of Nephrology



GBR – Medtech Innovation Briefing published by NICE



GER – Treatment of severe COVID-19 courses in intensive care medicine



IND – Cytokine Storm in COVID-19 Expert Management Considerations



ISR – AMAR approval



ITA – Brescia Renal COVID-19 Task Force Recommendations



PAN – National Guidelines on adult COVID-19 patients



CytoSorb Therapy - REGAIN CONTROL



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# REFRESH 2-AKI Is Now Being Resumed

- In November 2019, the Company announced a change in its CRO for the study and voluntarily paused enrollment at the recommendation of the DMC that requested additional clinical data and analyses, not pre-specified in the trial protocol, to improve safety endpoint monitoring
  - There were no specific adverse events of clinical outcomes cited
  - This was a voluntary pause by the Company, and NOT a clinical hold by the FDA
- Since that time, with our new CRO, we completed a comprehensive program to re-monitor existing data, collect new data, and analyze the safety data from the 153 patients included in the trial to date
- On July 28, 2020, we announced that the REFRESH 2 Data Monitoring Committee (DMC) reviewed these data, resulting in a favorable opinion on safety, and recommended the trial resume with only minor modifications
- Pending COVID-19 restrictions, our goal is to get the study back on track and moving to the scheduled interim analysis upon completing enrollment of 200 patients

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

- Earlier this year, CytoSorb received E.U. approval to remove two well-known blockbuster “blood thinners”, or anti-thrombotics, during cardiothoracic surgery. These agents are used in millions of patients to reduce risk of stroke and heart attacks



**Ticagrelor (Brilinta<sup>®</sup>, Brilique<sup>®</sup> - Astra-Zeneca)** is a blockbuster P2Y<sub>12</sub> anti-platelet agent (“blood thinner”) with more than \$1.6 billion in worldwide sales, used primarily in patients with acute coronary syndrome and those undergoing percutaneous coronary intervention (PCI) for stent placement

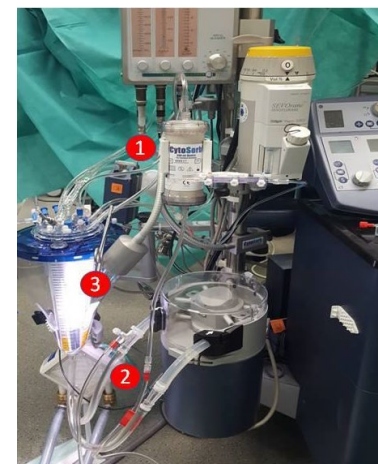


**Rivaroxaban (Xarelto<sup>®</sup> - Bayer, Janssen/J&J)** is a blockbuster Factor Xa inhibitor and novel oral anti-coagulant (NOAC) agent (“blood thinner”) with more than nearly \$7 billion in 2019 global sales used as lifelong therapy in patients with atrial fibrillation

**Problem:** Patients that require emergent or urgent cardiothoracic surgery on these blood thinners can develop potentially serious and life-threatening perioperative bleeding

