INVERNESS MEDICAL INNOVATIONS INC
Form S-3/A
August 05, 2003
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As filed with the Securities and Exchange Commission on August 5, 2003

Registration Statement No. 333-107288

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:

Scott F. Duggan, Esq.

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Exchange Place

Boston, Massachusetts 02109

(617) 570-1000

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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PROSPECTUS

134,698 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 134,698 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 4, 2003, the last reported sale price of our common stock on the American Stock Exchange was $20.82.

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 , 2003

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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 17 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.

About Inverness Medical Innovations, Inc.

We develop, manufacture and market consumer healthcare products, including self-test diagnostic products for the women s health market and vitamins and nutritional supplements. We also develop, manufacture and distribute a wide variety of clinical diagnostic products for use by medical and laboratory professionals. Our consumer self-test diagnostic products allow a wide variety of individuals to obtain accurate information regarding various medical conditions on a confidential, non-prescription basis, without the expense, inconvenience and delay associated with physician visits or laboratory testing. This information gives individuals greater control over their health and their lives, allowing them to make informed decisions and take action to protect their health, alone or in consultation with healthcare professionals. Our nutritional supplements also provide individuals with the ability to better manage their own health. Our existing self-test products are targeted at the women s health market, one of the largest existing markets for self-care diagnostics, and include home pregnancy detection tests and home ovulation prediction tests. We sell a wide variety of vitamins and nutritional supplements.

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

Pending Acquisition of Applied Biotech, Inc.

On July 30, 2003, we entered into an agreement pursuant to which we intend to acquire Applied Biotech, Inc. from Apogent Technologies, Inc. Applied Biotech is a developer, manufacturer and distributor of rapid diagnostic products in the areas of women s health, infectious disease and drugs of abuse testing. Under the terms of the agreement, we intend to acquire all of the stock of Applied Biotech in exchange for 692,506 shares of our common stock and additional consideration of either a payment of $13,400,000 in cash or a payment of $5,000,000 in cash and a one-year $8,400,000 subordinated promissory note. Our pending acquisition of Applied Biotech remains subject to certain closing conditions, including obtaining the consent of our lenders. Consequently, there can be no assurance that our acquisition of Applied Biotech will occur.

Acquisition of Ostex International, Inc.

On June 30, 2003, we acquired Ostex International, Inc., a company that develops and commercializes osteoporosis diagnostic products and holds significant intellectual property rights in the field of osteoporosis

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testing. The acquisition transaction was structured as a merger of one of our wholly owned subsidiaries with and into Ostex, with Ostex surviving the merger as our wholly owned subsidiary. In connection with the merger, we issued approximately 1.6 million shares of our common stock to Ostex s prior shareholders and we assumed options and warrants to purchase approximately 300,000 shares of our common stock.

Settlement with Pfizer, Inc.

In early June 2003, we settled our patent infringement litigation against Pfizer Inc. and one of its subsidiaries. In connection with the settlement, we entered into an agreement with Pfizer, through one of its wholly owned subsidiaries, pursuant to which we agreed to supply to Pfizer, and Pfizer agreed to purchase from us, its e.p.t.® pregnancy tests beginning on June 6, 2004 and continuing until June 6, 2009. Pfizer also agreed to minimum purchase obligations.

The Offering

This prospectus relates to up to 134,698 shares of our common stock that may be offered for sale by the selling stockholder. 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 stockholder.

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 stockholder 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 19.

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RISK FACTORS

There are various risks, including those described below, which 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 consider carefully 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 17 of this prospectus.

Our business has substantial indebtedness, which could result in adverse consequences for us.

As of March 31, 2003, we had approximately $108.3 million of gross indebtedness outstanding under our credit facilities and other debt-related instruments. Our substantial indebtedness could have important consequences to you. For example, it could:

- impair our ability to obtain additional financing;
- 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;
- 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; and
- place us at a competitive disadvantage compared to our competitors that have less debt.

Furthermore, we cannot assure you that our cash flow from operations and capital resources will be sufficient to pay our indebtedness. 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 or seek additional equity capital.

