

CELSION CORP
Form DEFA14A
March 04, 2005

OMB APPROVAL
OMB Number: 3235-0059
Expires: February 28, 2006
Estimated average burden
hours per response: 12.75

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

SCHEDULE 14A
(RULE 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement

Confidential, For Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

Definitive Proxy Statement

- Definitive Additional Materials
- Soliciting Material Pursuant to § 240.14a-12

Celsion Corporation

(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box):

- No fee required.
- Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

Edgar Filing: CELSION CORP - Form DEFA14A

.. Fee paid previously with preliminary materials.

.. Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount previously paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

Filed by: Celsion Corporation

Pursuant to Rule 14a-12

Under the Securities Exchange Act of 1934

Subject Company: Celsion Corporation

Commission File No. 001-15911

The following is the transcript of the fourth quarter earnings call of Celsion Corporation, which took place on March 3, 2005.

CORPORATE PARTICIPANTS

Dr. Augustine Cheung

Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Tony Deasey

Celsion Corp. - Executive Vice President, Chief Operating Officer

CONFERENCE CALL PARTICIPANTS

Alec Roberts

Analyst

Mitch Landgraf

Analyst

Mark Steinberg

Analyst

J.D. Haas

Analyst

Paul Irvin

Analyst

Anthony Bonavito

Glen Fine

Bob Green

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to your Celsion conference call. My name is Jean and I will be your conference coordinator. Celsion wishes to inform participants that forward-looking statements in this call are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Participants 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 by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers competitors and regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities & Exchange Commission.

[Operator Instructions.]

At this time, I will turn the call over to your host, Dr. Augustine Cheung, Chief Executive Officer.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Hi, good morning, fellow shareholders of Celsion. Welcome to Celsion's first quarter 2005 shareholder conference call. 2004 was a very busy year for us, presenting us with both opportunities and challenges. Our Board of Directors and our management team are pleased to report that we are capitalizing on our opportunities and have successfully addressed our challenges.

We believe that 2005 is going to be a very exciting year for Celsion. Today we will cover several topics. First, Tony will update you on Prolieve and reveal our fourth quarter financial results. Next, I will then bring you up-to-date on the progress of our ThermoDox program and the developments we expect in 2005. We will then discuss our progress in terms of the strategic repositioning of Celsion that we have initiated in 2001. Finally, we will talk about the requests that we are making to our shareholders at our annual meeting in May as outlined in the proxy materials that we filed this morning with the SEC to grant the Board of Directors the authority to recapitalize the company by effecting a reverse split of our common stock. At the end of our prepared remarks, we will be happy to take your questions. I will now turn over the call to Tony, who will talk to you about Prolieve.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Thanks, Augie. During the fourth quarter of 2004 Prolieve made a significant impact on the BPH market. During the quarter, Boston Scientific placed 44 machines in doctors' offices and approximately 1,500 patients underwent Prolieve treatments. In line for our forecast for the year, as of December 31, 101 machines were in service and almost 2,500 patients had received Prolieve treatments. Of greater significance than that, the utilization rate for our Prolieve units was averaging over six treatments per machine per month or nearly double the industry average of between three and four treatments per month.

We believe the positive reaction to Prolieve is the result of Boston Scientific's well-conceived product launch targeting high potential users, coupled with its very thorough training program. It's the overwhelming consensus of physicians who are using the Prolieve - we've been on mute there for a minute - Boston Scientific's December sales - let me start again. Thanks to all of you. During the fourth

quarter of 2004 Prolieve made a significant impact on the BPH market. During the quarter, Boston Scientific placed 44 machines in doctors offices and approximately 1,500 patients underwent Prolieve treatments. In line with our forecast for the year, as of December 31, 101 machines were in service and almost 2,500 patients had received Prolieve treatments.

Of greater significance than that, the utilization rate for our Prolieve units was averaging over six treatments per machine per month or nearly double the industry average of between three and four treatments per month. We believe the positive reception of Prolieve is the result of Boston Scientific's well-conceived product launch targeting high potential users, coupled with its very thorough training program. It's the overwhelming consensus of physicians who are using the Prolieve system that Prolieve is the most patient-friendly system for the treatment of BPH available in the market today.

Boston Scientific's December sales of Prolieve catheter kits were at an annual run rate of approximately \$9 million. To Celsion, this translated into the highest quarterly revenues in the Company's history, representing a 165% increase in revenues over the third quarter of last year.

We are very optimistic about 2005 and expect our revenues to exceed \$10 million. Revenues at this level would equate to a Prolieve run rate well in excess of the \$15 million crossover point on Boston Scientific's option to purchase Celsion's BPH assets.

