

INVERNESS MEDICAL INNOVATIONS INC  
Form 424B2  
May 22, 2002

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**Filed pursuant to Rule 424(b)(2)  
Registration No. 333-87180**

**PROSPECTUS SUPPLEMENT  
(To Prospectus dated May 8, 2002)**

**1,600,000 Shares**

**Common Stock**

Inverness Medical Innovations, Inc. is selling 1,600,000 shares of its common stock.

Our common stock is traded on the American Stock Exchange under the symbol "IMA." On May 21, 2002, the closing price of our common stock as quoted on the American Stock Exchange was \$24.98 per share.

**Our business involves significant risks. These risks are described under the caption "Supplemental Risk Factors" on page S-8 of this prospectus supplement and under the caption "Risk Factors" on page 2 of the accompanying prospectus.**

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

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	<b>Per Share</b>	<b>Total</b>
Public offering price	\$23.000	\$36,800,000
Underwriting discounts and commissions	\$ 1.265	\$ 2,024,000
Proceeds, before expenses, to Inverness Medical Innovations	\$21.735	\$34,776,000

The underwriter may also purchase up to an additional 240,000 shares of common stock at the public offering price, less the underwriting discounts and commissions, to cover over-allotments.

The underwriter expects to deliver the shares in New York, New York on May 28, 2002.

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**SG COWEN**

May 21, 2002

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**You should read this prospectus supplement, along with the accompanying prospectus, carefully before you invest. Both documents contain important information you should consider when making your investment decision. This prospectus supplement contains information about the common stock offered in this offering. This prospectus supplement may add, update or change information contained in the accompanying prospectus.**

**You should rely only on information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information that is different. We are offering to sell and seeking offers to buy shares of common stock only in jurisdictions where such offers and sales are permitted. The information contained in this prospectus supplement and the accompanying prospectus is accurate only as of their respective dates, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock.**

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## PROSPECTUS SUPPLEMENT SUMMARY

*This summary only highlights the more detailed information appearing elsewhere in this prospectus supplement. As this is a summary, it may not contain all information that is important to you. You should read this entire prospectus supplement and the accompanying prospectus, including the documents incorporated by reference, carefully before you decide to invest in our common stock.*

*This prospectus supplement and the accompanying prospectus contain forward-looking statements. You should read the explanation of the qualifications and limitations on such forward-looking statements on page 16 of the accompanying prospectus. You should also carefully consider the various risk factors beginning on page S-8 of this prospectus supplement and on page 2 of the accompanying 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 supplement or the accompanying prospectus refer collectively to Inverness Medical Innovations, Inc. and its subsidiaries, and their respective predecessor entities for the applicable periods, considered as a single enterprise.*

**Inverness Medical Innovations, Inc.**

We develop, manufacture and market consumer health care 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, nonprescription basis, without the expense, inconvenience and delay associated with physician visits or laboratory testing. This information gives individuals greater control over their health and their lives, allowing them to make informed decisions and take action to protect their health, alone or in consultation with health care 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. We have more than 40 patents in the United States and more than 300 patents in various foreign countries.

**Our History**

On November 21, 2001, Johnson & Johnson acquired Inverness Medical Technology, Inc., or IMT, our former parent, in a merger transaction and, simultaneously, our company was split off from IMT as a separate publicly traded company. Immediately prior to the consummation of these transactions, IMT restructured its operations so that we would hold all of IMT's non-diabetes businesses (women's health, nutritional supplements and clinical diagnostics). At the closing of the transaction, all of the shares of our common stock held by IMT were split-off from IMT in a pro rata distribution to IMT's stockholders, and IMT (which then consisted of its diabetes business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

On December 20, 2001, we acquired Unipath Limited, a global leader in home pregnancy and ovulation testing and natural family planning, and its associated companies and assets from Unilever plc and certain affiliated entities. The Unipath acquisition provides us with leading brand name consumer diagnostic products that complement our existing value branded and private label home pregnancy detection and ovulation prediction products. In connection with the acquisition of the

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Unipath business, we also acquired rights to certain antibody clones and other intellectual property rights.

On March 19, 2002, we acquired IVC Industries, Inc., a manufacturer and distributor of hundreds of different vitamin and nutritional supplement products sold under brand names and through private label arrangements with retailers. We are in the process of consolidating substantially all of our vitamin and nutritional supplement manufacturing at IVC and discontinuing most of our outsourced manufacturing arrangements.

**Our Products**

*Consumer Products*

Our consumer diagnostics business currently develops, manufactures and markets home pregnancy and ovulation prediction tests under our own brands and various private labels. Our ClearBlue brand of home pregnancy detection tests and our ClearPlan brand of ovulation prediction tests are global leaders in terms of both sales and technology, though ClearBlue has a smaller presence in the United States. Our Inverness Medical branded products are marketed to value-oriented consumers in the United States. In addition, we are a major domestic supplier of private label home pregnancy detection and ovulation prediction products. We also sell Persona, a contraceptive monitoring device sold overseas, primarily in Germany and the United Kingdom.

