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OSTEX INTERNATIONAL INC /WA/

Form 425

September 09, 2002

Filed by Inverness Medical Innovations, Inc.

Pursuant to Rule 425 under
the Securities Act of 1933,
as amended, and deemed
filed pursuant to Rule
14a-12 under the Securities
Exchange Act of 1934, as
amended

Subject Company: Ostex International, Inc.
Commission File No.: 0-25250

Certain matters discussed in this filing contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include statements about the anticipated timing and expected benefits of the acquisition of Ostex International, Inc., a Washington corporation ("Ostex"), by Inverness Medical Innovations, Inc. (the "Company"), potential product development and market opportunities, the anticipated impact of the acquisition on the Company and its future growth and the continued and future financial results of the Company. Actual results may differ materially due to numerous factors, including without limitation, the ability to satisfy the conditions to the consummation of the acquisition, the timing and content of the approvals necessary to consummate the acquisition, conditions in the capital markets in general and the healthcare capital markets specifically which may affect potential financing sources for the development of the Company's and/or Ostex's business, the effect of any operational and financial covenants contained within the terms of any additional borrowings obtained prior to consummation of the acquisition, the operational integration associated with the acquisition and any past or future acquisition transactions and other risks generally associated with such transactions including any unanticipated costs and difficulties with such integration, the effect of domestic and foreign healthcare regulatory efforts, technological advancements and patents attained by competitors, demand for and the potential market acceptance of Ostex's and the Company's current or future products, the intensely competitive environment in the Company's and Ostex's markets which could reduce market share or limit the ability to increase market share, the efficacy and safety of products, the content and timing of submissions to and decisions by regulatory authorities both in the United States and abroad, the ability to manufacture sufficient quantities of product for development and commercialization activities, the ability to successfully develop and commercialize products, and the risks and uncertainties described in the Company's press releases and its current and periodic reports filed with the Securities and Exchange Commission (the "Commission") under the federal securities laws including the Company's Annual Report on Form 10-K/A for the year-ended December 31, 2001 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2002. The Company does not undertake any obligation to update any forward-looking statements.

The Company will be filing relevant documents concerning the acquisition with the Commission including a registration statement on Form S-4 containing a prospectus/proxy statement. WE URGE INVESTORS TO READ THESE DOCUMENTS BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors will be able to obtain the prospectus/proxy statement and other documents that will be filed by the Company and Ostex with the Commission free of charge at the Commission's website, (<http://www.sec.gov>) or by

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directing a request after such a filing is made to Inverness Medical Innovations, Inc., 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453, Attn: Corporate Secretary, telephone (781) 647-3900 or Ostex International, Inc., 2203 Airport Way South, Suite 400, Seattle, Washington 98134, Attn: Corporate Secretary, telephone (206) 292-8082.

THE FOLLOWING DOCUMENTS WERE FILED BY THE COMPANY UNDER COVER OF FORM 8-K TODAY AND, TOGETHER WITH THE BODY OF THE FORM 8-K, ARE INCORPORATED BY REFERENCE INTO THIS FILING:

- o JOINT PRESS RELEASE ISSUED BY INVERNESS MEDICAL INNOVATIONS, INC. AND OSTEK INTERNATIONAL, INC. DATED SEPTEMBER 9, 2002, ENTITLED "INVERNESS MEDICAL INNOVATIONS TO ACQUIRE OSTEK INTERNATIONAL."
- o AGREEMENT AND PLAN OF MERGER DATED AS OF SEPTEMBER 6, 2002, BY AND AMONG INVERNESS MEDICAL INNOVATIONS, INC., GERAS ACQUISITION CORP. AND OSTEK INTERNATIONAL, INC.
- o VOTING AGREEMENT DATED AS OF SEPTEMBER 6, 2002, BY AND AMONG INVERNESS MEDICAL INNOVATIONS, INC., OSTEK INTERNATIONAL, INC. AND CERTAIN SHAREHOLDERS OF OSTEK INTERNATIONAL, INC.
- o STOCK OPTION AGREEMENT DATED AS OF SEPTEMBER 6, 2002, BY AND BETWEEN OSTEK INTERNATIONAL, INC. AND INVERNESS MEDICAL INNOVATIONS, INC.

