## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

## FORM 8-K

## **CURRENT REPORT** Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 19, 2005

# Celsion Corporation (Exact Name of Registrant as Specified in Charter)

**Delaware** (State or other jurisdiction of incorporation)

000-14242 (Commission File Number)

52-1256615 (IRS Employer Identification No.)

10220-L Old Columbia Road, Columbia, Maryland (Address of principal executive office)

21046-1705 (Zip Code)

Registrant's telephone number, including area code: (410) 290-5390

(Former name or former address, if changed since last report)

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following isions (see General Instruction A.2. below):
Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.135-4(c))

## Item 8.01. Other Events

- a) On May 19, 2005 Celsion Corporation (the "Company") held its Annual Meeting of Stockholders (the "Annual Meeting"), at which Mr. Anthony Deasey, the Company's Executive Vice President, Chief Operating Officer and Chief Financial Officer, and Dr. Augustine Cheung, the Company's President and Chief Executive Officer, spoke. Copies of Mr. Deasey's and Dr. Cheung's prepared remarks are filed as Exhibit 99.1 and Exhibit 99.2, respectively, hereto and are incorporated herein by reference.
- (b) At the Meeting, the stockholders voted to elect Dr. Claude Tihon to the Board of Directors, to serve as a Class I director for a term of three years, until the Company's annual meeting of stockholders in 2008 and until his successor is elected and shall have qualified.

The results of the voting on this matter are as follows:

NOMINEE	For	WITHHOLD
Claude Tihon	127.129.242	6.075.168

The stockholders also voted to authorize the Board of Directors to amend the Company's Amended and Restated Certificate of Incorporation, as amended, to effect a reverse split of the Company's common stock at ratios ranging from one-for-seven to one-for-fifteen. The results of voting on these matters are as follows:

	For	AGAINST	ABSTAIN
One-for-Seven	121,672,563	11,094,519	437,327
One-for-Eight	120,327,329	12,455,555	421,525
One-for-Nine	120,306,006	12,506,568	391,835
One-for-Ten	122,248,635	10,644,719	311,055
One-for-Eleven	120,046,261	12,778,168	379,980
One-for-Twelve	119,983,691	12,851,438	369,280
One-for-Thirteen	119,992,996	12,815,283	396,130
One-for-Fourteen	119,959,911	12,863,268	381,230
One-for-Fifteen	120,607,079	12,269,625	327,705

Finally, the stockholders voted to ratify the appointment of Stegman & Company as the Company's Independent Public Accountants for the fiscal year ending December 31, 2005. The results of the voting on this matter are as follows:

	FOR	AGAINST	ABSTAIN
Ratification of Stegman & Company	129,191,283	3,348,471	664,655

## **Item 9.01 Financial Statements and Exhibits**

Exhibit No.	Description
99.1	Prepared remarks delivered by Mr. Anthony Deasey, Executive Vice President, Chief Operating Officer and Chief Financial Officer of Celsion
	Corporation (the "Company"), at the Company's 2005 Annual Meeting of Stockholders on May 19, 2005, (the "Annual Meeting").
99.2	Prepared remarks delivered by Dr. Augustine Cheung, President and Chief Executive Officer of the Company, at the Annual Meeting.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELSION CORPORATION

Date: May 25, 2005 By: /s/ Anthony P. Deasey

Executive Vice President

## **Exhibit Index**

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## **Celsion Corporation**

Prepared remarks delivered by Mr. Anthony Deasey, Executive Vice President, Chief Operating Officer and Chief Financial Officer of Celsion Corporation (the "Company") at the Company's 2005 Annual Meeting of Stockholders on May 19, 2005

#### Good morning:

I plan to address two subjects today—first, the successful launch of Prolieve $^{\text{\tiny M}}$ , our BPH treatment system, and second our financial situation in general. We have what I think is good news on both fronts.

As I reported during our quarterly shareholder call last Wednesday, Prolieve is doing very well in the market. At last year's stockholder meeting we predicted that we would have over 100 control units in service by the end of 2004. At the end of the year we had 101 control units in service. By the end of April we had close to 200 machines in service.

