

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): August 20, 2001

Celsion Corporation

(Exact Name of Registrant as Specified in Charter)

Delaware

000-14242

52-1256615

(State or Other Jurisdiction  
of Incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

10220-I Old Columbia Road, Columbia, Maryland

21046-1705

(Address of principal executive office)

(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

## ITEM 5. OTHER EVENTS

On August 20, the Company released to its stockholders a letter regarding the status of its business and the development of its products and announcing a new stockholder communication program including quarterly stockholder letters and conference calls. On the same date, the Company issued a press release summarizing the stockholder letter. A copy of the stockholder letter is attached as Exhibit 99.1 to this Report on Form 8-K. A copy of the press release is attached as Exhibit 99.2 to this Report.

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 thereunto duly authorized.

CELSION CORPORATION

Date: August 20, 2001

By: /s/ Anthony P. Deasey

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Anthony P. Deasey  
Executive Vice President and  
Chief Financial Officer

## EXHIBIT INDEX

Exhibit	Description
99.1	Registrant's Letter to Stockholders dated August 20, 2001.
99.2	Registrant's Press Release dated August 20, 2001.

[CELSION(TM) LOGO]

CELSION CORPORATION  
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August 20, 2001

Dear Shareholder:

We have had a very productive seven months since our last report.

1. BENIGN PROSTATIC HYPERPLASIA (BPH) PIVOTAL PHASE II CLINICAL TRIALS HAVE BEEN EXPANDED TO TEN SITES WITH ACCELERATED PATIENT ENROLLMENT.

The final clinical (Pivotal Phase II) BPH study on 160 patients (120 of whom have been or will be treated with Celsion's investigational system and 40 with the drug Proscar) is currently underway at the following sites:

1. Montefiore Medical Center, New York
2. Regional Urology (LA), Shreveport, Louisiana
3. Pacific Urology Institute, Santa Monica, CA\*
4. Urology Associates of North Texas, Arlington, TX\*\*
5. University of Maryland, Baltimore, MD
6. Dr. Raymond Fay, San Francisco, CA
7. Urology San Antonio, San Antonio, TX\*
8. Kansas City Urology Care, Kansas City, MO\*\*
9. Research Associates in Urology, West Orange, NJ\*
10. Nevada Urology Associates, Reno, NV\*

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- \* Part of the Linked Urology Research Group.  
 \*\* Part of America's Doctors.

We expect that three additional sites will be active by the end of August.

Early in 2001 we concluded that the clinical sites we were selecting would not generate an adequate volume of patients to enable us to complete the trial within the timeframe that we had previously indicated. As a result, we changed our selection criteria to focus on office-based clinical sites with high patient volumes. More recently we have concentrated our efforts in two national, clinical trial groups--America's Doctors (indicated above by \*) and the Linked Urology Research Group (indicated above by \*\*). As a result of this change, our current sites employ over 150 urologists and collectively treat in excess of 20,000 patients each month.

Additionally, we recognized that we needed to bolster our clinical management resources and, therefore, formed a four-member dedicated group to manage the BPH Pivotal Phase II Clinical Trials. These two strategic decisions, together with the hiring of Dan Reale as President of the BPH Division, have resulted in a dramatic increase in patient enrollment. We began the BPH Phase II Clinical Trials in October 2000 and through July 31, 2001 we had treated 18 patients. By the end of August, we expect to more than double that number and, on the assumption that we will continue to increase our momentum, we anticipate that we could complete enrollment by the end of October. This would enable us to submit our application for premarketing approval (PMA) to the Food and Drug Administration (FDA) early in 2002 and, if the FDA finds the application adequate, could result in approval by the spring/early summer of 2002.

2. CELSION'S BREAST CANCER PIVOTAL PHASE II CLINICAL TRIALS ARE UNDERWAY AND THREE PATIENTS HAVE BEEN TREATED.

Given our limited cash and personnel resources and the proximity of our BPH product to commercialization, we decided, early this year, to focus our clinical resources towards completion of the BPH clinical trials. This having been said, the Company's Breast Cancer Pivotal Phase II Clinical Trials are underway at Columbia Breast Surgery Medical Center, FL, where one patient has been treated, and Halle Martin Luther Breast Center at Halle in Germany, which has treated two patients.

We are currently in negotiations with ten excellent additional sites, one of which, Oklahoma University, is in the final stages of its Institutional Review Board (IRB) approval process. Two protocols will be tested at each location; the first is designed to ablate (kill) small breast cancer tumors using heat alone. The second is designed to downsize large breast cancer tumors using a combination of heat and chemotherapy, thus allowing a surgeon to perform a lumpectomy rather than a mastectomy, thereby preserving the affected breast.

3. CELSION/DUKE UNIVERSITY HEAT ACTIVATED LIPOSOMES

We continue to make progress on the development of a cancer drug using the Heat Activated Liposome technology that we licensed from Duke University. We have successfully encapsulated a well known cancer drug-Doxorubicin-our first production batch has been manufactured and we are in the midst of large animal toxicity studies, being conducted at Roswell Park Cancer Institute in Buffalo, New York, to determine a safe dosage for use in human clinical trials. If all goes well, we should complete these trials by the end of October, which would enable us to file an Investigational New Drug (IND) application for the compound by the end of this calendar year. Assuming the FDA approval process runs its normal course, we could commence human Phase I clinical trials on this new drug early in 2002.