We also offer a wide variety of vitamins and nutritional supplements through retail drug store chains, mass merchandisers, food stores and warehouse clubs. We sell these products to value-oriented consumers under the Inverness Medical tradename, as well as under private labels. Through our recent acquisition of IVC, we are able to offer value-oriented customers IVC branded products. We also sell our Synergy Plus line of products primarily in health food stores.

*Clinical Diagnostics*

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We develop, manufacture and sell qualitative, visually-interpreted rapid diagnostic tests for use by medical professionals under our Clearview label and through our Organics subsidiary. These products are used in point-of-care environments or small laboratories where a rapid response is desired or where the volume of testing is too low to warrant high volume methods. These products are used to confirm pregnancy as well as to detect several infectious diseases, including HIV, hepatitis, chlamydia, streptococcal group A and infectious mononucleosis.

### Our Strategy

Our objective is to become the leading provider of innovative products in the areas of women's health and chronic disease self-management. The key elements of our strategy for achieving this goal are to:

*Continue developing innovative diagnostic products.* Prior to the split-off of our company as an independent public company in November 2001, our management team developed the first electrochemical blood glucose monitoring system and commercialized a system that measures blood glucose in the fastest time available with a small blood sample. In addition, our Unipath subsidiary, acquired in December 2001, was the first to develop a one-step home pregnancy test, a one-step ovulation test and an estrogen-based fertility monitor. We intend to leverage our collective experience in the rapid test diagnostic sector and our significant intellectual property portfolio to develop superior and innovative products in the areas of women's health and chronic disease self-management.

*Expand the application of our technology to develop products in other focus areas.* Currently, our diagnostic products are primarily used to detect pregnancy and predict ovulation. However, we believe there are additional market opportunities for us to pursue, both in women's health and in other areas.

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For example, we believe that the aging population may provide opportunities in other areas of women's health, such as osteoporosis and menopause, creating demand for consumer diagnostic products in those areas. We plan to continue investing in research and development and intend to begin commercially launching new products in our targeted areas by 2004, with a goal of launching at least one significant new product each year.

*Selectively acquire complementary product lines, companies and technologies.* We plan to pursue selective acquisitions that could advance our technologies, establish new products and increase market penetration and breadth of our product offerings. We have significant experience in evaluating and completing acquisitions of businesses, technologies and intellectual property and in integrating acquired businesses and commercializing acquired technology. We have recently completed and are integrating two acquisitions, Unipath and IVC.

*Maximize market penetration of our products.* We will continue to leverage our global marketing and sales force to further penetrate our existing markets through our relationships with leading retailers, including Walgreens, CVS, RiteAid and Boots, as well as with drug wholesalers and mass merchandisers. We believe that our high level of service and ability to provide a wide range of high quality consumer products, which include premium and value-oriented brands and private label products, enhances our existing customer relationships and helps us develop new relationships.

*Manufacture high quality products at low cost.* One of the most significant contributors to our growth will be to leverage and enhance manufacturing operations for our products. We produce nearly all of our disposable consumer diagnostic products at our facilities in Bedford, England and Galway, Ireland, both of which are ISO and FDA registered establishments that employ modern production techniques to produce consistent, high quality products at low cost.

### Corporate Information

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, MA 02453. Our telephone number is (781) 647-3900. Our website address is [www.invernessmedical.com](http://www.invernessmedical.com). The information found on our website is not a part of this prospectus supplement or the accompanying prospectus. Our common stock is listed on the American Stock Exchange under the symbol "IMA."

Additional information regarding our company, including our audited financial statements, is contained in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus. See "Incorporation of Documents by Reference" and "Where You Can Find More Information" on pages 24 and 25, respectively, of the accompanying prospectus.

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**The Offering**

Common stock we are offering	1,600,000 shares
Common stock to be outstanding after this offering	10,726,588 shares
Underwriter's over-allotment option	240,000 shares
Use of proceeds	We intend to use the net proceeds from the sale of the common stock offered hereby for working capital and other general corporate purposes, including possible acquisitions and strategic transactions. You should read the discussion under the heading "Use of Proceeds" for more information.
American Stock Exchange symbol	IMA

The number of shares of our common stock to be outstanding after this offering is based upon our shares of common stock outstanding as of March 31, 2002 and assumes that no options or warrants have been exercised and no shares of Series A Preferred Stock have been converted since March 31, 2002. In addition, this information excludes:

4,720,492 shares of common stock issuable upon conversion of shares of our Series A Preferred Stock outstanding as of March 31, 2002;

an aggregate of 2,303,018 shares of common stock subject to outstanding options as of March 31, 2002 at a weighted average exercise price of \$14.70 per share;

an additional 366,199 shares of common stock reserved for issuance upon exercise of options that may be granted subsequent to March 31, 2002 under our 2001 Stock Option and Incentive Plan;

500,000 shares of common stock reserved for issuance under our Employee Stock Purchase Plan;

563,818 shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2002 at a weighted average exercise price of \$14.32 per share; and

up to 240,000 shares of common stock issuable upon exercise of the underwriter's over-allotment option.

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You should read the discussion under the heading "Capitalization" for more information regarding the outstanding shares of our common stock and shares of our Series A Preferred Stock, as well as warrants and options to purchase our common stock.