In the fourth quarter our gross margin increased from 12% to 15% as the proportion of revenues derived from catheter kits increased. Operating expenses were flat compared to the third quarter. The loss per share was also flat compared to the third quarter at \$.02 per share. There has been a strong sustained and successful effort between the staffs of Celsion and Boston Scientific to establish a robust presence in this very large market. We are quite pleased with our progress to date and are excited about our future prospects.

Augie will now cover our progress in developing the heat-activated liposome business or, in his words, "life after Prolieve". Augie...

Augustine Cheung

Thank you, Tony. As you are all aware, Celsion's goal is to advance from a medical device company to a cancer drug development company. Our strategy is to focus on building a product pipeline of tumor targeting anti-cancer drugs based on Celsion's proprietary heat-activated drug delivery technology platform.

Our first formulation, which we trademarked as ThermoDox, has been safely administered to 13 patients in conjunction with heat provided by a modified Prolieve system in a Phase I study to treat prostate cancer. We are applying this experience to a second clinical indication and presently are investigating the use of ThermoDox in combination of Radiofrequency Ablation, also known as RFA, for treatment of liver cancer. We have undertaken this study in collaboration with the National Institutes of Health and the first patient was treated on February 14. We are making every effort to ensure that we achieve rapid enrollment in this study, including nationwide advertising to potential referring physicians and potential patients.

Obtaining an IND or, as some people call it, a drug approval for ThermoDox in combination with Radiofrequency Ablation for liver cancer presently is the primary focus of our cancer drug development program. This concentration is based on several factors. First, primary liver cancer afflicts over 500,000 people globally every year. When this number is aggregated with liver metastasis from other organs, such as breast, lung and colon, the incidence is close to 1 million cases per year. Of all of the cancers, liver is one of the most deadly with a five-year survival

rate on the order of a few percent. The average life expectancy of patients diagnosed with liver cancer is between one to two years. Currently, there is no cure for liver cancer.

Radiofrequency Ablation alone is the current standard of care for non-resectable liver cancer. However, its effect is limited to local tumor control. Most patients' life expectancy after RFA treatment is still very short due to the frequent recurrence of the cancer. Many experts believe that Radiofrequency Ablation's effectiveness is limited by the small ablation area, often referred as kill zone, which is on the order of a centimeter or about half an inch. It is the common belief that if the kill zone can be extended to eight to ten centimeters, the efficacy of the treatment would increase dramatically.

Combining ThermoDox Radiofrequency Ablation is expected to address the kill zone limitation of the Radiofrequency Ablation by expanding the kill zone to eight to ten centimeters. The ability to extend the kill zone with our procedure has been demonstrated in animal studies. Our clinical trial is designed to verify the findings in humans. If the animal data is confirmed, we could see a dramatic improvement in efficacy and should be able to extend the life expectancy of patients treated with our combination ThermoDox and RFA procedure.

One unique commercial advantage of our strategy is that while primary liver cancer is a very large global disease, its incidence in the US is relatively small with only about 11,000 new cases annually. But in the USA, our ThermoDox treatment should qualify for orphan drug status. Additionally, assuming that we can show effectiveness, given the length of any current treatment, the FDA also could grant us fast-track review and approval of ThermoDox with RFA for treatment of primary liver cancer. With the fast track this indication could be approved as early as 2008. At such time as we obtain this approval, we would be in a position to undertake studies to extend our indication to address liver metastases, which are equally drastic.

As I stated earlier, the incidence of primary liver cancer in the US is relatively low with fewer than 11,000 cases each year. However, the global potential for treating liver cancer is enormous. Of the 500,000 cases of primary liver cancer worldwide each year, 300,000 cases occur in China. Over the last three years we have put a great deal of effort into building a network in China to give us eventual access to that market. Over the next 12 months, we look to establish a maximum tolerable dose of ThermoDox in the treatment of liver cancer through completion of our Phase I study at NIH.

We then intend to move directly into a Phase II trial using sites in the US and overseas with an emphasis on Asia. We have already identified one site in Hong Kong that could be a significant contributor to the Phase II study.

Besides liver cancer, Radiofrequency Ablation is also used in the treatment of lung and kidney cancer worldwide. We believe that ThermoDox or the encapsulation of another chemotherapeutic agent in our heat-activated liposome, when used in combination with RFA, could also enhance the therapeutic efficacy of RFA in treating liver, lung and kidney cancer. By addressing some or all of these indications we can extend the reach of our drug without the need to develop any additional new heating devices or to sell any new heating devices.

