

# CytoSorbents Corporation (OTCBB: CTSO) Q3 2014 Earnings and Operating Results Conference Call November 12, 2014 @ 4:15 pm Eastern

This official company transcript has been edited for clarity and does not differ materially from the actual conference call. Slide numbers have been inserted to allow readers to follow along with the associated presentation.

### Operator:

Good day, everyone and welcome to the CytoSorbents 2014 Third Quarter Financial and Operating Results Conference Call. Today's call is being recorded and at this time I'd like to turn the conference over to our moderator, Amy Vogel. Please go ahead, Amy.

## Amy Vogel - Moderator:

Thank you operator and good afternoon. Welcome to CytoSorbents Third Quarter 2014 Operating and Financial Results Conference Call. With us today are:

- Dr. Phillip Chan, Chief Executive Officer and President
- Vincent Capponi, Chief Operating Officer
- Kathleen Bloch, Chief Financial Officer
- Dr. Christian Steiner, VP of Sales and Marketing from Germany, and
- Chris Cramer, VP of Business Development

Before I turn the call over to Dr. Chan, I'd like to remind listeners that during the call, management's prepared remarks may contain forward-looking statements which are subject to risks and uncertainties. Management may make additional forward-looking statements in response to your questions today. Therefore, the Company claims protection under Safe Harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Actual results may differ from results discussed today and therefore, we refer you to a more detailed discussion of these risks and uncertainties in the Company's filings with the SEC. Any projections as to the Company's future performance represented by management include estimates today as of November 12, 2014 and the Company assumes no obligation to update these projections in the future as market conditions change.

During today's conference call, we will first have an overview presentation covering the financial and operational highlights for the quarter by Dr. Chan and Ms. Bloch. We again have taken

everyone's submitted questions and will do our best to address them in the presentation, and also in the Q&A session with management to follow. Thanks everyone again for participating. If we do not answer your question, we would ask that you contact the Company directly after the call today.

At this time, I would like to turn the call over to Dr. Phillip Chan. Please go ahead Dr. Chan.

### **Phillip Chan - CEO:**

Thank you very much, Amy, and thank you everyone for joining the call today. It's a pleasure to be here and welcome. As usual, following a short introduction for new and potential investors with some recent operational highlights, Kathy will go over our financial progress for the third quarter of 2014. We will then discuss at length our plan to up-list to the NASDAQ Capital Market, answer some frequently asked questions and review the actions for which we are seeking shareholder consent. Then the rest of the management team will have their remarks that incorporate answers to many of the questions we have received from our analysts and shareholders. An official transcript of today's call will be available in the next few days on our website at www.cytosorbents.com.

- **Slide 4:** If we can fast-forward to Slide 4. CytoSorbents is an emerging leader in the \$20 billion critical care immunotherapy space and we are leading the prevention or treatment of life threatening inflammation in the intensive care unit.
- **Slide 5:** Most of us know that inflammation plays a protective role in the body, protecting us against injury and infection. But most of us may not know that inflammation actually plays a significant detrimental role in nearly every known disease. These can be life-threatening conditions like sepsis and trauma, autoimmune diseases like rheumatoid arthritis and psoriasis, heart disease, peripheral artery disease, cancer, cancer cachexia, neurodegenerative diseases such as Alzheimer's and multiple sclerosis, and many others. The problem is that uncontrolled inflammation wreaks havoc on the body and can be deadly.
- **Slide 6:** The problem is that severe, uncontrolled inflammation can lead to organ failure. Organ failure occurs when vital organs like the lungs, the heart, the kidneys, or the liver stops working, which is incompatible with life. Organ failure causes nearly half of all deaths in the ICU today, but little can be done to treat or prevent it. And that is where we come in.
- **Slide 7:** CytoSorb® removes the fuel to the fire of inflammation and represents a powerful immunotherapy tool to control inflammation. CytoSorb® is approved in the European Union as the only specifically approved extracorporeal cytokine filter and is clinically proven to reduce key cytokines in blood in critically-ill patients. CytoSorb® is approved for use in any situation where cytokines are elevated and has also been safe in more than 3,500 human treatments, with no serious device related adverse events reported.
- **Slide 8:** The heart of our technology is a highly biocompatible, very porous, state-of-the-art polymer bead that acts like a tiny sponge to remove harmful substances from blood. If you magnify these beads up close, they are roughly the size of a grain of salt and each bead has millions of pores and channels that are capable of removing substances from blood. Big things like cells cannot get into the pores and go around the beads, very small things go through the

beads, but appropriately sized molecules will get trapped in the vast network of pores and channels in every single bead and permanently eliminated from blood. Our technology is protected by 32 issued U.S. patents and multiple applications pending. We manufacture these beads at our ISO 13485 certified facility in New Jersey, and our beads are one of the highest-grade medical sorbents on the medical market today.

**Slide 9:** The goal of CytoSorb® is to try to prevent or treat organ failure, the leading cause of death in the intensive care unit. Our goal is to hopefully help stabilize patients while improving patient outcome and survival while decreasing the costs of ICU and patient care. Because we sit at the nexus of inflammation in so many of the diseases that you see in this slide as well as many others, we truly believe that we have the potential to revolutionize critical care medicine.

**Slide 10:** CytoSorb® is available for sale in all 28 countries of the European Union and is currently marketed in 19 countries around the world. We sell the product direct in Germany, Austria and Switzerland with our direct sales force, and we have now established distribution in the U.K., Ireland, Netherlands, Turkey, Russia, India, Taiwan, and most of the countries of the Middle East, covering a total of approximately 1.7 billion lives. We are currently expanding to other EU countries and countries outside the EU that will accept CE mark approval. I am pleased to say that we have now achieved registration of CytoSorb® in Saudi Arabia and are now waiting formal Saudi FDA approval following some initial field tests by the Ministry of Health.