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**Summary Consolidated Financial Data**  
(in thousands, except per share data)

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The following summary consolidated historical financial data are derived from, and qualified by reference to, the consolidated financial statements and related notes as well as the pro forma financial statements incorporated by reference in this prospectus supplement and the accompanying prospectus.

	Historical					Pro Forma(1)		
	Year Ended December 31,			Three Months Ended March 31,		Year Ended December 31,	Three Months Ended March 31,	
	1999	2000	2001	2001	2002	2001	2001	2002
<b>Consolidated Statement of Operations:</b>								
Net revenue	\$ 50,584	\$ 51,051	\$ 49,384	\$ 11,812	\$ 38,207	\$ 212,819	\$ 52,529	\$ 48,654
Cost of sales	26,890	25,075	25,821	5,826	17,359	111,899	26,159	25,931
Gross profit	23,694	25,976	23,563	5,986	20,848	100,920	26,370	22,723
Operating expenses:								
Purchased in-process research and development			6,980					
Charge related to asset impairment					12,682			12,682
Research and development	1,396	1,360	1,809	299	3,366	12,065	2,732	3,366
Sales and marketing	11,010	10,585	10,976	2,289	10,576	54,596	13,330	12,131
General and administrative	7,339	7,178	11,814	1,883	6,889	36,751	7,668	8,472
Stock-based compensation			10,441		10,145	10,441		10,145
Total operating expenses	19,745	19,123	42,020	4,471	43,658	113,853	23,730	46,796
Operating income (loss)	3,949	6,853	(18,457)	1,515	(22,810)	(12,933)	2,640	(24,073)
Interest and other expenses, net	(2,585)	(2,292)	(3,871)	(451)	(3,617)	(8,490)	(2,845)	(3,963)
Income (loss) from continuing operations before income taxes	1,364	4,561	(22,328)	1,064	(26,427)	(21,423)	(205)	(28,036)
Provision for income taxes	1,007	1,781	2,134	354	507	5,701	139	437
Income (loss) from continuing operations	357	2,780	(24,462)	710	(26,934)	(27,124)	(344)	(28,473)
Income (loss) from discontinued operations	183	(598)	58	(581)		58	(581)	
Income (loss) before extraordinary item and accounting change	540	2,182	(24,404)	129	(26,934)	(27,066)	(925)	(28,473)
Extraordinary (loss) gain			(327)		8,506	(327)		8,506
Cumulative effect of a change in accounting principle					(12,148)			(12,148)
Net income (loss)	\$ 540	\$ 2,182	\$ (24,731)	\$ 129	\$ (30,576)	\$ (27,393)	\$ (925)	\$ (32,115)
Income (loss) per common share basic and diluted:(2)								
Income (loss) from continuing operations	\$ 0.11	\$ 0.59	\$ (3.84)	\$ 0.12	\$ (4.02)	\$ (4.26)	\$ (0.06)	\$ (4.24)
Net income (loss)	\$ 0.16	\$ 0.46	\$ (3.88)	\$ 0.02	\$ (4.53)	\$ (4.30)	\$ (0.15)	\$ (4.75)

March 31, 2002

Actual As Adjusted(3)

March 31, 2002

**Balance Sheet Data:**

Cash and cash equivalents	\$	22,405	\$	56,872
Working capital		15,324		49,791
Total assets		264,398		298,865
Debt obligations		65,684		65,684
Redeemable convertible preferred stock		61,514		61,514
Total stockholders' equity		71,330		105,797

- (1) Reflects the effect of our acquisitions of the Unipath business and IVC as if such acquisitions occurred on January 1, 2001, excluding a non-recurring charge for the write-off of a portion of the Unipath purchase price as in-process research and development.
- (2) Computed as described in our historical financial statements and related notes incorporated by reference into this prospectus supplement and the accompanying prospectus.
- (3) Reflects the receipt and application of the net proceeds from the sale of 1,600,000 shares of common stock offered hereby at an offering price of \$23.00 per share after deducting underwriting discounts and commissions and estimated offering expenses.

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**SUPPLEMENTAL RISK FACTORS**

*An investment in our common stock involves various risks. In addition to the risks described under "Risk Factors" beginning on page 2 of the accompanying prospectus, you should carefully consider the following risk factors in conjunction with the other information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus before making a decision to purchase our common stock.*

**Shares eligible for public sale after this offering could adversely affect our stock price.**

The market price of our common stock could decline as a result of sales by our existing stockholders after this offering or the perception that these sales could occur. These sales also might make it difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Immediately after the closing of this offering, based on the number of shares outstanding as of March 31, 2002, we will have outstanding 10,726,588 shares of common stock, or 10,966,588 shares of common stock if the underwriter exercises its option to purchase additional shares of the stock from us. These numbers exclude shares of common stock issued upon the exercise of options and warrants, and the conversion of shares of Series A Preferred Stock, occurring subsequent to March 31, 2002. The shares that we are selling in this offering may be resold immediately in the public market. This offering of 1,600,000 shares of common stock is being made pursuant to a shelf registration statement that permits the sale of up to 5,000,000 shares of common stock. This means that, while the shelf registration statement remains effective, and assuming the underwriter does not exercise its over-allotment option, we have the ability to sell up to an additional 3,400,000 shares of common stock under that registration statement.