Turning to our prostate cancer study. In that study, a modified Prolieve device was used as a means of heat activation of the ThermoDox. In response to the warning letter that we received from the FDA in May 2004, we re-monitored all of our studies, including the prostate study. In the course of the re-monitoring, we determined that many of the good clinical practices of GCP compliance issues that arose in the Prolieve pivotal study were present in the prostate cancer study as well. As a result, we voluntarily suspended the study. We have since sought and received permission from the FDA to restart the study under a revised protocol. However, the anticipated development path for our prostate cancer treatment program is much longer than that for liver cancer since the prostate treatment will have to be taken through a Phase III trial and ultimately will have to demonstrate efficacy against radical prostatectomy, which is surgical removal of the prostate. Therefore, we expect that Celsion will only be able to complete the Phase I [sic] study in collaboration with a partner able to provide significant financial resources. Such a partner will be attracted by high quality published data upon completion of the Phase I study. We are currently recruiting institutions with significant stature to complete this study and ultimately publish based on its results. We expect that these recruiting efforts make take up to six months or more.

We are also actively working with clinicians that at Duke University and MIT to develop a breast cancer treatment utilizing a combination of Duke's temperature-sensitive liposome and MIT's APA focused heating technology.

We know many of you have been frustrated by the lack of good news over the last several months. Let me assure you that no news was not a signal that nothing was happening. Instead, in a very real sense, in this case, no news was good news. Over the last year we have made great progress. We have overcome product issues and regulatory hurdles. At the same time, we have built a clinical operations group, recruited CROs and successfully launched a new product. We also have a strong regulatory and quality group that will keep Celsion in compliance.

In accomplishing all of this, we have completed reshaped our company. Celsion today is a much stronger entity able to support a commercial product while developing future products to provide for life after Prolieve.

So what are we looking to accomplish during 2005? Ensuring the continuing success of Prolieve is our first objective. This product is the source of our future funding and we must make every effort to ensure its success in the marketplace.

Our second objective is to provide proof of principle that ThermoDox can effectively deliver its load of the anti-cancer drug doxorubicin to heat a tumor region and that doing so is effective in treating cancer. We are very excited about the medium term prospects for ThermoDox as an effective targeted cancer therapeutic. In the long term we believe that our heat-activated liposome has potential as the medium through which we can deliver other cancer drugs.

The fruits of our labor over the last year are the growing market acceptance of our Prolieve product and our ongoing Phase I clinical trials of ThermoDox for the treatment of prostate and liver cancer. We are very hopeful that Boston Scientific will exercise the option to purchase our Prolieve assets in the not-too-distant future and provide us funding for our cancer products. In the meantime, we expect that our ongoing ThermoDox-related studies will generate results that will become the backbone of Celsion's future.

During the last year we have significantly increased the depth and breadth of our management team until now, with the addition of only a few more key people, we will have the infrastructure necessary to succeed. In December, David Braitman, our Senior Vice President for Product Development, left the Company. We will be replacing him with a Medical Director whose specialty is in oncology. A search currently is underway to fill that position. Our search for a CEO is an ongoing process. Retaining the right person to serve as our future CEO is essential to Celsion's ultimate success. Therefore, while we have met with many candidates, we will not compromise on our requirements. This having been said, we are hopeful that we will be in a position to fill the position soon. In the meantime, the Board of Directors is confident that the current senior staff can manage the business effectively.

As you are aware, we filed our Preliminary Proxy Statement this morning. I will now ask Tony to take you through a couple of the items reflected in the Proxy Statement. Tony

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Thanks, Augie. First, you may have noticed that one of our directors is not standing for election to the Board of Directors. Leigh Stone has served on the Board since September 2004 and has decided for personal reasons not to stand for election. We thank him for his contributions during his time on the Board and as Chairman of the Audit Committee. We have begun to search for another Board member but were not able to

Edgar Filing: CELSION CORP - Form DEFA14A

identify a qualified candidate for inclusion in our Annual Meeting Proxy Statement. Commencing with the annual meeting on May 19, Max Link will reassume his role as Chairman of the Audit Committee.

Second, we're asking our shareholders to grant the Board of Directors the authority to effect a recapitalization by means of a reverse stock split at a ratio of not less than 1 to 7 and not more than 1 to 15 at some time in the next year.

When I came to Celsion in 2000, it was obvious that our first priority was to get a product approved and on the market. To that end, we raised, through a series, we raised cash through a series of private placement.

While this was effective in providing with the funding necessary to move the business forward, it has resulted in an increase in a number of shares outstanding from 60 million to 160 million over the last four years. Having this number of shares outstanding obviously depresses the stock price and the resulting low price of our stock prevents the vast majority of institutions from investing in Celsion.

As institutions cannot invest in Celsion, institutional analysts will not cover our story. With no institutional coverage, it's very difficult to establish and maintain a positive presence in the broader financial market. And as a result, we believe that the value of our technologies is not recognized by the market or reflected in our stock price. We're convinced that a market capitalization at \$72 million woefully undervalues our future prospects.