**Slide 11:** We have also been fortunate to have received a tremendous amount of government support for our technology. More than \$15 million in federal funding has gone into the development of this technology. First of all, DARPA, which is the leading research funding agency of the Department of Defense that has been responsible for funding such innovations as the Internet, global positioning satellites, robotic surgery and wheelchairs that can climb stairs, awarded us a \$3.8 million five-year contract as part of their Dialysis-Like Therapeutics program to treat sepsis and they have tasked us with removing cytokines and pathogen derived toxins. We are currently in year three of that program.

The U.S. Army also awarded us a Phase I and Phase II SBIR contract valued at \$1.15 million for trauma and burn injury research with our technology. The U.S. Air Force is funding a 30-patient randomized controlled human pilot study in trauma and rhabdomyolysis valued at \$3 million. This FDA approved trial has begun enrollment. The U.S. Department of Health and Human Services awarded us a \$0.5 million grant because of the potential of our technology to save lives and reduce cost under the QTDP program. One of our major collaborators at University of Pittsburgh received a \$7 million five-year grant from the NIH to pursue innovations around our technology for the treatment of sepsis. And last but not least, we were awarded a Phase I SBIR grant by NHLBI, the National Heart, Lung and Blood Institute, to advance our HemoDefend platform for the purification of blood transfusion products, to try to improve the quality and safety of blood transfusions.

**Slide 12:** Now more recently, we were the winner of the GREAT Tech awards. In October, CytoSorbents was awarded the United Kingdom GREAT Tech award for Health, sponsored by United Kingdom Trade and Investment and the British Consulate New York. The GREAT Tech awards selected one winner from each of six categories from a pool of more than 130 high growth companies from New York, New Jersey, Pennsylvania and Connecticut, and we were recognized for our innovative and potentially revolutionary blood purification technology that

could help save lives and reduce the high cost of ICU care. As part of the award, the Company will receive assistance, access and resources to further expand into the U.K. with its distribution partner, LINC Medical. The importance of this award is that the United Kingdom is the third largest medical device market in the European Union.

**Slide 13:** We also were pleased to have launched the International CytoSorb® Registry that is now available in both English and German, and is currently active with registrants that are submitting their data online. The English version is currently under beta testing and will go live in January.

Slide 14: We also established a world class Cardiac Surgery Advisory Board in the United States. It consists of major leaders in the area of cardiac surgery from around the country in such places as University of Kentucky, University of Michigan, Texas Children's Hospital in Houston, Cleveland Clinic Foundation, Columbia University and the University of Pittsburgh Medical Center. This group has helped us modify our clinical trial protocol in cardiac surgery where we are looking to use CytoSorb® intra-operatively in a heart-lung machine bypass circuit. The goal is to try and help reduce inflammatory mediators that are generated during cardiac surgery in order to potentially prevent post-operative complications such as organ dysfunction and organ failure. We are currently on track to submit our IDE application to the FDA to run this pivotal trial, and hopefully will submit by the end of 2014 and begin the trial next year.

Slide 15: We are also pleased to announce an expansion of our Biocon partnership. Chris Cramer will discuss this in greater depth in his comments. But according to Biocon, hundreds of patients have now benefitted from CytoSorb® therapy, and orders from Biocon continue to increase. We have now expanded the agreement beyond sepsis to now all critical care applications as well as cardiac surgery, with a focus on trying to control the systemic inflammatory response syndrome that is responsible for causing organ dysfunction and organ failure in many patients. This partnership continues to be focused on India and select emerging countries. We have negotiated a co-development agreement where Biocon has committed to conduct and publish results from multiple investigator initiated studies and patient case studies. Meanwhile, Biocon will continue to market CytoSorb® with their critical care antibiotics as the most comprehensive treatment of sepsis. I think very importantly, Biocon has also agreed, based on their results and their sales to date, to increase annual minimum sales targets which should result in significantly increased sales of CytoSorb® over the life of the agreement.

**Slide 16:** We are also pleased to announce our first cardiac surgery partnership. Following significant due diligence, we have entered into an initial partnership with a top four global medical device company in cardiac surgery and other cardiovascular diseases, to use CytoSorb® intra-operatively during cardiac surgery in the country of France. The partnership has already begun and is expected to continue over a total six-month evaluation period to determine various market parameters, to obtain clinical data, and to build key opinion leader support in France. Following a successful evaluation, the two parties plan to jointly determine how to expand upon both the size and geographic footprint of its partnership. France is currently the second largest medical device market and one of the highest volume cardiac surgery markets in the European Union. To give you an idea of the top cardiac surgery companies in the space... these include Medtronic, Sorin, Maquet, as well as Terumo.

**Slide 17:** And last but not least, I think there were a number of questions around Ebola, HemoDefend and our cardiac surgery studies. So I wanted to give everyone a quick update.

In terms of Ebola, CytoSorbents is currently in five of seven major hospitals in Germany that are prepared to accept Ebola patients. We have communicated with these hospitals and physicians and have made CytoSorb® an option to potentially treat patients should they wind up being admitted to these hospitals. We have also had communications with the World Health Organization, the Centers for Disease Control, the FDA, the National Institutes of Allergy and Infectious Disease, USAMRID of the Department of Defense, treatment hospitals in the United States, and others. Ebola patients have now undergone dialysis, a critical technical proof-of-concept that supports CytoSorb® use. To date, however, CytoSorb® has not been used to treat Ebola patients.

