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INVERNESS MEDICAL INNOVATIONS INC

Form S-3/A

May 14, 2002

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MAY 14, 2002

REGISTRATION STATEMENT NO. 333-85658

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
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AMENDMENT NO. 1

TO

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933  
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INVERNESS MEDICAL INNOVATIONS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE 04-3565120  
(State or other jurisdiction (I.R.S. Employer  
of Identification Number)  
incorporation or organization)

-----  
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, PRESIDENT AND CHIEF EXECUTIVE OFFICER  
Inverness Medical Innovations, Inc.  
51 Sawyer Road, Suite 200  
Waltham, Massachusetts 02453  
(781) 647-3900

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

COPIES OF ALL COMMUNICATIONS SHOULD BE SENT TO:
SCOTT F. DUGGAN, ESQ.
Goodwin Procter LLP
Exchange Place
Boston, Massachusetts 02109-2881
(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(c) 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 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8(a), MAY DETERMINE.

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

SUBJECT TO COMPLETION, DATED MAY 14, 2002

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PROSPECTUS

5,560,238 SHARES

INVERNESS MEDICAL INNOVATIONS, INC.

COMMON STOCK  
(par value \$0.001 per share)

This prospectus relates to the offer and sale by the selling stockholders identified in this prospectus, and any of their pledgees, donees, transferees or other successors in interest, of up to an aggregate of 5,560,238 shares of common stock of Inverness Medical Innovations, Inc. The shares include up to (1) 5,053,826 shares of common stock issued or issuable upon the conversion of Series A Convertible Preferred Stock and (2) 506,412 shares of common stock issuable upon the exercise of warrants. We are filing the registration statement of which this prospectus is a part at this time primarily to fulfill contractual obligations to do so, which we undertook at the time of the original issuance of the shares of Series A Convertible Preferred Stock and the warrants. We will not receive any of the proceeds from the sale of the common stock by the selling stockholders, but we are bearing the expenses of registration.

Our common stock is listed on the American Stock Exchange under the symbol "IMA." On May 13, 2002, the last reported sale price of our common stock on the American Stock Exchange was \$27.00.

SEE "RISK FACTORS" BEGINNING ON PAGE 2 FOR A DISCUSSION OF CERTAIN FACTORS THAT YOU SHOULD CONSIDER BEFORE YOU INVEST IN OUR COMMON STOCK.

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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.

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The date of this Prospectus is \_\_\_\_\_, 2002

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YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED OR INCORPORATED BY REFERENCE IN THIS PROSPECTUS. NEITHER WE NOR THE SELLING STOCKHOLDERS HAVE AUTHORIZED ANYONE ELSE TO PROVIDE YOU WITH DIFFERENT OR ADDITIONAL INFORMATION.

THIS PROSPECTUS IS NEITHER AN OFFER TO SELL NOR A SOLICITATION OF AN OFFER TO BUY SHARES OF COMMON STOCK IN ANY JURISDICTION IN WHICH AN OFFER OR SALE WOULD BE UNLAWFUL. YOU SHOULD NOT ASSUME THAT THE INFORMATION CONTAINED IN THIS PROSPECTUS IS CORRECT ON ANY DATE AFTER THE DATE OF THIS PROSPECTUS STATED AT THE BOTTOM OF THE COVER PAGE HEREOF, EVEN THOUGH THIS PROSPECTUS IS DELIVERED, OR THE SELLING STOCKHOLDERS OFFER OR SELL THE SHARES OF COMMON STOCK, ON A LATER DATE.

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 18 OF THIS PROSPECTUS. YOU SHOULD ALSO CAREFULLY CONSIDER THE VARIOUS RISK FACTORS BEGINNING ON PAGE 2 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.

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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. To a lesser extent, we develop, manufacture and market clinical diagnostic products for use by medical professionals. Our consumer self-test diagnostic products allow 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

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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 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 ovulation prediction tests. We also sell a wide variety of vitamins and nutritional supplements. Our clinical diagnostic products include test kits used by smaller laboratories, physicians' offices and other point-of-care sites for the detection of pregnancy and a wide variety of infectious diseases.

Inverness Medical Innovations, Inc. is a Delaware corporation. Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, MA 02453. Our telephone number is (781) 647-3900. Our website is <http://www.invernessmedical.com>. Our common stock is listed on the American Stock Exchange under the symbol "IMA."

### THE OFFERING

This prospectus relates to up to 5,560,238 shares of our common stock that may be offered for sale by the selling stockholders. The shares include up to (1) 5,053,826 shares of common stock issued or issuable upon the conversion of Series A Convertible Preferred Stock and (2) 506,412 shares of common stock issuable upon the exercise of warrants. 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 of Series A Convertible Preferred Stock and the warrants. Registration of the common stock does not necessarily mean that all or any portion of such stock will be offered for sale by the selling stockholders.

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

### PLAN OF DISTRIBUTION

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

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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 18 of this prospectus.

### RISKS RELATED TO THE SPLIT-OFF

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On November 21, 2001, we were split-off from Inverness Medical Technology, Inc. (IMT), our former parent, 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. We continue to face a unique set of challenges and risks arising out of the split-off.

OUR BUSINESSES WILL FACE CHALLENGES AS PART OF A STAND-ALONE COMPANY THAT WE DID NOT EXPERIENCE AS PART OF IMT.

As an independent, publicly owned company, we now face new issues and challenges that we did not experience when we were part of IMT. Examples of potential issues include:

- our inability to rely on the long-term financial strength of IMT;
- our inability to rely on the earnings, cash flow, assets and goodwill of IMT's diabetes business;
- our inability to rely on the experience and business relationships of some personnel who remained with IMT;
- greater difficulty in obtaining financing on terms satisfactory to us, if needed;
- greater difficulty in obtaining and maintaining insurance on terms that are acceptable to us;
- increased costs of hiring and retaining employees in departments previously shared by all the businesses of IMT, including the legal, risk management, tax, treasury, human resources and public relations departments; and
- generally increased overhead and administrative costs as a result of establishing a stand-alone company.