Additionally, the agreements governing our indebtedness subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

- incur additional indebtedness;
- acquire other businesses;
- make investments;

make loans to or extend credit for the benefit of third parties or our subsidiaries;

raise additional capital;

make capital or finance lease expenditures; and

dispose of or encumber assets.

These restrictions may limit our ability to pursue business opportunities or strategies that we would otherwise consider to be in our best interests.

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 March 31, 2003, we had approximately $67.2 million of gross indebtedness outstanding under our various credit facilities, substantially all of which was owed to General Electric Capital Corporation, Keybank

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National Association, The Royal Bank of Scotland Plc and Congress Financial Corporation. The agreements governing these various 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 expenditure, various leverage ratios, minimum EBITDA, total net worth and minimum cash requirement. 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 our ability to borrow additional funds in the future may be limited.

Rising interest rates would increase our interest costs and reduce our earnings.

We currently have, and may incur more, indebtedness that bears interest at variable rates. Accordingly, if interest rates increase, so will our interest costs, which would adversely affect our earnings, cash flow and our ability to service debt.

We may not be able to complete our pending acquisition of Applied Biotech, Inc.

Our pending acquisition of Applied Biotech, Inc. is subject to several closing conditions, most notably the consent of our lenders. As a result, we cannot assure you that the acquisition will occur. If the acquisition does not occur, we will have incurred certain expenses and we will not realize the expected benefits of the acquisition of Applied Biotech.

Our acquisitions of IVC Industries, Inc., the Wampole Division of MedPointe Inc. and Ostex International, Inc., and our pending acquisition of Applied Biotech, Inc. may not be profitable, and the integration of these businesses may be difficult and may lead to adverse effects.

In March 2002, we acquired IVC Industries, Inc. (now doing business as Inverness Medical Nutritionals Group or IMN) and in September 2002, we acquired the Wampole Division of MedPointe Inc. On June 30, 2003, we acquired Ostex International, Inc., and on July 30, 2003, we entered into an agreement to acquire Applied Biotech, Inc. The ultimate success of our IMN, Wampole and Ostex acquisitions, and, to the extent it is completed, our pending acquisition of Applied Biotech, will depend, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses with our preexisting businesses. However, the successful integration of independent companies is a complex, costly and time-consuming process. The difficulties of integrating companies include among others:

- consolidating manufacturing, research and development operations;
- coordinating sales, distribution and marketing functions;
- 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. Ultimately, the value of IMN, Wampole, Ostex, or any other company that we may acquire, 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 amount 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 cost savings;
- 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 that we have recorded in connection with our acquisitions of other businesses becomes impaired, we could have to take significant charges against earnings.

In connection with the accounting for our acquisition of the Unipath business in December 2001 and our acquisition of Wampole in September 2002, we have recorded a significant amount of goodwill and other intangible assets. In connection with the accounting for our acquisition of Ostex, we expect to record 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 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 U.S. Food and Drug Administration, contains state-of-the-art research

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laboratories and is equipped with specialized manufacturing equipment. This facility currently provides the manufacturing for our Clearblue and Clearview products, serves as our research and development center and serves as the administrative center for our European operations, and we anticipate using this facility to manufacture the e.p.t.® pregnancy test for Pfizer, Inc. in connection with our five year supply arrangement with Pfizer. We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business in 2001. Unilever currently leases this facility from a third party landlord. Pursuant to the terms of Unilever s lease, however, Unilever is not permitted to assign the lease or sublet the Bedford facility without obtaining the prior written consent of the landlord (which consent may not be unreasonably withheld). The landlord has indicated that it will not consent to an assignment of the lease to us. We, Unilever and the landlord are currently negotiating the terms of a sublease. The terms of our acquisition agreement obligate Unilever to use reasonable endeavors to obtain the landlord s consent to assignment or to a sublease of the facility and, if necessary, to pursue the assignment or sublease through the courts. There are no assurances that Unilever will be successful in obtaining the landlord s consent to assignment of the lease to us or to a sublease to us. If Unilever is unable to successfully acquire such consent or otherwise enable us to realize the benefit of our lease of the Bedford facility, 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 and the e.p.t.® pregnancy test for Pfizer, conducting our research and housing our European administrative staff. In either case, we may experience manufacturing delays and disruptions to our ongoing research and development while we are resolving these issues and increased production costs in the future. 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.

