INVERNESS MEDICAL INNOVATIONS INC
Form S-3/A
August 25, 2004
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As filed with the Securities and Exchange Commission on August 24, 2004

Registration Statement No. 333-116659

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 1 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 August 24, 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 August 23, 2004, the last reported sale price of our common stock on the American Stock Exchange was $15.05.

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, unexpected costs associated with the integration of our acquisitions, including the integration of the operations of Ostex and ABI and the product lines acquired from Abbott Laboratories, could adversely impact our liquidity. 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 third parties to supply production materials and in some cases there may not be alternative sources immediately available.

In addition, we rely on third parties to manufacture most of our professional diagnostic products and certain components of our consumer diagnostic products, including products in development. For example, 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.

We have announced that we intend to develop a centralized U.S. consumer products packaging and distribution facility which is scheduled to be operational in the third quarter of 2004, and that we intend to transition the manufacture of portions of certain products to China beginning in the third quarter of 2004. We may not commence 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.

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.