Last year in the nine months or so subsequent to receipt of the PMA approximately 2,500 patients were treated using Prolieve; during the first quarter of 2005 about 1,500 patients were treated; and in April alone close to 1,000 patients were treated.

Our machine utilization in the field is tracking at five to six treatments per month, which is significantly higher than the industry average of three to four. To all appearances, the prospects for the future of this product look terrific.

This has been accomplished through incredibly hard work on the part of the Prolieve team, which is comprised of both Celsion and Boston Scientific employees.

There is no question that Boston Scientific has been a committed partner. When we launched Prolieve they already had the largest sales force in this market and since then have added still more staff, until they now have almost 80 sales people supporting the product. They have also added technical personnel who are working alongside our technical staff to ensure that the product is sufficiently robust to perform reliably in the market. Boston Scientific also is investing in the development of programs designed to assist physicians in the field in raising patient awareness of the Prolieve treatment option. The Celsion and Boston Prolieve people are working together very well and through that co-operation we are progressing toward Celsion's goal of selling the Prolieve assets to Boston and Boston's goal of owning the pre-eminent product in the market.

The Celsion team is also outstanding. Since last year's stockholder meeting we have added a couple of key players—Mike Oleck, our Vice President of Operations and Ramesh Rao, our Director of Process Development. Both Mike and Ramesh have spent their entire careers in the Medical Device Industry, most recently working for Johnson & Johnson. Their skill and experience with both the engineering and regulatory processes have been invaluable as we enhance the reliability of our device.

However without the institutional knowledge of our long serving team of engineers led by Dennis Smith, our Vice President of Engineering, Celsion could not have succeeded.

With every additional month the product is in the market its reliability improves. This in turn increases the confidence and enthusiasm of the Boston Scientific sales force, which ultimately is reflected in revenue growth. However, ensuring Prolieve's success has its cost, as it puts an enormous strain on Celsion's resources, particularly in the clinical and regulatory areas, both of which also are critically important to development of our cancer treatment business, which we are

pursuing on a parallel path. As Max Link correctly observed, the continuing need to support Prolieve while nurturing our cancer treatment business painfully stresses our resources. This is a problem that the Board of Directors has directed management to resolve sooner rather than later.

In January we initiated discussions with Boston Scientific in the hope that they would exercise their purchase option early—that is, before sales reached the \$15 million sales crossover point. As you are all aware, however, the purchase option is entirely at Boston Scientific's discretion—they could elect never to buy the Prolieve assets. We have had extensive discussions, but they are not yet sufficiently comfortable with the product to make the "buy" decision. Boston has indicated that there are certain, clinical, regulatory and supply chain matters that they want us to address before they consider exercising their option. In order to address these matters expeditiously we have added resources. However this exacerbates the problems of stress on our finances. Therefore, as interim measure we are engaged in discussions with Boston Scientific to explore the possibility of Boston providing Celsion with debt financing. The amount and structure of such a financing ideally would be designed to provide sufficient financial resources to bridge Celsion either to the exercise of the option—and I cannot stress enough, Boston has no obligation to buy the Prolieve assets—or to a point where our cancer technologies have sufficient capital value to enable Celsion to raise funds through an equity deal or through a development partner. We are hopeful that we can reach a mutually beneficial deal that will both reflect Boston Scientific's confidence in the Prolieve product and demonstrate their continuing interest in our other technologies.

Thanks for your attention.

Dr. Cheung will now update you on the non Prolieve portions of our business or as he optimistically refers to it "Life after Prolieve".

## **Celsion Corporation**

## Prepared remarks delivered by Dr. Augustine Cheung, President and Chief Executive Officer of Celsion Corporation (the "Company") at the Company's 2005 Annual Meeting of Stockholders on May 19, 2005

Thanks, Tony.