We may not resolve these issues or overcome these challenges. As a result, we may not succeed in generating and expanding customer relationships, containing costs and expenses and enhancing our business. In addition, competitive and market factors specific to the consumer diagnostics, vitamins and nutritional supplements and clinical diagnostics industries will more significantly impact our smaller, less diversified company.

OUR BUSINESSES TRADITIONALLY RELIED ON IMT FOR FINANCIAL ASSISTANCE AND MAY HAVE DIFFICULTY WITH LIQUIDITY AND CAPITAL REQUIREMENTS WITHOUT THIS ASSISTANCE.

Prior to the split-off, our businesses relied on the earnings, assets and cash flow of IMT for liquidity, capital requirements and administrative services. In the past, when the liquidity needs of our businesses exceeded their cash flow, IMT provided the necessary funds. As a result of the split-off, we can no longer rely on IMT for financial assistance. Accordingly, if we are unable to generate sufficient cash flow or borrow sufficient amounts under our credit facilities to fund our working capital needs and to pay our debts, we will need to obtain additional financing. We do not know if we can obtain

additional financing or if the terms of any required financing will be acceptable to us. If we are unable to fund our working capital needs and

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additional growth through our existing credit facilities, cash flow, or additional financing, or if additional financing is not available under acceptable terms to us, our business prospects, results of operations, cash flow and future growth will be negatively affected.

OUR HISTORICAL FINANCIAL INFORMATION MAY NOT BE REPRESENTATIVE OF OUR RESULTS AS A SEPARATE COMPANY.

Certain historical financial information included in our reports filed from time to time with the Securities and Exchange Commission, including our annual report on Form 10-K, as amended, for the year ended December 31, 2001 and our quarterly report on Form 10-Q for the quarter ended March 31, 2002, reports on time periods prior to the split-off and reflects the operating history of our businesses when they were a part of IMT. As a result, this 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 such periods. This financial information also may not reflect what our results of operations, financial position and cash flows will be in the future. This is not only related to the various risks associated with the fact that we have not been a stand-alone company for a long period of time, but also because:

- various adjustments and allocations were made to the financial statements included in such reports because IMT did not account for us as a single stand-alone business for any period prior to the split-off; and
- the information 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 such financial information may not appropriately reflect our operations during the periods prior to the split-off presented as if we had operated as a stand-alone company during such periods.

THE CHANGE OF SOME PERSONNEL IN OUR COMPANY IN CONJUNCTION WITH THE SPLIT-OFF MAY IMPACT OUR BUSINESS.

Some of IMT's personnel became our initial employees, while others did not. In particular, certain significant employees of IMT who were engaged primarily in the diabetes care products business remained with that business. In addition, some members of IMT's management who worked substantially for IMT's diabetes care products business became our employees. Finally, some IMT personnel who provided services beneficial to our businesses through their work in IMT's accounting, sales, marketing, operations, quality assurance, regulatory compliance and other areas did not become part of our company after the split-off or, in certain cases, their services may only be available to us on a transitional basis for a short period of time. The loss of certain significant employees, the transition of personnel from IMT's diabetes business to our company and the loss of other IMT personnel who will not become our employees may impact or disrupt our sales and marketing activities, our research and development efforts or our administrative functions.

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

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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. Because we have been listed for only a short period of time, we cannot assure you that an active trading market in our common stock will develop or be sustained in the future. Our common stock may experience volatility until trading values become established. As a result, it could be difficult to make purchases or sales of our common stock in the market at any particular time.

IMT stockholders immediately prior to the split-off became stockholders of our company immediately after the split-off. Some stockholders who received our common stock in the split-off may

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decide that they do not want to maintain an investment in a company involved primarily in consumer and clinical diagnostic products and vitamins and nutritional supplements or in a public company that has a limited track record as a stand-alone company. If these stockholders decide to sell all or some of their shares or if the market perceives that those sales could occur, the trading value of your shares may decline. In addition, because we will be a smaller and less diversified company than IMT, market analysts and the investment community may not follow our common stock as closely as they have followed IMT common stock in the past. If there is only a limited following by market analysts or the investment community, the amount of market activity in our common stock may be reduced, making 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



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sales could occur;

- changes in investor perception of our industry, our businesses or our prospects; or
- other developments affecting us or our competitors.

WE ARE OBLIGATED TO INDEMNIFY IMT AND OTHERS FOR LIABILITIES WHICH COULD REQUIRE US TO PAY IMT 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. We are also required to indemnify IMT for losses, if any, arising from the failure to amend some outstanding warrants for the purchase of IMT common stock.

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 clinical 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

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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.

### RISKS RELATED TO OUR BUSINESS

OUR BUSINESS HAS SUBSTANTIAL INDEBTEDNESS WHICH COULD RESULT IN ADVERSE CONSEQUENCES FOR US.

As of March 31, 2002, we had approximately \$66.7 million of outstanding indebtedness under our credit facilities and other debt-related instruments. Our substantial level of debt affects our future operations in several important ways, including the following:

- our ability to obtain additional financing may be impaired;
- our flexibility to adjust to market conditions is limited, 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;
- we may need 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

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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

- we may be at a competitive disadvantage compared to our competitors that have less debt.

Furthermore, there can be no assurance 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 capital or finance lease expenditures; and
- dispose of assets.

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

OUR CREDIT FACILITIES CONTAIN CERTAIN FINANCIAL COVENANTS AND OTHER CONDITIONS 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, 2002, we had approximately \$59.3 million of outstanding indebtedness under our various credit facilities, substantially all of which were owed to The Royal Bank of Scotland plc and related entities 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 interest coverage, cash flow coverage, leverage and EBITDA. 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. Additionally, under the terms of our credit facilities with The Royal Bank of Scotland plc and related entities, if either Ron Zwanziger or David Scott ceases to be a member of our board of directors, the full amount of our indebtedness under these credit facilities will accelerate. Mr. Zwanziger and Dr. Scott, both of whom

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are executive officers of our company, are currently serving on our board of directors; however, there is no assurance that they will continue to do so.

RIISING INTEREST RATES WOULD INCREASE OUR INTEREST COSTS AND REDUCE OUR EARNINGS.

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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.

