INVERNESS MEDICAL INNOVATIONS INC
Form S-3/A
October 06, 2004
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As filed with the Securities and Exchange Commission on October 6, 2004

Registration Statement No. 333-116659

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 3 TO

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**04-3565120**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

51 Sawyer Road, Suite 200

Waltham, Massachusetts 02453

(781) 647-3900

(Address, including zip code, and telephone number, including area code of Registrant s principal executive offices)

Ron Zwanziger

Chairman, Chief Executive Officer and President

Inverness Medical Innovations, Inc.

51 Sawyer Road

Waltham, Massachusetts 02453

(781) 647-3900

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jay McNamara, Esq.

Associate General Counsel

Inverness Medical Innovations, Inc.

51 Sawyer Road

Waltham, Massachusetts 02453

(781) 647-3900

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ¨

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated October 6, 2004

PROSPECTUS

155,209 Shares

INVERNESS MEDICAL INNOVATIONS, INC.

Common Stock

(par value $0.001 per share)

This prospectus relates to the offer and sale by the selling stockholder identified in this prospectus, and any of its pledgees, donees, transferees or other successors in interest, of up to an aggregate of 155,209 shares of common stock of Inverness Medical Innovations, Inc. We are filing the registration statement of which this prospectus is a part at this time to fulfill contractual obligations to do so, which we undertook at the time of the original issuance of the shares. We will not receive any of the proceeds from the sale of the common stock by the selling stockholder, but we are bearing the expenses of registration.

Our common stock is listed on the American Stock Exchange under the symbol IMA. On September 30, 2004, the last reported sale price of our common stock on the American Stock Exchange was $20.80.

See Risk Factors beginning on page 3 for a discussion of certain factors that you should consider before you invest in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2004

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No dealer, sales representative or any other person has been authorized to give any information or to make any representations in connection with this offering other than those contained in this prospectus, and, if given or made, such information or representations must not be relied upon as having been authorized by our company or any other person.

This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the shares of common stock to which it relates or an offer to, or a solicitation of, any person in any jurisdiction where such an offer or solicitation would be unlawful. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create any implication that there has been no change in the affairs of our company or that information contained herein is correct as of any time subsequent to the date hereof.

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PROSPECTUS SUMMARY

This summary only highlights the more detailed information appearing elsewhere in this prospectus or incorporated herein by reference. As this is a summary, it may not contain all information that is important to you. You should read this entire prospectus carefully before deciding whether to invest in our common stock.

This prospectus contains forward-looking statements. You should read the explanation of the qualifications and limitations on such forward-looking statements on page 19 of this prospectus. You should also carefully consider the various risk factors beginning on page 3 of this prospectus, which risk factors may cause our actual results to differ materially from those indicated by such forward-looking statements. You should not place undue reliance on our forward-looking statements.

Unless the context otherwise requires, all references to we, us, our company or the Company in this prospectus refer collectively to Inverness Medical Innovations, Inc., a Delaware corporation, and its subsidiaries, and their respective predecessor entities for the applicable periods, considered as a single enterprise.

We have registered the following trademarks which appear in this prospectus: Clearblue®, Persona®, Clearview®, Ferro-Sequels, Stresstabs®, Protegra®, Posture®, SoyCare, ALLBEE®, and Z-BEC®.

The following are registered trademarks of parties other than us: e.p.t®.

About Inverness Medical Innovations, Inc.

We are a leading global developer, manufacturer and marketer of in vitro diagnostic products for the over-the-counter pregnancy and fertility/ovulation test market and the professional rapid diagnostic test market. Our business is organized into two reportable segments, consumer products and professional diagnostics. Through our consumer products segment, we hold a leadership position in the worldwide over-the-counter pregnancy and fertility/ovulation test market. We sell our pregnancy and fertility/ovulation test products in the premium branded sector, the value branded sector and the private label sector. In addition, we manufacture and market a variety of vitamins and nutritional supplements under our brands and those of private label retailers primarily in the U.S. consumer market. Through our professional diagnostics segment, we develop, manufacture and market an extensive array of innovative rapid diagnostic test products and other in vitro diagnostic tests to medical professionals and laboratories for detection of infectious diseases, drugs of abuse and pregnancy. Today, we are a leader in the worldwide professional rapid diagnostic test market. We have grown our consumer products and professional diagnostics segments by leveraging our strong intellectual property portfolio and making selected strategic acquisitions. Our consumer and professional diagnostic products are sold in approximately 90 countries through our direct sales force and an extensive network of independent global distributors.

Inverness Medical Innovations, Inc. is a Delaware corporation. Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our website is *http://www.invernessmedical.com*. The information found on our website is not part of this prospectus. Our common stock is listed on the American Stock Exchange under the symbol IMA.

Recent Developments

Acquisition of Viva Diagnostika

On June 2, 2004, we acquired Viva Diagnostika Diagnostische Produkte GmbH, or Viva Diagnostika, a closely held distributor of professional diagnostic products to the German marketplace. We paid approximately

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$2.6 million (2.1 million) in cash, and issued a total of 155,209 shares of our common stock in a private placement to the shareholders of Viva Diagnostika in exchange for all of the outstanding capital stock of Viva Diagnostika and an affiliated entity. Under the terms of the agreement, shortly after the acquisition, we also caused Viva Diagnostika and its affiliate to repay approximately $0.29 million (0.24 million) in loans outstanding to their former shareholders.

Acquisition of Advantage Diagnostics Corporation

On June 15, 2004, we acquired Advantage Diagnostics Corporation, or ADC, a closely held lateral flow diagnostic company that specializes in rapid test development and component manufacturing. We paid $2.4 million in cash and $210,000 in the form of payoff of ADC debt to acquire all of the stock of ADC though a merger transaction. The terms also provide for $1.5 million of contingent consideration payable to the ADC shareholders in the future upon the successful completion of a new product under development. The acquisition also eliminates a future royalty stream payable by our subsidiary, Applied Biotech, Inc., or ABI, to ADC under a ten year license agreement beginning in January 2003 relating to a proprietary drugs of abuse test system develop by ADC for ABI.

The Offering

This prospectus relates to up to 155,209 shares of our common stock that may be offered for sale by the selling stockholders. The shares include up to 155,209 shares of common stock issued to the selling stockholders as partial payment for the purchase of all of the outstanding capital stock of Viva Diagnostika and an affiliated entity from the selling stockholders on June 2, 2004. We are registering the common stock covered by this prospectus in order to fulfill our contractual obligations to do so, which we undertook at the time of the original issuance of the shares. Registration of the common stock does not necessarily mean that all or any portion of such stock will be offered for sale by the selling stockholders.

We have agreed to bear the expenses of the registration of the common stock under federal and state securities laws, but we will not receive any proceeds from the sale of any common stock offered under this prospectus.

Plan of Distribution

The selling stockholders may sell the securities through agents or dealers, directly to one or more individuals, institutional or other purchasers or through any combination of these methods of sale. The distribution of the securities may be effected in one or more transactions at market prices then prevailing at the time of sale, at prices related to such prevailing market prices, or at negotiated prices. See Plan of Distribution beginning on page 21.

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RISK FACTORS

The risk factors described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors, as well as the risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission, in connection with your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements on page 19 of this prospectus.

Our business has substantial indebtedness, which could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations.

We currently have, and we will likely continue to have, a substantial amount of indebtedness. As of June 30, 2004, we had approximately $192.8 million in aggregate principal indebtedness outstanding, of which $16.8 million is secured indebtedness, and $50.4 million of additional borrowing capacity under the revolving portions of our credit facilities. In addition, subject to restrictions in our credit facilities and the indenture governing the senior subordinated notes, we may incur additional indebtedness. During the year ended December 31, 2003 and the six months ended June 30, 2004, we had approximately $9.7 million and $12.3 million, respectively, of interest expense related to our indebtedness, which included $1.0 million and $3.5 million respectively, in non-cash interest primarily related to amortization of debt origination costs.

Our substantial indebtedness could affect our future operations in important ways. For example, it could:

- make it more difficult to satisfy our obligations under the senior subordinated notes, our credit facilities and our other debt-related instruments;
- require us to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and other business activities and may require us, in order to meet our debt service obligations, to delay or reduce capital expenditures or the introduction of new products and/or forego business opportunities, including acquisitions, research and development projects or product design enhancements;
- limit our flexibility to adjust to market conditions, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in which we operate;
- impair our ability to obtain additional financing;
- place us at a competitive disadvantage compared to our competitors that have less debt; and
- expose us to fluctuations in the interest rate environment with respect to our indebtedness that bears interest at variable rates.

We expect to obtain the money to pay our expenses and to pay the principal and interest on the senior subordinated notes, our senior credit facility and our other debt from cash flow from our operations and from additional loans under our senior credit facility, subject to continued

covenant compliance. Our ability to meet our expenses thus depends on our future performance, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt, including the notes, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on terms acceptable to us. In addition, the terms of existing or future debt agreements, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, may restrict us from adopting any of these alternatives.

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We have entered into agreements governing our indebtedness that subject us to various restrictions that may limit our ability to pursue business opportunities.