In order to ensure that you, our shareholders, are properly rewarded, we must find a way to access the institutional markets. Additionally, NASDAQ is the market of choice for biotechnology stocks. However, without a sustained \$5.00 stock price, we're ineligible for listing on that market.

As a final step in our repositioning, we need to restructure our equity base to ensure that we're eligible for the appropriate markets and meet the criteria for investments by institutional investors. We know many of you are concerned by the history of reverse splits. Let me try and address some of your concerns.

First, assuming that our shareholders approve this action, the Board of Directors has one year from the 2005 annual meeting of stockholders to execute a reverse split. On the one hand, this provides the Board with the flexibility to select a favorable time to effect the reverse. On the other hand, the Board's authority is limited, since if the reverse does not take place by the time of our stockholders' meeting in 2006, we must return to the shareholders for a new authorization. We've asked for approval for a number of reverse ratios, varying from one to seven to one to 15. If we decide to execute the reverse, the higher the stock price is at the time the reverse becomes effective, the lower the ratio would be. We've also researched a selection of 18 biotech companies that have done reverse splits in the last three years.

On average, these stocks have risen by 103%, with the largest increase at 318%. In four cases, the stock went down, but in each of those cases, the company made no progress or suffered some sort of a problem. While we cannot assure you that the results of a reverse split will be either positive or sustained, we're confident that we will make good progress in our business during the next 12 months.

Thus, we're also confident that Celsion's market capitalization should not be negatively impacted by this action.

This completes our prepared remarks, thank you for your attention. We're now open to your questions.

Operator

Thank you sir. Ladies and gentlemen, if you'd like to ask a question on the call, key star one on your touchtone phone. If you'd like to withdraw your question, please key star two. Your questions will be taken in the order they are received by. We'll take a question here from Mr. Alec Roberts, please go ahead.

Alec Roberts - Analyst

Yes, good morning. Well, I think you were correct in saying we were, at least myself and I'm sure many other investors have been, pretty much discouraged by the lack of news and thank you very much for the good news that we got today. I hope that you won't keep us in the dark for so long in the future.

I have a couple of questions, I look at the BSX site and I go to their area where they're talking about our Prolieve. But they also have another treatment there called the Holmium laser treatment. When you read their blurb, they seem to be giving as equal or as much attention as to ours. Do you have any idea of what that is and how it's competing with ours, the Holmium laser treatment?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

They do have another treatment as you say, but the emphasis in Boston Scientific right now is Prolieve. The Prolieve treatment is more patient- and physician-friendly than the other treatment. And absolutely in the division that's selling our product, their number one emphasis is our product.

Alec Roberts - Analyst

Well, I'm glad to hear that. My second question has to do with the agreement with Boston Scientific. I'm afraid, I tried to look up my past papers and I couldn't find it exactly. In your documentation which you put out from time to time, it says that we have a strategic allegiance, alliance with Boston Scientific in which Boston Scientific will initially distribute the Prolieve system worldwide. But its worldwide that concerns me, we don't include China in that, but what are the exclusions from that worldwide statement that if Boston Scientific were to exercise the purchase of the BPH, what is left in the hands of Celsion?

Tony Deasey - Celsion Corp. - Executive Vice President Chief Operating Officer

If Boston Scientific exercises their option, Celsion would no longer have any interest in Prolieve. They would buy the rights to Prolieve worldwide.

Alec Roberts - Analyst

Including China?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Including China and Central America, South and Central America.

Alec Roberts - Analyst

Oh, so they would take over the new Celsion China.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

But when you look at it Alec, the real market for this treatment is in the North America. That's where the economic benefit lies.

Alec Roberts - Analyst

My last question, then let somebody else carry on is how many units on the Prolieve are expected to be placed in the calendar year 2005. You hit 101 last year; it wasn't even a full year.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I think in 2005, we would expect to place somewhere in the region of 200 to 250 additional machines.

Alec Roberts - Analyst

Thank you.

Operator

And we'll take our next question from Mitch Landgraf. Please go ahead.

Mitch Landgraf - Analyst

Good morning and thank you for such an informative and positive conference call. It confirms a lot of the positives that people like myself who have believed in your company for a long time had a suspicion would be happening.

I'd like to clarify, in the last response. You said that then after exercising, BSX would have all of Prolieve. And my understanding of their written language was that it would be for Prolieve for the purpose of treating BPH. That if you used the technology for other, such as the cancer, that still remains Celsion's.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

You're correct. Cancer treatment, we use the same device...

Mitch Landgraf - Analyst

Right.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

In terms of machine and catheter. But the algorithm for the treatment is different. So you're absolutely correct, it is just for BPH.