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, technology we own or license may have potential applications to this field, and our research and development capabilities could be applied to this field. In conjunction with the split-off and merger, however, we agreed in the post-closing covenants agreement not to compete with IMT and Johnson & Johnson in the field of diabetes. In addition, Ron Zwanziger, our Chairman, President and Chief Executive Officer, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar obligations. Further, the license agreement 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.

OUR ACQUISITIONS OF CERTAIN ENTITIES AND BUSINESSES (THE UNIPATH BUSINESS) OF UNILEVER PLC (UNILEVER) AND IVC INDUSTRIES, INC. (IVC) MAY NOT BE PROFITABLE OR SUCCESSFULLY INTEGRATED AND WILL RESULT IN SIGNIFICANT CHARGES AGAINST EARNINGS.

On December 20, 2001, we acquired the Unipath business from Unilever and certain affiliated entities. On March 19, 2002, we acquired IVC. The value of the Unipath business and IVC to us may not be greater than or equal to their purchase prices. Further, we cannot guarantee that we will realize any of the benefits or strategic objectives we are seeking to obtain by acquiring the Unipath business or IVC. In connection with accounting for the acquisition of the Unipath business, we have recorded a significant amount of intangible assets. Under Statement of Financial Accounting Standards (SFAS) No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS, 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. In addition, in connection with the acquisition of the Unipath business, the portion of the purchase price allocated to in-process research and development projects that had not reached technological feasibility was charged to expense during the fourth quarter of 2001. To bring these projects to technological feasibility, high-risk development and testing issues will need to be resolved that will require substantial additional effort and expense.

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 PRIMARY OPERATING FACILITY OF THE UNIPATH BUSINESS WHICH IS LOCATED IN BEDFORD, ENGLAND.

The primary operating facility of the Unipath business that we acquired from Unilever is located in Bedford, England. The Bedford facility is a multi-purpose facility that is registered with the United States Food and Drug Administration (FDA), contains state-of-the-art research laboratories and is equipped with

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specialized manufacturing equipment. This facility currently provides the manufacturing for the Unipath business that we recently acquired, serves as our research and development center and serves as the administrative center for our European operations. We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the

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Unipath business. 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 recently indicated that it will not consent to an assignment of the lease to us but will consider a sublease. The terms of our acquisition of the Unipath business 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 a 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 its 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, 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. Additionally, there are no assurances 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.

IF WE CHOOSE TO ACQUIRE OR INVEST IN NEW AND COMPLEMENTARY BUSINESSES, PRODUCTS OR TECHNOLOGIES INSTEAD OF DEVELOPING THEM OURSELVES, THESE ACQUISITIONS OR INVESTMENTS COULD DISRUPT OUR BUSINESS AND, DEPENDING ON HOW WE FINANCE THESE ACQUISITIONS OR INVESTMENTS, COULD RESULT IN SIGNIFICANT DILUTION TO OUR EXISTING STOCKHOLDERS.

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 complementary 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;

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- 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:

- dilutive issuances of 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 liabilities;
- unfavorable financing terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the writedown of which may result in significant charges to earnings.

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

### MANUFACTURING PROBLEMS OR DELAYS COULD SEVERELY AFFECT OUR BUSINESS.

We produce our consumer products in our manufacturing facilities located in New Jersey and in Bedford, England and Galway, Ireland and our clinical diagnostic tests in our manufacturing facilities located in Bedford and in Yavne, Israel. Our production processes are complex and require specialized and expensive equipment. We rely on third parties to supply production materials and in some cases there may not be alternative sources immediately available. In addition, until we are able to consolidate manufacturing of our vitamins and nutritional supplements in our New Jersey manufacturing facilities, we will continue to rely, in part, upon third parties to manufacture these products. Any event impacting these facilities or our contract manufacturers or suppliers could delay or suspend shipments of products, or could result in the delivery of inferior products. Our revenues from the affected products would decline until such time as we were able to 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.

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 governments, as well as the FDA. 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

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order to meet our customers' demands.

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 clinical 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 THE NUTRITIONAL SUPPLEMENTS THAT WE SOLD PRIOR TO ACQUIRING IVC HAVE DECLINED EACH YEAR 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 the nutritional products that we sold prior to acquiring IVC have declined each year since 1998 and we have budgeted for future sale declines for those products. We believe that those products have under-performed because they are, for the most part, aging brands with limited brand retention 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.

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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 generate attention in the marketplace. Positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also impact individual brands. Conversely, news that challenges individual segments or products can have a negative impact on the industry overall as well as on sales of the challenged segments or products. Most of our vitamin and nutritional supplements products, including most of the vitamins and nutritional products that we acquired from IVC, serve well-established market segments and, absent unforeseen new developments or trends, are not expected to benefit from rapid growth. A few of the vitamin and nutritional products acquired with IVC 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 challenges the safety or effectiveness of these product could negatively impact the profitability of our vitamin and nutritional supplements business.

SALES OF OUR CLINICAL DIAGNOSTICS PRODUCTS COULD SUFFER IF ECONOMIC TRENDS IN THE HEALTH CARE INDUSTRY HARM OUR NICHE MARKET OF SMALL AND MEDIUM SIZED LABORATORIES.

Our Clearview-Registered Trademark- clinical diagnostic products are low cost alternatives to expensive and time consuming centralized testing marketed to point-of-care professionals. Organics sells clinical diagnostics products

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targeted at a niche market of small and medium sized decentralized laboratories in developing nations. To the extent that trends or changes in the health care industry favor economies of scale and centralized, automated laboratory testing, sales of our clinical diagnostics products could suffer.

REVENUE FROM OUR CLINICAL DIAGNOSTICS BUSINESS MAY DECLINE IN THE FUTURE BECAUSE TRENDS IN THE OVERALL MARKET FAVOR DIRECT DISEASE DETECTION OVER IMMUNE RESPONSE TESTING.

New technologies have made it possible to directly identify the presence of disease rather than detecting the presence of antibodies produced through an immune response. The trend of the overall market currently favors direct detection over antibody detection. Virus detection through nucleic acid testing, or NAT, is already mandatory for hepatitis C virus and other markers in France, Australia and certain other developed nations. We believe that the threat from direct detection technology in our core market of small and medium sized decentralized laboratories, small blood banks, physicians and other point of care facilities, particularly in under developed nations, is several years away. However, this trend poses a risk to our core clinical diagnostics business in the long term.