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 anti-coagulant effect

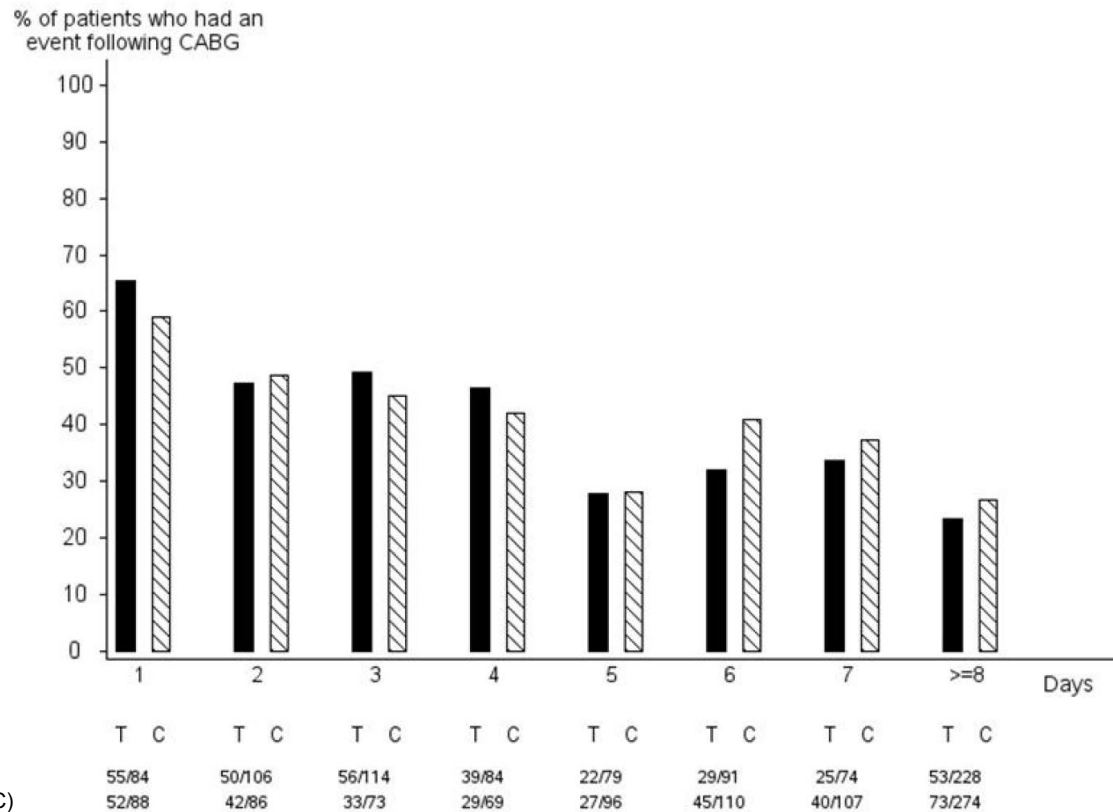
We believe CytoSorb can quickly become a cost-effective standard of care to prevent bleeding due to antithrombotics, helping to drive sales growth



# Risk of Bleeding Is High in CABG Patients on Ticagrelor

In the ticagrelor registration PLATO (PLAeLeT inhibition and patient Outcomes) trial, 1584 patients underwent CABG surgery, randomized between those who received either ticagrelor or clopidogrel. Those patients (%) with life-threatening bleeding are shown. Bleeding risk is high despite waiting up to 7 days off the drug prior to surgery

**Figure 2 – ‘Major fatal/life-threatening’ CABG-related bleeding by days from last dose of study drug to CABG procedure (PLATO)**



Ticagrelor (T)  
Clopidogrel (C)

**PLATO Major bleed, fatal/life-threatening:** any major bleed as described above and associated with a decrease in Hb of more than 5 g/dL (or a fall in hematocrit (Hct) of at least 15%); transfusion of 4 or more units.

**Fatal:** A bleeding event that directly led to death within 7 days.

# CytoSorb Reduces Bleeding Complications



43 patients  
emergency surgery with ticagrelor

32 patients with intra-operative CytoSorb

11 patients control without CytoSorb



CPB + CytoSorb  
(n=32)

CPB alone  
(n=11)

55 patients

12 patients  
emergency surgery with rivaroxaban

7 patients with intra-operative CytoSorb

5 patients control without CytoSorb



CPB + CytoSorb  
(n=7)

CPB alone  
(n=5)



CPB + CytoSorb (n)	CPB alone (n)	Outcome	CPB + CytoSorb (n)	CPB alone (n)
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