## 4. CELSION/SLOAN-KETTERING GENE THERAPY

Dr. Gloria Li at Memorial Sloan-Kettering has successfully developed a temperature activated, gene-based, biological modifier. The modifier is expressed by an increase in temperature induced by Celsion's focused heat at the tumor site. The activated modifier is intended to eliminate the tumor cells' ability to repair DNA damage when they are treated with radiation or chemotherapy. Clinically, the use of the biological modifier is intended to enhance significantly the efficacy and reduce drastically the amount, and thus the toxicity, of required radiation and chemotherapy. Thus far, researchers at Sloan-Kettering have successfully demonstrated the concept in small animals. They are currently conducting an efficacy study using human tumors in mice and are preparing to commence large animal toxicity studies. Celsion is in active discussion with clinicians at Memorial Sloan-Kettering regarding the design of clinical trials in order to file an IND application for the "biological modifier" and begin patient studies. While this development is still a long way from commercialization, the initial results show great promise.

## 5. CASH POSITION

As we accelerate our clinical trials to commercialize our various businesses we have increased our cash "burn rate" to an average of \$650,000 per month. At the end of June our cash balance was \$4.6MM, which implies that we have sufficient cash to take us through the end of this calendar year and to complete several significant milestones. As we indicated at the Annual Meeting, we intend to raise additional funds in the fall of this year. We are exploring a wide variety of avenues including strategic alliances and various equity infusions.

## 6. OTHER DEVELOPMENTS

There have been several other positive developments in the business.

## STRATEGIC ALLIANCES

In mid-May, we signed a Memorandum of Understanding with Inabata, a Japanese trading company 30% owned by Sumitomo Corporation, to explore opportunities to develop our business in Asia and Japan. So far, we are delighted with our relationship, which has generated several potential business opportunities. We are presently negotiating with several Japanese pharmaceutical companies to license our BPH and temperature sensitive liposome technologies for Japan. While there is no assurance that these negotiations will be successfully concluded, we are encouraged that our technology has generated a high level of interest among potential medical and pharmaceutical partners. We are also discussing with Inabata manufacturing and distribution opportunities in China.

## PERSONNEL

We have made three significant additions to our senior staff:

First, we hired Dan Reale as President of the BPH Division. Dan is a seasoned entrepreneurial executive, who has spent his entire career in the medical products industry largely with three successful bio-medical start-ups. Dan's focus and energy will act as a catalyst as we work to bring our BPH product to market in the middle of 2002.

Next, we reassigned Kurt O'Neill, our former Controller, to manage our clinical programs. Kurt has been instrumental in signing up the new clinical sites and working with the sites' clinical personnel to expedite the enrollment of patients.

Finally, we added Dr. Kris Venkat to our Board of Directors and engaged him to work with us to develop our pharmaceutical business. Kris has vast experience in the pharmaceutical field and will work with management to develop an operating plan and identify and negotiate with potential strategic partners for this business.

\* \* \*

We recognize that our communication over the last seven months has been less frequent than may have been desired by you, our shareholders. In the future, we expect to issue a shareholder letter each quarter and, additionally, to host a quarterly shareholder conference call. The first of these calls has been scheduled for August 28, 2001 at 10:00 a.m. Eastern Daylight Savings Time. If you wish to participate please call 952 556 2803 (or toll free 877 679 9049) and register ten minutes before the call. A recording of the call may be accessed between 11 a.m. on August 28, 2001 and 11 a.m. August 29, 2001 at 703 326 3020 (or toll free 800 615 3210) with an access code of 547 1289.

To conclude, we are making excellent progress on many fronts, and we believe that we will meet several major milestones in the second half of the year. We feel confident that, as we clear each milestone, the market will recognize the value Celsion has within its reach.

Thank you for your continued support.

/s/ SPENCER J. VOLK

/s/ AUGUSTINE Y. CHEUNG

Spencer J. Volk  
President  
Chief Executive Officer

Augustine Y. Cheung  
Chairman and Founder  
Chief Scientific Officer



NEWS RELEASE

[CELSION(TM) LOGO]

## For Further Information Contact:

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## CELSION REPORTS PROGRESS TOWARDS COMPLETION OF BPH CLINICAL TRIALS

COLUMBIA, MD - AUGUST 15, 2001: In a letter to shareholders issued today, CELSION CORPORATION (AMEX:CLN) reported that it is moving forward towards completion of its Benign Prostatic Hyperplasia (BPH) Pivotal Phase II Clinical Trials. The Company reported that it has engaged 10 active clinical sites, collectively employing over 150 urologists treating more than 20,000 patients each month. The Company also reported a significant increase in patient enrollment during recent months. According to the letter, if the acceleration in enrollment is sustained, enrollment in the trials could be completed by the end of October 2001.

In the same letter, Celsion updated its shareholders on the progress of its other businesses including the Pivotal Phase II Clinical Trials of the Company's investigational system using focused heat to treat breast cancer; the status of development of its doxorubicin-laden heat activated liposome cancer drug, currently in large animal toxicity studies; progress in the development of its heat activated gene therapy; developments arising from its relationship with Inabata; and its cash position.

Celsion also advised shareholders that, in future, it expects to host quarterly shareholder conference calls, the first of which will take place on August 28, 2001 at 10:00 a.m. Eastern Daylight Savings Time. Call-in information is contained in the letter to shareholders, which is available on the Company's web site at [www.celsion.com](http://www.celsion.com)

ABOUT CELSION: Celsion Corporation, based in Columbia, Maryland, is a research and development company dedicated to commercializing medical treatment systems for cancer and other diseases using focused heat technology delivered by patented microwave technology. Celsion has research, license or commercialization agreements with leading institutions such as Duke University Medical Center, Massachusetts Institute of Technology, Harbor UCLA Medical Center, the University of California at San Francisco, the Center for Breast Surgery at Columbia Hospital in Florida, Montefiore Medical Center, Memorial Sloan Kettering Cancer Center in New York and Duke University. For more information on Celsion, visit our website: <http://www.celsion.com>.

Forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing, capital structure, and other financial items; changes in approaches to medical treatment; introduction of new products by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

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