In terms of HemoDefend, at the recent American Association of Blood Bank (AABB) Conference in Philadelphia, data from the RECESS trial, where new blood, meaning blood 10-days or younger, and old blood, meaning blood 21 days old or greater, was given to patients undergoing complex cardiac surgery. The data from the RECESS trial showed that the age of blood had no statistically significant impact on progression to organ dysfunction or death. Although this was not what we expected to see, we do not believe this diminishes the potential value of HemoDefend to improve the quality and safety of blood by removing contaminants that can cause transfusion reactions. In fact, HemoDefend may have significant applications in other blood transfusion products where the need is potentially even greater than that seen in packed red blood cells. We currently await subgroup analysis, particularly in patients receiving more units of blood than average or patients undergoing more complex types of surgeries where there is a higher risk of hemolysis and injury, as well as a breakdown of the very high serious adverse event rate approaching 50% in this trial, in these patients undergoing complex cardiac surgery.

We also await the results of the ABLE trial, a Canadian based trial, where fresh versus standard issue blood has been given to critically-ill patients. That trial has been completed and we have heard that the results may be released at either the American Society of Hematology meeting in December of this year or the Society of Critical Care Medicine Conference in January of 2015. While we wait for these, we continue HemoDefend development.

And last but not least, in cardiac surgery we have multiple investigator initiated studies ongoing at Hamburg, Vienna, Cologne and others, some of which are expected to be completed in the next several months provided that enrollment continues during the holiday season. Once we have data from that we will be pleased to share that with the group.

So with that, let me turn it now over to Kathy Bloch, our Chief Financial Officer, who will cover Q3 2014 operating and financial highlights. Kathy?

#### **Kathleen Bloch - CFO:**

Thank you, Phil. Good afternoon everyone.

**Slide 18:** For today's call, I will be providing an update regarding primarily CytoSorbents' revenues.

**Slide 19:** For the quarter ended September 30, 2014, we achieved record CytoSorb® quarterly sales of \$1.0M, that is the first time in our Company history, and it is in fact a 406% increase over product sales of approximately \$204K in the same period of 2013.

In fact, quarterly sales of \$1.0M have exceeded CytoSorb® sales for the entire year of 2013 which were \$822K.

Product gross margins for Q3 2014 were approximately 65%.

**Slide 20:** For the first nine months of 2014 our total revenue was approximately \$3.2M which is an increase of 111% compared to total revenues of approximately \$1.5M for the first nine months of 2013.

CytoSorb® product sales fueled the increase in total revenues, with \$2.3 million in sales in the first nine months of 2013, a 346% increase from \$508K in CytoSorb® revenue in the first nine months of 2013.

Grant income for the nine months ended September 30, 2014 was approximately \$985K, which is tracking similarly to our grant income of approximately \$1.0M for the nine months ended September 30, 2013.

For the first nine months of 2014 our blended gross margins were approximately 44%, and our CytoSorb® product gross margins were approximately 66%.

**Slide 21:** So let's look at the Company's historical quarterly sales for each of the last nine quarters since we began commercialization of CytoSorb® in late 2012.

With our record third quarter product sales of more than \$1.0M, the Company has posted its fifth consecutive quarter of double-digit quarter-over-quarter growth. Our quarter over quarter growth between Q3 2014 and Q2 2014 was 56%. Our current annual run rate is now in excess of \$4.1 million, as compared to an annual run rate of approximately \$814K one year ago.

**Slide 22:** Next, we'll look at our chart summarizing our twelve-trailing months of CytoSorb® product sales and once again it continues to demonstrate the positive trend that sales are taking overall. Sales for the twelve months ended September 30, 2014 were approximately \$2.6 million, as compared to sales for the twelve months ended September 30, 2013 of approximately \$406,000. This represents an increase of more than \$1.3 million, or a year over year product sales increase of 331%.

With regard to expectations, sales momentum remains strong.

The Company has always stated that sales growth would be achieved as a result of its revenue multipliers: 1) the direct sales team is reaching down past the KOLs directly to the treating physicians in the ICUs; 2) we are in multiple ICUs in each treating hospital, 3) we are being used for many different applications including sepsis, cardiac surgery, pancreatitis, and burn injury, to name a few, 4) repeat orders from existing distributors; and 5) the establishment of distributor relationships in new territories.

Our balance sheet remains secure with \$7.8 million in cash and short-term investments at September 30, 2014, and we are continuing to execute on our stated path for the commercialization of CytoSorb.

Now, I'd like to turn the call back to Phil to discuss the benefits of the up-listing. Phil?

#### Phillip Chan - CEO:

**Slide 23:** Well, thank you very much, Kathy. Now I would like to go into more detail about the planned up-listing to the NASDAQ Capital Market and a quick summary of the approvals we we are seeking in our recently sent proxy statement. I also want to clear up some misperceptions about some of these issues and answer a number of frequently asked questions concerning the planned reverse split.

**Slide 24:** As we have said before, we believe that there are many potential benefits of uplisting. First and foremost, we believe that up-listing to the NASDAQ Capital Market will increase our visibility in the investor community. Currently many institutional investors, because our stock is under a dollar on the OTCBB, cannot invest in our company for a number of restrictive reasons. We believe that these reasons would go away once we do an up-listing and that they would no longer be restricted from owning our shares.

We also believe that our analyst coverage and the news releases will be more impactful. Many of the analysts that currently cover our company are focused predominantly on institutional investors who cannot currently own our stock. If we are successful in up-listing, we believe that this analyst coverage would be much more impactful. Another potential benefit of up-listing is increased liquidity for investors. As I will show you some data in just a moment, the average daily trading volume increased by three times in the three months following an OTC to NASDAQ national market up-listing.

In addition, the median stock appreciation of 2013 OTC to NASDAQ up-listed companies was 69% in 2013 and the median stock appreciation of 2014 OTC to NASDAQ up-listed companies was 15% in 2014. These are based on historical data and past results do not predict future performance. We also cannot predict the performance of our stock post-split or post-up-listing. And we can also provide no assurances that our application for listing to the NASDAQ Capital Market will be accepted. However, we are in the midst of this currently and we are very encouraged by our potential to be up-listed by the end of the year.