Manufacturing problems or delays could severely affect our business.

We produce most of our consumer products in our manufacturing facilities located in New Jersey, Bedford, England and Galway, Ireland and some of our professional diagnostic tests in our manufacturing facilities located in Bedford, England, Seattle, Washington 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 product 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 diagnostics products, including products in development. 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.

We may not be successful in manufacturing, shipping and selling our new digital pregnancy test.

We recently 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. Instead of interpreting colored lines for a result, the digital display will spell out Pregnant or Not Pregnant. However, manufacturing or distribution problems, or other factors beyond our control, could negatively impact the effectiveness of our ongoing new product launch and prevent us from meeting customers demand or our own sales forecasts. In addition, we cannot assure you that the market will accept this new product or that any such acceptance will not dilute market acceptance of our other consumer pregnancy test products or the e.p.t.® pregnancy test, which we will in the future manufacture for Pfizer. Accordingly, there is no assurance that this new product will increase our overall revenues or profitability.

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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 Agency, or the DEA, and local health agencies. These regulatory agencies may conduct periodic inspections 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 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.

Sales of our branded 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.

Sales of our branded nutritional products have declined each year since 1998 until the year 2002 when they increased slightly as compared to 2001. We believe that those products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The 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 seen during 2002, sales for the first quarter of 2003 suggest that the overall trend of declining sales for these products may continue. In any case, we do not expect significant sales growth of our existing branded nutritional products and we may experience further declines in sales of those products in the future.

The vitamin and nutritional supplements market is subject to significant fluctuations based upon media attention and new developments.

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

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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.

We market our Orgenics professional diagnostic products to small and medium sized customers in more than 90 countries at considerable cost that reduces the operating margins for those products.

Because small and medium sized laboratories are the principal customers of our Orgenics professional diagnostic products, we sell these products worldwide in order to maintain sufficient sales volume. Our Orgenics professional diagnostic products are marketed in more than 90 countries, including many third world and developing nations where smaller laboratories are the norm, more expensive technologies are not affordable and infectious diseases are often more prevalent. This worldwide sales strategy is expensive and results in lower margins than would be possible if we could generate sufficient sales volume by operating in fewer markets.

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. The current material legal proceedings are:

- a lawsuit by Abbott Laboratories against us and Princeton BioMeditech Corporation (referred to as PBM), which manufactured products for our consumer diagnostics business while we were part of IMT, claiming, among other things, that some of our products relating to pregnancy detection and ovulation prediction infringe patents to which Abbott asserts it is the exclusive licensee;

- a counterclaim by 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

- an action brought by approximately 65 consumers in London alleging defects in our Persona contraceptive device leading to unwanted pregnancies. We believe that any liability in this matter is fully covered by separate insurance provided by Unilever in connection with our acquisition of the Unipath business.

Because the above claims each seek damages and reimbursement for costs and expenses without specific amounts, we are unable to assess the probable outcome of or potential liability arising from the lawsuits.

In connection with our split-off from IMT, we agreed to assume, to the extent permitted by law, and indemnify IMT for, all liabilities arising out of the women s health, nutritional supplements and professional diagnostics businesses before or after the split-off to the extent such liabilities are not otherwise retained by IMT. Through our acquisitions of the Unipath business, IMN, Wampole and Ostex, we also assumed or acquired substantially all of the liabilities of those businesses. We are unable to assess the materiality or costs associated with these lawsuits at this time.

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.

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,

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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 effect quality or capacity issues that result in late shipments, we will harm our reputation and likely lose customers. 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 continue to successfully market and sell its e.p.t.® pregnancy test.