Mitch Landgraf - Analyst

And if I may, though, my question was in both the written press release and in what you mentioned today, it is, the wording has always been that we treated our first patient in the liver cancer trials on February 14th.

I appreciate the added information that you said today in regard to the enrollment and it's nice to hear a word like orphan and fast track talked about openly. But can you say how many patients are currently enrolled or being treated?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

We just treated the first patient and right now, NIH is actively recruiting patients from the internal patient base. But also, they do advertising on their nationwide network. They will be screening patients regularly. You understand that we still have some exclusion criteria, so not every week you will find the right patient.

But when the new schedule, the network that refers physician and patients, we expect a much more rapid enrollment.

Mitch Landgraf - Analyst

Thank you and keep up the good work.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Thank you.

Operator

We'll take a question from Mark Steinberg.

Mark Steinberg - Analyst

Yes, good morning. I had a question about the FDA. And I know now that it was mentioned that there are new reviews going on. But has the SBA come back and determined that the Company is actually in compliance and if not, when so you expect that to happen?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

The FDA process, we got the warning letter and we responded, since then we've communicated with the FDA on a continual basis. It's most likely that when we have patients enrolled in clinical studies, whether it's the post-market study for BPH or the liver study or the prostate study when it restarts.

At that point, the FDA will come back and audit us. I don't believe, we won't get a notice to say that we're clean. We'll go through an audit process and they'll do that when we're back treating patients, most likely. They could come in before, but that's the most likely.

Mark Steinberg - Analyst

OK, thank you.

Operator

And we'll take your next question from J.D. Half (ph), please go ahead.

J.D. Haas - Analyst

Yeah, first of all, bravo on the Prolieve sales and also bravo on the reverse split, I think it's been a long time coming. I wanted some further clarification on the prostate cancer trials. Am I to understand that we will not resume Phase I trials until we have a strategic partner?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

No, we did not say that.

J.D. Haas - Analyst

Go ahead.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I think Dr. Cheung in his remarks actually said Phase I when he meant Phase III.

J.D. Haas - Analyst

Phase III.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

No, we will continue the Phase I on our own, what we'd like to do is get the Phase I completed, get data from that that we can then use to try to attract a partner. And what we said is that this is going to be a very big study and it's very unlikely that we could afford to take that all the way through Phase III.

We did say that we are very selective in selecting the new sites to finish the study because we want to have well-known institutions who will complete the study and also publish the data, because that will provide the basis for a strategic partner to enter into negotiations with us.

J.D. Haas - Analyst

Right.

So, now when we restart the Phase I trial for prostate cancer, it said in your press release that you didn't anticipate completing that until next year. I felt that we already had gotten a few levels of that completed and there were only like two or three levels to go. Why does it take until next year to complete that study?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Edgar Filing: CELSION CORP - Form DEFA14A

Yeah, again, like as we stated, we need to identify the site, then they have to go through the IRB process to get the approval and then we do not know exactly when we'll get to MTD. So, let's assume like two or three cohorts. So I think if you add up all the time, you just have to take that long.

J.D. Haas - Analyst

We're starting from ground zero then?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

We're starting from where we...

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

We basically used the data that we got from the previous study or from the study to the point where we suspended it. And we used that data where we got to 30 milligrams per meter squared as the basis of going back to the FDA with a new protocol which we're using to start the new study.

J.D. Haas - Analyst

Right, right.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

We're starting at a level relatively close to that, slightly below that 30 milligrams level.

J.D. Haas - Analyst

OK, so then last question, how many patients do you anticipate? I think with your initial protocol, you said it would be about 30 patients. How many patients do you anticipate that you'll have to treat for this revised phase I protocol?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

You never know when you're going to reach maximum dose, but it's our belief that it's going to be somewhere in the 12 to 15 patient range. But you know, it could be more.

J.D. Haas - Analyst

OK, very good, thank you gentlemen.

Operator

And again, if you'd like to ask a question in the call, simply key star one. We'll take a question from Mr. Paul Irvine, please go ahead.

Paul Irvine Analyst

Yes, I was wondering if there's any agreement of restrictions that Boston Scientific has where we are unable to report the monthly the number of units that are used and also the number of kits that are sold.

Tony Deasey - *Celsion Corp. - Executive Vice President, Chief Operating Officer*

There's no restriction with Boston Scientific, but I don't think that would be a good practice for us to get into releasing monthly data.

Paul Irvin - *Analyst*

OK.

Tony Deasey - *Celsion Corp. - Executive Vice President, Chief Operating Officer*

Because months fluctuate and if you have a couple of good months and then you sort of settle in the market and it goes down and people react to that, so I think you're much better to look at this on a three month basis than on a monthly basis.