# FDA Breakthrough Designation Sets Stage for Potential Expedited U.S. Regulatory Path

- In April 2020, the FDA granted Breakthrough Designation to CytoSorb to remove ticagrelor during cardiopulmonary bypass in emergent or urgent cardiothoracic surgery
  - Highlights the unmet medical need recognized by the FDA
  - Through the Breakthrough Devices program, FDA intends to help patients have more timely access to such medical devices by expediting their development, assessment, and review, while maintaining standards for regulatory approval on safety and efficacy. FDA will prioritize review on future regulatory submissions (e.g. Q-submissions, IDE applications and marketing submissions)
- We are in the process of defining the regulatory path for the therapy with FDA
  - 510(k) vs *de novo* 510(k) vs PMA
  - If a clinical trial is needed, Portola and PhaseBio have established an FDA precedent that surrogate markers such as platelet aggregation or Factor Xa activity can be used as primary endpoints for FDA approval
  - In a sub-study of the Hassan paper, 4/5 (80%) patients treated with CytoSorb had a rise in the multiple electrode aggregometry (MEA) assay > 22, that correlates with a restoration of platelet function
- Meanwhile additional data collection on drug levels, platelet function, and health economics continues with the U.K. TISORB (to obtain U.K. NICE recommendation) and Germany CyTation Trials, and collection of real-world experience via the STAR (Safe and Timely Antithrombotic Removal) Registry

# CytoSorb Antithrombotic Removal KOL Event Highlights

## Opportunity Beyond Cardiac Surgery



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

WORKING TO SAVE LIVES



**CytoSorb Antithrombotic Removal**  
**July 13, 2020**

[Replay webcast available here](#)



**Dr. C. Michael Gibson, MS, MD**

- Harvard University
- Interventional Cardiologist
- CEO of the Baim Institute for Clinical Research, Boston, MA
- Founder of wikidoc.org



**Dr. Robert Storey, BM, DM, FESC**

- Professor of Cardiology
- Clinical Theme Lead for Cardiovascular Disease research
- Director of the Cardiovascular Research Unit
- University of Sheffield, UK



**Prof. Dr. med. Michael Schmoeckel MA**

- Chairman, Dept of Cardiac Surgery
- Cardiothoracic Surgeon
- Asklepios-Klinik St. Georg, Hamburg, Germany



**Hosted by Dr. Efthymios Deliargyris  
MD, FACC, FESC, FSCAI**

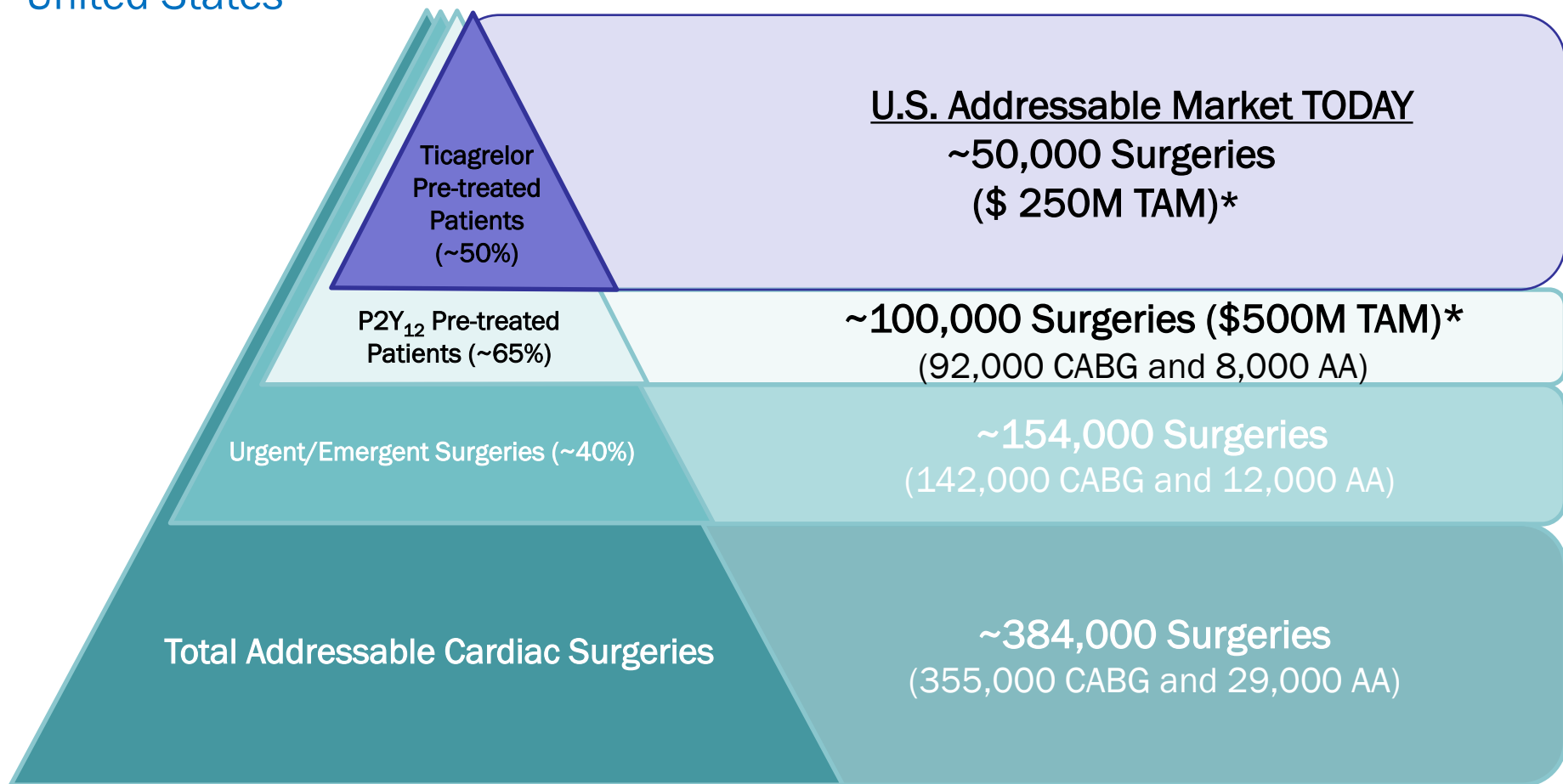
- Chief Medical Officer - CytoSorbents
- Interventional Cardiologist and Cardiologist