Under the terms of a recent manufacturing, packaging and supply agreement that we entered into with Pfizer Inc., through one of its wholly owned subsidiaries, Pfizer will purchase its e.p.t.® pregnancy tests from us beginning on June 6, 2004 and continuing until June 6, 2009. Provided Pfizer meets its minimum purchase requirements under the contract, we stand to profit. However, if Pfizer s sales of its e.p.t.® pregnancy test fail to grow as forecast we may not generate as much revenue or profit under this arrangement as we currently project.

Our private label nutritional supplements business is a low margin business susceptible to changes in costs and pricing pressures.

Our private label nutritional supplements business operates on low profit margins and we rely on our ability to efficiently mass produce nutritional supplements in order to make meaningful profits from this business. 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 mass merchandisers will auction off the right to manufacture a particular product to the lowest, often anonymous bidder.

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

Recent years have witnessed 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.

A significant number of our employees, including sales, support and research and development personnel, are located outside of the United States. 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; and

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

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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 42% of our net revenues were generated from outside the United States during 2002. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 68% of our net product sales of Clearblue products coming from outside the United States during 2002. In addition, IMN generated almost 17.5% of its net product sales outside of the United States during 2002. 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 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 consumer diagnostics business 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.

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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 and health food stores. As most of these companies are privately held, we are unable to obtain the information necessary to assess precisely 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 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 companies may challenge patents 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 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 may increasingly be subject to third party infringement claims as the number of competitors grows and the functionality of products and

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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, require us to develop non-infringing technology or enter into royalty 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 in the post-closing covenants agreement not to compete with IMT and Johnson & Johnson in the field of diabetes. 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.

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We are obligated to indemnify IMT and others for liabilities and could be required to pay IMT and others amounts that we may not have.

The restructuring agreement, post-closing covenants agreement and related agreements entered into in connection with the split-off and merger transaction with Johnson & Johnson provide that we will indemnify IMT and other related persons for specified liabilities related to our businesses, statements in the proxy statement/prospectus issued in connection with the split-off and merger about our businesses and breaches of our obligations under the restructuring agreement, post-closing covenants agreement and related agreements.

In addition, under our tax allocation agreement with IMT and Johnson & Johnson, we will indemnify Johnson & Johnson and IMT for any unpaid tax liabilities attributable to the pre-split-off operation of our consumer diagnostics, vitamins and nutritional supplements and professional diagnostics businesses.

While no claims for indemnification have yet been made, and may never be made, we are unable to predict the amount, if any, that may be required for us to satisfy our indemnification obligations under these agreements. However, if claims are made for indemnification and we are liable for such claims, the amount could be substantial. In such an event, we may not have sufficient funds available to satisfy our potential indemnification obligations. In addition, we may be unable to obtain the funds on terms satisfactory to us, if at all. If we are unable to obtain the necessary funds, we will need to consider other alternatives, including sales of assets, to raise necessary funds.

You are unlikely to be able to exercise effective remedies against Arthur Anderson 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 two years in the period ended December 31, 2001 included in our Annual Report on Form 10-K for the year ended December 31, 2002 and incorporated by reference into this prospectus were audited by Arthur Andersen.

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. 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 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;

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- 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.

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. 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.

The holders of our Series A Preferred Stock are entitled to receive liquidation payments in preference to the holders of our common stock.

As of March 31, 2003, there were 323,060 shares of our Series A Preferred Stock outstanding. Pursuant to the terms of the certificate of designation creating our Series A Preferred Stock, upon a liquidation or a deemed liquidation of our company, the holders of the shares of our Series A Preferred Stock are entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is $30 per share of our Series A Preferred Stock (or $40.50 per share in certain circumstances), plus the amount of any dividends that have accrued on those shares, subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting

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our Series A Preferred Stock. Dividends accrue on the shares of our Series A Preferred Stock at the rate of up to $2.10 per share per annum based on the percentage of trading days on which the closing market price of our common stock is less than $15.00. As a result of these terms, the holders of our common stock may be disproportionately affected by any reduction in the value of our assets or fluctuations in the market price of our common stock.