The agreements governing our indebtedness, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

- incur additional indebtedness;
- pay dividends or make distributions or repurchase or redeem our stock;
- acquire other businesses;
- make investments;
- make loans to or extend credit for the benefit of third parties or our subsidiaries;
- enter into transactions with affiliates;
- raise additional capital;
- make capital or finance lease expenditures;
- dispose of or encumber assets; and
- consolidate, merge or sell all or substantially all of our assets.

These restrictions may limit our ability to pursue business opportunities or strategies that we would otherwise consider to be in our best interests. In particular, all acquisitions of other businesses, other than very small acquisitions, will require us to obtain our lenders consent under our senior credit facility. We have been required to obtain, and have obtained, our lenders consent under our senior credit facility in order to complete our acquisitions of the Wampole Division of MedPointe Inc., or Wampole, Ostex International, Inc., or Ostex, ABI, and the assets related to Abbott Laboratories rapid diagnostics product lines, or the Abbott rapid diagnostics product lines.

Our credit facilities contain certain financial covenants that we may not satisfy which, if not satisfied, could result in the acceleration of the amounts due under our credit facilities and the limitation of our ability to borrow additional funds in the future.

As of June 30, 2004, we had approximately $12.9 million of indebtedness outstanding under our various credit facilities and approximately $50.4 million of additional borrowing capacity under these credit facilities. The agreements governing these credit facilities subject us to various

financial and other covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to fixed charge coverage, capital expenditures, various leverage ratios, minimum EBITDA, total net worth and minimum cash requirements. If we violate any of these covenants, there may be a material adverse effect on us. Most notably, our outstanding debt under one or more of our credit facilities could become immediately due and payable, our lenders could proceed against any collateral securing such indebtedness, and our ability to borrow additional funds in the future may be limited.

A default under any of our agreements governing our indebtedness could result in a default and acceleration of indebtedness under other agreements.

The agreements governing our indebtedness, including our senior credit facility and the indenture governing the senior subordinated notes, contain cross-default provisions whereby a default under one agreement could result in a default and acceleration of our repayment obligations under other agreements. If a cross-default were to occur, we may not be able to pay our debts or borrow sufficient funds to refinance them. Even if new financing were available, it may not be on commercially reasonable terms or terms that are acceptable to us. If some or all of our indebtedness is in default for any reason, our business, financial condition and results of operations could be materially and adversely affected.

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We may not be able to satisfy our debt obligations upon a change of control, which could limit our opportunity to enter into a change of control transaction.

Upon the occurrence of a change of control, as defined in the indenture governing the senior subordinated notes, each holder of our senior subordinated notes will have the right to require us to purchase the notes at a price equal to 101% of the principal amount, together with any accrued and unpaid interest. Our failure to purchase, or give notice of purchase of, the senior subordinated notes would be a default under the indenture, which would in turn be a default under our senior credit facility. In addition, a change of control may constitute an event of default under our senior credit facility. A default under our senior credit facility would result in an event of default under our 3% convertible notes, 10% subordinated notes and, if the lenders accelerate the debt under our senior credit facility, the indenture, and may result in the acceleration of any of our other indebtedness outstanding at the time. As a result, if we do not have enough cash to repay all of our indebtedness or to repurchase all of the senior subordinated notes, we may be limited in the change of control transactions that we may pursue.

Our acquisitions, and in particular our acquisitions of ABI and the Abbott rapid diagnostics product lines, may not be profitable, and the integration of these businesses or product lines may be costly and difficult and may cause disruption to our business.

Since we commenced activities in November 2001, we have acquired and attempted to integrate into our operations Unipath Limited and its associated companies and assets, or the Unipath business, IVC Industries, Inc. (now doing business as Inverness Medical Nutritionals Group, or IMN), Wampole, and Ostex. On August 27, 2003, we acquired ABI, and on September 30, 2003, we acquired the Abbott rapid diagnostics product lines. We have also made smaller acquisitions such as our recent acquisitions of Viva Diagnostika and Advantage Diagnostics Corporation. The ultimate success of all of our acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses or product lines into our existing businesses. However, the successful integration of independent companies or product lines is a complex, costly and time-consuming process. The difficulties of integrating companies and acquired assets include among others:

- consolidating manufacturing and research and development operations, where appropriate;
- integrating newly acquired businesses or product lines into a uniform financial reporting system;
- coordinating sales, distribution and marketing functions;
- establishing or expanding manufacturing, sales, distribution and marketing functions in order to accommodate newly acquired businesses or product lines;
- preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships;
- minimizing the diversion of management s attention from ongoing business concerns; and
- coordinating geographically separate organizations.

We may not accomplish the integration of our acquisitions smoothly or successfully. The diversion of the attention of our management from our current operations to the integration effort and any difficulties encountered in combining operations could prevent us from realizing the full benefits anticipated to result from these acquisitions and adversely affect our other businesses. Additionally, the costs associated with the integration of our acquisitions, including our costs associated with the integration of the operations of Ostex and ABI and the product lines acquired from Abbott Laboratories, can be substantial. To the extent that we incur integration costs that are not anticipated when we finance our acquisitions, these unexpected costs could adversely impact our liquidity or force us to borrow additional funds. Ultimately, the value of any company, product line or assets that we have acquired may not be greater than or equal to their purchase prices.

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If we choose to acquire or invest in new and complementary businesses, products or technologies instead of developing them ourselves, such acquisitions or investments could disrupt our business and, depending on how we finance these acquisitions or investments, could result in the use of significant amounts of cash.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, from time to time we may seek to acquire or invest in businesses, products or technologies instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth opportunities;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future acquisitions or investments may result in:

- issuances of dilutive equity securities, which may be sold at a discount to market price;
- use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- unfavorable financing terms;

large one-time expenses; and

the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

Any of these factors could materially harm our business or our operating results.

If goodwill and/or other intangible assets that we have recorded in connection with our acquisitions of other businesses become impaired, we could have to take significant charges against earnings.

In connection with the accounting for our acquisitions of the Unipath business, Wampole, Ostex, ABI and the Abbott rapid diagnostics product lines, we have recorded a significant amount of goodwill and other intangible assets. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect our reported results of operations in future periods.

We could experience significant manufacturing delays, disruptions to our ongoing research and development and increased production costs if Unilever is unable to successfully assign or sublease to us the lease for the multi-purpose facility that we currently use in Bedford, England.

One of our primary operating facilities is located in Bedford, England. The Bedford facility is a multi-purpose facility that is registered with the FDA, contains state-of-the-art research laboratories and is equipped

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with specialized manufacturing equipment. This facility currently provides the manufacturing for our Clearblue and Clearview products, serves as our primary research and development center and serves as the administrative center for our European operations. We also use this facility to manufacture the digital and non-digital e.p.t pregnancy tests for Pfizer in connection with our supply arrangements with Pfizer for these products. We are currently using the Bedford facility pursuant to our acquisition agreement with Unilever relating to our acquisition of the Unipath business in late 2001. Unilever currently leases this facility from a third party landlord. Pursuant to the terms of Unilever s lease, Unilever cannot assign the lease or sublet the Bedford facility to us without first obtaining the landlord s consent. The landlord has not yet, and may not in the future, consent to an assignment of the lease or a sublease to us. The terms of our acquisition agreement obligate Unilever to provide to us the benefit of its lease of the Bedford facility. If Unilever is unable to successfully acquire such consent or otherwise enable us to realize the benefit of Unilever s lease of the Bedford facility, or if its lease is terminated, we may be forced to renegotiate a lease of the Bedford facility on substantially less favorable terms or seek alternative means of producing our products, conducting our research and housing our European administrative staff. In either case, we may experience increased production costs or manufacturing delays, which could prevent us from meeting contractual supply obligations or jeopardize important customer relationships. We may also suffer disruptions to our ongoing research and development while we are resolving these issues. We cannot assure you that we will be able to renegotiate a lease for the Bedford facility on terms that are acceptable to us or find an acceptable replacement for this facility. Any one or more of these events may have a material adverse effect on us.

We may experience manufacturing problems or delays, which could result in decreased revenues or increased costs.

We currently produce most of our consumer products in our manufacturing facilities located in New Jersey, San Diego, Bedford, England and Galway, Ireland and some of our professional diagnostic tests in our manufacturing facilities located in Bedford, England, San Diego and Yavne, Israel. Our production processes are complex and require specialized and expensive equipment. Replacement parts for our specialized equipment can be expensive and, in some cases, can require lead times of up to a year to acquire. In addition, our private label consumer products business, and our private label and bulk nutritional supplements business in particular, rely on operational efficiency to mass produce products at low margins per unit. We also rely on numerous third parties to supply production materials and in some cases there may not be alternative sources immediately available.

In addition, we currently rely on nine significant third-party manufacturers, as well as numerous other less significant manufacturers, to produce many of our professional diagnostic products and certain components of our consumer diagnostic products, including products in development. In addition, certain of the Abbott rapid diagnostics product lines are currently manufactured for us by Abbott Laboratories in Chicago under the terms of a transitional arrangement. Any event impacting our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including, without limitation, wars, terrorist activities, natural disasters and outbreaks of infectious disease (such as SARS), could delay or suspend shipments of products or the release of new products or could result in the delivery of inferior products. Our revenues from the affected products would decline or we could incur losses until such time as we were able to restore our production processes or put in place alternative contract manufacturers or suppliers. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

Sales of our new digital pregnancy test may dilute sales of our other consumer pregnancy test products or the non-digital e.p.t pregnancy test, which we manufacture for Pfizer, and, therefore, these sales may not increase our overall revenues or profitability.