Pursuant to the terms of a stock purchase agreement and other contractual arrangements, the holders of 5,560,238 shares of common stock issued or issuable upon conversion of our Series A Preferred Stock or upon exercise of certain of our warrants are entitled to have their shares registered under the Securities Act of 1933. Accordingly, we have filed a registration statement to permit the resale of such shares. When such registration statement is declared effective, such shares would be available for sale in the open market.

All of our executive officers and directors have generally agreed not to sell any shares of our common stock for a period of 90 days after the date of this prospectus supplement without the consent of SG Cowen Securities Corporation. As a result, the holders of an aggregate of 3,787,418 shares of common stock (consisting of outstanding shares of common stock and shares of common stock underlying Series A Preferred Stock), including 1,253,332 of the shares being registered for resale pursuant to the above-mentioned resale registration statement, will be contractually restricted from selling their shares for a period of 90 days after the date of this prospectus supplement. However, SG Cowen Securities Corporation can waive this restriction and allow these stockholders to sell their shares at any time. Sales of a substantial number of shares of our common stock following the expiration or waiver of these lock-up periods could cause our stock price to fall.



We also may issue shares of our common stock from time to time as consideration for future acquisitions and investments. In the event any such acquisition or investment is significant, the number of shares that we may issue may in turn be significant. In addition, we may grant registration rights covering shares issued in connection with any such acquisitions and investments.

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**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 supplement and the accompanying prospectus, could be impaired if the Securities and Exchange Commission ceases accepting financial statements audited by Arthur Andersen or if for any reason 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 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 supplement and the accompanying 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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**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;

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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 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 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, IVC's lender. 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 earnings before interest expense, taxes, depreciation and amortization, or 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 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.

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**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, contains state-of-the-art research laboratories and is equipped with 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 which we entered into in connection with our acquisition of the 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 of the Bedford facility 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 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.

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### USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of our common stock in this offering will be approximately \$34.5 million, at an offering price of \$23.00 per share and after deducting the underwriting discounts and commissions and our estimated offering expenses. If the underwriter exercises its over-allotment option in full, the net proceeds from this offering will be approximately \$39.7 million. We intend to use the net proceeds for general corporate purposes, including working capital, capital expenditures and costs in connection with possible acquisitions and strategic transactions, if and when suitable opportunities arise. In addition, we may choose to repay outstanding indebtedness with a portion of the net proceeds, although we do not have any obligations or present intentions to do so.

Due to the rapidly changing nature of the markets in which we operate, the amounts we actually spend for general corporate purposes will depend on a number of factors, including revenue growth, if any, and the amount of cash we generate from operations. As a result, we will retain broad discretion in the allocation and use of a significant portion of the net proceeds of this offering. Until allocated for specific use, we will invest these proceeds in government securities and other short-term, investment-grade securities.

### DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings to support our growth strategy and do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

### PRICE RANGE OF COMMON STOCK

On November 23, 2001, our common stock began trading on the American Stock Exchange under the symbol "IMA." Prior to that date, there was no established public trading market for shares of our common stock. The following table sets forth, for the periods indicated, the high and low closing sale prices of our common stock on the American Stock Exchange.

Year ended December 31, 2001	High	Low
4th Quarter (beginning November 23)	\$ 19.35	\$ 15.47
Year ended December 31, 2002		
1st Quarter	\$ 25.41	\$ 18.00
2nd Quarter (through May 21, 2002)	\$ 28.21	\$ 22.75

On May 21, 2002, the last reported sale price of our common stock on the American Stock Exchange was \$24.98 per share. As of May 8, 2002, there were 9,410,960 shares of our common stock outstanding and we had approximately 330 holders of record of our common stock. We believe that the number of beneficial owners of our common stock on that date was substantially greater.

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## CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2002 (unaudited):

on an actual basis; and

on an as adjusted basis to give effect to the receipt and application of the net proceeds from the sale of 1,600,000 shares of common stock offered hereby at an offering price of \$23.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses we expect to pay.

You should read this table in conjunction with the consolidated financial statements and notes incorporated by reference herein and the information under "Selected Consolidated Financial Data."

	March 31, 2002	
	Actual	As Adjusted
	(in thousands, except share amounts)	
Current portion of long-term debt	\$ 6,887	\$ 6,887
Long-term liabilities:		
Long-term debt, net of current portion	\$ 58,797	\$ 58,797
Deferred income taxes	2,005	2,005
Other liabilities	3,800	3,800
Total long-term liabilities	64,602	64,602
Series A redeemable convertible preferred stock, \$0.001 par value:		
Authorized 2,666,667 shares		
Issued 2,526,913 shares		
Outstanding 2,360,246 shares	61,514	61,514
Stockholders' equity:		
Preferred stock, \$0.001 par value:		
Authorized 2,333,333 shares, none issued		
Common stock, \$0.001 par value:		
Authorized 50,000,000 shares		
Issued and outstanding 9,126,588 actual shares and 10,726,588 as adjusted shares	9	11
Additional paid-in capital	151,663	186,128
Notes receivable from stockholders	(14,691)	(14,691)
Accumulated deficit	(66,741)	(66,741)
Accumulated other comprehensive income	1,090	1,090
Total stockholders' equity	71,330	105,797
Total capitalization	\$ 197,446	\$ 231,913