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WE MARKET OUR ORGENICS CLINICAL DIAGNOSTICS PRODUCTS TO SMALL AND MEDIUM SIZED CUSTOMERS IN MORE THAN 90 COUNTRIES AT CONSIDERABLE COST THAT REDUCES THE OPERATING MARGINS IN OUR ORGENICS CLINICAL DIAGNOSTICS BUSINESS.

Because small and medium sized laboratories are the principal customers of our Orgenics clinical diagnostic products, we sell these products worldwide in order to maintain sufficient sales volume. Our Orgenics clinical diagnostics products are marketed in more than 90 countries, including many third world and developing nations where smaller laboratories are the norm, where more expensive technologies are not affordable and where 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 clinical diagnostics business. The current material legal proceedings are:

- a lawsuit by Abbott Laboratories against us and Princeton BioMeditech Corporation, which manufactured products for our consumer diagnostics business while it was 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 lawsuit by Becton, Dickinson and Company alleging that pregnancy and ovulation test kits that we sell, and which we will continue to sell through our consumer diagnostics business, infringe U.S. Patent No. 4,703,017;
- complaints by Intervention, Inc. against us, four of our private label customers, whom we are defending under agreement, and certain other

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parties alleging that under Section 17200 of the California Business and Professions Code the defendants' labeling on their home pregnancy tests is misleading as to the level of accuracy under certain conditions; and

- an action brought by 69 consumers in London alleging defects in our Persona contraceptive device leading to unwanted pregnancies.

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, its liabilities in these lawsuits together with any other liabilities arising out of the women's health, nutritional supplements and clinical 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 and IVC 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. With the exception of certain customers of IVC, customers of our branded and private label consumer products businesses purchase products through purchase orders only and are not obligated to make future purchases. During

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calendar year 2001, purchase orders from Walgreen Co., CVS and Rite Aid accounted for approximately 29% of the net sales of our consumer products businesses, excluding the Unipath businesses and IVC. The loss of major customer, such as Walgreen, CVC or Rite Aid or the failure to generate new accounts could dramatically reduce revenues or prevent us from achieving projected growth.

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 is subject to numerous risks, including:

- decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;
- lower productivity resulting from difficulties managing our sales, support



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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.

BECAUSE OUR BUSINESS RELIES HEAVILY ON FOREIGN OPERATIONS AND, TO A LESSER EXTENT, FOREIGN SALES, 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. Organics has always made substantially all of its sales outside of the United States. Through our recent acquisitions of the Unipath business and IVC, we expect foreign sales to grow significantly. The Unipath business generated approximately 70% of its net product sales outside of the United States during 2001 and IVC generated almost 14% of its net product sales outside of the United States during its fiscal year ending July 31, 2001. 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 and South American 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.

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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, Organics Ltd., which develops, manufactures and sells certain of our clinical diagnostic products, is incorporated under the laws of the State of Israel. The administrative offices and development and manufacturing operations of our Organics business are located in Yavne, Israel. Although most of Organics' 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 Organics business could be adversely affected by any major hostilities involving Israel, including the current armed conflict with the Palestinian authority.

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 clinical 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 our maintaining a competitive position in the development of products and technologies in our areas of focus. Competitors may

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be more successful in:

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

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.

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.

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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;

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- 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 clinical 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 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 were made against us and we could not develop non-infringing

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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;

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- 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.

WE MAY BE UNABLE TO HIRE, RETAIN OR MOTIVATE KEY PERSONNEL, UPON WHOM THE SUCCESS OF OUR BUSINESS WILL DEPEND.

We are highly dependent upon certain members of our management and scientific staff, particularly Ron Zwanziger, David Scott and Jerry McAleer. We believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel. We face significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. We may fail to retain our key employees. Further, we may fail to attract, assimilate, retain or train other needed qualified employees in the future. We do not have employment agreements with all of our key employees. The loss of any of our key employees, including our scientists, may impact or disrupt our sales and marketing activities, our research and development efforts, our capital-raising efforts or our administrative functions.

WE MAY BE LIABLE FOR CONTAMINATION OR OTHER HARM CAUSED BY HAZARDOUS MATERIALS THAT WE USE.

Our research and development processes involve the use of hazardous materials. We are subject to federal, state and local regulation governing the use, manufacture, handling, storage and disposal of hazardous materials. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any contamination or injury. We may also incur expenses relating to compliance with environmental laws. Such expenses or liability could have a significant negative impact on our financial condition.

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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;

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- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;
- the availability and extent of reimbursement for our products;
- increased research and development expenses;
- the timing of any future acquisitions;
- general economic conditions; or
- general stock market conditions, other economic or external factors.

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, 2002, there were 2,360,246 shares of Series A Preferred Stock outstanding. Pursuant to the terms of the certificate of designation creating the 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 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 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 by-laws which 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 acquirors of 15% or more of our stock. Finally, the board of directors may in the future adopt a shareholder rights plan, which could delay, deter or prevent a change of control.

BECAUSE WE DO NOT INTEND TO PAY DIVIDENDS, 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 in the foreseeable future. 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 after the offering or even maintain the price at which you purchased your shares.

TERRORIST ATTACKS, SUCH AS THE ATTACKS THAT OCCURRED IN NEW YORK AND WASHINGTON, D.C. ON SEPTEMBER 11, 2001, AND OTHER ATTACKS OR ACTS OF WAR COULD ADVERSELY AFFECT OUR OPERATIONS, PROFITABILITY AND THE MARKETS IN WHICH WE OPERATE.

On September 11, 2001, the United States was the target of terrorist attacks of unprecedented scope. Attacks such as these could cause major instability in the United States and international financial markets and reduce consumer confidence. The terrorist attacks and the national and global responses to these terrorist attacks, many of which are still being formulated, including recent military, diplomatic and financial responses and any possible reprisals in the future, could result in disruptions of our manufacturing operations and the distribution of our products. These developments will subject us to increased risks and, depending on their magnitude, could have a material adverse effect on our business.