In the second quarter of 2003, we shipped the first orders for our new digital pregnancy test, Clearblue Easy Digital, which is the first consumer pregnancy test on the market to display test results in words. We also entered into a supply agreement with Pfizer pursuant to which we began in December 2003 supplying Pfizer with a digital version of its e.p.t pregnancy tests on a non-exclusive basis. Instead of interpreting colored lines for a

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result, the digital display will spell out Pregnant or Not Pregnant. We cannot assure you that sales of these new products will not dilute sales of our other consumer pregnancy test products or the non-digital e.p.t pregnancy test, which we will manufacture for Pfizer for a period of five years beginning in June 2004. Accordingly, there is no assurance that these new products will increase our overall revenues or profitability.

We may experience difficulties that may delay or prevent our development, introduction or marketing of new or enhanced products.

We intend to continue to invest in product and technology development. The development of new or enhanced products is a complex and uncertain process. We may experience research and development, manufacturing, marketing and other difficulties that could delay or prevent our development, introduction or marketing of new products or enhancements. We cannot be certain that:

- any of the products under development will prove to be effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, regulatory approval to market any of our products that are in development or contemplated;
- any of such products can be manufactured at acceptable cost and with appropriate quality; or
- any such products, if and when approved, can be successfully marketed.

While we currently expect to submit a pro-thrombin test for FDA approval in late 2004 and to launch a congestive heart failure product in 2005 and new infectious disease products (including a high sensitivity strep throat test, rapid influenza A & B tests and a rapid HIV test) in 2004, the factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay these launches. In addition, we cannot assure you that the market will accept these products. Accordingly, there is no assurance that our overall revenues will increase if and when these new products are launched.

We may experience difficulties that may delay or prevent us from completing our plans to centralize our U.S. consumer products packaging and distribution facilities, and our plans to manufacture certain products in China.

Consistent with our announced plans, our U.S. consumer products packaging and distribution facility has recently commenced operations, and we have begun to transition the manufacture of certain products to China. We may not complete our plans with respect to these operations in the time projected, or at all, if we are unable to develop or finalize the necessary third party relationships; acquire the required facilities, equipment or materials; or obtain any necessary consents or approvals. In addition, even if we do succeed in developing these new operations on schedule, operational problems, or other factors beyond our control, may prevent or delay us from recognizing cost savings, margin improvements or other benefits that we may expect.

If we fail to meet strict regulatory requirements, we could be required to pay fines or even close our facilities.

Our facilities and manufacturing techniques generally must conform to standards that are established by government agencies, including those of European and other foreign governments, as well as the FDA, and, to a lesser extent, the U.S. Drug Enforcement Administration, or the DEA, and local health agencies. These regulatory agencies may conduct periodic audits of our facilities to monitor our compliance with applicable regulatory standards. If a regulatory agency finds that we fail to comply with the appropriate regulatory standards, it may impose fines on us or if such a regulatory agency determines that our non-compliance is severe, it may close our facilities. Any adverse action by an applicable regulatory agency could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers demands. These

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regulatory agencies may also impose new or enhanced standards that would increase our costs as well as the risks associated with non-compliance. For example, we anticipate that the FDA may soon finalize and implement good manufacturing practice, or GMP, regulations for nutritional supplements. GMP regulations would require supplements to be prepared, packaged and held in compliance with certain rules, and might require quality control provisions similar to those in the GMP regulations for drugs. While our manufacturing facilities for nutritional supplements have been subjected to, and passed, third party inspections against anticipated GMP standards, the ongoing compliance required in the event that GMP regulations are adopted would involve additional costs and would present new risks associated with any failure to comply with the regulations in the future.

If we deliver products with defects, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

The manufacturing and marketing of consumer and professional diagnostic products involve an inherent risk of product liability claims. In addition, our product development and production are extremely complex and could expose our products to defects. Any defects could harm our credibility and decrease market acceptance of our products. In addition, our marketing of vitamins and nutritional supplements may cause us to be subjected to various product liability claims, including, among others, claims that the vitamins and nutritional supplements have inadequate warnings concerning side effects and interactions with other substances. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. In the event that we are held liable for a claim for which we are not indemnified, or for damages exceeding the limits of our insurance coverage, that claim could materially damage our business and our financial condition.

Our sales of brand name nutritional supplements have been trending downward since 1998 due to the maturity of the market segments they serve and the age of that product line and we may experience further declines in sales of those products.

Our aggregate sales of all of our brand name nutritional products, including, among others, Stresstabs, Ferro-Sequels, Protegra, Posture-D, SoyCare, ALLBEE and Z-BEC, have declined each year since 1998 until the year 2002 when they increased slightly as compared to 2001. We believe that these products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The overall age of this product line means that we are subject to future distribution loss for under-performing brands, while our opportunities for new distribution on the existing product lines are limited. Though we did experience a slight increase in sales during 2002, the overall trend of declining sales for these products continued in 2003. As a result we do not expect significant sales growth of our existing brand name nutritional products and we may experience further declines in overall sales of our brand name nutritional products in the future.

Our sales of specific vitamins and nutritional supplements could be negatively impacted by media attention or other news developments that challenge the safety and effectiveness of those specific vitamins and nutritional supplements.

Most growth in the vitamin and nutritional supplement industry is attributed to new products that tend to generate greater attention in the marketplace than do older products. Positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also impact individual brands. Conversely, news that challenges individual segments or products can have a negative impact on the industry overall as well as on sales of the challenged segments or products. Most of our vitamin and nutritional supplements products serve well-established market segments and, absent unforeseen new developments or trends, are not expected to benefit from rapid growth. A few of our vitamin and nutritional products are newer products that are more likely to be the subject of new scientific studies or announcements, which could be either positive or negative. News or other developments that challenge the safety or effectiveness of these products could negatively impact the profitability of our vitamin and nutritional supplements business.

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We could suffer monetary damages, incur substantial costs or be prevented from using technologies important to our products as a result of a number of pending legal proceedings.

We are involved in various legal proceedings arising out of our consumer diagnostics, nutritional supplements and professional diagnostics business. Our material pending legal proceedings are:

- a counterclaim by Princeton BioMeditech Corporation, or PBM, against us in a patent infringement suit maintained by our subsidiaries, Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc., against PBM et. al. in which PBM alleges that we have breached various obligations to PBM arising out of its joint venture with us; and

- a suit brought by Quidel Corporation alleging that we are infringing U.S. Patent No. 4,943,522 and seeking a declaratory finding that Quidel does not infringe certain of our patents and certain other patents owned by co-defendant Armkel LLC and that the patents are invalid and/or unenforceable.

Because of the nature of our business, we may be subject at any particular time to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our businesses will not have a material adverse effect on us.

The profitability of our consumer products businesses may suffer if we are unable to establish and maintain close working relationships with our customers.

For the year ended December 31, 2003 and the six months ended June 30, 2004, 69% and 65% of our net product sales were derived from our consumer products businesses. Our consumer products businesses rely to a great extent on close working relationships with our customers rather than long-term exclusive contractual arrangements. Customer concentration in these businesses is high, especially in our private label nutritional supplements business. In addition, customers of our branded and private label consumer products businesses purchase products through purchase orders only and are not obligated to make future purchases. We therefore rely on our ability to deliver quality products on time in order to retain and generate customers. If we fail to meet our customers needs or expectations, whether due to manufacturing issues that affect quality or capacity issues that result in late shipments, we will harm our reputation and customer relationships and likely lose customers. Additionally, if we are unable to maintain close working relationships with our customers, sales of all of our products and our ability to successfully launch new products could suffer. The loss of a major customer and the failure to generate new accounts could significantly reduce our revenues or prevent us from achieving projected growth.

The profitability of our consumer products businesses may suffer if Pfizer Inc. is unable to successfully market and sell its e.p.t pregnancy tests.

Under the terms of a manufacturing, packaging and supply agreement that we entered into with Pfizer Inc., through one of its wholly-owned subsidiaries, Pfizer began purchasing its non-digital e.p.t pregnancy tests from us on June 6, 2004 and is to continue to do so until June 6, 2009.

Additionally, under the terms of a separate supply agreement, in December 2003, we began supplying Pfizer with a digital version of its e.p.t pregnancy test on a non-exclusive basis. The amount of revenues or profits that we generate under these agreements will depend on the volume of orders that we receive from Pfizer. As a result, if Pfizer is unable to successfully market and sell its e.p.t pregnancy tests, or if other events adversely affect the volume of Pfizer s sales of its e.p.t pregnancy tests, then our future revenues and profit may be adversely affected.

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Because sales of our private label nutritional supplements are generally made at low margins, the profitability of these products may suffer significantly as a result of relatively small increases in raw material or other manufacturing costs.