Paul Irvine - Analyst

OK, and could you tell us, during the last 12 months, has any company has approached CLN on the possibility of buying the Company?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

We wouldn't be allowed to comment on that, sorry.

Paul Irvine - Analyst

And what is the China venture doing right now in the way of BPH use in that area or in South America?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

On the China venture, we have submitted the papers to the China FDA, waiting for the response to have the approval to start patient and marketing of the product. We have not received the approval yet at this point.

Paul Irvine - Analyst

Do you have any idea of what kind of a time frame we should look for?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Well, I really hate to address, three to six months, that's the best guess.

Paul Irvine - Analyst

OK, I would imagine the costs associated with that and ongoing costs. Boston Scientific of course would be entitled to any work that was accomplished. There's no agreement where they'll reimburse us above the \$60 million because of money expended there, I guess.

Tony Deasey - *Celsion Corp. - Executive Vice President, Chief Operating Officer*

No, they buy the assets at the time that they exercise their option.

The costs of getting the product introduced in China are relatively low. Because you can use the data that you had in the U.S. and the US submission and things like that are the basis of your permission.

Paul Irvine - *Analyst*

OK, and are the losses that are being sustained in the China venture being included in the profit and loss for the Corporation?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Yes, yes they are.

Paul Irvine - Analyst

Anything going on in South America?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

No, we have a distributor in Mexico, but we haven't yet started developing that market.

Paul Irvine - Analyst

And as far as BPH being advertised, I know when the New York area first started offering it, there was good advertising on a radio station, a popular radio station in that area. Boston Scientific I guess is the only one that if any advertising is being done, they are the only ones doing it. Is that correct?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Yeah, advertising would either be done by Boston Scientific or by the clinical sites themselves. I think advertising in New York was sponsored by Montefiore.

Paul Irvine - Analyst

It seems to be a problem, I had a client of mine that was interested in pursuing the BPH procedure. So I called Boston Scientific and they do not give you the name of a doctor in your area that can supply the treatment. But they tell you to speak to your doctor or your hospital. It seems a little bit ridiculous that somebody calling for BPH Prolieve to speak to your hospital when this is a treatment that's done in a doctor's office. I don't think the hospital would be any help.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Edgar Filing: CELSION CORP - Form DEFA14A

We don't have any machines installed in hospitals to my knowledge. Why don't you ask me in e-mail...

Paul Irvine - Analyst

I got it from Celsion.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I would take it up with Boston Scientific.

Paul Irvine - Analyst

Yeah, I got the information from Celsion right away when this was in Florida, for your locations in Florida. But I thought it was really detrimental to the forwarding of sales for Boston to be so restrictive. Possibly insurance problems or...

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I honestly can't explain that but I'm sure that it's all being part of the introductory plan that people are learning there as well as here. And I think over time you'll find that will all be sorted out. I'm glad you got the information from us.

Paul Irvine - Analyst

OK, and could you give us an idea of, you said 101 machines by the end of the year. Could you give us some indication of the number in January and February?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I think somebody just asked, we won't put out monthly data. We answered an earlier question and said we hope to place 200 to 250 machines this year. And I don't think, we won't expand on that right now.

Paul Irvine - Analyst

And as I understand it, Boston Scientific was offering it on a trial basis to doctors. Do you have any idea?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

The way the product is being marketed is the machine, a doctor has the option of having a machine placed in his surgery for evaluation for the period of up to 60 days. During which time, he performs procedures, his staff are trained and at the end of that period, he can elect whether to buy the machine, or return it. In most cases, the doctors are buying the machines. But that is the way we have gained market penetration.

Paul Irvine - Analyst

OK, and could you give us some idea of what's going on with gene based therapies?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Edgar Filing: CELSION CORP - Form DEFA14A

Right now, OK, because of the regulatory climate in the U.S.A., it's very difficult to gain the approval to start these trials. So we're exploring possibility of partnering with someone overseas, see if we can move this technology forward, in the different regulatory environment. But I think that's all I can comment.

Paul Irvine - Analyst

Okay. And then in China, the funding of that operation, are we funding that 100% or is the...?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Yes, the 50/50 joint venture in which both Celsion and our partners over there put up some money. I expect the future funding will be raised locally.

Paul Irvine - Analyst

In China? Okay, and can you give us some indication of what your burn rate is right now?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Average burn rate for this year is estimated to be around \$800,000 a month. Now, that number takes into account expenses less income generated from Prolieve. We expect it to be somewhere around \$800,000 a month.

Operator

And we'll take a question from Anthony Bonavito. Please go ahead.

Anthony Bonavito

Gentlemen, you seem to be very optimistic about the prospects of your Company and you feel you've stated that you feel it's undervalued. I've noticed no insider acquisition of stock in the open market. I'm just curious why you're unwilling to dip into your own pockets and buy the stock if you feel it's undervalued.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

We've been investing in the Company and we have a lot of us have large blocks of shares at this point.