The ability of our stockholders to control our policies and effect a change of control of our company is limited, 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. 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; and

- 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.

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. 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.

Our historical financial information relating to periods beginning prior to our split-off from Inverness Medical Technology, Inc. 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 Securities and Exchange Commission report on time periods prior to the split-off

reflects 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

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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

- 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.

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SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 cont 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 prospectus. These differences may be the result of various factors, including those factors described in the Risk Factors section of this prospectus and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. 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 pending acquisition of Applied Biotech, Inc., 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 accounting standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board or the Securities and Exchange Commission.

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 in the Risk Factors section 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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REGISTRATION RIGHTS OF THE SELLING STOCKHOLDER

We are filing this registration statement pursuant to the terms of registration rights granted to the selling stockholder in an agreement we entered into on June 19, 2003 with Genicon Sciences Corporation. The shares of common stock covered by the registration of which this prospectus is a part were issued to Genicon in exchange for a license of certain of Genicon s intellectual property to us.

Under the terms of our agreement with Genicon, we agreed to file the registration statement of which this prospectus is a part to register the sale by Genicon of the shares of common stock issued to Genicon. We also agreed to keep the registration statement effective until the earlier of: (1) one year following the date the registration statement is declared effective, (2) the date on which Genicon may sell all of its shares covered by the registration statement that are then held by Genicon within a three-month period in accordance with Rule 144 under the Securities Act, or (3) such time as all the shares covered by the registration statement have been sold pursuant to a registration statement.

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THE SELLING STOCKHOLDER

The following table sets forth the number of shares of common stock beneficially owned by the selling stockholder as of June 30, 2003, the number of shares of common stock covered by this prospectus and the total number of shares of common stock that the selling stockholder will beneficially own upon completion of this offering. This table assumes that the selling stockholder 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 stockholder named below, or by any of its pledgees, donees, transferees or other successors in interest. The amounts set forth below are based upon information provided to us by representatives of the selling stockholder, or on our records, as of June 30, 2003 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 30, 2003	Common Stock Offered Hereby	Common Stock to be Owned After Offering(1)	Percentage of All Common Stock(2)
Genicon Sciences Corporation	134,698	134,698	-0-	*
Total	**134,698**	**134,698**	**-0-**	

* Less than one percent

(1) Assumes that the selling stockholder will sell all shares of common stock offered by it under this prospectus.

(2) This number represents the percentage of common stock to be owned by the selling stockholder after completion of the offering, based on the number of shares of common stock outstanding as of June 30, 2003 (16,765,903 shares).

USE OF PROCEEDS

We will not receive any proceeds from the sale by the selling stockholder of the common stock covered by this prospectus.

PLAN OF DISTRIBUTION

The selling stockholder, or its pledgees, donees, transferees, or any of its successors in interest (including shareholders and noteholders of the selling stockholder that receive their shares from the selling stockholder as a gift, distribution upon liquidation or dissolution, partnership distribution or other non-sale related transfer after the date of this prospectus), may sell the securities from time to time on the American Stock Exchange or any other stock exchange or automated interdealer quotation system on which the securities are listed, in the over-the-counter market, in privately negotiated transactions or otherwise, 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 prices otherwise negotiated. The selling stockholder as used in this section of the prospectus shall refer to the selling stockholder, or its pledgees, donees, transferees, or any of its successors in interest (including shareholders and noteholders of the selling stockholder that receive their shares from the selling stockholder as a gift, distribution upon liquidation or dissolution, partnership

distribution or other non-sale related transfer after the date of this prospectus). The selling stockholder may sell the securities by one or more of the following methods, without limitation:

(a) block 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;

(b) purchases by a broker or dealer as principal and resale by the broker or dealer for its own account pursuant to this prospectus;

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(c) a special offering, an exchange distribution or a secondary distribution in accordance with the rules of any stock exchange on which the securities are listed;

(d) ordinary brokerage transactions and transactions in which the broker solicits purchases;

(e) privately negotiated transactions;

(f) short sales;

(g) through the writing of options on the securities, whether or not the options are listed on an options exchange;

(h) through the distribution of the securities by the selling stockholder to its partners, members, noteholders or stockholders, including through distributions in connection with the dissolution or liquidation of the selling stockholder;

(i) one or more underwritten offerings on a firm commitment or best efforts basis;

(j) sales at other than a fixed price to or through a market maker or into an existing trading market, on an exchange or otherwise, for such securities;

(k) through agreements between a broker or dealer and the selling stockholder to sell a specified number of the securities at a stipulated price per share; and

(l) any combination of any of these methods of sale.