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# Total Addressable Market For Ticagrelor Removal

United States



Ticagrelor market share expected to grow from today due to:

- 1) Going off-patent in 2024 and price erosion from generic competition
- 2) CytoSorb making it reversible, giving it a competitive marketing advantage vs other anti-platelet drugs like Plavix<sup>®</sup> (clopidogrel) and Effient<sup>®</sup> (prasugrel)

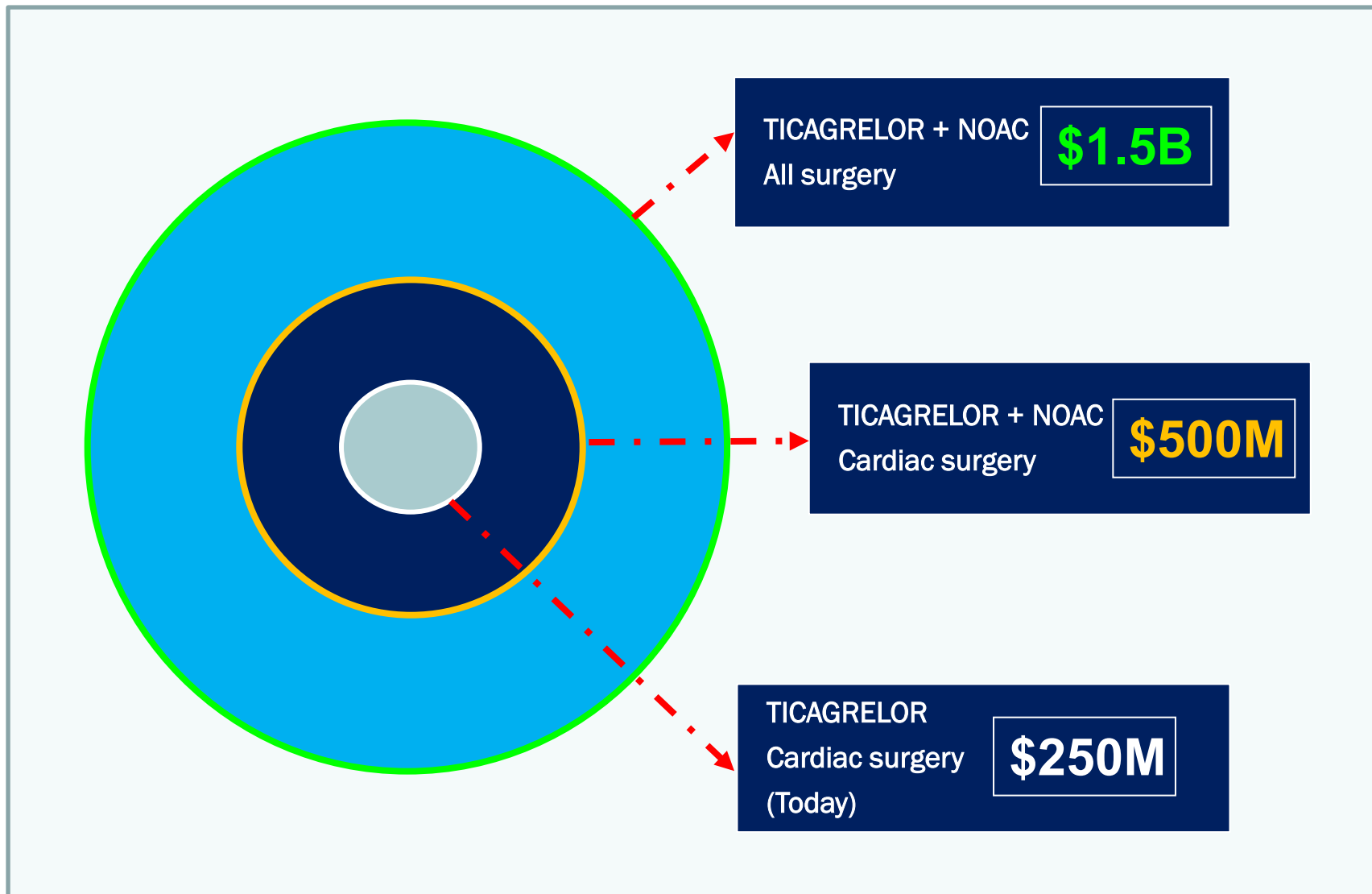
- **CABG:** Coronary Artery Bypass Graft surgery
- **AA:** Aortic Aneurysm Repair



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



# Financial Highlights



# Q2 2020 Comparative Revenue Results

	Quarter Ended June 30, 2020	Quarter Ended June 30, 2019	% Incr.
Product revenue	\$ 9,520,328	\$ 5,850,417	62.7%
Grant and other income	274,575	382,109	(28.1)%
Total revenue	\$ 9,794,903	\$ 6,232,526	57.2%

- Q2 2020 CytoSorb® sales were a record high of \$9.5M, a ~63% increase over \$5.9M in Q2 2019
- ~\$38M annualized product sales run rate (as of Q2 2020) versus ~\$23.4M as of Q2 2019
- Total revenue in Q2 2020 increased ~57% to \$9.8M, which includes both product sales and grant revenue, compared to \$6.2M in Q2 2019
- Q2 2020 gross profit was \$6.5M, an increase of approximately 49% from \$4.4M for Q2 2019
- Q2 2020 product gross margins were 78% (excluding certain Production ramp up costs), compared to 76% for Q2 2019



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# Comparative 6-Month Revenue Results