THE FOLLOWING IS THE TRANSCRIPT OF A CONFERENCE CALL HELD BY THE COMPANY AT 10:00 A.M. (EASTERN TIME) ON SEPTEMBER 9, 2002 TO DISCUSS ITS POTENTIAL ACQUISITION OF OSTEK INTERNATIONAL, INC. TELEPHONIC REPLAYS AND ON DEMAND WEBCASTS OF THIS CALL ARE BEING MADE AVAILABLE BY THE COMPANY THROUGH SEPTEMBER 11, 2002 AND SEPTEMBER 16, 2002, RESPECTIVELY.

September 9, 2002 Transcript of Inverness Medical Technologies
Teleconference taking place September 9, 2002 at 10:00 a.m. Eastern Time.

This replay will be available through September 11, 2002.

Dial in number: (973) 341-3080
Pin #: 348-25-24

OPERATOR: Good morning, ladies and gentlemen, and welcome to the Inverness Medical Technology call regarding proposed acquisition of Ostex. At this time, all participants have been placed on a listen-only mode, and the floor will be open for questions and comments following the presentation. It is now my pleasure to hand this over to your host, Mr. Doug Guarino. Doug, the floor is yours.

MR. GUARINO: Thank you, Mandy, good morning and welcome to the Inverness Medical Innovations conference call to discuss the planned acquisition of Ostex International. Before we get to that discussion, though, I would first like to draw your attention to the fact that certain matters discussed in

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this conference call will constitute forward-looking statements within the meaning of the U.S. securities laws. These statements reflect our current views with respect to the future events or financial performance and are based on management's current assumptions and information currently available. Actual results and the timing of certain events could differ materially from those projected or contemplated by the forward-looking statements due to a number of factors, including: our ability to satisfy the conditions of the consummation of the acquisition, the timing and content of the approvals necessary to consummate the acquisition, demands for our products, conditions in the financial markets, including our ability to obtain financing on satisfactory terms, fluctuations in interest rates and foreign currency exchange rates, the effect of any operational and financial covenants contained within the terms of any additional borrowing, operational integration associated with this and any past or any future acquisition transactions and other risks generally associated with such transactions, our ability to complete the pending acquisition of Wampole Laboratories, potential market acceptance of the company's current and future product offer, the intensely competitive environment and our chosen markets which could reduce our market share, limit our ability to increase market share or reduce our operating margins on products sales, the efficacy and safety of products, the content and timing of submissions to and decisions by regulatory authorities, both in the United States and abroad, manufacturing problems or delays and the risks that we may be unable to meet projected demand for products, the ability of company to successfully develop and commercialize products, the effect of pending and future legal proceedings in the company's financial performance and product offerings, and the other risks and uncertainties described in the company's press releases and in its reports filed from time to time with the SEC under the Securities Exchange Act of 1934, including without limitation the company's Form 10-K/A for the year ended December 31, 2001 and Form 10-Q for the quarter ended June 30, 2002. The company undertakes no obligation to update any forward-looking statements.

Additionally, please note that Inverness Medical Innovations and Ostex International will be filing relevant documents concerning the acquisition with the SEC including a Registration Statement on Form S-4 containing a Prospectus/Proxy Statement. We urge investors to read these documents because they will contain important information. Investors will be able to obtain the Prospectus/Proxy Statement and other documents that will be filed by Inverness and Ostex with the SEC free of charge at the SEC's website, sec.gov, or by directing a request after such a filing is made to Inverness Medical Innovations. Our address is 51 Sawyer Road, Suite 200, Waltham, MA 02453, Attention: Corporate Secretary, telephone number: (781) 647-3900. Or you can call Ostex International at 2203 Airport Way South, Suite 400, Seattle, WA 98134 Attention: Corporate Secretary Telephone: (206) 292-8082.