The selling stockholder may also transfer the securities by gift.

The selling stockholder may arrange for other brokers or dealers to participate in effecting sales of the securities. These brokers or dealers may act as principals or agents of the selling stockholder. Broker-dealers may agree with the 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 the 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. Broker-dealers will receive commissions or other compensation from the selling stockholder in amounts to be negotiated immediately prior to the sale that will not exceed those customary in the types of transactions involved. Broker-dealers may also receive compensation from purchasers of the securities which is not expected to exceed that customary in the types of transactions involved. The selling stockholder may also sell the securities in accordance with Rule 144 under the Securities Act, rather than pursuant to this prospectus, regardless of whether the securities are covered by this prospectus.

From time to time, the selling stockholder may pledge, hypothecate or grant a security interest in some or all of the securities owned by it. 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 the selling stockholder s securities offered under this prospectus will decrease as and when it takes such actions. The plan of distribution for the selling stockholder s securities will otherwise remain unchanged. In addition, the 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.

To the extent required under the Securities Act, the aggregate amount of the selling stockholder s securities being offered and the terms of the offering, the names of any agents, brokers, dealers or underwriters and any applicable commission with respect to a particular offer will be set forth in an accompanying prospectus

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supplement. Any underwriters, dealers, brokers or agents participating in the distribution of the securities may receive compensation in the form of underwriting discounts, concessions, commissions or fees from the selling stockholder and/or purchasers of the selling stockholder s securities, for whom they may act (which compensation as to a particular broker-dealer might be in excess of customary commissions).

The selling stockholder 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, 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.

The 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 the selling stockholder, including, without limitation, in connection with distributions of the securities by those broker-dealers. The 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. The 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 stockholder and other persons participating in the sale or distribution of the securities will be subject to applicable provisions of the Securities Exchange Act, and the rules and regulations thereunder, including Regulation M. This regulation may limit the timing of purchases and sales of any of the securities by the selling stockholder and any other person. The anti-manipulation rules under the Securities Exchange Act may apply to sales of securities in the market and to the activities of the selling stockholder and its 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.

We have agreed to indemnify and hold harmless the selling stockholder and each person, if any, who controls the selling stockholder within the meaning of the Securities Act (and, with respect to the selling stockholder, its officers, directors and underwriters) against specified liabilities, including liabilities under the federal securities laws. The selling stockholder has agreed to indemnify and hold harmless us, certain directors, officers and control persons against specified liabilities, including liabilities under the federal securities laws.

The securities offered hereby were originally issued to the selling stockholder pursuant to an exemption from the registration requirements of the Securities Act. We agreed to register the securities under the Securities Act. We have agreed to pay certain of the expenses relating to the offering and sale of the securities.

We will not receive any proceeds from the sale by the selling stockholder of the common stock covered by this prospectus.

We cannot assure you that the selling stockholder will sell all or any portion of the securities offered hereby.

We will supply the selling stockholder and 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 in connection with any resale or redistribution by the selling stockholder, we will file a prospectus supplement setting forth:

the aggregate number of shares to be sold;

the purchase price;

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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 the 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.