Another positive benefit is that, many shareholders who currently buy and sell our stock have found it very difficult to find brokers who will accept stock certificates. In fact this is the case for most OTC Bulletin Board companies. This problem would go away with an up-listing to a national market. This has been a chronic problem for many people and the source of great frustration in owning shares in our company.

Another potential benefit of up-listing is increased credibility. As we all know credibility is extremely important amongst investors, strategic partners, journalists as well as customers. Along with the NASDAQ up-listing, we are subject to very rigorous governance standards, SEC reporting and Sarbanes Oxley compliance standards. Also we believe that by up-listing to a national market, we can eliminate the perceived stigma of being a "penny stock".

And finally, another potential benefit of up-listing is the potential for lower costs of capital and less shareholder dilution. As a nationally listed company, we would have many more options to raise capital at attractive rates.

**Slide 25:** On this slide we are basically just looking at some data provided by NASDAQ where it is showing the average daily volume in the three months prior to an up-list, or an upgrade as they call it, from the OTCBB to the NASDAQ, and then the average daily volume three months after the upgrade. You can see that there is a three-fold increase in trading volume, supporting the notion that there would be increased liquidity following an up-listing.

**Slides 26 – 28:** Also if you look at the next several slides, what you see here is the class of 2013 OTC upgrades to the NASDAQ, and again, the median stock appreciation for these companies was 69% in 2013. Once our slide deck is published you will be able to see these data in greater detail. And for the 2014 class of OTC upgrades to the NASDAQ, again, the median stock appreciation was 15% through October 2014.

**Slide 29:** So the question many have asked is why are we up-listing now? The answer to that is that CytoSorbents is an evolving company whose fundamentals continue to improve. We believe our profile compares favorably to other recently up-listed healthcare companies. What I have done here is list many of the features of our company and put it all onto one slide so that investors can see the tremendous progress that we have made.

First of all, CytoSorb® is approved in the European Union with direct sales and distribution in 19 countries worldwide and growing. We address a massive multibillion-dollar market opportunity, addressing a major unmet medical need of critical care, as well as cardiac surgery. We have demonstrated strong growth with total trailing 12-month revenues of \$4.1 million, of which \$2.6 million are CytoSorb® sales. As Kathy mentioned, we have now exhibited five quarters of double-digit increases in CytoSorb® sales and we have now had our first \$1 million product sales quarter in Q3 of 2014. We have solid product gross margins of 65% and we now have cash and short-term investments of approximately \$7.8 million.

We now have 45 employees across our U.S. corporation and our subsidiary in Berlin, Germany. This is tremendous growth from where we were just three years ago. We are currently vertically integrated and we are an ISO 13485 certified medical device manufacturer producing our polymer as well as our CytoSorb® cartridges out of our New Jersey facility. We have now had a strategic partnership with Biocon focused on India and select emerging countries. And we have now established an initial partnership with a major cardiac surgery device company for a first initial evaluation in France.

We have 40+ investigator initiated studies being planned with many enrolling, Christian will talk about this in a little bit, and more than 150 key opinion leaders. The United States cardiac surgery pivotal trial IDE application will be filed soon. And we also have a trauma trial here also enrolling. We have had a tremendous amount of technology validation by major government organizations including DARPA, the U.S. Army, the U.S. Air Force, NIH and NHLBI. And we have been able to attract a world-class trauma board, cardiac surgery advisory board, as well as a sepsis advisory board to help advise the company.

Last but not least, we are currently covered by four analysts from Brean Capital, H.C. Wainwright, Merriman Capital and Zacks. Our goal was to have the fundamentals and progress in place to warrant and maintain a NASDAQ listing and to be able to attract institutional investors. We believe that our company is well-positioned to do this now.

Now with that, let me turn it back over to Kathy who will briefly describe the tremendous progress we've made on the path to up-listing. Kathy?

### **Kathleen Bloch - CFO:**

**Slide 30:** Thanks Phil. We have been very busy preparing for the up-listing. In the previous conference call we talked about the progress we have made, including choosing DLA Piper as our legal advisor, the adoption of a Code of Business Conduct and Ethics as well as an Insider Trading Policy, both of which are required governance items for the major exchanges. We also formally established NASDAQ compliant committees of the Board of Directors, and have adopted a charter for each Committee, also required.

In addition, since our last call we have simplified our capital structure with the conversion on October 9, 2014 of 100 percent of our Series A and Series B preferred shareholders to common shareholders. This was a very important step in the up-listing process, since we believe most institutional investors would prefer to invest in a company that does not have preferred shares with priority interests.

Of course it is also necessary for us to complete a reverse stock split to bring our Stock Price to the minimum price required by NASDAQ for up-listing companies. In that regard, on November 6, 2014, we filed our proxy with a Consent Solicitation to our shareholders asking that they approve five actions recommended by our Board of Directors. Phil will talk more about those later.

We also benefit from analyst coverage by Brean, HC Wainwright, Merriman, and Zacks.

And as Phil discussed previously, we have made significant operating progress, led by increasing CytoSorb® sales.

Yesterday we filed our application to up-list to the NASDAQ National Market. NASDAQ has assigned us a listing analyst and they will now begin their review process.

And the two remaining steps toward the up-listing are currently underway. We have selected a consultant who will assist management with the documentation and testing of our system of internal controls, another requirement for a Company traded on a major exchange. And we are continuing investor outreach in an attempt to generate interest in our stock, particularly among institutional investors. And based upon all of this progress we believe we are in a strong position to execute the up-listing before the end of this year.

And, now, I'll turn the call back over to Phil. Phil?

## **Phillip Chan - CEO:**

Thank you very much, Kathy.

**Slide 31:** I would also note that we do not believe that the up-list is a singular event. We absolutely plan to support the company following the up-list with a very defined strategy. Following the up-list we have several goals.