OUR INDEPENDENT PUBLIC ACCOUNTANT, ARTHUR ANDERSEN LLP, HAS BEEN INDICTED ON FEDERAL OBSTRUCTION OF JUSTICE CHARGES. THE INDICTMENT MAY IMPAIR OUR ABILITY TO ACCESS THE CAPITAL MARKETS, TO MAKE TIMELY FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION AND TO SATISFY ANY CLAIMS ARISING FROM THE PROVISION OF AUDITING SERVICES TO US.

Our independent public accountant, Arthur Andersen LLP, has informed us that on March 14, 2002, an indictment was unsealed charging it with federal obstruction of justice arising from the government's investigation of Enron Corp. Arthur Andersen has indicated that it intends to contest vigorously the indictment. As a public company we are required to file periodically with the Securities and Exchange Commission financial statements audited or reviewed by an independent public accountant. The Securities and Exchange Commission has recently adopted rules under which it will continue accepting financial statements audited or reviewed by Arthur Andersen. However, our access to the capital markets and our ability to make timely Securities and Exchange Commission filings, including filings incorporated by reference into this prospectus, could be impaired if the Securities and Exchange Commission ceases accepting financial statements audited by Arthur Andersen or if for any reason

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Arthur Andersen is unable to perform auditing services for us.

Although we do not believe that the outcome of the current indictment would materially adversely affect us, should we seek to access the public capital markets after we complete the offering of the securities offered hereby, and, if prior to that time the Securities and Exchange Commission ceases accepting financial statements audited by Arthur Andersen or if Arthur Andersen becomes unable to make the representations to us required by the Securities and Exchange Commission, it is possible that our existing audited financial statements might not satisfy the Securities and Exchange Commission's

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requirements. In that case, we may be unable to access the public capital markets unless another independent accounting firm is able to audit the financial statements originally audited by Arthur Andersen.

It is also possible that events arising out of the indictment may adversely affect the ability of Arthur Andersen to satisfy any claims arising from its provision of auditing services to us, including claims that may arise out of Arthur Andersen's audits of our financial statements incorporated by reference into this prospectus.

Any delay or inability to access the public capital markets caused by these circumstances could have a material adverse effect on our business, profitability and growth prospects.

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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 contain these words 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. 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;

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- 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;
- 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, and organizational restructuring 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 STOCKHOLDERS

We are filing this registration statement pursuant to the terms of registration rights granted to the selling stockholders in connection with certain capital raising transactions, described below, used to help finance our acquisition of the Unipath business. We acquired the Unipath business on



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December 20, 2001.

On December 20, 2001, we sold 1,995,000 shares of Series A Convertible Preferred Stock to private investors, including certain of our directors and related persons, at a purchase price of \$30.00 per share for aggregate consideration of \$59.85 million. The Series A Convertible Preferred Stock is currently convertible into common stock at a 2-for-1 ratio. As of March 31, 2002, 166,667 of these shares of Series A Convertible Preferred Stock were converted into 333,334 shares of common stock. Accordingly, as of March 31, 2002, the 1,828,333 of these shares of Series A Convertible Preferred Stock that remained outstanding were convertible into 3,656,666 shares of common stock. Under the terms of the related securities purchase agreement, we agreed to file the registration statement of which this prospectus is a part to register the sale by those investors of the shares of common stock underlying the shares of Series A Convertible Preferred Stock acquired by them. We also agreed to use our best efforts to cause the registration statement to be declared effective by the Securities and Exchange Commission by June 20, 2002, and to keep the registration statement effective until the earliest of (1) December 20, 2003, (2) the date on which the investors may sell their shares within a three-month period in accordance with Rule 144(k) and (3) such time as all of such shares have been sold pursuant to a registration statement.

On December 20, 2001, we sold subordinated promissory notes and warrants to private investors, including Zwanziger Family Ventures, LLC, an entity affiliated with Ron Zwanziger, our Chairman, President and Chief Executive Officer, for an aggregate purchase price of \$20.0 million. The notes were subsequently retired using the proceeds from the sale of additional shares of Series A Convertible Preferred Stock, as discussed below. The warrants, however, are still outstanding and are exercisable for an aggregate of 55,189 shares of common stock at an exercise price of \$18.12 per share. Under the terms of the related note and warrant purchase agreement, in connection with the filing of the registration statement of which this prospectus is a part, we agreed to use our reasonable best efforts to register the sale by the warrant holders of the shares of common stock issuable upon exercise of their warrants.

On December 20, 2001, we obtained a mezzanine credit facility from RBS Mezzanine Limited for an aggregate principal amount of up to \$10.0 million. In connection with the provision of this facility, we issued to RBS Mezzanine Limited a warrant to purchase 65,000 shares of common stock at an exercise price of \$0.001 per share. Under the terms of the warrant agreement, in connection with the filing of the registration statement of which this prospectus is a part, we agreed to use our reasonable best efforts to register the sale by RBS Mezzanine Limited of the shares of common stock issuable upon exercise of this warrant.

As a condition to our obtaining the mezzanine credit facility, RBS Mezzanine Limited required Zwanziger Family Ventures, LLC to enter into a lock-up agreement pursuant to which it agreed not to sell or transfer shares of common stock for a three-year period (subject to continuing volume limitations after such period). In consideration of such agreement, we issued to Zwanziger Family Ventures, LLC a warrant to purchase 385,000 shares of common stock at an exercise price of \$17.15 per share. Under the terms of the warrant agreement, in connection with the filing of the registration statement of which this prospectus is a part, we agreed to use our reasonable best efforts to register the sale by Zwanziger Family Ventures, LLC of the shares of common stock issuable upon exercise of this warrant.

In addition, on March 6, 2002, we sold an additional 531,913 shares of Series A Convertible Preferred Stock to private investors at a purchase price of

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\$39.01 per share for an aggregate consideration of \$20.75 million. The proceeds from the sale of these shares were used primarily to retire the subordinated promissory notes issued on December 20, 2001. As of March 31, 2002, these shares of Series A Convertible Preferred Stock were convertible into 1,063,826 shares of common stock. The investors purchasing these shares of Series A Convertible Preferred Stock have the same registration rights as the investors who purchased shares of Series A Convertible Preferred Stock on December 20, 2001.