Sales of our private label nutritional supplements, which for the year ended December 31, 2003 and the six months ended June 30, 2004, provided approximately 18% and 16%, respectively, of our net product sales, generate low profit margins. We rely on our ability to efficiently mass produce nutritional supplements in order to make meaningful profits from these products. Changes in raw material or other manufacturing costs can drastically cut into or eliminate the profits generated from the sale of a particular product. For the most part, we do not have long-term supply contracts for our required raw materials and, as a result, our costs can increase with little notice. The private label nutritional supplements business is also highly competitive such that our ability to raise prices as a result of increased costs is limited. Customers generally purchase private label products via purchase order, not through long-term contracts, and they often purchase these products from the lowest bidder on a product by product basis. The internet has enhanced price competition among private label manufacturers through the advent of on-line auctions, where customers will auction off the right to manufacture a particular product to the lowest bidder. The resulting margin erosion in our nutritionals business has resulted in a reduction of approximately 200 basis points in our overall gross margin and contributed to our significant losses in 2004 through June, as compared to our income in the comparable period in 2003.

Retailer consolidation poses a threat to our existing retailer relationships and could result in lost revenue.

In recent years there has been a rapid consolidation within the mass retail industry. Drug store chains, grocery stores and mass merchandisers, the primary purchasers of our consumer diagnostic products and vitamins and nutritional supplements, have all been subject to this trend. Because these customers purchase through purchase orders, consolidation can interfere with existing retailer relationships, especially private label relationships, and result in the loss of major customers and significant revenue streams.

Our financial condition or results of operations may be adversely affected by international business risks.

Approximately 36% of our net revenues were generated from outside the United States for the year ended December 31, 2003. A significant number of our employees, including manufacturing, sales, support and research and development personnel, are located in foreign countries, including England, Ireland and Israel. Conducting business outside of the United States subjects us to numerous risks, including:

- increased costs or reduced revenue as a result of movements in foreign currency exchange rates;
- decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;
- lower productivity resulting from difficulties managing our sales, support and research and development operations across many countries;
- lost revenues resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;
- lost revenues resulting from the imposition by foreign governments of trade protection measures;

higher cost of sales resulting from import or export licensing requirements;

lost revenues or other adverse affects as a result of economic or political instability in or affecting foreign countries in which we sell our products or operate; and

adverse effects resulting from changes in foreign regulatory or other laws affecting the sales of our products or our foreign operations.

Because our business relies heavily on foreign operations and revenues, changes in foreign currency exchange rates and our ability to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our foreign operations. Three of our manufacturing facilities are outside the United States, in Bedford, England, Galway, Ireland and Yavne, Israel. Approximately 36% of our net revenues

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were generated from outside the United States during the year ended December 31, 2003. Our Clearblue pregnancy test product sales have historically been much stronger outside the United States, with 75% of net product sales of these products coming from outside the United States during the year ended December 31, 2003. In addition, the Abbott rapid diagnostics product lines, which were acquired on September 30, 2003, generate a majority of their sales outside the United States. Furthermore, Persona is sold exclusively outside of the United States and our Orgenics professional diagnostic products have always been sold exclusively outside of the United States. Because of our foreign operations and foreign sales, we face exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European subsidiaries. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could impact our actual cash flow.

Our Orgenics subsidiary is located in Israel, and its operations could be negatively affected due to military or political tensions in the Middle East.

Our wholly-owned subsidiary, Orgenics, which develops, manufactures and sells certain of our professional diagnostic products, is incorporated under the laws of the State of Israel. The administrative offices and development and manufacturing operations of our Orgenics business are located in Yavne, Israel. Although most of Orgenics s sales currently are to customers outside of Israel, political, economic and military conditions in Israel could nevertheless directly affect its operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Despite its history of avoiding adverse effects, our Orgenics business could be adversely affected by any major hostilities involving Israel.

Intense competition could reduce our market share or limit our ability to increase market share, which could impair the sales of our products and harm our financial performance.

The medical products industry is rapidly evolving and developments are expected to continue at a rapid pace. Competition in this industry, which includes both our consumer diagnostics and professional diagnostics businesses, is intense and expected to increase as new products and technologies become available and new competitors enter the market. Our competitors in the United States and abroad are numerous and include, among others, diagnostic testing and medical products companies, universities and other research institutions. Our future success depends upon maintaining a competitive position in the development of products and technologies in our areas of focus. Our competitors may:

- develop technologies and products that are more effective than our products or that render our technologies or products obsolete or noncompetitive;
- obtain patent protection or other intellectual property rights that would prevent us from developing our potential products; or
- obtain regulatory approval for the commercialization of their products more rapidly or effectively than we do.

Also, the possibility of patent disputes with competitors holding foreign patent rights may limit or delay expansion possibilities for our diagnostics businesses in certain foreign jurisdictions. In addition, many of our existing or potential competitors have or may have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

The market for the sale of vitamins and nutritional supplements is also highly competitive. This competition is based principally upon price, quality of products, customer service and marketing support. There are numerous companies in the vitamins and nutritional supplements industry selling products to retailers such as mass merchandisers, drug store chains, independent drug stores, supermarkets, groceries and health food stores. As most of these companies are privately held, we are unable to obtain the information necessary to assess precisely

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the size and success of these competitors. However, we believe that a number of our competitors, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources.

The rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would reduce our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect our intellectual property. Our patent position is generally uncertain and involves complex legal and factual questions. The degree of present and future protection for our proprietary rights is uncertain.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents which are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our customers may not provide a competitive advantage;
- other parties may challenge patents or patent applications licensed or issued to us or our customers;
- patents issued to other companies may harm our ability to do business; and
- other companies may design around technologies we have patented, licensed or developed.

In addition to patents, we rely on a combination of trade secrets, nondisclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If they do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection or prosecute potential infringements of our patents. We also realize that our trade secrets may become known through other means not currently foreseen by us. Despite our efforts to protect our intellectual property, our competitors or customers may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our intellectual property rights or design around our proprietary technologies.

Claims by other companies that our products infringe on their proprietary rights could adversely affect our ability to sell our products and increase our costs.

Substantial litigation over intellectual property rights exists in both the consumer and professional diagnostic industries. We expect that our products and products in these industries could be increasingly subject to third party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our products or technology may infringe. Any of these third parties might make a claim of infringement against us. Any litigation could result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, have an impact on prospective customers, cause product shipment delays or require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty

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or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement was made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue may decrease and we could be exposed to legal actions by our customers.

We have initiated, and may need to further initiate, lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would reduce our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Currently, we have initiated a number of lawsuits against competitors who we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, our stock price could decline.

Non-competition obligations and other restrictions will limit our ability to take full advantage of our management team, the technology we own or license and our research and development capabilities.

Members of our management team have had significant experience in the diabetes field. In addition, technology we own or license may have potential applications to this field and our research and development capabilities could be applied to this field. However, in conjunction with our split-off from Inverness Medical Technology, Inc., or IMT, we agreed not to compete with IMT and Johnson & Johnson in the field of diabetes for 10 years. In addition, Mr. Ron Zwanziger, our Chairman, Chief Executive Officer and President, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar restrictions. Further, our license agreement with IMT prevents us from using any of the licensed technology in the field of diabetes. As a result of these restrictions, we cannot pursue opportunities in the field of diabetes.

You are unlikely to be able to exercise effective remedies against Arthur Andersen LLP, our former independent public accountants.

Although we have dismissed Arthur Andersen LLP as our independent public accountants and have now engaged BDO Seidman, LLP, our consolidated financial statements as of December 31, 2001 and for the year then ended included in our Annual Report on Form 10-K for the year ended December 31, 2003, as amended by Amendment No. 1 on Form 10-K/A filed on April 22, 2004, and incorporated by reference into this prospectus were audited by Arthur Andersen.

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On March 14, 2002, Arthur Andersen was indicted on federal obstruction of justice charges arising from the government s investigation of Enron Corporation. On June 15, 2002, a jury in Houston, Texas found Arthur Andersen guilty of these federal obstruction of justice charges. In light of the jury verdict and the underlying events, Arthur Andersen subsequently substantially discontinued operations and dismissed essentially its entire workforce. You are therefore unlikely to be able to exercise effective remedies or collect judgments against Arthur Andersen. In addition, Arthur Andersen has not consented to the inclusion of its report in this prospectus, and the requirement to file its consent has been dispensed with in reliance on Rule 437a under the Securities Act of 1933. Because Arthur Andersen has not consented to the inclusion of its report in this prospectus, you will not be able to recover against Arthur Andersen under Section 11 of the Securities Act of 1933 for any untrue statement of a material fact contained in the financial statements audited by Arthur Andersen or any omissions to state a material fact required to be stated in those financial statements.

Our operating results may fluctuate due to various factors and, as a result, period-to-period comparisons of our results of operations will not necessarily be meaningful.

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. Such factors include:

- the timing of new product announcements and introductions by us and our competitors;
- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;
- increased research and development expenses;
- the timing of any future acquisitions;
- general economic conditions; or
- general stock market conditions or other economic or external factors.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict our future performance by viewing our historical operating results.

Our historical financial information relating to periods beginning prior to our split-off from IMT on November 21, 2001 may not be representative of our results as a separate company.

On November 21, 2001, we were split-off from IMT and became an independent, publicly owned company as part of a transaction by which IMT was acquired by Johnson & Johnson. Prior to that time, we had been a majority owned subsidiary of IMT, and the businesses that we acquired in connection with the restructuring that preceded the split-off represented approximately 20% of IMT s net product sales during the calendar quarter concluded immediately prior to the split-off. The historical financial information relating to any periods beginning prior to November 21, 2001, included in our reports filed with the SEC, report on time periods prior to the split-off and reflect the operating history of our businesses when we were a part of IMT. As a result, the financial information may not reflect what our results of operations, financial position and cash flows would have been had we been a separate, stand-alone company during those periods. This financial information also may not reflect what our results of operations, financial position and cash flows will be in the future. This is not only related to the various risks associated with the fact that we have not been a stand-alone company for a long period of time, but also because:

- various adjustments and allocations have been made to produce these financial statements because IMT did not account for us as a single stand-alone business for those periods presented; and

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the information, to the extent it does not report on a period ending on or after November 21, 2001, does not reflect many significant changes that occurred in our financial condition, capital structure and operations as a result of our separation from IMT.