Ok, with that, let me turn the call over to Inverness Medical's Chairman and CEO, Ron Zwanziger.

MR. ZWANZIGER: Thanks very much, Doug. Thanks to everyone and thank you for joining us to discuss our pending acquisition of Ostex International. Though you can see from our joint press release that this is a fairly straightforward transaction on the financial side, we thought it nonetheless useful to hold a call to provide some commentary on the transaction and to share the sense of enthusiasm we have for the opportunities presented by this combination.

First let me point out that this acquisition will significantly expand our IP platform, intellectual property platform, in the women's health arena. Specifically, while we have long had an interest in the osteoporosis diagnostic market and have made some headway in our related R&D, this is one area in

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women's health diagnostics where we have been missing a critical leading edge intellectual property component. Upon our acquisition of Ostex, we will have put this missing piece in place. Of course we are familiar with, and already made inroads with the very same consumer demographics on the nutritional side of the business with our Posture D and Soy Care product lines.

It would be an understatement to say merely that osteoporosis is an important area without providing some facts. Osteoporosis, or thinning of the bone, affects well over 20 million Americans, roughly 80% of whom are women. In fact, studies indicate that a 50-year-old Caucasian post-menopausal woman has the exact same risk of dying from an osteoporosis-related hip fracture as she does from breast cancer.

In the past, the only way to diagnose the problem has been by having an X-ray called a bone density. Unfortunately, the bone density shows bone loss for damage that was already done. This new NTX technology developed by Ostex affords both doctors and patients a way to detect osteoporosis before it advances, indicating both early signs of increasing bone loss and the efficacy of any medication-based treatment regimen.

Feedback from the market indicates to us that NTX biochemical assay underlying the Ostex Osteomark products is earning high marks from medical professionals and is the possible future standard in the prevention of, and monitoring the progression of, osteoporosis. Some physicians

feel the availability of accurate and easily available monitoring of NTX levels will greatly improve patient compliance with osteoporosis treatment regimens, hence leading to better treatment and clinical outcome. This thinking is based on similar experiences in other medical conditions where patients taking potent medication and fearful of potentially unpleasant side effects are more likely to be compliant where there is a marker to assure them that their treatment is being effective.

For those of you who have followed us for a while, I am sure you can see the corollaries to our previous successes in the diabetes market utilizing medical technologies to advance the treatment and diagnostic options available to the patient, thus improving both compliance and treatment outcome.

As to the specifics of the current Ostex business, our preliminary review indicates that Ostex has been having some success and, in fact, deriving most revenues from the sale of its enzyme-linked immunosorbent assay-based Osteomark serum and urine test kit product lines into clinical labs. We believe that we are in an ideal position to improve on Ostex' sales success, particularly if we utilize the additional distribution resources available to us upon completion of our pending acquisition of Wampole Laboratories.

As you may know, Ostex recently launched a point-of-care device for the osteoporosis market based on the NTX assay. Given our past experience in the development and production of inexpensive, disposable devices, we see great opportunity in this area and believe there is a potential to achieve a market-leading technology over time. In the short term, we anticipate substantial cost-efficiencies through the merging of operations. In addition, we expect relatively models R& D expenditures in this area as we have had very similar technology under development at Inverness.

In sum, we are confident in saying that Ostex provides us with a very cost-efficient route to expanding our intellectual property platform in the area of women's health diagnostics.

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Now we would be happy to take your questions. Operator, can you take over please.

OPERATOR: Thank you, the floor is now open for questions. If you have a question or a comment you may press the numbers 1 followed by 4 on your touch tone phone at this time. If at any point your question has been answered, you may remove yourself from the queue by pressing the # key. We do ask all parties to please pick up their hand sets while posing their question to ensure optimum sound quality.

The first question is coming from John Putnam of Belmont Harbor Capital. Please state your question:

JOHN PUTNAM: Thanks. Good morning, Ron. I was wondering if you might comment on how you can see the roll-out of an Inverness product that would utilize this technology. And secondly, if you might comment on what kind of dilution you see from the acquisition.