First is to continue to drive growth in CytoSorb® sales. We will continue to build key opinion leaders support, drive deep into accounts, and expand to multiple indications in multiple ICUs within each hospital. We plan to continue geographic expansion with new distributors and strategic partners, drive country by country product registrations and also invest in the support infrastructure of both direct and distributor sales.

We also plan to continue to pursue strategic partnerships for CytoSorb® and for our pipeline. We also plan to prioritize clinical data with build out of our clinical trial capability, start of the U.S. pivotal cardiac surgery trial, obtain data from investigator initiated studies, make progress in our U.S. Air Force funded trauma pilot and other funded studies, as well as continue to build upon the data being held by the CytoSorb® registry.

We also plan to continue to aggressively spread the word on CytoSorbents via meetings with institutional investors, investor conferences, additional analyst coverage and an upgraded PR strategy. We also plan to aggressively pursue research grant programs in new product development.

**Slide 32:** All of you have now been sent a consent solicitation statement seeking your approval of five proposals needed to up-list. Your vote is required before December 1, 2014. The first item is to approve a 25:1 reverse split for our common stock. The second is to reduce authorized common stock from 800 million to 50 million shares. The third is to reduce authorized preferred stock from 100 million to 5 million shares. The fourth is to approve the 2014 Long-Term Incentive Plan for CytoSorbents employees. And the fifth is to change the domicile of the company from the State of Nevada to the State of Delaware. We would encourage you to review your proxy statement. Most of the reasons why we are doing this are contained therein, as well as in the press release that came out very recently on this consent solicitation.

**Slide 33:** What I want to do now is to try to clear up some misperceptions of what we are trying to do. In particular, there is considerable misperception on the effect of decreasing the authorized shares of common stock from 800 million to 50 million shares.

Now most don't realize this, but this is actually a protective provision that the Board is putting in place to prevent the excessive issuance of new shares. I think people misunderstand some terms and so I thought we should define these terms for our shareholders.

First, the total authorized shares. This is what you are voting for. The total authorized shares are the total number of shares authorized, or voted for by shareholders, that a company can issue and sell. In fact, all companies have an authorized share number.

The second term is total outstanding shares. This is the total number of issued and outstanding shares, after giving effect to the reverse split to be approved by shareholders, which now also

includes common shares from the conversion of the Series A and Series B Preferred Shares. The total outstanding shares are often reflected in a stock float or the shares that are available for trading.

Next is the fully-diluted share count. This includes the total outstanding shares plus shares underlying outstanding warrants, options, and others. When companies talk about acquiring another company for a certain amount of money and this is then translated into a price per share, it's typically the fully-diluted share count that is used because it consists of all the ownership of the company.

The final definition is the authorized but unissued share count. This is a very important concept. These are shares that are currently authorized by shareholders but are currently not issued or otherwise allocated. They can be issued and sold by the company to raise needed capital to grow the business; for example to run clinical studies, to expand manufacturing, or for general working purposes. Or they can be used to retain and attract key talent that is necessary for the success of the company. Without available shares, companies cannot raise capital and run the risk of bankruptcy or illiquidity to the peril of all shareholders. We believe that a strategy of careful investment to drive growth while limiting shareholder dilution is the correct strategy to pursue now, to enhance the return on investment to all shareholders.

As many of our long-term shareholders know, we have been very conscious about preventing shareholder dilution which is why we have applied for grants and have obtained a tremendous amount of non-dilutive funding with the goal in mind of protecting our shareholder's interest. But at this current time with our phase of rapid growth, we believe that investing in growth versus being too focused on preventing shareholder dilution, is in fact the best way to achieve increases in shareholder value.

**Slide 34:** Slide 34 goes over what our capital structure looks like. After giving effect to a 25:1 reverse split, our capital structure will approximately look as follows. We would have approximately 23 million shares outstanding. We would have approximately 4 million shares underlying warrants, options, and others. And the sum of these two numbers, 23 million plus 4 million, make up the fully-diluted share count. I would note that this does not include the 2.4 million of unallocated shares under the 2014 Option Plan, assuming stockholder approval.

Now what remains is the authorized but unissued shares of 23 million, making the total authorized shares, adding the fully-diluted share count plus these authorized but unissued shares, of 50 million.

There are three important notes to make about this. First, the reason why we asking shareholders to approve a reduction in the authorized share count from 800 million to 50 million is because a reverse split does not automatically decrease the authorized share count. We are therefore reducing the number of shares that the company can issue after the split to only 23 million, versus the ability to issue up to 773 million shares, a protective feature for shareholders [\*Corrected from the original statement].

The second very important thing to note, and this is a common misperception amongst shareholders, is that setting the authorized share count to 50 million does not mean that

shareholders incur immediate dilution. If we never sell or issue, or if we only issue or sell part of the authorized but unissued shares, shareholders will not incur, or only partially incur, dilution to their ownership. However, the authorized but unissued shares give the company the flexibility to fund and grow the business that would hopefully benefit all shareholders.

If we do wind up selling authorized but unissued shares to raise capital, the fully diluted share count would increase and therefore shareholders would incur a proportional level of dilution. However, the dilution is offset in part by the increase in net value of the company from the cash that is raised from the sale of these shares, and hopefully by the growth achieved by the infusion of new capital.

**Slide 35:** The second common misperception is the reverse split, and particularly the reverse split ratio. First of all, why do we need a reverse split? We need a reverse split for two reasons. One is to meet the minimum \$4 per share price requirement to be a NASDAQ Capital Market company. The second is to make the total number of shares in the company a manageable and practical number that is acceptable to institutional investors. So why is the reverse split at a ratio of 25:1 then? Well, this ratio is arbitrary but was selected because it achieved the goals that we just talked about. And it's very important for investors to note, the size of the ratio, whether or not it be 5:1, 10:1, 25:1, 100:1, does not change your ownership or the share value of your shares and is not in itself dilutive. This is simply a math exercise.