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### THE SELLING STOCKHOLDERS

The following table sets forth the number of shares of common stock beneficially owned by the selling stockholders as of March 31, 2002, the number of shares of common stock covered by this prospectus and the total number of shares of common stock that the selling stockholders will beneficially own upon completion of this offering. This table assumes that the selling stockholders will offer for sale all of the shares of common stock covered by this prospectus.

The common stock offered by this prospectus may be offered from time to time by the selling stockholders named below, or by any of their 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 stockholders, or on our records, as of March 31, 2002 and are accurate to the best of our knowledge. It is possible, however, that the selling stockholders 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 MARCH 31, 2002 (1) -----	COMMON STOCK OFFERED HEREBY -----	COMMON STOCK TO BE OWNED AFTER OFFERING (2) -----	PERCENTAGE OF ALL COMMON STOCK -----
Auda Classic PLC.....	16,022	5,852 (4)	10,170	
The Avram J. Goldberg and Carol R. Goldberg Charitable Remainder Unitrust (12).....	16,666	16,666 (4)	0	
BNP Paribas.....	1,223	1,223 (5)	0	
J. Alexander Bodkin.....	43,332	33,334 (4)	9,998	
Ernest A. Carabillo, Jr. (13).....	25,549	20,000 (4)	5,549	
Martin Carmichael III (14).....	4,133	3,334 (4)	799	
Stephen W. Carr (14).....	6,666	6,666 (4)	0	
CLSP, L.P.....	170,200	170,200 (4)	0	
CLSP II, L.P.....	34,624	34,624 (4)	0	
CLSP Overseas Ltd.....	52,096	52,096 (4)	0	
CLSP SBS-I, L.P.....	51,110	51,110 (4)	0	
CLSP SBS-II, L.P.....	25,304	25,304 (4)	0	
Howard A. Cubell (14).....	1,666	1,666 (4)	0	
The Dialogue Fund LP.....	30,000	30,000 (4)	0	
Galleon Healthcare Offshore, Ltd.....	442,192	442,192 (6)	0	
Galleon Healthcare Partners, L.P.....	147,486	147,486 (7)	0	
Richard Gibbs.....	46,666	46,666 (4)	0	
Thelma N. Gibbs.....	23,774	13,334 (4)	10,440	

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GKJK Holdings, LP.....	51,268	51,268 (4)	0
Orit Goldstein(15).....	909,832	666,666 (4)	243,166
GS Private Equity Partners 2000, L.P....	194,852	194,852 (4)	0
GS Private Equity Partners 2000 -- Direct Investment Fund, L.P.....	72,642	72,642 (4)	0
GS Private Equity Partners 2000 Offshore Holdings, L.P.....	65,838	65,838 (4)	0
Irwin Heller.....	20,000	20,000 (4)	0
IMA, LLC.....	133,334	133,334 (4)	0
Robert P. Khederian(13).....	210,000	200,000 (4)	10,000
mRNA Fund II, L.P.(16).....	3,820	3,820 (4)	0
Lawrie Okurowski.....	47,740	5,519 (8)	42,221

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NAME -----	COMMON STOCK BENEFICIALLY OWNED AS OF MARCH 31, 2002 (1) -----	COMMON STOCK OFFERED HEREBY -----	COMMON STOCK TO BE OWNED AFTER OFFERING (2) -----	PERCENTAGE OF ALL C STOCK -----
Oxford Bioscience Partners IV L.P. (16).....	380,780	380,780 (4)	0	
John D. Patterson, Jr.(17).....	3,334	3,334 (4)	0	
Jay Pearlstein.....	39,611	33,334 (4)	6,277	
Perry Partners International, Inc.....	446,074	408,664 (4)	37,410	
Perry Partners LP.....	200,853	170,710 (4)	30,143	
RBS Mezzanine Limited.....	65,000	65,000 (9)	0	
Leroy Schecter.....	479,336	333,334 (4)	146,002	1
Andre A. Schwartz.....	12,594	8,334 (4)	4,260	
Paul D. Schwartz(14).....	23,361	13,334 (4)	10,027	
Machelle M. Seibel.....	31,101	20,000 (4)	11,101	
Sidney R. Rabb Trust f/b/o Carol R. Goldberg(18).....	16,666	16,666 (4)	0	
US Boston Corporation PSRP U/A/D 10/1/84 A/C L. Okurowski.....	50,868	8,279 (8)	42,589	
The Willard L. Umphrey 1996 Revocable Trust U/A/D 3/26/96(19).....	198,302	103,517 (10)	94,785	
Arie H. Zwanziger and Miriam Zwanziger(20).....	113,044	66,666 (4)	46,378	
Zwanziger Family Ventures, LLC(21).....	1,686,285	1,412,594 (11)	273,691	2
TOTAL.....	6,595,244	5,560,238	1,035,006	
	=====	=====	=====	

\* Less than one percent

(1) Includes shares issuable upon conversion of Series A Convertible Preferred Stock or exercise of warrants.

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- (2) Assumes that the selling stockholders will sell all shares of common stock offered by them under this prospectus.
- (3) For each selling stockholder, this number represents the percentage of common stock to be owned by such selling stockholder after completion of the offering, based on the number of shares of common stock outstanding as of March 31, 2002 (9,126,588 shares) and assuming (i) all shares of Series A Convertible Preferred Stock and warrants held by such selling stockholder have been converted or exercised, as applicable, and (ii) none of the shares of Series A Convertible Preferred Stock and warrants held by other persons have been converted or exercised, as applicable.
- (4) Represents shares of common stock issuable upon conversion of Series A Convertible Preferred Stock.
- (5) Represents 1,223 shares of stock issuable upon exercise of warrants held by BNP Paribas.
- (6) Represents (i) 249,934 shares of common stock issued upon conversion of Series A Convertible Preferred Stock and (ii) 192,258 shares of common stock issuable upon conversion of Series A Convertible Preferred Stock.
- (7) Represents (i) 83,400 shares of common stock issued upon conversion of Series A Convertible Preferred Stock and (ii) 64,086 shares of common stock issuable upon conversion of Series A Convertible Preferred Stock.