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. We incorporate by reference the specific documents listed below and 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 until the selling stockholder sell all of the securities registered hereunder:

Annual Report on Form 10-K for the year ended December 31, 2002;

Quarterly Report on Form 10-Q for the quarter ended March 31, 2003;

Current Report on Form 8-K, event date September 20, 2002, which was filed on October 4, 2002, as amended by the Current Report on Form 8-K/A filed on October 8, 2002 and the Current Report on Form 8-K/A filed on November 6, 2002;

Current Report on Form 8-K, event date February 19, 2003, which was filed on February 19, 2003;

Current Report on Form 8-K, event date April 11, 2003, which was filed on April 18, 2003, as amended by the Current Report on Form 8-K/A filed on May 29, 2003;

Current Report on Form 8-K, event date June 6, 2003, which was filed on June 10, 2003;

Current Report on Form 8-K, event date June 30, 2003, which was filed on July 9, 2003;

Current Report on Form 8-K, event date July 30, 2003, which was filed on August 1, 2003; and

the description of our common stock contained in the Registration Statement on Form 8-A, filed on November 21, 2001, and all amendments and reports updating such description.

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 Inverness Medical Innovations, Inc. appearing in Inverness Medical Innovations, Inc. s Form 10-K for the year ended December 31, 2002, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of our company, as of December 31, 2001 and 2000, and for each of the two years in the period ended December 31, 2001, incorporated by reference in this prospectus and elsewhere in the registration statement were audited by Arthur Andersen LLP, independent public accountants.

The financial statements of MedPointe Inc.-Wampole Division as of March 31, 2002 and 2001 and for the periods from September 29, 2001 to March 31, 2002 and April 1, 2001 to September 28, 2001 and for the year ended March 31, 2001 have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering these financial statements refers to a discussion in Note 1 to the Wampole financial statements regarding, effective September 28, 2001 MedPointe Inc. s acquisition of all of the outstanding stock of Carter-Wallace, Inc., of which Wampole was a division, in a business combination accounted for as a purchase. As a result of the acquisition, the financial information for the period after the acquisition is presented on a different cost basis than that for the periods before the acquisition and, therefore, is not comparable. Also, the audit report covering these financial statements refers to a discussion in Note 2 to the Wampole financial statements regarding MedPointe Inc. s adoption of the provisions of Statement of Financial Accounting Standards (SFAS) No. 141, *Business Combinations*, and the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, effective September 28, 2001 in connection with its acquisition of Carter-Wallace, Inc.

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

Goodwin Procter LLP, Boston, Massachusetts, will pass upon the validity of the shares of our common stock offered by this prospectus. The owners and presidents of four professional corporations, which are partners in the firm of Goodwin Procter LLP beneficially own an aggregate of approximately 4,133 shares of Inverness common stock, 6,666 shares of Inverness common stock, 1,666 shares of Inverness common stock and 23,361 shares of Inverness common stock, respectively.

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134,698 Shares

INVERNESS MEDICAL INNOVATIONS, INC.

Common Stock

PROSPECTUS

, 2003

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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	$ 218.00
Accountants fees and expenses	15,000.00
Blue Sky fees and expenses	0.00
Legal fees and expenses (other than Blue Sky)	20,000.00
Printing expenses	5,000.00
Miscellaneous	10,000.00
TOTAL	$ 50,218.00

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 Goodwin Procter LLP
*23.1	Consent of Ernst & Young LLP
*23.2	Consent of KPMG LLP
23.3	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1	Power of Attorney (contained in signature page)

* Filed herewith.
Previously filed.

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

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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 a 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 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 hereof.

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 August 5, 2003.

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)	August 5, 2003
/s/ DUANE L. JAMES **Duane L. James**	Vice President of Finance and Treasurer (Principal Financial Officer and Principal Accounting Officer)	August 5, 2003
* **Ernest A. Carabillo, Jr.**	Director	August 5, 2003
* **Carol R. Goldberg**	Director	August 5, 2003
* **Robert P. Khederian**	Director	August 5, 2003
* **John F. Levy**	Director	August 5, 2003
* **Jerry McAleer, Ph.D.**	Director	August 5, 2003

*	Director	August 5, 2003
David Scott, Ph.D.		
*	Director	August 5, 2003
Peter Townsend		
*	Director	August 5, 2003
John A. Quelch		
* By: /s/ RON ZWANZIGER		
Ron Zwanziger		
Attorney-in-fact		

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