Another question is, would waiting until we are further along be better? Well, as we have stated many times, there are many benefits of up-listing that we can't access any other way. We believe that we are ready and that any delay to up-listing is counter-productive to the short and long-term goals of the company and is in fact a disservice to our shareholders. There currently is a lack of purchase power in the current shareholder base. I think all of us can witness this on a daily basis by looking at the muted effect of positive news releases and the drifting average daily trading volume. Up-listing is intended to bring in new, long-term institutional shareholders with deep pockets who can potentially take large positions in our stock and in doing so potentially shift the supply-demand curve of our stock in our favor.

**Slide 36:** Another question "Is the reverse split a good thing or a bad thing?" Well, it depends on why the reverse is split is being done.

Consider these three scenarios. The first scenario is Company "X" whose fundamentals are deteriorating with a drop in the stock price. In order to maintain a national exchange listing, they need to meet the minimum share price requirement and therefore need to enact a reverse split. The problem is that in many cases, this is generally unsuccessful as the stock price continues to deteriorate as the fundamentals and the business deteriorates.

In the second scenario, Company "Y" has stagnant growth and fundamentals but wants a higher share price because of the perceived stigma of being a penny stock and the perceived premium of being a higher priced stock. So it does a reverse is split, solely for the purpose of increasing the share price. I think history has shown that the results here are mixed.

But as I have shown you data on the vast number of companies that are making this up-listing from the OTC bulletin board to the NASDAQ for the purposes of growing, this is really where we differ from the previous two situations.

In the third situation, Company "C" is growing rapidly and seeks to up-list to the NASDAQ Capital Market to target a significantly larger investor base that includes institutional investors. The fundamentals of this company are increasing and the goal of the up-listing is to improve visibility, credibility and liquidity of the company and the stock, as well as reduce the cost of capital and increase the interest in the company and its stock.

We believe that CytoSorbents is such an example. Although there can be no guarantees about post-split stock performance, NASDAQ has again summarized their historical data that shows that the median stock appreciation has been positive for companies undergoing the path that we are taking.

**Slide 37:** Another question that we have received is "Where did the rest of my shares go? Have I been diluted by 25 times and have I been cheated?" The answer to this is absolutely no. No ownership percentage has been taken from you or will be taken from you under this reverse split. And no dilution will be incurred solely by the reverse split. What you should really try to think about is your ownership as a percentage of the company rather than in share numbers.

What I have done is put together a simple example of how a reverse, or forward split for that matter, affects a shareholder's ownership and value of his or her shares. This is only an illustrative example but in principle is similar to the reverse split we are proposing. What you can see here is that in a reverse split, it doesn't matter if it's a 25 to 1 or 10 to 1 or 5 to 1. What happens is that there is a simultaneous reduction in both your shares but also the fully diluted shares of the company. Because of that, your percent ownership remains the same and because of that, the value of your shares also remains the same.

In a forward split, where you are getting more shares for every share that you have, it's the same phenomenon. It is a math exercise. Whether or not it's 1:5, 1:10 or 1:25, at the end of the day your ownership is still the same, the value of your shares is still the same. This is a very important concept for investors to understand. We would be happy to answer any other questions about this once you have had a chance to digest this information. Please feel free to reach out to us.

**Slide 38:** Another question is "Wouldn't I make more money if the reverse split was at a lower ratio and I had more shares?" So it's the same with all your other stock holdings whether or not you own Apple, Microsoft, Google or Intel or whatever the stock maybe. You need to look at the percent increase in the share price, not the absolute dollar increase. When you do this, you can see that whether or not the stock is that \$6.25 with a 25:1 reverse split, or \$1.25 with a 5:1 reverse split...if the stock increases 50%, you make the same amount of money and your ownership continues to remain the same. The same can be said if the stock increase is 300%. There is no difference.

What we are proposing with the 25:1 reverse split is simply a math exercise to meet the minimum share price requirements of the NASDAQ as well as to make a final, fully diluted share count manageable to outside institutional investors.

**Slide 39:** Another commonly asked question is "Isn't it easier for a \$0.25 stock on the OTCBB to go to \$1, which represents a four-fold increase, than for a \$6.25 stock to go to \$25 on the NASDAQ, also a four-fold increase?"

What I would say to this is: The stock price of any company is simply a matter of supply and demand. If supply exceeds demand than the stock price will fall. If demand exceeds supply, then the stock price will rise. We believe that making the stock available to a vast pool of investment capital held by institutional investors that cannot buy our stock today on the OTCQB or BB, combined with good news, can improve demand for our stock and, again, shift this supply-demand curve in our favor.

Although it's true that low float penny stocks have been known to be very volatile and can increase by significant percentages, these are often not sustainable increases in market cap value. For investors this can be fraught with danger depending when the stock is bought and sold.

And although no guarantee can be made about the post-split or post-uplisting stock performance, our goal with the up-listing is to build increased liquidity and a sustainable increase in share price that will benefit all shareholders regardless of when you buy or sell. You are encouraged to read the consent solicitation statement for more details.

**Slide 40:** On this next slide, what I have tried to do is demonstrate this volatility that I was talking about on the OTC bulletin board compared to stock appreciation on either the S&P 500 Index or the Russell 2000 Index, which is the index for small cap stocks. The chart on the left is the Bloomberg San Diego OTC Bulletin Board Small Cap Index from the period of 2010 to 2014. And what you can see is that after all this time, there is surely a lot of volatility, but ultimately there has been very little in the way of return. In contrast, looking at the S&P 500 Index and the Russell 2000 Index, both of them have advanced 100% during this period of time with much more stability.

**Slide 41:** So with that, we again recommend that you review the consent solicitation statement, the proxy statement that you have been sent, and vote in favor of the following five proposals before December 1, 2014. The earlier you get in your vote, the better. This is a key step towards up-listing to NASDAQ and something that we believe will benefit all shareholders.