The information in the table above does not include:

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4,720,492 shares of common stock issuable upon conversion of shares of our Series A Preferred Stock outstanding as of March 31, 2002;

an aggregate of 2,303,018 shares of common stock subject to outstanding options as of March 31, 2002 at a weighted average exercise price of \$14.70 per share;

an additional 366,199 shares of common stock reserved for issuance upon exercise of options that may be granted subsequent to March 31, 2002 under our 2001 Stock Option and Incentive Plan;

500,000 shares of common stock reserved for issuance under our Employee Stock Purchase Plan;

563,818 shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2002 at a weighted average exercise price of \$14.32 per share; and

up to 240,000 shares issuable upon exercise of the underwriter's over-allotment option.

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### SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and notes and the other information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus. The selected consolidated balance sheet data as of December 31, 2000 and 2001 and the selected consolidated statement of operations data for the years ended December 31, 1999, 2000 and 2001 have been derived from our consolidated financial statements that have been audited by Arthur Andersen, LLP, independent public accountants, and are incorporated by reference into this prospectus supplement and the accompanying prospectus. The selected consolidated balance sheet data as of December 31, 1997, 1998 and 1999 and the selected consolidated statement of operations data for the years ended December 31, 1997 and 1998 have been derived from our audited consolidated financial statements not included or incorporated by reference in this prospectus supplement and the accompanying prospectus. The selected consolidated statement of operations data for the three-month periods ended March 31, 2001 and 2002 and the selected consolidated balance sheet data at March 31, 2002 are derived from unaudited consolidated financial statements incorporated by reference into this prospectus supplement and the accompanying prospectus. The unaudited consolidated financial statements for the three-month periods have been prepared on a basis consistent with our audited consolidated financial statements and, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of our consolidated financial position and consolidated results of operations for these periods. The consolidated results of operations for the three months ended March 31, 2002 are not necessarily indicative of results for the year ending December 31, 2002 or any future period. The pro forma information is not necessarily indicative of either the results which would have actually been reported if the acquisitions of the Unipath business and IVC occurred on January 1, 2001 or results which may be reported in the future.

When you read this selected financial data, it is important that you also read the historical financial statements and related notes and the unaudited pro forma combined condensed financial statements and related notes incorporated by reference into this prospectus supplement and the accompanying prospectus, as well as the section of this prospectus supplement entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The historical results are not necessarily indicative of future results.

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Historical					Pro Forma(1)				
Year Ended December 31,					Three Months Ended March 31,		Year Ended December 31,	Three Months Ended March 31,	
1997	1998	1999	2000	2001	2001	2002	2001	2001	2002
(in thousands, except per share data)									

#### Consolidated Statement of Operations:

Net revenue	\$	50,635	\$	54,685	\$	50,584	\$	51,051	\$	49,384	\$	11,812	\$	38,207	\$	212,819	\$	52,529	\$	48,654
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	Historical						Pro Forma(1)					
	1997	1998	1999	2000	2001	2002	1997	1998	1999	2000	2001	2002
Cost of sales	24,724	26,720	26,890	25,075	25,821	5,826	17,359	111,899	26,159	25,931		
Gross profit	25,911	27,965	23,694	25,976	23,563	5,986	20,848	100,920	26,370	22,723		
<b>Operating expenses:</b>												
Purchased in-process research and development					6,980							
Charge related to asset impairment		5,859					12,682			12,682		
Research and development	6,210	2,323	1,396	1,360	1,809	299	3,366	12,065	2,732	3,366		
Sales and marketing	12,101	13,169	11,010	10,585	10,976	2,289	10,576	54,596	13,330	12,131		
General and administrative	8,998	9,600	7,339	7,178	11,814	1,883	6,889	36,751	7,668	8,472		
Stock-based compensation	81				10,441		10,145	10,441		10,145		
Total operating expenses	27,390	30,951	19,745	19,123	42,020	4,471	43,658	113,853	23,730	46,796		
Operating (loss) income	(1,479)	2,986	3,949	6,853	(18,457)	1,515	(22,810)	(12,933)	2,640	(24,073)		
Interest and other expenses, net	(2,377)	(2,077)	(2,585)	(2,292)	(3,871)	(451)	(3,617)	(8,490)	(2,845)	(3,963)		
(Loss) income from continuing operations before income taxes	(3,856)	(5,063)	1,364	4,561	(22,328)	1,064	(26,427)	(21,423)	(205)	(28,036)		
Provision for income taxes	1,456	1,115	1,007	1,781	2,134	354	507	5,701	139	437		
(Loss) income from continuing operations	(5,312)	(6,178)	357	2,780	(24,462)	710	(26,934)	(27,124)	(344)	(28,473)		
(Loss) income from discontinued operations	(791)	(2,882)	183	(598)	58	(581)		58	(581)			
(Loss) income before extraordinary item and accounting change	(6,103)	(9,060)	540	2,182	(24,404)	129	(26,934)	(27,066)	(925)	(28,473)		
Extraordinary (loss) gain					(327)		8,506	(327)		8,506		
Cumulative effect of a change in accounting principle							(12,148)			(12,148)		
Net (loss) income	\$ (6,103)	\$ (9,060)	\$ 540	\$ 2,182	\$ (24,731)	\$ 129	\$ (30,576)	\$ (27,393)	\$ (925)	\$ (32,115)		
<b>(Loss) income per common share basic and diluted:(2)</b>												
(Loss) income from continuing operations	\$ (3.32)	\$ (2.53)	\$ 0.11	\$ 0.59	\$ (3.84)	\$ 0.12	\$ (4.02)	\$ (4.26)	\$ (0.06)	\$ (4.24)		
Net (loss) income	\$ (3.82)	\$ (3.71)	\$ 0.16	\$ 0.46	\$ (3.88)	\$ 0.02	\$ (4.53)	\$ (4.30)	\$ (0.15)	\$ (4.75)		