You have heard from Max that we have finally found the CEO with the right experience to lead Celsion into the future, when the company will be fully focused on the development of heat-activated cancer therapeutics. I look forward to working with Dr. Olanoff towards the fulfillment of Celsion's vision.

Max outlined the difficulties and dilemma faced by Celsion's management last year. In response to the FDA warning letter, to ensure full regulatory compliance, management was given the task of modifying and upgrading our business infrastructure within a period of less than six months, while at the same time continuing to work diligently to move the business forward on two entirely different fronts.

The first priority of Celsion's management is to focus on the continued development of the Prolieve™ business so that Boston Scientific will exercise its purchase option. As Max indicated, while necessary, this process is straining our limited technical, human and financial resources. Management is doing all we can to position Prolieve so that Boston will exercise the purchase option as soon as possible. As you have already heard from Tony, we have made significant progress in developing the business, as indicated by Boston's willingness to discuss bridge financing. We believe that Boston will exercise its option to purchase Prolieve in the not too distant future.

After the sale of Prolieve, Celsion will become strictly a biotechnology company, focused on the business of development and commercialization of heat-activated cancer drugs. This is our future. The development effort for ThermoDox $^{\text{TM}}$  as a cancer drug must be pursued vigorously.

Before moving on to describe the future of Celsion Corporation, I would like to revisit the past, reexamine Celsion's vision and purpose, and take us through the evolution history of Celsion Corporation as a biotechnology company.

When Cheung Laboratories (Celsion) was formed in 1982, our dream was to become a cancer treatment company and our goal was to develop and commercialize non-invasive microwave heating systems to induce hyperthermia therapy for treatment of cancer. Hyperthermia is believed to significantly enhance the efficacy and reduce toxicity to cancer patients undergoing radiation treatment. Our mission was to create hyperthermia treatments which would help to restore cancer patients to full health. We succeeded in obtaining a PMA to commercialize our first-generation systems. However, due to technology limitations at that time, commercial hyperthermia systems, including ours, ultimately were unable to provide the anticipated health restoration benefits to cancer patients.

We did not give up. We collaborated with institutions such as MIT and others to develop the APA microwave technology platform, which allows the engineering of microwave heating systems with the capability to focus microwave energy precisely at cancerous tumors anywhere within the human body. The first clinical indication selected for commercialization of the APA technology was breast cancer. At the same time we also were developing a minimally invasive approach to treat BPH using the combination of balloon compression and microwave heating. Further collaborative research and development efforts with scientists from Duke University, Memorial Sloan-Kettering Cancer Center and the National Cancer Institute also resulted in the creation of Celsion's heat-activated drug and gene delivery technology platforms.

In 2001, we outlined a strategic plan to transition Celsion from a medical equipment developer to a biopharmaceutical company focused on the development of heat-activated cancer drugs. The first step was to complete development and obtain approval of the BPH product and then to increase our "war chest" by monetizing the BPH technology. In January 2003, we engaged Boston Scientific as our marketing partner for BPH and also granted Boston a 5-year option to purchase our BPH assets for a minimum of price \$60 million. In February 2004, we received the PMA for Prolieve, our BPH system, and thereafter, together with Boston Scientific, we launched Prolieve in the urology marketplace.

Unfortunately, the FDA issued a warning letter in May 2004, citing Celsion for non-compliance with GCP, or Good Clinical Practices, in the manner it conducted the pivotal clinical trial for Prolieve. The warning letter required that Celsion provide satisfactory responses in a timely manner or face the possibility of having the PMA revoked.

We responded with a plan to put the Company into full regulatory compliance by the end of October 2004. The plan included external reviews and re-monitoring of all our clinical trial as well as undertakings to take necessary corrective actions. We also committed to build strong clinical and regulatory departments, staffed by experienced professionals, to ensure Good Clinical Practice compliance by year end 2004. The FDA accepted our response as satisfactory and required us to provide monthly progress updates, as well as a final report by our late-October deadline.