**Slide 42:** And with that I would like to finalize my comments with this slide. This is Joseph Rubin, our Co-founder and Board Director, who passed away recently. Many of you have seen our press release on his tremendous lifetime achievements. We want to take a moment and commemorate Joe's involvement in the Company and the massive contributions he has made to the Company since its inception.

I would like to now go to the Q&A session with management, and with that I will turn it back to Amy.

### **Amy Vogel - Moderator:**

Thank you Dr. Chan. Over the last week, we have collected a number of questions from investors.

# Q: Christian, could you please give us an update on the development of the commercialization of CytoSorb?

# **Christian Steiner**

Yes, certainly. First of all we are excited and proud that we have reached this milestone exceeding \$1M in CytoSorb® product revenue for one quarter. This was a major effort of the sales team and reflects our progress in the commercialization of our CytoSorb® therapy. This success is based on a strong re-order business in our direct sales and excellent progress of our distribution partners, both in old and new markets. The growth of our unit sales was even higher than our dollar revenues suggest, since the Euro to dollar exchange rate went down and the majority of our business in Europe is done in Euros.

Commercialization includes a massive amount of effort in addition to the actual sales process. For example:

- It has been very difficult to find and hire the right sales reps that are best suited for our business. However, we have 7 reps currently and will have 10 reps at the beginning of the new year as planned
- We are also adding new support people to our direct sales team as well as leadership on the distribution side to allow us to grow faster, and to help manage our rapidly increasing distributor business
- Training and education of new sales personnel and new distribution partners and continued education of the current sales force is critical. In the past quarter alone, we conducted four training sessions at our Berlin office, and 5 training sessions at distributors.
- Clinical data is critically important for the further development and commercialization of
  the therapy. As Phillip mentioned, we are pleased with the launch of our International
  CytoSorb® Registry after ethics board approval and successful beta-testing completion.
  This study project is now running and many German-speaking centers have started using
  the Registry. The English platform is in beta-testing and will launch officially in early
  January 2015. Many international sites have already announced their interest to
  participate.
- The Investigator Initiated Trials are also a very important part of our strategy to generate additional clinical data. Of the more than 40 studies being planned, eleven trials are actively recruiting patients and another six to eight studies will start recruitment in the next several weeks. More than twenty other projects are in either in preparation or in ethics committee review. To speed up and oversee the development in this field we have hired a European Medical Director who will start in the first quarter of 2015.

 Reimbursement is also very important in establishing new therapies and usually requires both medical as well as health-economics evidence. We are actively seeking to improve the reimbursement situation in a number of countries

All this work is normally not visible to the public, but is expected to lead us to new performance levels in the coming weeks, months and quarters.

# Q: Christian, can you elaborate a little bit more on the progress with the distribution business?

We continue our aggressive geographic expansion in the EU and in countries outside of Europe that accept European regulatory approval and will have more to discuss before the end of the year. One of the challenges we face is the transfer of knowledge about how to best use CytoSorb. We have begun to formalize this during distributor training. This has worked very well with our partners in India and Turkey, for example. In India we recently organized a roadshow together with Biocon where one of our experienced key opinion leaders in Germany was able to teach more than 350 thought leaders in India in a multi-city lecture series. We already had more than 70 sites in India before the roadshow and we look forward to see how this number will grow as a result of our marketing efforts, as well as the increased number of applications, including cardiac surgery, that Biocon will go after.

As Phil mentioned, another major success was the registration of CytoSorb® in Saudi Arabia after a long and demanding process. We have already trained the sales team of our partner TechnoOrbits, and CytoSorb® has been used to now treat the first patients in a field test by the Ministry of Health. Pending this evaluation, we hope to obtain SFDA approval that would extend throughout the Gulf Cooperation Council countries of the Middle East.

# Q: Thank you Christian, can you please comment on the acceptance of the CytoSorb® Therapy by key opinion leaders?

Sure. As you can remember, from the beginning we have counted and reported the number of key opinion leaders that were using or were committed to using our CytoSorb® therapy in patient care or in clinical studies. I think we have now outgrown this way of measuring our progress since we can now see the growing acceptance from the number of treatments, reorders, and projects that we are doing. It is clear that the current acceptance is based on high interest and especially because of the positive experiences users are seeing with our CytoSorb® therapy. Nevertheless we know that we owe the medical community hard data and medical evidence. So we are working on this. While we were very focused on the German speaking community in the beginning, since this is covered by our direct sales team, we are now starting to have more projects prepared on an international basis. This could only be achieved with help of our successes so far.

# Q: Thanks. One last question: German University hospitals have treated a number of Ebola patients. Was anyone of these patients treated with CytoSorb?

No, not as of now. Germany does have seven centers with approximately 50 ICU beds where the equipment is adequate and the personnel have been trained and educated to treat Ebola patients. Five of these University hospitals are already using CytoSorb® in different indications.

All sites are informed about the availability of the therapy and the current state of knowledge. However, it is of course solely the decision of the treating medical doctors on what therapies are applied to help these patients suffering from such a terrible disease. But we have received positive feedback from a number of doctors at these sites, who think that our cytokine reduction approach makes a lot of sense.

Q: Thanks very much Christian. Another topic on many people's minds is the progress regarding the new manufacturing facility. Vince, can you provide us an update?

### Vince Capponi

As I mentioned in previous quarterly updates, we had initiated a number of infrastructure upgrades to accommodate further growth within our existing facility. These upgrades would allow us to increase production capacity within our current manufacturing facility with minimal cost. We have now completed those infrastructure upgrades and have begun the process of hiring manufacturing personnel to complete a second shift. The addition of a second shift provides additional capacity to bridge our transition from the current location into a new facility.