Anthony Bonavito

Through options?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Yes, and also buying the open market.

Anthony Bonavito

I haven't seen any maybe...

Dr. Augustine Cheung - *Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer*

Not recently.

Anthony Bonavito

Recently meaning like in the last 6 to 9 months. Well, I'm just curious. I don't see the justification in telling us that you feel you're very optimistic about the prospects, you feel it's undervalued, you're going to do a

reverse split to be able to sell it to the institutions, yet we see no one, not only insiders, but directors, no one buying any stock at all at these cheap values, according to you.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Well, I think it's in the first place, I actually did buy stock not too long ago. I bought 30,000 shares and I've bought stock in the open market three times since I've been at the Company. The other side of that is that the senior managers particularly have a very large proportion of their future net worth already in the Company in terms of options. Dr. Cheung has, I think, it says in the proxy he has over 4 million shares plus options. I have nearly 2 million. Any good financial advisor would tell you that we should be diversifying.

Anthony Bonavito

Any good financial advisor would probably also encourage you to buy a stock that you feel is extremely undervalued. Your options are just that; they're options. I'm sure you've probably executed some of them, but others you don't have to execute. So you're giving us a really standard answer that almost all of management gives us, yet there's really no justification as to why. I mean, you said yourselves earlier in your call that you felt that the stock price was extremely undervalued but we don't see, or I don't see you guys stepping up and really making the statement that, "Hey, we believe in this company and we're showing you by going in, reaching into our own pockets and buying the stock at these", according to your own words, extremely undervalued prices.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

We've given you the only answer we can give. We're very heavily invested already. We're investing our time. We have kids at college and things like that that we have to pay, too. So I personally have stepped up, I know Dr. Max Link has stepped up. Certainly from my perspective, I look at I have an awful lot of my future lying on this stock where the stock price is now.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

All of us, including our management team, do have all have a very large position already and I think that we are in a quiet period also. We have last year we had a warning letter. We are making many changes. Sometimes it is difficult for us to make a decision to buy. I hope that you understand.

Anthony Bonavito

Well, to be honest with you, I really don't understand. I just think that if you guys really believed in what you're doing and the prospects of the Company, that you would, certainly from my perspective, make the other shareholders feel a little bit better if you guys were stepping up. It's just hard to hear you say that, "Hey, we feel that this Company's got great prospects..."

Dr. Augustine Cheung - *Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer*

Well, I...

Anthony Bonavito

...and it's truly undervalued, yet we don't see anybody stepping up to the plate and buying additional stock, especially if you've...

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

No, I understand your statement. Company is in a very rapid transition period. We are making many changes that we were not allowed to let people know in the open market. We are subject to many insider news information. There are many times often that we considered that. That's a quiet period and we have asked employees to refrain from buying stock. It's a different issue. It's not that. You think that because I know that you have good future, I'm going to buy a bunch of stock and benefit from it. It's that until everything is disclosed to the public, I think it's best that at that point, people can buy the stock. We (inaudible) position and then while we are doing everything, all the changes in which we know that some changes are difficult. So I don't know.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I think the net net is that all of us are here, we're working very hard, very long for the shareholders. We're contributing every day and our hearts and soul are here.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Right.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

We have to manage our finances as we can. I would love to go into the market and buy \$1 million worth of stock; I just don't have \$1 million to buy it.

Anthony Bonavito

Sure. All right, thank you very much.

Operator

We'll take a question from Alec Roberts. Please go ahead.

Alec Roberts - Analyst

I'm sorry to come back on sort of past history, but you mentioned, Tony, in your presentation, and I've just forgotten the details, if you'd refresh me on the \$15 million crossover. The purchase with the possible purchase by Boston Scientific, there was a bit's not just \$60 million, is it? There's a condition.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

The purchase option Boston Scientific has for the BPH assets is the greater of \$60 million, or four times trailing 12 months sales.

Alec Roberts - Analyst

Oh, four times...

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

The \$15 million would be a run rate that would be forward looking.

Alec Roberts - Analyst

Right, okay.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

But once it gets to a forward looking \$15 million, then one would expect, one would expect that Boston would start looking at buying the assets.

Alec Roberts - Analyst

Right. And how much money, at \$800,000 per month burn rate, taking into account the profits and so on from Prolieve, how long can we go without any further infusion of cash?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

At \$800,000 a month, we would anticipate we could get through this year without further infusion of cash.

Operator

We'll take a question from Glen Fine.

Glen Fine

I think the question was answered. I was concerned with the burn rate and cash on hand. If you could be more specific in giving me a dollar amount of cash on hand so that we can feel comfortable in the next 12 to 24 months.