The adjustments and allocations we made in preparing the financial information for any periods beginning prior to November 21, 2001 may not appropriately reflect our operations during those periods as if we had operated as a stand-alone company.

Period-to-period comparisons of our operating results may not be meaningful due to our acquisitions.

We have engaged in a number of significant acquisitions in recent years which make it difficult to analyze our results and to compare them from period to period, including the acquisitions of the Unipath business in December 2001, IVC Industies, Inc. in March 2002, Wampole in September 2002, Ostex in June 2003, ABI in August 2003 and the Abbott rapid diagnostics product lines in September 2003. Period-to-period comparisons of our results of operations may not be meaningful due to these acquisitions and are not indications of our future performance. Any future acquisitions will also make our results difficult to compare from period to period in the future.

Our stock price may fluctuate significantly and stockholders who buy or sell our common stock may lose all or part of the value of their investment, depending on the price of our common stock from time to time.

Our common stock has only been listed on the American Stock Exchange since November 23, 2001 and we have a limited market capitalization. As a result, we are currently followed by only a few market analysts and a portion of the investment community. Limited trading of our common stock may therefore make it more difficult for you to sell your shares.

In addition, our share price may be volatile due to our operating results, as well as factors beyond our control. During 2003, the sales price of our common stock ranged from $13.40 to $27.50, and during 2002, it ranged from $7.70 to $28.25. It is possible that in some future periods the results of our operations will be below the expectations of the public market. In any such event, the market price of our common stock could decline. Furthermore, the stock market may experience significant price and volume fluctuations, which may affect the market price of our common stock for reasons unrelated to our operating performance. The market price of our common stock may be highly volatile and may be affected by factors such as:

our quarterly and annual operating results, including our failure to meet the performance estimates of securities analysts;

changes in financial estimates of our revenues and operating results or buy/sell recommendations by securities analysts;

the timing of announcements by us or our competitors of significant products, contracts or acquisitions or publicity regarding actual or potential results or performance thereof;

changes in general conditions in the economy, the financial markets or the health care industry;

government regulation in the health care industry;

changes in other areas such as tax laws;

sales of substantial amounts of common stock or the perception that such sales could occur;

changes in investor perception of our industry, our businesses or our prospects;

the loss of key employees, officers or directors; or

other developments affecting us or our competitors.

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Anti-takeover provisions in our organizational documents and Delaware law may limit the ability of our stockholders to control our policies and effect a change of control of our company and prevent attempts by our stockholders to replace or remove our current management, which may not be in your best interests.

There are provisions in our certificate of incorporation and bylaws that may discourage a third party from making a proposal to acquire us, even if some of our stockholders might consider the proposal to be in their best interests, and prevent attempts by our stockholders to replace or remove our current management. These provisions include the following:

- our certificate of incorporation provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this provision may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire;

- our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control;

- our certificate of incorporation prohibits our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;

- our certificate of incorporation provides for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

- our bylaws require advance written notice of stockholder proposals and director nominations.

Additionally, we are subject to Section 203 of the Delaware General Corporation Law, which, in general, imposes restrictions upon acquirers of 15% or more of our stock. Finally, the board of directors may in the future adopt other protective measures, such as a stockholder rights plan, which could delay, deter or prevent a change of control.

Because we do not intend to pay dividends on our common stock, you will benefit from an investment in our common stock only if it appreciates in value.

We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends on our common stock in the foreseeable future. In addition, our senior credit facility currently prohibits the payment of dividends and the indenture governing the terms of our senior subordinated notes restricts the amount of any dividends that we may pay. As a result, the success of your investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

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SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. You can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. You should read statements that contain these w carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this offering memorandum. These differences may be the result of various factors, including those factors described in the Business and Risk factors sections in this offering memorandum and other risk factors identified from time to time in our periodic filings with the SEC. Some important additional factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

- economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- competitive factors, including technological advances achieved and patents attained by competitors and generic competition;
- domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and government laws and regulations relating to sales and promotion, reimbursement and pricing generally;
- government laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products and licensing;
- manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products, including our ability to successfully maintain relationships with suppliers, or to put in place alternative suppliers on terms that are acceptable to us;
- difficulties inherent in product development, including the potential inability to successfully continue technological innovation, complete clinical trials, obtain regulatory approvals in the United States and abroad, gain and maintain market approval of products and the possibility of encountering infringement claims by competitors with respect to patent or other intellectual property rights which can preclude or delay commercialization of a product;
- significant litigation adverse to us including product liability claims, patent infringement claims and antitrust claims;
- product efficacy or safety concerns resulting in product recalls or declining sales;
- the impact of business combinations, including acquisitions and divestitures, such as our acquisitions of Applied Biotech, Inc. and the Abbott rapid diagnostics product lines, and organizational restructurings consistent with evolving business strategies;
- our ability to satisfy the financial covenants and other conditions contained in our credit facilities;

our ability to obtain required financing on terms that are acceptable to us; and

the issuance of new or revised standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board, the Public Company Accounting Oversight Board or the SEC.

The foregoing list sets forth many, but not all, of the factors that could impact upon our ability to achieve results described in any forward-looking statements. Readers should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described above and elsewhere in this prospectus could harm our business, prospects, operating results and financial condition. We do not undertake any obligation to update any forward-looking statements as a result of future events or developments.

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THE SELLING STOCKHOLDERS

We are filing this registration statement pursuant to the terms of registration rights granted to the selling stockholders in two agreements entered into on June 2, 2004 with the selling stockholders. The shares of common stock covered by the registration of which this prospectus is a part were issued to the selling stockholders as partial payment for the purchase of all of the outstanding capital stock of Viva Diagnostika and an affiliated entity named DMD, Dienstleistungen & Vertieb fur Medizin und Diagnostik GmbH, or DMD GmbH, from the selling stockholders. In connection with the acquisition two of the selling stockholders, Dr. Willy Wegst and Bernd Stammel, who were managing directors of Viva Diagnostika and DMD GmbH prior to the acquisition, have entered into agreements to remain with Viva Diagnostika and DMD-GmbH as managing directors on a continuing basis.

Under the terms of our agreements with the selling stockholders, we agreed to file the registration statement of which this prospectus is a part to register the sale by the selling stockholders of the shares of common stock issued to them. We also agreed to keep the registration statement effective until the earlier of: (1) June 2, 2006 and (2) the date on which all the shares covered by the registration statement have been sold.

The following table sets forth the number of shares of common stock beneficially owned by the selling stockholders as of June 10, 2004, the number of shares of common stock covered by this prospectus and the total number of shares of common stock that the selling stockholders will beneficially own upon completion of this offering. This table assumes that the selling stockholders will offer for sale all of the shares of common stock covered by this prospectus.

The common stock offered by this prospectus may be offered from time to time by the selling stockholders named below. The amounts set forth below are based upon information provided to us by representatives of the selling stockholders, or on our records, as of June 10, 2004 and are accurate to the best of our knowledge. It is possible, however, that the selling stockholder may acquire or dispose of additional shares of common stock from time to time after the date of this prospectus.

Name	Common Stock Beneficially Owned as of June 10, 2004	Common Stock Offered Hereby	Common Stock to be Owned After Offering (1)	Percentage of All Common Stock (2)
Dr. Willy Wegst	35,991	35,991	0	0
Gerda Wegst	18,897	18,897	0	0
Bernd Stammel	28,745	28,745	0	0
Susanne Stammel	18,897	18,897	0	0
Dr. Heinz-Peter Nachreiner	28,745	28,745	0	0
Gabriele Beutler-Nachreiner	18,897	18,897	0	0
DMD AG	5,037	5,037	0	0
Total	155,209	155,209	0	0

(1) Assumes that the selling stockholders will sell all shares of common stock offered by them under this prospectus.
(2) This number represents the percentage of common stock to be owned by the selling stockholders after completion of the offering, based on the number of shares of common stock outstanding as of June 10, 2004 (20,258,328 shares).

USE OF PROCEEDS

We will not receive any proceeds from the sale by the selling stockholders of the securities covered by this prospectus.