MR. ZWANZIGER: Well, taking the second part of your question first, John, we actually see that there will be sufficient efficiencies in the merging of the operation. We anticipate that actually in 2003, there may not be any dilution. Of course, dilution is always relative to some number that you already assume, but to the extent that you might be in the mid 30's cents per share next year, I'll guess that if that's an assumption you were to make, then probably it's not dilutive. And, indeed, thereafter it should be accretive. As to your first question as to an Inverness product, first of all I have to emphasize that as we just said they've got their ELISA-based kits that they're selling well. And of course, Ostex has just introduced recently their Point-Of-Care which we're very excited about and think that there is some mileage there, although I think the cost of the product needs to come down and we'll work on that. But we do, in fact, anticipate at some point a point-of-care product designed around one of our own platforms. And that could take a couple of years before that came out. Next question, Operator?

OPERATOR: The next question is coming from Sam Navarra of Galleon Group. Please state your question.

SAM NAVARRA: Hey Ron, how are you?

MR. ZWANZIGER: Good

SAM NAVARRA: Listen, obviously you've been putting a lot of effort into acquiring intellectual property recently, and I guess this must be an incremental situation. Just could you talk a little more about the plan there and where this fits on the IT strategy.

MR. ZWANZIGER. Well, um, the area of women's health diagnostics, this was really the only piece that we see that we felt we needed to be able to make a significant impact in osteoporosis, and so I think this kind of really rounds out the IP as far as we can see from our wish to be a strong player in the area of women's diagnostics. So I think in that sense, I think we've rounded out our portfolio. We're actually quite excited about their IP. Their IP has been tested in court and so there is... We think it's pretty good intellectual property.

KEVIN COLLAR: Hey, Ron, Kevin Collar here.

MR. ZWANZIGER: Hey, Kevin.

MR. COLLAR: What's the time table for moving from their technology platform to

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your technology platform or, in other words, the cost reduction?

MR. ZWANZIGER: Well, I think cost reductions can take place anyway. We don't have to literally switch to... and it's not so clear that it's a complete switch-over to ours, but I think cost reductions will start coming in, I would think fairly quickly - 3 or 4 quarters you'll see cost reductions. We're talking about cost reductions on their Point-of-Care?

MR. COLLAR: Yes.

MR. ZWANZIGER: ... not on their ELISA-base.

MR. NAVARRA: But nevertheless, the time table to cross over to your technology. Is there anything like that?

MR. ZWANZIGER: Ah, to really cross over for quite a difference would be a couple of years.

MR. NAVARRA: Ok. Thanks.

OPERATOR: Thank you. The next question is coming from Scott Wilkin of SG Cowen. Please state your question.

MR. WILKIN: Thank you, Ron. We were hoping to get from you some understanding of the market size ultimately for this test and if you could also talk to some sales guidance as you see it for the product line in your hands, I think the sales are running around \$5 million. Maybe you could talk in, over the next couple of years, what you think that goes to.

MR. ZWANZIGER: Well, the market size is a very difficult...it's very difficult to estimate because you...it's so related to how fast you can bring down the cost of the unit and, therefore, how likely it is that you can get companies that have therapeutic agents in this marketplace, and I don't know how familiar you are, Scott, that Procter & Gamble has Actinal in the treatment of osteoporosis, Merck is out there with Posturemax, and the question is how quickly will they get involved -and they are already, in fact, involved with NTX--these companies, directly or indirectly and how quickly would they get involved. And to some extent, it depends on how quickly it would bring the cost down. Um, so it's really very hard to estimate. Our guess is that in the U.S. the market could end up being, depending on a very wide range of assumptions, could be \$75 million to \$100 million. It may be as low as \$50 million. Then, you,.. of course in the rest of the world, treatments are obviously the same. So I think it's a fairly significant market size and, of course, our gross margins will be very good. As to sales guidance, I think we ought to be fairly cautious. You just pointed out that they're running about around \$5 million. I think one should be cautious and prudent, and I think if you assume that number again for next year, I think that's a conservative position to take place, and rather higher in the following year and thereafter.

