

INVERNESS MEDICAL INNOVATIONS INC
Form 10-K/A
October 06, 2004

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K/A
(Amendment No. 2)**

**FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

or

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from _____ to _____
Commission file number 000-16789**

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction of incorporation or organization)

04-3565120
(I.R.S. Employer Identification No.)

51 Sawyer Road, Suite 200, Waltham, Massachusetts
(Address of principal executive offices)

02453
(Zip Code)

(781) 647-3900

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class
Common Stock, \$0.001 per share par value
Securities registered pursuant to Section 12(g) of the Act: None

Name of Each Exchange on Which Registered
American Stock Exchange

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been

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subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

The aggregate market value of the voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's stock on the American Stock Exchange on June 30, 2003 (the last business day of the registrant's most recently completed second fiscal quarter) was \$249,917,109. For this computation, the registrant has excluded the market value of all shares of common stock reported as beneficially owned by executive officers and directors of the registrant; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of March 12, 2004, the registrant had 20,094,405 shares of common stock, par value \$0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission on or prior to April 29, 2004 are incorporated by reference into Part III of this Form 10-K.

EXPLANATORY NOTE

We are filing this Amendment No. 2 (the "Amended Report") to our Annual Report on Form 10-K for the fiscal year ended December 31, 2003 (the "Original Report"), as amended, in order to file a revised, redacted version of Exhibit 10.45 thereto and to incorporate by reference a revised, redacted version of Exhibit 2.1 thereto.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, we are including only Item 15, "Exhibits, Financial Statement Schedules and Reports on Form 8-K," of Part IV below. The remaining Items of our Original Report are not amended hereby.

The Amended Report speaks as of the date of the filing of the Original Report, March 15, 2004. All information contained in the Original Report, as amended by Amended Report, is subject to updating and supplementing as provided in our reports filed with the Securities and Exchange Commission subsequent to the date of the Original Report.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)

1. Financial Statements.

The financial statements listed below have been filed as part of this report on the pages indicated:

Report of Independent Auditors	F-2
Report of Independent Public Accountants	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2003, 2002 and 2001	F-5
Consolidated Balance Sheets as of December 31, 2003 and 2002	F-6
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the Years Ended December 31, 2003, 2002 and 2001	F-7
Consolidated Statements of Cash Flows for the Years Ended December 31, 2003, 2002 and 2001	F-10
Notes to Consolidated Financial Statements	F-13

2. Financial Statement Schedules.

All schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and have been omitted.

3. Exhibits.

- 2.1 Sale Agreement, dated December 20, 2001, between Inverness Medical Innovations, Inc. (the "Company") and Unilever U.K. Holdings Limited (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-3/A, as amended, dated August 24, 2004 (File No. 333-116659))
- 2.2 Amendment to Agreement and Plan of Merger dated as of February 18, 2003, by and among Inverness Medical Innovations, Inc., Geras Acquisition Corp. and Ostex International, Inc. (incorporated by reference to Exhibit 99.2 to the Company's Current Report of Form 8-K dated February 19, 2003)
- 2.3 Stock Purchase Agreement, dated as of July 30, 2003, by and among Inverness Medical Innovations, Inc., Applied Biotech, Inc. and Erie Scientific Company (incorporated by reference to Exhibit 2.1 to the Company's Current Report of Form 8-K dated August 27, 2003)
- 2.4 Asset Purchase Agreement, as of September 30, 2003, by and among Abbott Laboratories and Inverness Medical Innovations, Inc. and Inverness Medical Switzerland GmbH, Morpheus Acquisition Corp. and Morpheus Acquisition LLC. (incorporated by reference to Exhibit 2.1 to the Company's Current Report of Form 8-K dated September 30, 2003)
- 3.1 Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 3.2 Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated December 20, 2001)

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- 3.3 Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 4.1 Specimen certificate for shares of Common Stock of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
- 4.2 Registration Rights Agreement, as of September 30, 2003, by and among Inverness Medical Innovations, Inc. and Abbott Laboratories (incorporated by reference to Exhibit 99.2 to the Company's Current Report of Form 8-K dated September 30, 2003)
- *4.3 Indenture, dated as of February 10, 2004, between Inverness Medical Innovations, Inc., the Guarantors named therein and U.S. Bank Trust National Association
- *4.4 Registration Rights Agreement, as of February 10, 2004, by and among Inverness Medical Innovations, Inc., the guarantors named therein and UBS Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated
- 10.1 Post-Closing Covenants Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT, the Company, certain subsidiaries of IMT and certain subsidiaries of the Company (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.2 Tax Allocation Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT and the Company (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.3 Supply of Goods Agreement, dated July 28, 1998, between Schleicher & Schuell GmbH and Unipath Limited (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.4 Lease, dated as of January 12, 1999, by and among Cambridge Diagnostics Ireland Limited and the Industrial Development Agency (Ireland) (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
- 10.5 Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
- 10.6 Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
- 10.7 Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan First Amendment (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.8 Restricted Stock Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Ron Zwanziger (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.9 Promissory Note, dated August 16, 2001, from Ron Zwanziger to the Company (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