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PLAN OF DISTRIBUTION

The selling stockholders may resell or redistribute the securities listed elsewhere in this prospectus from time to time on any stock exchange or automated interdealer quotation system on which the securities are listed, in the over-the-counter market, in privately negotiated transactions, or in any other legal manner, at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. Persons who are pledgees, donees, transferees, or other successors in interest of any of the named selling stockholders (including but not limited to persons who receive securities from a named selling stockholder as a gift, partnership distribution or other non-sale-related transfer after the date of this prospectus) may also use this prospectus and are included when we refer to selling stockholders in this prospectus. Selling stockholders may sell the securities by one or more of the following methods, without limitation:

- block trades (which may include cross trades) in which the broker or dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by the broker or dealer for its own account;
- an exchange distribution or secondary distribution in accordance with the rules of any stock exchange on which the securities are listed;
- ordinary brokerage transactions and transactions in which the broker solicits purchases;
- an offering at other than a fixed price on or through the facilities of any stock exchange on which the securities are listed or to or through a market maker other than on that stock exchange;
- privately negotiated transactions, directly or through agents;
- short sales;
- through the writing of options on the securities, whether or the options are listed on an options exchange;
- through the distribution of the securities by any selling stockholder to its partners, members or stockholders;
- one or more underwritten offerings;
- agreements between a broker or dealer and one or more of the selling stockholders to sell a specified number of the securities at a stipulated price per share; and
- any combination of any of these methods of sale or distribution, or any other method permitted by applicable law.

The selling stockholders may also transfer the securities by gift. We do not know of any current arrangements by the selling stockholders for the sale or distribution of any of the securities.

The selling stockholders may engage brokers and dealers, and any brokers or dealers may arrange for other brokers or dealers to participate in effecting sales of the securities. These brokers, dealers or underwriters may act as principals, or as an agent of a selling stockholder. Broker-dealers may agree with a selling stockholder to sell a specified number of the securities at a stipulated price per security. If the broker-dealer is unable to sell securities acting as agent for a selling stockholder, it may purchase as principal any unsold securities at the stipulated price. Broker-dealers who acquire securities as principals may thereafter resell the securities from time to time in transactions in any stock exchange or automated interdealer quotation system on which the securities are then listed, at prices and on terms then prevailing at the time of sale, at prices related to the then-current market price or in negotiated transactions. Broker-dealers may use block transactions and sales to and through broker-dealers, including transactions of the nature described above. The selling stockholders may also sell the securities in accordance with Rule 144 under the Securities Act of 1933, as amended, rather than pursuant to this prospectus, regardless of whether the securities are covered by this prospectus.

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From time to time, one or more of the selling stockholders may pledge, hypothecate or grant a security interest in some or all of the securities owned by them. The pledgees, secured parties or persons to whom the securities have been hypothecated will, upon foreclosure in the event of default, be deemed to be selling stockholders. The number of a selling stockholder s securities offered under this prospectus will decrease as and when it takes such actions. The plan of distribution for that selling stockholder s securities will otherwise remain unchanged. In addition, a selling stockholder may, from time to time, sell the securities short, and, in those instances, this prospectus may be delivered in connection with the short sales and the securities offered under this prospectus may be used to cover short sales.

The selling stockholders and any underwriters, brokers, dealers or agents that participate in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, and any discounts, concessions, commissions or fees received by them and any profit on the resale of the securities sold by them may be deemed to be underwriting discounts and commissions.

A selling stockholder may enter into hedging transactions with broker-dealers and the broker-dealers may engage in short sales of the securities in the course of hedging the positions they assume with that selling stockholder, including, without limitation, in connection with distributions of the securities by those broker-dealers. A selling stockholder may enter into option or other transactions with broker-dealers that involve the delivery of the securities offered hereby to the broker-dealers, who may then resell or otherwise transfer those securities. A selling stockholder may also loan or pledge the securities offered hereby to a broker-dealer and the broker-dealer may sell the securities offered hereby so loaned or upon a default may sell or otherwise transfer the pledged securities offered hereby.

The selling stockholders and other persons participating in the sale or distribution of the securities will be subject to applicable provisions of the Securities Exchange Act of 1934 and the related rules and regulations adopted by the SEC, including Regulation M. This regulation may limit the timing of purchases and sales of any of the securities by the selling stockholders and any other person. The anti-manipulation rules under the Securities Exchange Act of 1934 may apply to sales of securities in the market and to the activities of the selling stockholders and their affiliates. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making activities with respect to the particular securities being distributed for a period of up to five business days before the distribution. These restrictions may affect the marketability of the securities and the ability of any person or entity to engage in market-making activities with respect to the securities.

The selling stockholders have agreed to indemnify and hold harmless us, certain directors, officers and control persons against specified liabilities, including liabilities under the federal securities laws. The selling stockholders may agree to indemnify any brokers, dealers or agents who participate in transactions involving sales of the securities against specified liabilities arising under the federal securities laws in connection with the offering and sale of the securities.

The securities offered hereby were originally issued to the selling stockholders pursuant to an exemption from the registration requirements of the Securities Act. We agreed to register the securities under the Securities Act. We will pay all expenses relating to the offering and sale of the securities, with the exception of commissions, discounts and fees of underwriters, broker-dealers or agents, taxes of any kind and any legal, accounting and other expenses incurred by the selling stockholder.

We will not receive any proceeds from sales of any securities by the selling stockholders.

We can not assure you that the selling stockholders will sell all or any portion of the securities offered hereby.

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We will supply the selling stockholders and the any stock exchange upon which the securities are listed with reasonable quantities of copies of this prospectus. To the extent required by Rule 424 under the Securities Act of 1933 in connection with any resale or redistribution by a selling stockholder, we will file a prospectus supplement setting forth

- the aggregate number of shares to be sold;
- the purchase price;
- the public offering price;
- if applicable, the names of any underwriter, agent or broker-dealer; and
- any applicable commissions, discounts, concessions, fees or other items constituting compensation to underwriters, agents or broker-dealers with respect to the particular transaction (which may exceed customary commissions or compensation).

If a selling stockholder notifies us that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange, distribution or secondary distribution or a purchase by a broker or dealer, the prospectus supplement will include any other facts that are material to the transaction. If applicable, this may include a statement to the effect that the participating broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus.

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INCORPORATION OF DOCUMENTS BY REFERENCE

The Securities and Exchange Commission allows us to incorporate by reference the information that we file with them. Incorporation by reference means that we can disclose important information to you by referring you to other documents that are legally considered to be part of this prospectus and later information that we file with the Securities and Exchange Commission will automatically update and supersede the information in this prospectus, any supplement and the documents listed below. Our SEC file number is 001-16789. We incorporate by reference the specific documents listed below.

- Annual Report on Form 10-K for the year ended December 31, 2003, as amended by Amendment No. 1 on Form 10-K/A filed on April 22, 2004;
- Quarterly Report on Form 10-Q for the quarter ended March 31, 2004;
- Quarterly Report on Form 10-Q for the quarter ended June 30, 2004;
- Current Report on Form 8- K, event date August 27, 2003, which was filed on September 10, 2003, as amended by the Current Report on Form 8-K/A filed on November 10, 2003;
- Current Report on Form 8-K, event date September 30, 2003, which was filed on October 9, 2003, as amended by the Current Report on Form 8-K/A filed on November 20, 2003;
- Current Report on Form 8-K, event date January 14, 2004, which was filed on January 22, 2004;
- Current Report on Form 8-K, event date February 10, 2004, which was filed on February 12, 2004; and
- the description of our common stock contained in the Registration Statement on Form 8-A, which was filed on November 21, 2001, and all amendments and reports updating such description.

We also incorporate by reference any future filings made with the Securities and Exchange Commission under Section 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934: (1) on or after the date of filing of the registration statement containing this prospectus and prior to the effectiveness of the registration statement and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold by the selling stockholders or this registration statement has been withdrawn. Those documents will become a part of this prospectus from the date that the documents are filed with the Securities and Exchange Commission.

Upon oral or written request and at no cost to the requester, we will provide to any person, including a beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus. All requests should be made to: Inverness Medical Innovations, Inc., 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453, Attn: Corporate Secretary. Telephone requests may be directed to the Corporate Secretary at (781) 647-3900. You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or the documents incorporated by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

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WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act, and we are required to file reports and proxy statements and other information with the Securities and Exchange Commission. You may read and copy these reports, proxy statements and information at the Securities and Exchange Commission s Public Reference Room at 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site that contains reports, proxy and information statements and other information regarding registrants, including Inverness Medical Innovations, Inc., that file electronically with the Securities and Exchange Commission. You may access the Securities and Exchange Commission s web site at http://www.sec.gov.

EXPERTS

The consolidated financial statements of our company as of and for the years ended December 31, 2002 and 2003, incorporated by reference in the prospectus constituting a part of this registration statement on Form S-3 have been audited by BDO Seidman LLP, independent certified public accountants, to the extent and for the periods set forth in their reports incorporated herein by reference, and are incorporated herein in reliance upon such reports given upon the authority of said firm as experts in auditing and accounting.

The consolidated financial statements of our company, as of December 31, 2001, and for the year then ended, incorporated by reference in this prospectus and elsewhere in the registration statement were audited by Arthur Andersen LLP, independent public accountants.