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- (8) Represents shares of common stock issuable upon exercise of warrants issued in connection with our \$20.0 million private placement of subordinated notes and warrants.
- (9) Represents shares of common stock issuable upon exercise of a warrant granted to the selling stockholder in connection with the provision of our \$10.0 million mezzanine credit facility.
- (10) Represents (i) 89,720 shares of common stock issuable upon conversion of Series A Convertible Preferred Stock and (ii) 13,797 shares of common stock issuable upon exercise of warrants issued in connection with our \$20.0 million private placement of subordinated notes and warrants.
- (11) Represents (i) 1,000,000 shares of common stock issuable upon conversion of Series A Convertible Preferred Stock, (ii) 27,594 shares of common stock issuable upon exercise of warrants issued in connection with our \$20.0 million private placement of subordinated notes and warrants and (iii) 385,000 shares of common stock issuable upon exercise of a warrant issued to the selling stockholder in consideration of its agreement not to sell or transfer shares of common stock for a three-year period (subject to continuing volume limitations after such period), which agreement was required by the banks as a condition to our obtaining the \$10.0 million mezzanine credit facility.
- (12) Carol R. Goldberg, one of our directors, is a trustee of The Avram J. Goldberg and Carol R. Goldberg Remainder Unitrust.
- (13) Selling stockholder is a director of our company.
- (14) Selling stockholder is the owner and president of a professional

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corporation that is a partner of Goodwin Procter LLP, our legal counsel.

- (15) Orit Goldstein is the sister of Ron Zwanziger, our Chairman, Chief Executive Officer and President. Of the shares attributed to her, Ms. Goldstein disclaims beneficial ownership of (i) 4,894 shares of common stock owned by her husband, (ii) 900 shares of common stock held in her husband's IRA and (iii) 100,230 shares of common stock owned by the Zwanziger Family Trust, of which Ms. Goldstein is a trustee.
- (16) Jonathan Fleming, general partner of the selling stockholder's general partner, is a former director of our former parent, Inverness Medical Technology, Inc.
- (17) John D. Patterson, Jr. is a partner of Foley, Hoag & Eliot LLP, our legal counsel.
- (18) Carol R. Goldberg, one of our directors, is a trustee and sole beneficiary of the Sidney R. Rabb Trust f/b/o Carol R. Goldberg.
- (19) Willard Umphrey, the trustee and beneficiary of the selling stockholder, is a former director of both our company and our former parent, Inverness Medical Technology, Inc.
- (20) Arie H. Zwanziger and Miriam Zwanziger are the parents of Ron Zwanziger, our Chairman, Chief Executive Officer and President.
- (21) Zwanziger Family Ventures, LLC is a beneficial owner of over 5% of our common stock. Ron Zwanziger, our Chairman, Chief Executive Officer and President, is a manager of Zwanziger Family Ventures, LLC.

### USE OF PROCEEDS

We will not receive any proceeds from the sale by the selling stockholders of the common stock covered by this prospectus. We will, however, receive the proceeds from the exercise of the warrants, if and when exercised by selling stockholders holding warrants. If those selling stockholders exercise in full their respective warrants covering an aggregate of 506,412 shares of common stock, we estimate that our net proceeds would be approximately \$7,617,442. We expect to use substantially all of the net proceeds from the exercise of the warrants for working capital and other general corporate purposes.

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### PLAN OF DISTRIBUTION

The selling stockholders, or their pledgees, donees, transferees, or any of their successors in interest, 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 stockholders" as used in this section of the prospectus shall refer to the selling stockholders, or their pledgees, donees, transferees, or any of their successors in interest. The selling stockholders 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;

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- (b) purchases by a broker or dealer as principal and resale by the broker or dealer for its own account pursuant to this prospectus;
- (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 any selling stockholder to its partners, members or stockholders;
- (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 one or more of the selling stockholders 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 stockholders may also transfer the securities by gift. We do not know of any arrangements by the selling stockholders for the sale of any of the securities.

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

as amended, rather than pursuant to this prospectus, regardless of whether the

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securities are covered by this prospectus.

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

To the extent required under the Securities Act of 1933, the aggregate amount of selling stockholders' 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 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 a selling stockholder and/or purchasers of a 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 stockholders and any underwriters, brokers, dealers or agents that participate in the distribution of the securities may be deemed to be "underwriters" within the meaning of the Securities Act of 1933, and any discounts, concessions, commissions or fees received by them and any profit on the resale of the securities sold by them may be deemed to be underwriting discounts and commissions.

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

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

We have agreed to indemnify and hold harmless the selling stockholders and each person, if any, who controls a selling stockholder within the meaning of the Securities Act of 1933 (and, with respect to one selling stockholder, its

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officers, directors and underwriters) against specified liabilities, including liabilities under the federal securities laws. The selling stockholders have agreed to indemnify and hold harmless us, certain directors, officers and control persons against specified liabilities, including liabilities under the federal securities laws.

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The securities offered hereby were originally issued to the selling stockholders pursuant to an exemption from the registration requirements of the Securities Act of 1933. We agreed to register the securities under the Securities Act of 1933. We will pay all expenses relating to the offering and sale of the securities, with the exception of commissions, discounts and fees of underwriters, broker-dealers or agents, taxes of any kind and any legal, accounting and other expenses incurred by the selling stockholders.

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

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

We will supply the selling stockholders 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 of 1933 in connection with any resale or redistribution by a selling stockholder, we will file a prospectus supplement setting forth:

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

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

### 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 stockholders sell all of the securities registered



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hereunder:

- our Annual Report on Form 10-K, as amended, for the year ended December 31, 2001;
- our Current Report on Form 8-K, event date December 20, 2001, which was filed on January 4, 2002, as amended by our Current Report on Form 8-K/A filed on March 5, 2002 and our Current Report on Form 8-K/A filed on May 7, 2002;
- our Current Report on Form 8-K, event date March 6, 2002, which was filed on March 14, 2002;
- our Current Report on Form 8-K, event date March 19, 2002, which was filed on March 29, 2002, as amended by our Current Report on Form 8-K/A filed on April 24, 2002;
- our Current Report on Form 8-K, event date April 11, 2002, which was filed on April 11, 2002;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2002; and
- the description of our common stock contained in our Registration Statement on Form 8-A, filed on November 21, 2001, and all amendments and reports updating such description.