	December 31,						March 31,	
	1997	1998	1999	2000	2001	2002		
<b>Balance Sheet Data:</b>								
Cash and cash equivalents	\$ 5,099	\$ 1,111	\$ 661	\$ 3,071	\$ 52,024	\$ 22,405		

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	December 31,				March 31,	
Working capital (deficit)	(1,401)	(1,986)	(4,060)	(6,464)	21,022	15,324
Total assets	67,182	70,191	72,210	74,958	278,571	264,398
Debt obligations	26,595	23,163	19,076	12,830	78,124	65,684
Redeemable convertible preferred stock					51,894	61,514
Total stockholders' equity	18,442	28,932	34,953	41,812	89,614	71,330

- (1) Reflects the effect of our acquisitions of the Unipath business and IVC as if such acquisitions occurred on January 1, 2001, excluding a non-recurring charge for the write-off of a portion of the Unipath purchase price as in-process research and development.
- (2) Computed as described in our historical financial statements and related notes incorporated by reference into this prospectus supplement and the accompanying prospectus.

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### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

We develop, manufacture and market consumer health care 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 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 health care 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.

On November 21, 2001, pursuant to an agreement and plan of split-off and merger dated May 23, 2001, Johnson & Johnson acquired Inverness Medical Technology, Inc., or IMT, our former parent, in a merger transaction and, simultaneously, our company, Inverness Medical Innovations, Inc., was split off from IMT as a separate publicly traded company. Immediately prior to the consummation of these transactions, IMT restructured its operations so that we and our subsidiaries would hold all of IMT's non-diabetes businesses (women's health, nutritional supplements and clinical diagnostics). At the closing of the transactions, all of the shares of our common stock held by IMT were split-off from IMT in a pro rata distribution to IMT's stockholders and IMT (which then consisted of its diabetes business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

On December 20, 2001, we acquired Unipath Limited, a global leader in home pregnancy and ovulation testing and natural family planning, and its associated companies and assets from Unilever Plc and certain entities affiliated with Unilever. The Unipath acquisition provides us with leading brand name consumer diagnostic products that compliment our existing value branded and private label home pregnancy detection and ovulation prediction products. In connection with the acquisition of the Unipath business, we also acquired rights to certain antibody clones and other intellectual property rights.

On March 19, 2002, we acquired IVC Industries, Inc., a manufacturer and distributor of hundreds of different vitamin and nutritional supplement products sold under brand names and through private label arrangements with retailers. With the addition of IVC, we intend to consolidate our vitamin and nutritional supplement manufacturing at IVC and discontinue most of our outsourced manufacturing arrangements. The aggregate purchase price of IVC was approximately \$27.3 million, which consisted of \$5.6 million in cash representing \$2.50 for each outstanding share of IVC's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of our common stock with an aggregate fair value of \$1.3 million, approximately \$1.6 million in estimated costs to exit certain activities of IVC, primarily severance costs, \$17.4 million in assumed debt and approximately \$1.4 million in estimated direct acquisition costs. The acquisition was funded by our existing cash.

Our businesses have developed to a significant extent through strategic acquisitions as well as through internal development. We intend to pursue aggressively opportunities for the acquisition of or investment in new and complementary businesses, products and technologies. We are currently considering potential strategic acquisitions. However, we currently have no material binding commitments or agreements with respect to any such acquisitions. We may not enter into any agreements relating to any such acquisitions or, if we do, we may not complete any of them. In order

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to finance any such acquisitions, one or more of which may be very significant to our company, we may have to incur indebtedness, use our existing cash and/or issue securities. We currently have no commitments for any financing and we may be unable to obtain financing, if required, on terms and conditions acceptable to us. We may sell equity securities at a discount to our common stock's then market value due to the illiquidity of privately placed securities or otherwise. Any issuance of equity securities may result in substantial dilution to existing stockholders, which may be increased as a result of any discount to our common stock's market price.