The consolidated financial statements of Applied Biotech, Inc. and subsidiary as of June 30, 2003, and the related consolidated statements of operations, stockholder s equity and cash flows for the nine months ended June 30, 2003 incorporated by reference in the prospectus constituting a part of this registration statement on Form S-3 have been audited by BDO Seidman, LLP, independent certified public accountants, to the extent and for the periods set forth in their report incorporated herein by reference, and are incorporated herein in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

The statements of net assets sold of the Rapid Diagnostics Product Lines of the Abbott Diagnostics Division and Ross Products Division of Abbott Laboratories as of September 30, 2003 and December 31, 2002 and 2001, and the related statements of net sales in excess of expenses for the nine-month period ended September 30, 2003 and the years ended December 31, 2002 and 2001, incorporated by reference in this registration statement have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report incorporated by reference in the registration statement, and are incorporated by reference in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Arthur Andersen LLP has not consented to the inclusion in this prospectus of its reports on the financial statements of our company described above, and the requirement to file its consent to such inclusion with the Securities and Exchange Commission has been dispensed with in reliance upon Rule 437a under the Securities Act. Because Arthur Andersen LLP has not consented to the inclusion of its reports in this document, you will not be able to recover against Arthur Andersen LLP under Section 11 of the Securities Act for any untrue statements of a material fact contained in the financial statements described above that were audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

LEGAL MATTERS

Paul T. Hempel, Esq., our General Counsel, will pass upon the validity of the shares of our common stock offered by this prospectus. Mr. Hempel owns an aggregate of approximately 2,552 shares of our common stock, as well as options to purchase an additional 57,645 shares of our common stock.

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Inverness Medical Innovations, Inc. and Subsidiaries

Unaudited Pro Forma Condensed Combined Financial Statement

The following unaudited pro forma condensed combined statement of operations is presented for illustrative purposes only and does not purport to be indicative of the results of operations for future periods or the results that actually would have been realized had Inverness and its acquired businesses (Ostex, ABI and the Abbott Business, each as defined and described in Note 1 of the notes to these unaudited pro forma condensed combined financial statements) been a consolidated company during the specified period.

The unaudited pro forma condensed combined statement of operations is based on the respective audited and unaudited historical consolidated financial statements and the notes thereto of Inverness and its acquired businesses, as listed above, after giving effect to each of the acquisitions using the purchase method of accounting and assumptions and adjustments described below and in the notes of the unaudited pro forma condensed combined financial statements. Actual operating results of the acquired businesses are included in Inverness historical financial results only from the respective dates of the acquisitions.

The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2003 assumes each of the acquisitions, as listed above, occurred on January 1, 2003.

The pro forma adjustments are based upon available information and upon certain assumptions as described in the notes to the unaudited pro forma condensed combined financial statements that Inverness management believes are reasonable in the circumstances.

The unaudited pro forma condensed combined statement of operations and accompanying notes should be read in conjunction with the historical consolidated financial statements and accompanying notes thereto of Inverness included in its Annual Report on Form 10-K/A for the year ended December 31, 2003, which was filed with the Securities and Exchange Commission on April 22, 2004.

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Inverness Medical Innovations, Inc. and Subsidiaries

Unaudited Pro Forma Condensed Combined Statement of Operations

For the Year Ended December 31, 2003

(in thousands, except per share data)

	Historical Inverness	Historical Ostex	Pro Forma Ostex Adjustments		Historical ABI	Pro Forma ABI Adjustments		Historical Abbott Business	Pro Forma Abbott Business Adjustments		Pro Forma Combined Company
Net product sales	$ 286,984	$ 3,376	$		$ 17,925	$		$ 42,640	$ (6,896)	k	$ 340,731
									(3,298)	l	
License revenue	9,728	62	(44)	a					(354)	l	9,392
Net revenue	296,712	3,438	(44)		17,925			42,640	(10,548)		350,123
Cost of sales	168,120	1,491	221	b	13,091	274	f	30,291	(7,579)	m	202,897
									(3,652)	l	
									400	n	
									240	o	
Gross profit	128,592	1,947	(265)		4,834	(274)		12,349	43		147,226
Operating expenses:											
Research and development	24,280	686			758						25,724
Sales and marketing	51,705	270			1,144			2,996			56,115
General and administrative	35,452	2,338	(348)	c	4,586	(1,528)	g	1,092			41,028
			(564)	d							
Charge related to asset impairment					41,425	(41,425)	h				
Stock-based compensation	447										447
Total operating expenses	111,884	3,294	(912)		47,913	(42,953)		4,088			123,314
Operating income (loss)	16,708	(1,347)	647		(43,079)	42,679		8,261	43		23,912
Interest expense, including amortization of discounts	(9,711)	(205)	209	e	(59)	(555)	i		(2,355)	p	(12,676)
Other income	6,441				35						6,476
Income (loss) before income taxes	13,438	(1,552)	856		(43,103)	42,124		8,261	(2,312)		17,712
Income tax provision (benefit)	1,169				(3,909)	3,909	j		1,487	q	2,656
Net income (loss)	$ 12,269	$ (1,552)	$ 856		$ (39,194)	$ 38,215		$ 8,261	$ (3,799)		$ 15,056
Dividends, interest and amortization of beneficial conversion feature related to Series A Preferred Stock	$ (957)										$ (957)
Net income available to common stockholders:											
Basic	$ 11,312										$ 14,099
Diluted	$ 11,492										$ 14,279

Net income available to common stockholders:					
Basic	$ 0.72				$ 0.78
Diluted	$ 0.64				$ 0.70
Weighted average shares basic	15,711	854 r	451 r	1,156 r	18,172
Weighted average shares diluted	17,834	854 r	451 r	1,156 r	20,295

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Inverness Medical Innovations, Inc. and Subsidiaries

Notes to Unaudited Pro Forma Condensed Combined Financial Statement

(in thousands, except per share amounts)

Note 1. Basis of Presentation and Purchase Prices

Included in the accompanying unaudited pro forma condensed combined statement of operations are the historical results of Inverness and the following entities and businesses, as defined below, which Inverness has acquired since January 1, 2003:

Ostex

ABI

the Abbott Business

On June 30, 2003, Inverness acquired Ostex International, Inc. (Ostex). The preliminary aggregate purchase price of Ostex was $33,424, which consisted of 1,597 shares of Inverness common stock with an aggregate fair value of $23,537 based upon a fair value per share of $14.74, the assumption of fully-vested stock options and warrants to purchase an aggregate of 303 shares of Inverness common stock, which options and warrants had an aggregate fair value of $1,752, estimated exit costs of $3,632, which primarily consisted of severance and costs to vacate Ostex s manufacturing and administrative facilities in accordance with Emerging Issues Task Force (EITF) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*, direct acquisition costs of $1,628 and $2,875 in assumed debt. The fair value of the shares issued was determined based on the average market price of the securities over the periods just prior to and following the date of the merger agreement, as amended, pursuant to EITF Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination*. The fair value of the assumed fully-vested stock options and warrants was calculated using the Black-Scholes option pricing model. Since the date of its acquisition by Inverness, Ostex s financial results are included in Inverness historical results for the year ended December 31, 2003.

On August 27, 2003, Inverness acquired all of the stock of Applied Biotech, Inc. (ABI) from Apogent Technologies Inc. The preliminary aggregate purchase price of ABI was $28,840, which consisted of $13,400 in cash, 693 shares of Inverness common stock with an aggregate fair value of $14,267 based upon a fair value per share of $20.60 and estimated direct acquisition costs of $1,173. The fair value of the shares issued was determined based on the average market price of the securities over the periods just prior to and following the date of the merger agreement, pursuant to EITF Issue No. 99-12. The aggregate purchase price is preliminary as Inverness is working to settle a working capital adjustment with Apogent under the purchase agreement and management is in the process of finalizing a restructuring plan for the operations of ABI, both of which could result in adjustments to the aggregate purchase price. Since the date of its acquisition by Inverness, ABI s financial results are included in Inverness historical results for the year ended December 31, 2003.

On September 30, 2003, Inverness acquired from Abbott Laboratories (Abbott) certain assets related to Abbott s Fact plus line of consumer diagnostic pregnancy tests and Abbott TestPack, Abbott TestPack plus and Signify lines of professional rapid diagnostics for various testing needs, including strep throat, pregnancy and drugs of abuse (the Abbott Business). The acquired assets also include certain transferred and licensed intellectual property related to these products. The aggregate purchase price was $94,987, which consisted of $55,000 in cash, $37,500 in the form of 1,551 shares of Inverness common stock and direct acquisition costs of $2,487. Since the date of its acquisition by Inverness, the

financial results of the Abbott Business are included in Inverness historical results for the year ended December 31, 2003.

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Note 2. Pro Forma Adjustments

The following describes the pro forma adjustments made to the accompanying unaudited pro forma condensed combined statement of operations:

a Represents the reversal of Ostex s historical amortization of deferred license revenue. The deferred license revenue was eliminated in conjunction with purchase accounting adjustments.

b Reflects amortization expense on acquired intangible assets, detailed below, in connection with the acquisition of Ostex. No amortization expense was recorded on acquired goodwill in accordance with Statement of Financial Accounting Standard (SFAS) No. 142, *Goodwill and Other Intangible Assets*. The estimated fair values of acquired intangible assets in connection with the acquisition of Ostex and the respective useful lives are as follows:

	Fair Value*	Life
Core technology	$ 5,532	15 years
Customer relationships	1,096	15 years
Goodwill	24,840	Indefinite
Total intangibles	$ 31,468	

* Fair values of the Ostex intangible assets are based on the results of an independent appraisal.

c Represents adjustment to depreciation expense based on appraised value assigned to Ostex fixed assets.

d Represents the elimination of certain acquisition related expenses incurred by Ostex.

e Represents reversal of Ostex s historical interest expense on debt that was prepaid by Inverness upon acquisition.

f Reflects amortization expense on acquired intangible assets, detailed below, in connection with the acquisition of ABI. No amortization expense was recorded on acquired goodwill in accordance with SFAS No. 142. The fair values of acquired intangible assets in connection with the acquisition of ABI and the respective useful lives are as follows:

	Fair Value*	Life
Customer relationships	$ 2,000	15 years
Manufacturing know-how	3,500	15 years
Goodwill	10,115	Indefinite
Total intangibles	$ 15,615	

* Fair values of the ABI intangible assets are based on an independent appraisal.

g Represents reversal of historical amortization recorded by ABI based on the historical carrying value of its intangible assets.

h Represents reversal of impairment charge related to intangible assets of ABI based on historical carrying values.