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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.

### WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, 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 also obtain copies at the prescribed rates from the Public Reference Section of the Securities and Exchange Commission at its principal office in Washington, D.C. 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

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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. as of December 31, 2001 and 2000, and for each of the three years in the period ended December 31, 2001, incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by Arthur Andersen LLP, independent public accountants, as indicated in their report with respect thereto, and are incorporated by reference herein in reliance upon the authority of said firm as experts in accounting and auditing in giving said reports.

The financial statements of the Unipath Division of Unilever Plc as of November 30, 2001 and December 31, 2000, and for the eleven months ended November 30, 2001 and each of the two years in the period ended December 31, 2000, incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by Arthur Andersen LLP, independent public accountants, as indicated in their report with respect thereto, and are incorporated by reference herein in reliance upon the authority of said firm as experts in accounting and auditing in giving said report.

The consolidated financial statements of IVC Industries, Inc. as of July 31, 2001 and 2000, and for each of the three years in the period ended July 31, 2001, incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by Amper, Politziner & Mattia P.A., independent public accountants, as indicated in their reports with respect thereto, and are incorporated by reference herein in reliance upon the authority of said firm as experts in accounting and auditing in giving said reports.

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered hereby will be passed upon by our counsel, Goodwin Procter LLP. 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 our common stock, 6,666 shares of our common stock, 1,666 shares of our common stock and 23,361 shares of our common stock, respectively.

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5,560,238 SHARES  
INVERNESS MEDICAL INNOVATIONS, INC.  
COMMON STOCK

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PROSPECTUS

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, 2002

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

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### 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.....	\$11,637.58
Accountants' fees and expenses.....	10,000.00
Blue Sky fees and expenses.....	0.00
Legal fees and expenses (other than Blue Sky).....	35,000.00
Printing expenses.....	5,000.00
Miscellaneous.....	10,000.00
TOTAL.....	\$71,637.58

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 by-laws of Inverness Medical Innovations, Inc. ("Innovations") provides that Innovations 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 Innovations, or is or was serving, or has agreed to serve, at the request of Innovations, 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.

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Section 145(g) of the Delaware General Corporation Law and Article V of the by-laws of Innovations provide that Innovations 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.

Innovations has obtained insurance covering its directors and officers against losses and insuring Innovations 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 Innovations eliminates a director's personal liability for monetary damages to Innovations 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 Innovations 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, File No. 001-16789)
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, File No. 001-16789)
4.3	--Amended and Restated By-laws 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, File No. 001-16789)
+5.1	--Opinion of Goodwin Procter LLP
*23.1	--Consent of Arthur Andersen LLP

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- \*23.2 --Consent of Arthur Andersen LLP
- \*23.3 --Consent of Amper, Politziner & Mattia P.A.
- 23.4 --Consent of Goodwin Procter LLP (included in Exhibit 5.1)
- 24.1 --Power of Attorney (contained in signature page)
- 99.1 --Stock Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.2 to the Company's Form 8-K dated March 6, 2002, File No. 001-16789)

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EXHIBIT NO.	DESCRIPTION
99.2	--Note and Warrant Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.3 to the Company's Form 8-K dated December 20, 2001, File No. 001-16789)
99.3	--Form of Warrant for the Purchase of Common Stock of the Company issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.5 to the Company's Form 8-K dated December 20, 2001, File No. 001-16789)
99.4	--Warrant Agreement, dated as of December 20, 2001, by and between the Company and RBS Mezzanine Limited (incorporated by reference to Exhibit 10.26 to the Company's Form 10-K, as amended, for the year ended December 31, 2001, File No. 001-16789)
99.5	--Warrant to Purchase Common Stock of the Company, dated December 20, 2001, issued to RBS Mezzanine Limited (incorporated by reference to Exhibit 10.27 to the Company's Form 10-K, as amended, for the year ended December 31, 2001, File No. 001-16789)
99.6	--Warrant for the Purchase of Common Stock of the Company, dated as of December 20, 2001, issued to Zwanziger Family Ventures, LLC (incorporated by reference to Exhibit 10.28 to the Company's Form 10-K, as amended, for the year ended December 31, 2001, File No. 001-16789)

\* Filed herewith.

+ Previously filed.

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### ITEM 17. UNDERTAKINGS.

#### A. The undersigned Registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high and 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 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 undersigned registrant

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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 undersigned 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

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of 1933, may be permitted to directors, officers and controlling persons of the undersigned registrant pursuant to the foregoing provisions, or otherwise, the undersigned 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 undersigned registrant of expenses incurred or paid by a director, officer or controlling person of the undersigned 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 undersigned 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 May 14, 2002.

INVERNESS MEDICAL INNOVATIONS, INC.

By: /s/ RON ZWANZIGER

-----  
 Ron Zwanziger CHAIRMAN, PRESIDENT AND  
 CHIEF EXECUTIVE OFFICER

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.

NAME -----	TITLE -----	DATE -----
/s/ RON ZWANZIGER ----- Ron Zwanziger	Chairman, President and Chief Executive Officer (Principal Executive Officer)	May 14,
/s/ DUANE L. JAMES ----- Duane L. James	Vice President of Finance and Treasurer (Principal Financial Officer and Principal Accounting Officer)	May 14,
* -----	Director	May 14,

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Ernest A. Carabillo, Jr.

*		
-----	Director	May 14,
Carol R. Goldberg		
*		
-----	Director	May 14,
Robert P. Khederian		
*		
-----	Director	May ,
John F. Levy		
*		
-----	Director	May 14,
David Scott		
*		
-----	Director	May 14,
Peter Townsend		
-----	Director	May ,
Alfred M. Zeien		

\*By: /s/ RON ZWANZIGER  
 -----  
 Ron Zwanziger  
 ATTORNEY-IN-FACT

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EXHIBIT INDEX

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