Since our last meeting we have identified and contracted with an engineering firm for the new manufacturing, R&D and corporate center. We are completing the initial engineering phase of the project focusing on the manufacturing and office layout while concurrently working with our recently-signed real estate broker to identify a new site. Our objective is to identify an existing facility that will not require extensive modification to keep costs down and expedite facility renovations to allow for occupancy in a timely manner. The new manufacturing facility is a progressive step to a final manufacturing facility and is expected to be able to meet our production needs for the next several years, while increasing operational efficiency and helping us to work through any scaling issues.

Q: Chris, can you tell us more about the recent Biocon partnership expansion announcement? What's changing and what can we expect from the partnership moving forward?

# **Chris Cramer**

Thanks Amy. Biocon has been an exceptional partner and I'm very excited about our expanded relationship. Let me just add some color commentary to what Phil talked about earlier in the call.

As you know, we initiated our relationship in September 2013 to launch CytoSorb® in India and select emerging markets to enable physicians to treat sepsis. As Biocon began working with its customers, it became very clear that they were increasingly identifying other conditions where high levels of cytokines have also been known to cause organ failure. In particular, we saw a broader opportunity to treat patients experiencing a Systemic Inflammatory Response Syndrome, also known as SIRS, brought about by cytokine storm. SIRS is caused by a wide range of life-threatening conditions seen in the intensive care unit and can also be caused by surgical interventions, particularly cardiac surgery.

Throughout my discussions with Biocon, we identified an opportunity to address this market need and felt strongly that we could accelerate product adoption by continuing to build the CytoSorb® clinical evidence base. That said, there are several important new developments to highlight.

- First, the approved applications have grown to encompass all critical care applications in the intensive care unit. While sepsis will continue to be a strategic focus, Biocon will now also promote CytoSorb® for a broad range of conditions involving the SIRS response including lung injury, post-operative SIRS, pancreatitis, burns, trauma, and tropical diseases such as Dengue Fever and malaria to name a few.
- Additionally, because Biocon has a strong Cardiac Care commercial organization and CytoSorb® can be used to attempt to control inflammation associated with cardiac surgery, Biocon will now promote CytoSorb® for intra-operative use during cardiac surgery.
- Finally, Biocon will take a leadership role in developing new clinical evidence by coordinating and publishing results from multiple Investigator Initiated Trials and patient case studies. To ensure that we have a voice in guiding these studies, these efforts will be jointly overseen through a Clinical Trial Steering Committee consisting of representatives from both companies.

So, let me take a moment to explain what this means and how this will benefit CytoSorbents.

- First, these are large markets and we'll now have the ability to help more patients. For example, there are more than one million new cases of severe sepsis in India each year. Cardiovascular disease is also a major problem. About 100,000 cardiac surgery procedures are performed in India each year. This number is expected to grow rapidly as, according to the World Health Organization, it is a small fraction of the 2.5 million patients that are in need of heart surgery.
- Next, top line product revenue will benefit. Given the strong market demand, we've
  agreed to increase annual minimum sales targets which will result in significantly
  increased revenue to CytoSorbents.
- Lastly, new clinical evidence will be created. Biocon will lead these efforts, using their resources and key opinion leaders in its network. These are costs that CytoSorbents otherwise would have borne. Also, the results of these studies and publications will support product adoption not only in the expanded Biocon territory, but will also benefit CytoSorb® sales efforts elsewhere.

Overall, I believe this is a major step forward in advancing our partnership and it sends a strong signal about the future of CytoSorb. I look forward to taking our relationship with Biocon to the next level.

Q: You recently announced an initial partnership with a leading global medical device company in the treatment of cardiovascular disease. Can you talk about the goals of this initial partnership and what it means for CytoSorbents?

Cardiac surgery is a large and strategically important opportunity for the company. There are about 1.5 million cardiac procedures performed each year worldwide and the number of people suffering from cardiovascular diseases is growing. Similar to the ICU conditions that CytoSorb® can be used for, high risk cardiac surgery patients may routinely suffer the same harmful effects of excess inflammation that if left untreated, can cause organ injury. We are very excited because we believe CytoSorb® holds the promise to improve patient safety while decreasing serious complications and their high associated costs, particularly in those undergoing complex cardiothoracic procedures.

Because of the particular nature of this partnership, we've jointly agreed with the partner not to disclose their name at this time. While we cannot mention them by name, suffice to say we are in excellent company, working with one of the leading global medical device companies in the treatment of cardiovascular disease. They are known throughout the world for their long tradition of innovation and have influenced nearly all of the modern equipment used by cardiothoracic surgeons and their teams today.

Under the terms of this agreement, the partnership will commence with an initial market evaluation period to determine various market parameters, obtain clinical data, and build key opinion leader support in France. Following a successful evaluation, the parties will jointly determine how to expand upon both the size and geographic footprint of the partnership.

The focus of this initial collaboration will be to introduce CytoSorb® to, and work with, some of the top cardiac professionals in France. Currently, we're working with the partner to simultaneously register the product in France and to start educating select KOLs on our product. Over the coming months, we'll work these physicians to implement CytoSorb® in their clinical practice and gain valuable insights. The experience gained during the market evaluation period will enable us to build support for CytoSorb® and strategically position it for success in the intraoperative cardiac surgery market.

I'm confident that with a positive evaluation in France, we will be able to broaden our relationship with this partner. At such time in the future, we will be able to release more information about this partnership.

Thanks, Chris. We've covered the major questions. Dr. Chan, do you have any closing remarks?

### Dr. Chan:

Thank you, Amy. Thank you everyone for participating on the call today. If you have any additional questions, feel free to forward them to Ms. Amy Vogel at <a href="mailto:avogel@CytoSorbents.com">avogel@CytoSorbents.com</a> and we will try to address them in our next update. Thank you again and have a great evening.

**Operator:** Thank you. That does conclude our conference for today. I'd like to thank everyone for their participation and have a great day.