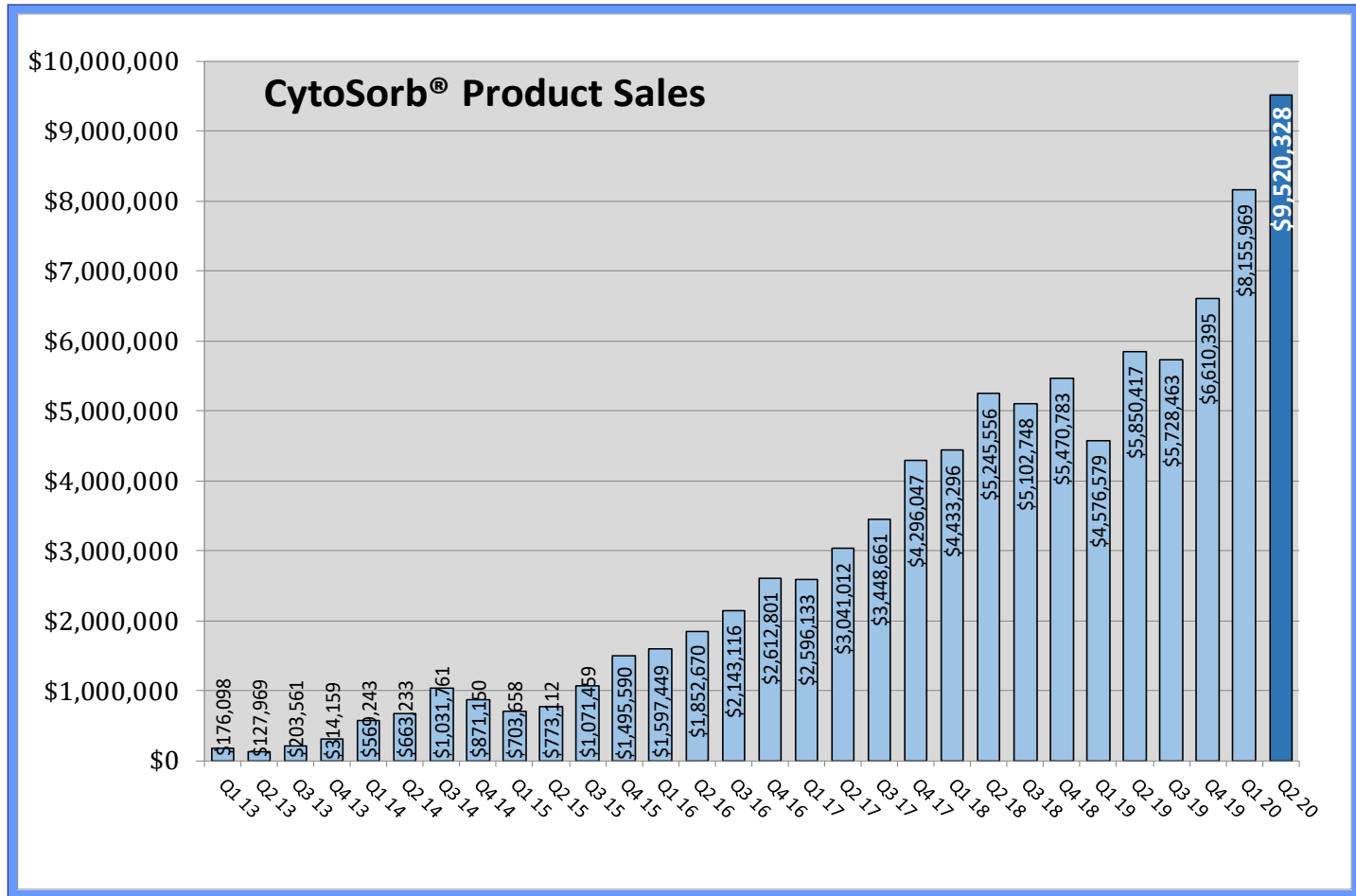
	6 Months Ended June 30, 2020		6 Months Ended June 30, 2019		% Incr.
Product revenue	\$17,676,297		\$10,426,996		69.5%
Grant and other income	\$825,915		\$997,159		(17.2)%
Total revenue	\$18,502,212		\$11,424,155		62.0%

- CytoSorb® product sales for 1H 2020 were \$17.7M, a 69.5% increase over product sales of \$10.4M for the same period a year ago
- Grant revenue was approximately \$826K for the 1H 2020, as compared to \$997K in the first half of 2019
- Total revenue for 1H 2020, which includes both product sales and grant revenue, was \$18.5M as compared to \$11.4M for 1H 2019, an increase of 62%