Tony Deasey - *Celsion Corp. - Executive Vice President, Chief Operating Officer*

In the 10-K that we're filing in a couple of weeks, we have in excess of \$10 million in cash. At the end of this quarter, we probably will have somewhere in the region of \$8 to \$8.5 million.

Glen Fine

Okay, so you see things going smoothly till this time next year?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Yes, and you know a lot can happen between now and then. And in terms of financing this business, we've financed it through some very difficult times and I'm sure that with very good progress on Prolieve and progress in the other studies, in the event that we have to go to the market at the end of the year, then I'll be really, really, really disappointed if the stock price is where it is now.

Glen Fine

Okay, just to follow up on that in terms of financing, shares outstanding stand at 160 million. I know you issued last year 50 million additional for the purposes of development. Are those shares going to be used to leverage financing or is this strictly a leverage for talent?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

What we did last year was we got an authorized we increased the shares, authorized shares, so we can issue up we went up from 200 to 250 million. So we increased our authorization by 50 million. We have not issued any of those shares.

Glen Fine

Okay. So you have the ability to issue additional shares and sell them on the open market to raise capital? Is that correct?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Effectively, yes.

Glen Fine

Effectively, yes. Okay, and the reverse split you don't see affecting that either way? It's just strictly to adjust the share price...

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Yes.

Glen Fine

...to bring it up in the range and put it on the radar of the institutions.

Tony Deasey - *Celsion Corp. - Executive Vice President, Chief Operating Officer*

Yes, and in the event that you did have to do a financing, I think it would be a much cleaner financing with institutions than having to do a funding with high net worth individuals and smaller institutions. But that's the objective is to get coverage by institutional analysts and get stock into the hands of institutions because we think that will add stability and it will help to get Celsion's story, which we think is really strong, out into the marketplace.

Glen Fine

Okay, fantastic. One follow-up to the Boston Scientific rights to purchase Prolieve. I understand, or I think I understand that they have to exercise their option once you hit certain milestones.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

They do not have to...

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

They don't have to pay for...

Glen Fine

They do not have to.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

It's entirely at their option. They could let the option run out. They do not have to exercise.

Glen Fine

Okay, so I misunderstood when I thought that was sort of like in the bank. Soon as you get to the \$15 million they're going to step up, otherwise, once sales hit \$20 million, then they have to pay \$80 million.

Augustine Cheung

Right.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Well, theoretically, if they don't step up and sales do get to \$20 million, they would have to pay \$80 million.

Glen Fine

That's right. Or their option expires and then it goes out on the marketplace and anybody else. So the question with regards to talks with other companies, obviously you guys can't discuss it. But it's always open.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Yes.

Glen Fine

Opportunities are out there.

Operator

I'll take a question from Mr. Bob Green. Please go ahead.

Bob Green

I have just a couple of questions on the machines placed and the six treatments per month. I think I heard you say that should if that continues at that rate, we should get \$10 million a year in income?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

\$10 million a year in revenues.

Bob Green

In revenue. What percent would go to CLN?

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

That was I was projecting Celsion revenue.

Bob Green

That should more than cover expenses, then, if we got

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Well, no, because out of the revenue we have to purchase the catheters and we have to pay for machines. So you'll see in our press release, right now we have around a 15% gross margin. We expect that gross margin will increase as we sell more catheters. Hopefully we'll get up to the 40 to 50% range this year. If we averaged for the year 30% gross margin, then we would get \$3 million of that revenue would become cash that was available to fund the rest of the business.

Bob Green

Okay. Breast cancer and APA, is there a timeline when that's going to proceed?

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Well, we're working on it right now. We will try our best to move that forward. I know a lot of people are concerned about giving up on fight for breast cancer. It is not true for this Company. But we really until

we have something significant, we will not be able to tell you what we are doing, but MIT and Duke are actively participating in this effort.

Bob Green

Okay. One more question. On the Prolieve treatment, is there any way to get a list of the sites that provide that? I know some people that would like to get into it and we just can't find a list of the sites.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

Can you send me an email?

Bob Green

Sure.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

And I will get that into the hands of Boston Scientific.

Bob Green

We'd appreciate that.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

And sorry?

Bob Green

Appreciate that.

Tony Deasey - Celsion Corp. - Executive Vice President, Chief Operating Officer

I think you've got my email address on the press release.

Operator

And folks, there are no questions at this time. I'll turn the call back over to the presenters for closing remarks.

Dr. Augustine Cheung - Celsion Corp. - Founder, President, Chief Executive Officer, Chief Scientific Officer

Well, thank you very much.

Operator

Ladies and gentlemen, thank you for joining us on the call today. You may now disconnect.