In the course of external review, we identified additional compliance issues. Thereafter, we voluntarily suspended the Phase II studies for treatment of breast cancer using APA focused heat and the Phase I dose escalation study using ThermoDox in combination with Prolieve for the treatment of prostate cancer.

Our actions in response to the warning letter, although both necessary, and beneficial to the Company in the long run, nevertheless led to significant delays in product development timelines and imposed a heavy burden on our limited financial and human resources. As a result, we were forced to refocus the Company's efforts and limit our spending to projects of the highest priority.

Therefore, we decided on the following immediate priorities:

- 1. Continue to develop Prolieve, to maximize the possibility that Boston Scientific will exercise its purchase option in the shortest timeframe possible.
- 2. Continue to develop ThermoDox by concentrating first on a cancer indication that was selected on the basis of rapid proof of principle and, ultimately, a fast track to market. Liver cancer, a disease representing a drastic un-met medical need, met our criteria and, in addition, holds the potential for a very large worldwide market. Therefore, we decided to seek an NDA for ThermoDox in combination with Radiofrequency Ablation (RFA) for the treatment of liver cancer.
- 3. Postpone or eliminate all other business activities, as they would represent distractions from the above focus.

Our need to prioritize and focus has led to several business decisions.

First, we have decided not to restart the suspended clinical trials for the development of the APA breast cancer system within Celsion. I remain convinced that this technology can be a very powerful tool for the treatment of cancer. We are actively seeking alternative ways of moving this technology forward. These alternatives could include moving the assets into a separately funded subsidiary or selling the business, with Celsion retaining a residual interest. This does not suggest that Celsion is giving up on the fight against breast cancer. It simply means that we are seeking a means through which dedicated financial and human resources can be focused against the eventual success of the product, with Celsion eventually benefiting from any future market success.

Celsion also is continuing to fight against breast cancer in partnership with Duke University. We recently signed a letter of intent with Duke University Medical Center to provide the heating equipment and ThermoDox for an institution sponsored Phase I clinical trial to evaluate the use of focused heat to activate ThermoDox for the management of recurrent chest wall, or RCW, lesions. We expect that this Duke-Celsion collaboration will provide proof of principle for the effectiveness of ThermoDox in the treatment of RCW. Celsion will retain the right to use data generated by the Phase I study to perform additional trials with an eye to eventual commercialization of ThermoDox for this indication, while conserving our financial and human resources in the short term.

## Second, on Gene Therapy:

The regulatory climate in the US is unfavorable for the development of gene therapy products. In contrast, China's regulatory climate is favorable for the development of heat-activated gene therapy for cancer treatment. In fact, late in 2003, the SFDA in China approved the commercialization of the world's first gene therapy product (P53). We are actively exploring the alternatives for forming a venture or working with an existing venture to accelerate development of our gene technology in China. Again, the ultimate structure of such a venture has yet to be determined, but Celsion intends to retain a residual interest so that Celsion's shareholders will benefit from the ultimate commercialization of our gene technology.

#### Third, on Prostate Cancer

We have decided to postpone restarting the Phase I dose escalation study for prostate cancer using ThermoDox and Prolieve until we have made further progress on development of ThermoDox in combination with RFA for treatment of liver cancer. We expect to make a decision on when and how to restart our effort on prostate cancer at a later date.

Our decision to focus on development of ThermoDox in conjunction with RFA for treatment of liver cancer was based on a number of considerations.

Liver cancer is a global disease. Primary liver cancer afflicts over 500,000 people every year. When this number is aggregated with liver metastases from other organs such as breast, lung and colorectal cancer, the incidence is close to 1,000,000 cases each year worldwide. ThermoDox plus heat for the treatment of liver cancer has vast market potential.

Among all cancers, liver cancer is one of the most deadly. The five-year survival rate for liver cancer patients is a few percent. The average life expectancy of patients after first diagnosis is between one to two years. In many cases, death occurs within months. Currently, there is no cure and no satisfactory treatment for liver cancer. Therefore, an effective treatment for liver cancer would address a drastic unmet medical need.