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- 10.10 Pledge Agreement, dated as of August 16, 2001, between Ron Zwanziger and the Company (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.11 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Jerry McAleer (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.12 Promissory Note, dated December 4, 2001, from Jerry McAleer to the Company (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.13 Pledge Agreement, dated as of December 4, 2001, between Jerry McAleer and the Company (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.14 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and David Scott (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.15 Promissory Note, dated December 4, 2001, from David Scott to the Company (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.16 Pledge Agreement, dated as of December 4, 2001, between David Scott and the Company (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.17 Stock Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated March 14, 2002)
- 10.18 Note and Warrant Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K dated December 20, 2001)
- 10.19 Form of Subordinated Promissory Note issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K dated December 20, 2001)
- 10.20 Form of Warrant for the Purchase of Shares of Common Stock of the Company issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K dated December 20, 2001)
- 10.21 Warrant for the Purchase of Shares of Common Stock of the Company, dated as of December 20, 2001, issued to Zwanziger Family Ventures, LLC (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.22 Loan and Security Agreement, dated as of October 16, 2000, between IVC and Congress Financial Corporation (incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

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- 10.23 Amendment No. 1 to Loan and Security Agreement, dated June 13, 2001, by and between Congress Financial Corporation and IVC (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.24 Amendment No. 2 to Loan and Security Agreement, dated as of June 14, 2001, by and between Congress Financial Corporation and IVC (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.25 Amendment No. 3 to Loan and Security Agreement, dated as of March 19, 2002, by and between Congress Financial Corporation and IVC (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.26 Agreement, dated December 1, 1986, between Bernard Levere, Zelda Levere, Pioneer Pharmaceuticals, Inc. and Essex Chemical Corp. and Unconditional Guarantee by Essex Chemical Corp. (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.27 Option to Assume and Extend Lease, dated as of February 1995, between Bernard Levere, Zelda Levere and International Vitamin Corporation (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
- 10.28 Inverness Medical Innovations, Inc. Executive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
- 10.29 Licensing Agreement, dated March 14, 1988, between Unilever Plc and Behringwerke AG (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K, as amended, for the period ended December 31, 2001)
- 10.30 Supplemental Agreement, dated October 16, 1994, between Unilever Plc, Unilever NV and Behringwerke AG (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, as amended, for the period ended December 31, 2001)
- 10.31 Supply of Goods Agreement, dated December 19, 1994, between AFC Worldwide and Unipath Limited (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 30, 2002)
- 10.32 Amendment to Supply of Goods Agreement, dated March 14, 2002, between Schleicher & Schuell GmbH and Unipath Limited (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 30, 2002)
- 10.33 Amendment No. 1 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8 (File No. 333-90530))
- 10.34 Subordinated Note and Warrant Purchase Agreement dated as of September 20, 2002 between the Company and the investors named therein ("Note and Warrant Purchase Agreement") (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K dated September 20, 2002)

