

INVERNESS MEDICAL INNOVATIONS INC

Form 8-K

July 07, 2005

## UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 8-K

### CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

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Date of Report (Date of earliest event reported): **June 30, 2005**

## INVERNESS MEDICAL INNOVATIONS, INC.

(Exact name of registrant as specified in charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**1-16789**  
(Commission File Number)

**04-3565120**  
(IRS Employer  
Identification No.)

**51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453**  
(Address of Principal Executive Offices) (Zip Code)

**(781) 647-3900**

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(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  
  - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  
  - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  
  - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 1.01 Entry into a Material Definitive Agreement.**

**Item 2.01 Completion of Acquisition or Disposition of Assets.**

**Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.**

*Amended and Restated Credit Facility*

On June 30, 2005, we and certain of our subsidiaries entered into a third amended and restated credit agreement with General Electric Capital Corporation, as administrative agent, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, a co-syndication agent and a co-lead arranger, UBS Securities LLC, as a co-syndication agent, and GECC Capital Markets Group, Inc., as a co-lead arranger (the Credit Agreement). The Credit Agreement provides initially for revolving lines of credit in the aggregate amount of \$80,000,000, subject to continued covenant compliance, and term loans in the aggregate amount of \$20,000,000. A portion of the revolving lines of credit in the aggregate amount of \$30,000,000 may convert into term loans on September 29, 2005 upon certain circumstances. As of the date of this current report, term loans in the aggregate amount of \$20,000,000 have been borrowed and are outstanding, and revolving loans in the aggregate amount of \$69,000,000 have been borrowed and are outstanding.

We must repay the term loans in eleven consecutive quarterly installments, beginning on September 30, 2005, with each such installment prior to March 31, 2008 to be in an amount equal to 0.25% of the total amount of the term loans outstanding on September 29, 2005 (after giving effect to any required conversion of the revolving lines of credit as described above); the final installment will be due on March 31, 2008 in the amount of the remaining principal balance of the term loans. We may repay any existing or future borrowings under the revolving lines of credit at any time but no later than March 31, 2008. We are required to make mandatory prepayments in various amounts under the credit facilities if we sell assets not in the ordinary course of business above certain thresholds, if we issue stock or sell equity securities, if we issue subordinated debt, or if we have excess cash flow. The term loans and borrowings under the revolving lines of credit bear interest at either (i) the LIBOR Rate, as defined in the Credit Agreement, plus applicable margins or, at our option, (ii) a floating Index Rate, as defined in the Credit Agreement, plus applicable margins.

The lenders are entitled to accelerate repayment of the loans under the Credit Agreement upon the occurrence of any of various events of default, which include, among other events, our failure to pay when due any principal, interest or other amounts in respect of the loans, our breach of any of our covenants (subject, in some cases, to various grace periods) or representations under the loan documents, our default under any of our other significant indebtedness agreements or other material agreements, a bankruptcy event with respect to us or any of our material subsidiaries or if we undergo a change of control.

Borrowings under the credit facilities are secured by the stock of certain of our United States and foreign subsidiaries, substantially all of our intellectual property rights, substantially all of the assets of our businesses in the United States and a significant portion of the assets of our businesses outside the United States.

Under the Credit Agreement, we must comply with various financial and non-financial covenants. The primary financial covenants consist of a minimum fixed charge coverage ratio, a maximum senior consolidated leverage ratio, a maximum total leverage ratio and minimum earnings before interest, taxes, depreciation and amortization. The primary non-financial covenants prevent or limit our ability to pay dividends, conduct certain mergers or acquisitions, make certain investments and loans, incur future indebtedness, alter our capital structure and sell stock or assets.

*Acquisition of the Determine®/DainaScreen® rapid diagnostic business*

On June 30, 2005, immediately following the execution of the Credit Agreement, we and certain of our subsidiaries completed our acquisition of the Determine®/DainaScreen® rapid diagnostic business (the Determine Business ) from Abbott Laboratories and certain of its subsidiaries (collectively, Abbott ) for \$56.5 million in cash. The purchase price for the acquisition of the Determine Business was funded with the proceeds from the Credit Agreement described above. The Determine Business produces diagnostic tests that are designed to provide rapid qualitative results for detecting several diseases, including hepatitis, HIV 1/2 and syphilis. We acquired assets consisting of manufacturing equipment located in Matsudo, Japan, customer relationships,

relationships with certain manufacturing employees and know-how and certain transferred and licensed intellectual property related to the Determine/DainaScreen products.

Abbott developed the Determine<sup>®</sup>/DainaScreen<sup>®</sup> rapid diagnostic test in 1998 to meet a global need for an inexpensive but accurate and self-contained test for HIV 1/2, fecal occult blood, syphilis and hepatitis. The tests are sold to hospitals, blood banks, doctors and through other channels in more than 100 countries, and in 2001, the Determine product line became an integral component of Abbott's global "Access to HIV Care" program (the "Humanitarian Program"), which provides free or low-cost testing products for HIV testing in underdeveloped countries around the world.