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i Represents interest expense on $13,400 of debt incurred by Inverness to fund the cash portion of the ABI purchase price and amortization of related financing costs.

j Represents the reversal of the historical federal income tax benefit of ABI to reflect an income tax provision on a combined basis for the reporting period.

k Represents adjustment for the difference between net product sales recorded in the historical results of the Abbott Business and the contractually agreed upon amounts pursuant to a distribution agreement entered into as part of the acquisition.

l Represents the elimination of intercompany sales and cost of sales of products that Abbott purchased from a subsidiary of Inverness and royalties Abbott paid to a subsidiary of Inverness prior to its acquisition by Inverness.

m Represents adjustment to cost of sales for the difference between cost of sales recorded in the historical results of the Abbott Business and the contractually agreed upon cost of certain products pursuant to a supply agreement entered into as part of the acquisition.

n Represents adjustment to depreciation expense included in the historical results of the Abbott Business based on management estimates of the value of the acquired fixed assets.

o Reflects amortization expense on the acquired intangible asset, Tradename-Fact plus, in connection with the acquisition of the Abbott Business. No amortization was recorded on the acquired intangible asset, Tradename-Signify, as it was estimated to have an indefinite life. In addition, no amortization expense was recorded on acquired goodwill in accordance with SFAS No. 142. The fair values of acquired intangible assets in connection with the acquisition of the Abbott Business and the respective useful lives are as follows:

	Fair Value*	Life
Trade name Fact plus	$ 1,600	5 years
Trade name Signify	6,400	Indefinite
Goodwill	86,451	Indefinite
Total intangibles	$ 94,451	

* Fair values of intangible assets related to the Abbott Business are based on an independent appraisal.

p Represents interest expense on $55,000 of debt incurred by Inverness to fund the cash portion of the purchase price of the Abbott Business and amortization of related financing costs.

q Represents estimated income taxes on a combined pro forma basis to include the Abbott Business.

r Represents adjustment to the historical number of weighted average Inverness shares outstanding giving effect to the issuance of shares of Inverness common stock in connection with the acquisitions of Ostex, ABI and the Abbott Business, as if such transactions occurred on January 1, 2003.

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Note 3. Pro Forma Net Income Per Share

For the year ended December 31, 2003, the unaudited pro forma basic and diluted net income per share amounts are calculated based on the weighted average number of Inverness common shares outstanding prior to the respective acquisitions plus the adjustments to such shares giving effect to the Inverness common shares issued upon the closings of the respective acquisitions, as if such transactions occurred on January 1, 2003. Common stock equivalents resulting from assumed conversion or exercise of convertible debt, stock options or warrants are also included in the diluted net income per share calculation. Common stock equivalents resulting from assumed conversion of preferred stock are not included in the diluted net income per share calculation because inclusion thereof, together with the add back of redemption interest and dividends, would be antidilutive.

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155,209 Shares

INVERNESS MEDICAL INNOVATIONS, INC.

Common Stock

PROSPECTUS

, 2004

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Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. ***Other Expenses of Issuance and Distribution.***

The expenses in connection with the issuance and distribution of the securities being registered are set forth in the following table (all amounts except the registration fee are estimated):

Registration fee Securities and Exchange Commission	$ 380.12
Accountants fees and expenses	20,000.00
Blue Sky fees and expenses	0.00
Legal fees and expenses (other than Blue Sky)	10,000.00
Printing expenses	10,000.00
Miscellaneous	5,000.00
TOTAL	$ 45,380.12

All expenses itemized above shall be borne by our company.

Item 15. ***Indemnification of Directors and Officers.***

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that the person is or was a director, officer, employee or agent of the corporation or is or was serving at the corporation s request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with the action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person s conduct was unlawful. The power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of expenses, including attorneys fees but excluding judgments, fines and amounts paid in settlement, actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit. And with the further limitation that in these actions, no indemnification shall be made in the event of any adjudication of negligence or misconduct in the performance of the person s duties to the corporation, unless a court believes that in light of all the circumstances indemnification should apply.

Article V of the bylaws of Inverness Medical Innovations, Inc. (the Company) provide that the Company shall, to the extent legally permitted, indemnify each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding by reason of the fact that such person is or was, or has agreed to become, a director or officer of the Company, or is or was serving,

or has agreed to serve, at the request of the Company, as a director, officer, trustee, partner, employee or agent of, or in a similar capacity with, another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. The indemnification provided for in Article V is expressly not exclusive of any other rights to which those seeking indemnification may be entitled under any law, agreement or vote of stockholders or disinterested directors or otherwise, and shall inure to the benefit of the heirs, executors and administrators of such persons.

Section 145(g) of the Delaware General Corporation Law and Article V of the bylaws of the Company provide that the Company shall have the power to purchase and maintain insurance on behalf of its officers, directors, employees and agents, against any liability asserted against and incurred by such persons in any such capacity.

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The Company has obtained insurance covering its directors and officers against losses and insuring the Company against certain of its obligations to indemnify its directors and officers.

Section 102(b)(7) of the General Corporation Law of the State of Delaware provides that a corporation may eliminate or limit the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provisions shall not eliminate or limit the liability of a director (i) for any breach of the director s duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the General Corporation Law of the State of Delaware regarding the unlawful payment of dividends, or (iv) for any transaction from which the director derived an improper personal benefit. No such provision shall eliminate or limit the liability of a director for any act or omission occurring prior to the date when such provision becomes effective.

Pursuant to the Delaware General Corporation Law, Article VII of the certificate of incorporation of the Company eliminates a director s personal liability for monetary damages to the Company and its stockholders for breach of fiduciary duty as a director, except in circumstances involving a breach of the director s duty of loyalty to the Company or its stockholders, acts or omissions not in good faith, intentional misconduct, knowing violations of the law, self-dealing or the unlawful payment of dividends or repurchase of stock.

Item 16. ***Exhibits.***

Exhibit No.	Description
4.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company s Form 10-K, as amended, for the year ended December 31, 2001)
4.2	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)
4.3	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.3 to the Company s Form 10-K, as amended, for the year ended December 31, 2001)
4.4	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))
**5.1	Opinion of Paul T. Hempel, Esq., General Counsel of Inverness Medical Innovations, Inc.
**10.1	Sale Agreement, dated December 20, 2001 between the Company and Unilever U.K. Holdings Limited
*23.1	Consent of BDO Seidman, LLP
*23.2	Consent of BDO Seidman, LLP
*23.3	Consent of Deloitte & Touche LLP
**23.4	Consent of Paul T. Hempel, Esq., General Counsel of Inverness Medical Innovations, Inc. (included in Exhibit 5.1)
**24.1	Power of Attorney (contained in signature page)

* Filed herewith.
** Previously filed.

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Item 17. ***Undertakings.***

A. The undersigned Registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the registration statement.

provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

5. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on October 6, 2004.

INVERNESS MEDICAL INNOVATIONS, INC.

By: /s/ RON ZWANZIGER

Ron Zwanziger

Chairman, Chief Executive Officer and President

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ RON ZWANZIGER **Ron Zwanziger**	Chairman, President and Chief Executive Officer (Principal Executive Officer)	October 6, 2004
/s/ CHRISTOPHER J. LINDOP **Christopher J. Lindop**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	October 6, 2004
* **Ernest A. Carabillo, Jr.**	Director	October 6, 2004
* **Carol R. Goldberg**	Director	October 6, 2004
* **Robert P. Khederian**	Director	October 6, 2004
* **John F. Levy**	Director	October 6, 2004
* **Jerry McAleer, Ph.D.**	Director	October 6, 2004

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Signature	Title	Date
David Scott, Ph.D.	Director	
*	Director	October 6, 2004
Peter Townsend		
*	Director	October 6, 2004
John A. Quelch		
Alfred M. Zeien	Director	

*By: /s/ RON ZWANZIGER
Ron Zwanziger

Attorney-in-Fact

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EXHIBIT INDEX

Exhibit No.	Description
4.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company s Form 10-K, as amended, for the year ended December 31, 2001)
4.2	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)
4.3	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.3 to the Company s Form 10-K, as amended, for the year ended December 31, 2001)
4.4	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))
**5.1	Opinion of Paul T. Hempel, Esq., General Counsel of Inverness Medical Innovations, Inc.
**10.1	Sale Agreement, dated December 20, 2001 between the Company and Unilever U.K. Holdings Limited
*23.1	Consent of BDO Seidman, LLP
*23.2	Consent of BDO Seidman, LLP
*23.3	Consent of Deloitte & Touche LLP
**23.4	Consent of Paul T. Hempel Esq., General Counsel of Inverness Medical Innovations, Inc. (included in Exhibit 5.1)
**24.1	Power of Attorney (contained in signature page)

* Filed herewith.
** Previously filed.