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- 10.35 Form of Subordinated Promissory Note issued pursuant to the Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated September 20, 2002)
- 10.36 Form of Warrant Agreement issued pursuant to the Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K dated September 20, 2002)
- 10.37 Subordinated Note Purchase Agreement dated as of September 20, 2002 between the Company and the investors named therein ("Note Purchase Agreement") (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K dated September 20, 2002)
- 10.38 Form of Subordinated Promissory Note issued pursuant to the Note Purchase Agreement (incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K dated September 20, 2002)
- 10.39 Form of Convertible Subordinated Promissory Note issued pursuant to the Note Purchase Agreement (incorporated by reference to Exhibit 99.6 to the Company's Current Report on Form 8-K dated September 20, 2002)
- 10.40 Second Amended and Restated Credit Agreement, dated as of September 30, 2003, by and among Inverness Medical Innovations, Inc., Wampole Laboratories, Inc., Inverness Medical (UK) Holdings Limited, the other Credit Parties Signatory thereto, the lenders signatory thereto from time to time, General Electric Capital Corporation, as administrative agent for lenders, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as co-syndication agent, UBS AG, Stamford Branch, as co-syndication agent, and GECC Capital Markets Group, Inc. and ML Capital, as co-lead arrangers (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q dated November 14, 2003)
- *10.41 First Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of November 17, 2003, by and among General Electric Capital Corporation, as agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, Inc. and Inverness Medical (UK) Holdings Limited, as borrowers, the other credit parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent and co-syndication agent, UBS Securities LLC, as co-syndication agent, and the lenders signatory thereto from time to time
- *10.42 Second Amendment to Second Amended and Restated Credit Agreement, dated as of December 31, 2003, by and among General Electric Capital Corporation, as agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, Inc. and Inverness Medical (UK) Holdings Limited, as borrowers, the other credit parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent and co-syndication agent, UBS Securities LLC, as co-syndication agent, and the lenders signatory thereto from time to time
- *10.43 Commercial Lease, dated August 1, 1998, by and between The Chang Family Trust and Applied Biotech, Inc.
- *10.44 Amendment to Commercial Lease, dated April , 2003, by and between The Chang Family Trust and Applied Biotech, Inc.
- **10.45 Manufacturing, Packaging and Supply Agreement, dated as of June 6, 2003, among Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH, Unipath, Ltd. and Warner-Lambert Company LLC+

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- *10.46 First Amendment to Subordinated Promissory Notes, dated as of November 14, 2003
 - *10.47 First Amendment to Convertible Subordinated Promissory Notes, dated as of January 15, 2004
 - *14.1 Inverness Medical Innovations Business Conduct Guidelines
 - *21.1 List of Subsidiaries of the Company as of March 15, 2004
 - *23.1 Consent of BDO Seidman, LLP
 - **31.1 Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes
 - **31.2 Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes
 - *32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes
-

*
Previously filed.

**
Filed herewith.

+
Portions of this exhibit have been granted confidential treatment by the Securities and Exchange Commission.

(b) *Reports on Form 8-K*

On October 9, 2003 we filed a Current Report on Form 8-K dated September 30, 2003 (Item 2) in connection with our acquisition of certain assets from Abbott Laboratories.

On November 5, 2003 we filed a Current Report on Form 8-K dated November 5, 2003 (Item 12) in connection with our press release relating to our financial results for the third quarter of 2003.

On November 10, 2003 we filed a Current Report on Form 8-K/A (Amendment No. 1) dated August 27, 2003 (Item 7) in order to file the financial statements and pro forma financial information required by Item 7 of Form 8-K, in connection with our acquisition of the Applied Biotech, Inc.

On November 20, 2003 we filed a Current Report on Form 8-K/A (Amendment No. 1) dated September 30, 2003 (Item 7) in order to file the financial statements and pro forma financial information required by Item 7 of Form 8-K, in connection with our acquisition of certain assets from Abbott Laboratories.

On December 17, 2003 we filed a Current Report on Form 8-K dated December 10, 2003 (Item 5) in connection with our entry into manufacturing and supply agreement with Warner-Lambert Company, LLC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVERNESS MEDICAL INNOVATIONS, INC.

Date: October 6, 2004

By: /s/ RON ZWANZIGER

 Ron Zwanziger

Chairman, Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ RON ZWANZIGER <hr/> Ron Zwanziger	Chief Executive Officer, President and Director (Principal Executive Officer)	October 6, 2004
/s/ CHRISTOPHER J. LINDOP <hr/> Christopher J. Lindop	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	October 6, 2004
/s/ ERNEST A. CARABILLO, JR. <hr/> Ernest A. Carabillo, Jr.	Director	October 6, 2004
/s/ CAROL R. GOLDBERG <hr/> Carol R. Goldberg	Director	October 6, 2004
/s/ ROBERT P. KHEDERIAN <hr/> Robert P. Khederian	Director	October 6, 2004
/s/ JOHN F. LEVY <hr/> John F. Levy	Director	October 6, 2004
/s/ JERRY MCALEER <hr/> Jerry McAleer	Director	October 6, 2004
/s/ JOHN A. QUELCH <hr/> John A. Quelch	Director	October 6, 2004
/s/ DAVID SCOTT <hr/> David Scott	Director	October 6, 2004
/s/ PETER TOWNSEND <hr/>	Director	October 6, 2004

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Signature

Title

Date

Peter Townsend

/s/ ALFRED M. ZEIEN

Director

October 6, 2004

Alfred M. Zeien

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DOCUMENTS INCORPORATED BY REFERENCE

EXPLANATORY NOTE

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

SIGNATURES