In accordance with the terms of the acquisition, Abbott will provide us with certain transitional and other post-closing services pursuant to a manufacturing and support services agreement entered into concurrently with the closing of the acquisition of the Determine Business. Currently, the products of the Determine Business are manufactured at Abbott's facility located in Matsudo, Japan. We will rent manufacturing floor space from Abbott and Abbott will provide us with certain support services at its Matsudo facility for a period of up to 54 months from the date of the closing of the acquisition, where we will continue to manufacture the products using the acquired equipment and a work force of former Abbott employees. We plan to transfer manufacturing operations to our own facilities and we will need to identify and build out an appropriate manufacturing facility and obtain various manufacturing and product licenses in Japan.

In addition, Abbott will continue to distribute the Determine/DainaScreen products, which are marketed outside of the United States, for up to 32 months and will receive a sales commission on the net sales of these products. Abbott will act as our exclusive distributor, although we will have certain rights to terminate the distribution arrangement on a country by country basis in the future. In order to commence distributing the products directly or through our own distributors, we or our distributors will be required to obtain various marketing or sales licenses in many of the countries where the products are currently sold.

Pursuant to a supply agreement entered into concurrently with the closing of the acquisition, we will act as the exclusive supplier on a cost-plus basis of Abbott's Humanitarian Program for a period of at least seven and a half years, subject to certain early termination rights granted to Abbott that are exercisable in the future in the event of product innovations by other potential suppliers to this program or as a result of significant pricing increases by us. Abbott, at its sole discretion, may elect to extend the Humanitarian Program supply agreement for two additional three-year periods.

As rapid diagnostic tests, the Determine/DainaScreen products contain mechanical and biological components, including certain reagents that are proprietary to Abbott. The reagents used in the products are currently produced by Abbott using biological materials. We entered into a reagent supply agreement with Abbott simultaneously with the closing of the transaction, whereby Abbott will supply reagents to us for the period during which we occupy the Matsudo plant and thereafter for up to a maximum of 5 years after the closing date. After this agreement expires, we will be required to produce the reagents for use in the products.

We also entered into a license and material transfer agreement with Abbott which will provide us with access to and a license of certain Abbott-owned intellectual property that is used currently to produce the products and the reagents. We will also need to enter into additional licenses with third-parties in order to obtain access to intellectual property that will be necessary to fully manufacture and sell the Determine/DainaScreen product lines following termination or expiration of the license agreement with Abbott.

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We previously entered into a material relationship with Abbott whereby we purchased from Abbott certain assets related to Abbott's Fact plus® line of consumer diagnostic pregnancy tests and the Abbott TestPack®, Abbott TestPack plus® and Signify® lines of professional rapid diagnostics for various testing needs (the Rapid Diagnostic Asset Purchase Agreement). We remain subject to the terms and obligations of that certain Rapid Diagnostic Asset Purchase Agreement, dated September 30, 2003.

**Item 9.01 Financial Statements and Exhibits**

(a) **FINANCIAL STATEMENTS OF BUSINESS ACQUIRED**

The audited statements of net assets sold of the Determine/DainaScreen Rapid Diagnostics Product Line of Abbott Diagnostics Division of Abbott Laboratories as of February 28, 2005 and November 30, 2004 and 2003, and the related statements of net sales in excess of expenses for the three month period ended February 28, 2005 and the years ended November 30, 2004, 2003 and 2002, are each incorporated by reference herein from Exhibit 99.1 to the Current Report on Form 8-K filed by us on June 20, 2005. The accompanying description regarding such financial statements contained in Item 9.01(a) of the Current Report on Form 8-K filed on June 20, 2005 is also incorporated by reference herein.

The interim financial statements for the period ending May 31, 2005 required to be filed pursuant to this Item 9.01(a) will be filed by amendment to this Current Report on Form 8-K as soon as practicable, but in no event later than 71 days after the date this Current Report on Form 8-K is required to be filed.

(b) **PRO FORMA FINANCIAL INFORMATION**

The pro forma financial statements required to be filed pursuant to this Item 9.01(b) will be filed by amendment as soon as practicable, but in no event later than 71 days after the date this Current Report on Form 8-K is required to be filed.

(c) **EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
2.1	Asset Purchase Agreement, dated as of May 28, 2005 by and among Abbott Laboratories, Abbott Cardiovascular, Inc., Abbott Japan Co., Ltd., Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Inverness Medical Japan, Ltd.
10.1	Third Amended and Restated Credit Agreement, dated as of June 30, 2005, by and among Wampole Laboratories, LLC and Inverness Medical (UK) Holdings Limited, as Borrowers, the Other Credit Parties Signatory thereto, as Credit Parties, the Lenders Signatory thereto from time to time, as Lenders, General Electric Capital Corporation, as administrative agent, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, a co-syndication agent and a co-lead arranger, UBS Securities LLC, as a co-syndication agent and GECC Capital Markets Group, Inc., as a co-lead arranger.

**SIGNATURES**

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

INVERNESS MEDICAL INNOVATIONS,  
INC.

Date: July 7, 2005

By: /s/ Christopher J. Lindop  
Name: Christopher J. Lindop  
Title: Chief Financial Officer