## Results of Operations

### *Three Months Ended March 31, 2002 Compared to Three Months Ended March 31, 2001*

*Net Product Sales.* Net product sales for the three months ended March 31, 2002 increased \$25.7 million, or 217%, to \$37.5 million from \$11.8 million for the three months ended March 31, 2001. The significant increase resulted predominantly from the recently acquired Unipath business which had net product sales of \$21.6 million for the three months ended March 31, 2002. Our nutritional supplements business experienced growth in net product sales of \$2.1 million, of which \$1.6 million resulted from the addition of IVC. Additionally, our subsidiary in Ireland, Cambridge Diagnostics Ireland Limited, or CDIL, contributed \$2.2 million of the increase in net product sales through its diabetes related packaging contract with a subsidiary of Johnson & Johnson. Consistent with total net product sales, net product sales of our consumer products segment, which includes our consumer diagnostic products and our vitamins and nutritional supplements, were \$32.9 million for the three months ended March 31, 2002, an increase of \$23.7 million, or 259%, as compared to \$9.2 million for the three months ended March 31, 2001. Net product sales of our clinical diagnostics products segment for the three months ended March 31, 2002 increased \$2.7 million, or 101%, to \$5.3 million from \$2.7 million for the three months ended March 31, 2001. The increase in sales of our clinical diagnostic products was entirely the result of the addition of the Unipath business.

*License and Other Revenue.* License and other revenue represent license and royalty fees from intellectual property license agreements with third parties. These license agreements were acquired as part of the Unipath business. For the three months ended March 31, 2002, license revenue was \$706,000. There were no license and other revenue for the three months ended March 31, 2001.

*Gross Profit.* Total gross profit for the three months ended March 31, 2002 increased \$14.9 million, or 248%, to \$20.8 million from \$6.0 million for the three months ended March 31, 2001. Total gross margin of net product sales was 56% for the three months ended March 31, 2002 compared to 51% for the three months ended March 31, 2001. The increase in gross profit and margin of total net product sales primarily resulted from the addition of the Unipath business which generated total gross profit of \$14.0 million and gross margin of 65% for the three months ended March 31, 2002. Only \$291,000 of the increase in total gross profit resulted from the addition of IVC since March 19, 2002 with a corresponding gross margin of 18%. As a result of IVC's lower gross margins, we expect overall gross margins of approximately 50% in future quarters. Gross profit from our consumer diagnostic product sales was \$18.2 million for the three months ended March 31, 2002, an increase of \$13.6 million, or 298%, from \$4.6 million for the three months ended March 31, 2001. Gross margin from our consumer diagnostic product sales was 56% for the three months ended March 31, 2002 as compared to 50% for the three months ended March 31, 2001. Gross profit from our clinical diagnostics product sales was \$2.7 million for the three months ended March 31, 2002, an increase of \$1.3 million, or 88%, from \$1.4 million for the three months ended March 31, 2001. Gross margin from our clinical diagnostic product sales was 52% for the three months ended March 31, 2002 as compared to 54% for the three months ended March 31, 2001.

*Charge Related to Asset Impairment.* During the three months ended March 31, 2002, we recorded a noncash impairment charge of \$12.7 million to write off a portion of the value that was assigned to

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trademarks and brand names related to certain of our nutritional supplement lines we bought in 1997. This charge was recorded in connection with the results of a separate impairment review performed on the carrying value of the goodwill related to such nutritional supplement lines, as discussed below in the caption "Cumulative Effect of a Change in Accounting Principle." No impairment charge was recorded during the three



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months ended March 31, 2001.

*Research and Development Expense.* Research and development expense for the three months ended March 31, 2002 increased \$3.1 million, or 1027%, to \$3.4 million from \$299,000 for the three months ended March 31, 2001. The significant increase resulted from the addition of the Unipath business, which houses a large research and development center in its facility in Bedford, England. Prior to the acquisition of the Unipath business, our research and development expense was primarily related to clinical diagnostic products incurred by our Organics subsidiary in Israel. We anticipate a continuing increase in research and development activities and expenses in the future as a result of the addition of the Unipath business.

*Sales and Marketing Expense.* Sales and marketing expense for the three months ended March 31, 2002 increased \$8.3 million, or 362%, to \$10.6 million from \$2.3 million for the three months ended March 31, 2001. Of this increase, \$7.6 million resulted from the addition of the Unipath business and \$184,000 resulted from the addition of IVC since its acquisition date. The remaining increase in sales and marketing expenses resulted primarily from our new radio advertising efforts in an attempt to boost our nutritional supplement product sales. Sales and marketing expense as a percentage of net product sales increased to 28% for the three months ended March 31, 2002 from 19% for the three months ended March 31, 2001.

*General and Administrative Expense.* General and administrative expense for the three months ended March 31, 2002 increased \$5.0 million, or 266%, to \$6.9 million from \$1.9 million for the three months ended March 31, 2001. The addition of the Unipath business contributed \$3.5 million to this increase in general and administrative expenses. During the three months ended March 31, 2002, we also incurred approximately \$1.0 million in legal fees for our defenses in certain litigations which were inactive during the three months ended March 31, 2001. The remaining increase in general and administrative expense resulted primarily from increases in other professional fees, insurance and rent due to the relocation of our corporate headquarters in May 2001. General and administrative expense as a percentage of net product sales increased to 18% for the three months ended March 31, 2002 from 16% for the three months ended March 31, 2001.