MR. WILKIN: Just to follow up on the market size, does your \$75 to \$100 million view just physician-office- and lab-base, or does it assume any consumer, or self-based tests?

MR. ZWANZIGER: No, it does assume that there will be a consumer element to the business.

MR. WILKIN: It does?

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MR. ZWANZIGER: It does assume that. And if it was only physician-office based as you probably know from our history, that's not good enough for us. We like a product to be with a retail orientation.

MR. WILKIN: Can you talk about, then, maybe the percentage you see being retail based and what sort of steps need to be overcome to get that kind of test on the market as a consumer self-test.

MR. ZWANZIGER: We actually don't think it's that difficult to get a consumer product in the marketplace, and, in fact, there has been some signs (I don't know whether you would call it exactly a consumer test), but physicians are... For example, in Germany, physicians are actually giving patients product to take home. But most of the time, at the moment, the patient simply comes back to the doctor's office after 3 months to get the NTX level adjusted. And that's going on in Germany. Interestingly, if you think about Prothrombin in Germany, that's how the market there started, with Prothrombin, where the patients were coming in once a week, and the same test eventually made its way into the home. And so I think you could see a parallel there developing. So I think it'll be a relatively straightforward conversion.

MR. WILKIN: Do you have maybe a timetable in mind that could share - in the U.S. -in getting this into the market as a retail product?

MR. ZWANZIGER: I don't want to raise expectations too much here, but we're on top of it. We'll be on top of it promptly. As I have to say, so is Ostex. Ostex is really quite aggressive about this area - has been quite aggressive about this area.

MR. WILKIN: Ok, well I'll get back in the queue.

OPERATOR: Ladies and gentlemen, we ask you for any further questions, please press 1 followed by 4 on your touch tone telephone at this time. Please hold for further questions.

Thank you, a next question is coming from Matt Meyers of Newcastle Partners. Please state your question.

MR. MEYERS: Hey guys, can you talk a bit about under what circumstances you would have the option to purchase 19.9% of Ostex?

MR. ZWANZIGER: I think it's in a situation where there's competing bid developed.

MR. MEYERS: Ok. And would those be new shares, or would there be a selling shareholder?

MR. ZWANZIGER: No. It's a standard feature of an M&A transaction. Those would be new shares issued.

OPERATOR: Thank you and as a reminder for any further questions you may press 1 followed by 4 on your touchtone telephone at this time. Thank you, our next question is coming from Bob Yedid of Hill House Capital. Please state your question.

MR. YEDID: Good morning, Ron. I'm sorry I missed some of your opening remarks. Obviously you've done a number of acquisitions. Can you talk about the management team here at Ostex and if they're...you know now if senior management, some of the key R&D people are staying onboard and will continue to work with Inverness after the deal here.

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MR. ZWANZIGER: We'll be working those issues in the next few weeks, and we've got a couple of months to sort that out before the acquisition closes.

MR. YEDID: Okay, fine, thank you.

OPERATOR: Thank you, gentlemen. At this time we're showing no further questions.

MR. ZWANZIGER: Well as always we thank you for your continued support and look forward to speaking with you on our next call. Thank you very much. Good bye.

OPERATOR: Excuse me, sir, we just got one last question coming to you. It's coming from Blair Schultz at K2 Investments.

MR. SCHULTZ: I apologize, guys. I missed the early part of this call. I was wondering if there was kind of restrictions on this deal being completed within the revenue requirements or any kind of conditions.

MR. ZWANZIGER: Well, there's no conditions as to revenue levels, but there's just the customary conditions of closing on a public transaction.

MR. SCHULTZ: And the time frame for this deal?

MR. ZWANZIGER: We think likely end of fourth quarter, beginning of first, something like that.

MR. SCHULTZ: Ok. Perfect. Thanks then.

MR. ZWANZIGER: All right, well, thank you very much everybody. Good bye.

OPERATOR: Thank you for your participation. This does conclude today's teleconference. You may disconnect your lines at this time and have a wonderful day.