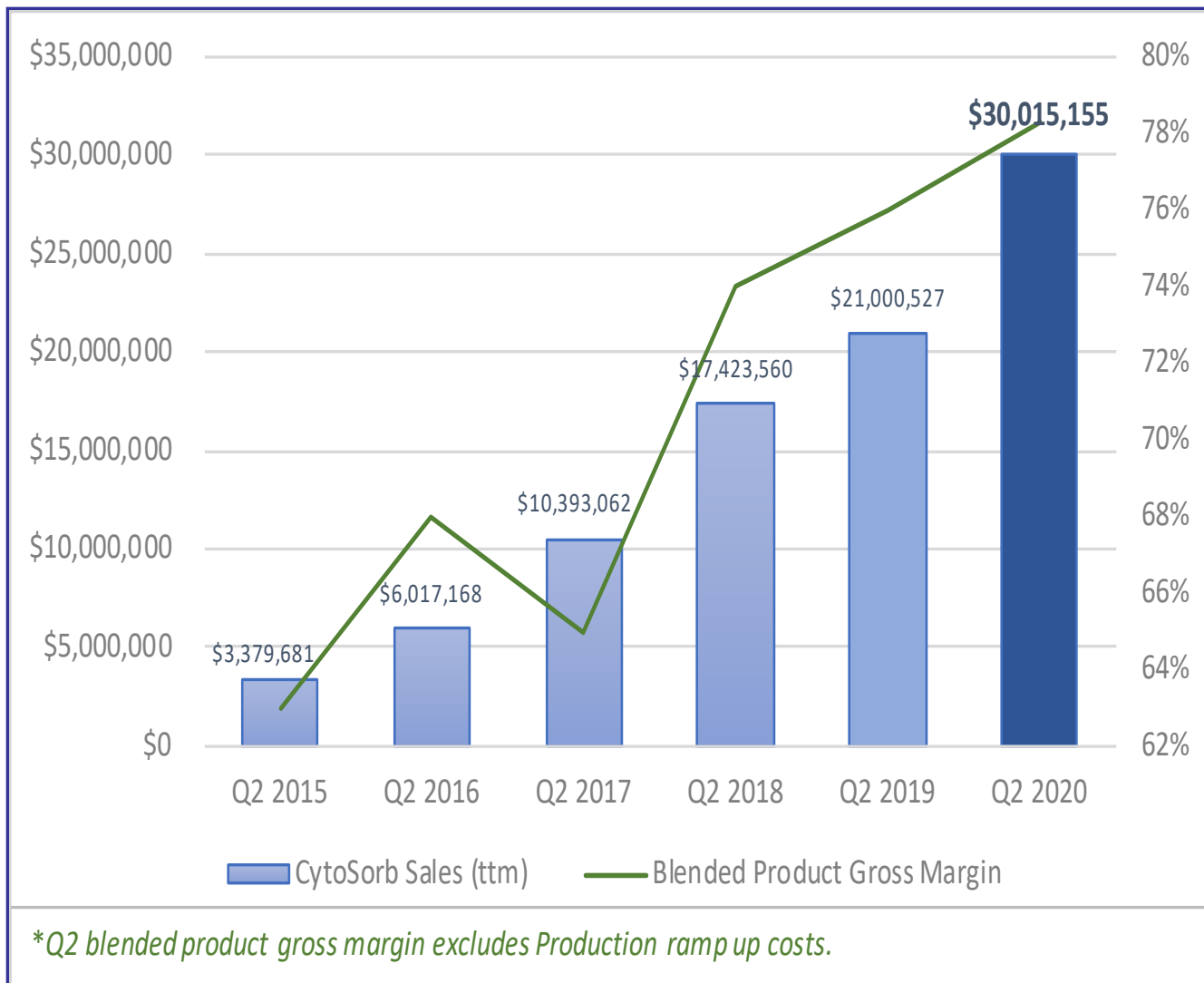


# Quarterly Product Sales

Q2 2020 product sales were a record high of \$9.5M.