In spite of the fact that RFA is the current standard of care for liver cancer, its success is limited to local tumor control. Life expectancy for most patients after successful RFA tumor ablation is still short—only a few months, due to frequent cancer recurrence. Many experts believed that the effectiveness of RFA is limited by its relatively small ablation area (kill zone). The small cancer kill zone provided by RFA alone does not address the presence of satellite centers of micro-tumors consisting of aggregates of viable cancer cells in the tumor margin which is outside the ablation area. It is a common belief that if the kill zone can be expanded to cover the tumor margin, efficacy of the treatment will increase dramatically. We believe that combining RFA with ThermoDox will significantly increase the cancer kill zone, thus leading to effective local tumor control and reduction in recurrent rate. In large animal studies, we have demonstrated that combined use of ThermoDox with RFA increased the size of cancer kill zone. Now we need to prove the same in humans.

Over the next six months, our development effort will be centered on a Phase I dose escalation study to establish safety and establish the Maximum Tolerated Dose, or MTD for ThermoDox. Currently, the study is led by the NCI. [NCI treated a patient this morning and] we expect them to finish the first cohort of patients in the very near future. We have decided to expand the study to include three additional sites, one in Hong Kong and two others in the US. We expect Hong Kong will be up and running by early summer and the other US sites to be active by the end of the third quarter. Together, these sites should enroll enough patients to allow the completion of the Phase I study by the end of 2005 or early in 2006. Thus, in 2006 we should be in a position to start a Phase II/A proof of principle study followed by a randomized Phase II study to establish efficacy of ThermoDox and RFA for treatment of primary liver cancer

Some of you may want to know how long it is going to take for success. Obviously, we selected liver cancer as our primary focus based its potential to meet a critical unmet medical need, as well as its market potential. There are other strategic reasons for its selection. First, even though primary liver cancer has a very high global in incidence, the incidence in the USA is relatively small. As a result, the indication could be eligible for "orphan" designation, which would offer significant competitive and financial advantages. We also believe that because there is a drastic unmet medical need for treatment of the disease, compelling survival data from a Phase II study could permit us to seek expedited review and approval from the FDA. Another important consideration is that survival periods are relatively short—a few months. Therefore, the endpoint to demonstrate survival enhancement by ThermoDox when used in conjunction with RFA could be reached in a relatively short period. Thus, we should complete our trials quickly. The fact that we are trying to demonstration improvement over a standard of care (RFA) should also allow us to accrue patients relatively easily.

Another significant strategic advantage is our choice of RFA as the heat source. Although it shows only limited success, RFA is a standard of care for liver cancer worldwide and, therefore already has wide market coverage for this indication. Our approval strategy is to demonstrate the enhanced efficacy by ThermoDox over RFA. However, RFA is also being used for treatment of Lung, Kidney and Pancreatic cancer worldwide. The approval for RFA for lung and kidney cancer is pending in the USA but expected soon. It would be natural for us to expand into the treatment of lung and kidney cancer using ThermoDox and RFA. If shown effective to treat liver, lung and kidney cancer, ThermoDox could become a blockbuster cancer drug.

Obviously, ThermoDox is not the only heat-activated cancer drug that can be developed by Celsion. Our technology platform allows us to encapsulate much water soluble cancer therapeutics, providing the potential of a rich cancer product pipeline. Under the leadership of Dr. Olanoff, an experienced drug developer, Celsion is in a position to fully capture the product potential offered by our exciting heat-activated drug delivery platform.

I know that many of you were frustrated by the lack of "good news" from Celsion last year. I also know that this lack of "good news" was perceived by many as lack of progress. I hope that my summary will change your perception today. Let me assure you that Celsion will never deviate from it vision of restoring health to cancer patients. We will not stand still and become complacent in our quest to reach our goal. We now have an experienced and dedicated board and a focused and seasoned management team. We are united in our effort to move Celsion forward to realize our dream of helping cancer patients by building a very successful and responsible biotechnology cancer company.

Now we will be happy to answer any question you may have.