# Trailing Twelve Months Product Sales



# Working Capital and Cap Table

	Working Capital as of						
	6/30/2020	3/31/2020	12/31/2019	9/30/2019	6/30/2019	3/31/2019	12/31/2018
<b>Current Assets:</b>							
Cash and short-term investments	\$35,114	\$26,389	\$12,232	\$15,978	\$16,342	\$19,647	\$22,369
Grants and accounts receivable, net	3,890	5,396	4,580	3,448	3,450	3,267	3,943
Inventories	1,987	1,967	2,114	1,768	1,463	1,214	833
Prepaid expenses and other current assets	957	3,778	2,088	1,157	960	700	1,119
<b>Total current assets</b>	<b>41,948</b>	<b>37,529</b>	<b>21,014</b>	<b>22,351</b>	<b>22,215</b>	<b>24,828</b>	<b>28,264</b>
<b>Current Liabilities:</b>							
Accounts payable	2,727	1,770	2,039	2,072	2,150	1,841	1,486
Accrued expenses and other current liabilities	5,853	5,084	5,558	3,691	3,432	2,815	4,386
Current maturities of long-term debt	6,667	4,167	1,667	2,500	2,667	1,666	667
Lease liability - current portion	418	443	428	414	400	389	-
Deferred revenue	-	-	-	-	-	-	-
<b>Total current liabilities</b>	<b>15,664</b>	<b>11,464</b>	<b>9,692</b>	<b>8,677</b>	<b>8,649</b>	<b>6,711</b>	<b>6,539</b>
<b>Net Working Capital</b>	<b>\$ 26,284</b>	<b>\$ 26,065</b>	<b>\$ 11,322</b>	<b>\$ 13,674</b>	<b>\$ 13,566</b>	<b>\$ 18,117</b>	<b>\$ 21,725</b>

## Cap Table 6/30/2020

Fully Diluted Common Shares	
Common Stock	36,811,870
Options	5,248,328
Restricted Stock Unit Awards	230,004
	42,290,202



# Guidance

- CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However:
- Provided that the current order pattern continues, and notwithstanding uncertainty related to the COVID-19 pandemic, we expect that Q3 2020 will be one of Company's strongest quarters in terms of product sales





# Q&A Session

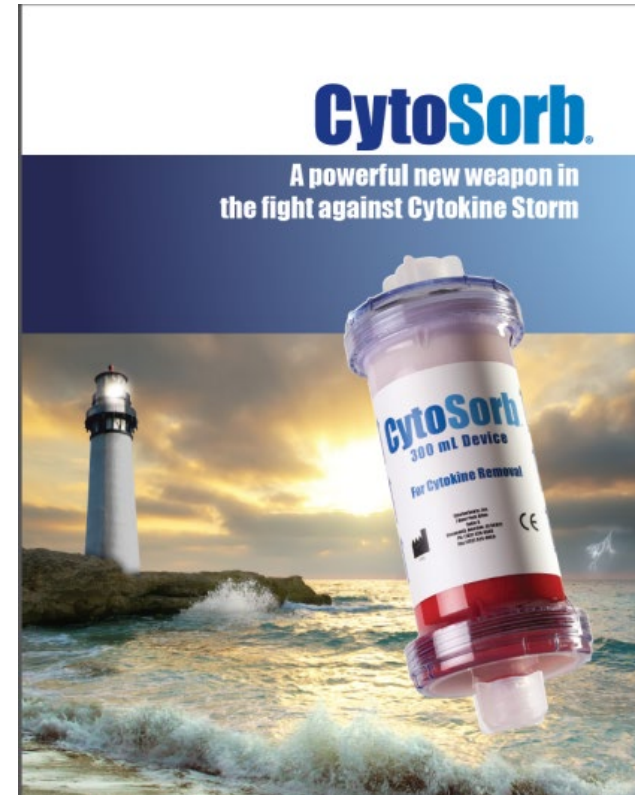
## CytoSorbents Corporation

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