*Stock-Based Compensation.* During the three months ended March 31, 2002, we recorded noncash compensation expenses of \$10.1 million. This amount represents the amortization of the remaining deferred compensation recorded in 2001 in connection with the sale of restricted stock to our chief executive officer. We recorded this deferred compensation because the stock was sold below the market value of our stock on the measurement date. The deferred compensation was originally set to amortize over the vesting period of the restricted stock. However, because of an amendment in the terms of the restricted stock agreement in February 2002, we fully amortized the deferred compensation during the three months ended March 31, 2002. There was no charge for stock-based compensation during the three months ended March 31, 2001.

*Interest Expense.* Interest expense for the three months ended March 31, 2002 increased \$3.8 million, or 1013%, to \$4.1 million from \$373,000 for the three months ended March 31, 2001. The significant increase in interest expense resulted from various debt financings obtained to fund the acquisition of the Unipath business in December 2001. Also, of the total increase in interest expense, \$2.7 million was noncash and represented the amortization of original issue discount and beneficial conversion features related to such debt financings.

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*Other Income (Expense), Net.* Other income (expense), net, includes interest income and other income and expenses. Interest income for the three months ended March 31, 2002 increased by \$334,000, or 785%, to \$376,000 from \$43,000 for the three months ended March 31, 2001. The increase in interest income resulted from higher average cash balances during the three months ended March 31, 2002 due to a \$41.4 million capitalization by IMT during our split-off from IMT in November 2001. A significant portion of other income and expense generally represents foreign currency exchange gains and losses. For the three months ended March 31, 2002, we recognized \$188,000 in realized and unrealized foreign exchange transaction gains as compared to losses of \$122,000 for the three months ended March 31, 2001.

*Income Taxes.* For the three months ended March 31, 2002, we recorded provisions of \$507,000 for income taxes compared to \$354,000 for the three months ended March 31, 2001. Of the provision recorded for the three months ended March 31, 2002, \$471,000 related to the Unipath business. The remaining business recorded a total provision of \$35,000 for the three months ended March 31, 2002 as compared to \$354,000 for the three months ended March 31, 2001. This decrease resulted from corporate losses available to offset profits in the U.S. businesses.

*(Loss) Income from Continuing Operations.* Loss from continuing operations was \$26.9 million, or \$4.02 per basic and diluted common share, for the three months ended March 31, 2002 compared to income from continuing operations of \$710,000, or \$0.12 per basic and diluted common share, for the three months ended March 31, 2001. The significant loss for the three months ended March 31, 2002 resulted from various factors as described above.

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*Loss from Discontinued Operations.* During the three months ended March 31, 2001, we recorded a loss from discontinued operations of \$581,000. The discontinued operations represent the diabetes related segments of the entities that we acquired through the split-off from IMT that were then transferred back to IMT on November 21, 2001.

*Extraordinary Gain.* During the three months ended March 31, 2002, we recorded an extraordinary gain of \$8.5 million related to the early retirement of our subordinated promissory notes and the repurchase of the beneficial conversion feature associated with these subordinated promissory notes.

*Cumulative Effect of a Change in Accounting Principle.* On January 1, 2002, we adopted Statement of Financial Accounting Standard (SFAS) No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires annual independent appraisals to be obtained for all reporting units, as defined in the statement, with values recorded for goodwill and other intangible assets. Based on the results of an independent appraisal obtained on the nutritional supplements business that we acquired in 1997, we recorded an impairment charge of \$12.1 million to write-off the carrying value of the goodwill related to that business.

*Net (Loss) Income.* Net loss for the three months ended March 31, 2002 was \$30.6 million as compared to net income of \$129,000 for the three months ended March 31, 2001. The basic and diluted net loss per common share for the three months ended March 31, 2002 was \$4.53 compared to a basic and diluted income per common share of \$0.02 for the three months ended March 31, 2001.

### **Year Ended December 31, 2001 Compared to Year Ended December 31, 2000**

*Net Product Sales.* Net product sales in 2001 decreased \$1.7 million, or 3%, to \$49.4 million from \$51.1 million in 2000. The product sales decline was predominantly due to decreases in product sales of certain of our nutritional supplement product lines, which are included in our consumer products business segment. The net sales of our nutritional supplements decreased by \$5.8 million, or 31%, to \$13.1 million in 2001 compared to \$18.9 million in 2000. Our marketing efforts in the past have been

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limited due to the size and resources of our company, which, added to the effect of the competitive nature of this business, caused our nutritional supplements sales to decline. Partially offsetting the decrease in product sales of nutritional supplements is the increase in consumer diagnostic products, such as pregnancy and ovulation tests, which are also included in our consumer products business segment. Net product sales of consumer diagnostic products were \$25.7 million in 2001, an increase of \$4.2 million, or 15%, from \$21.5 million in 2000. Approximately \$1.9 million of the consumer diagnostic product sales increase was contributed by the Unipath business that we acquired on December 20, 2001. Net sales of our clinical diagnostics products in 2001 decreased \$90,000, or 1%, to \$10.6 million from \$10.7 million in 2000.

*Gross Profit.* Total gross profit for 2001 decreased \$2.4 million, or 9%, to \$23.6 million from \$26.0 million in 2000. Gross margin of net product sales was 48% in 2001 compared to 51% in 2000. The decrease in gross profit and margin primarily resulted from the net decline in sales of our consumer products, primarily nutritional supplements. Gross profit from our nutritional supplements product sales was \$6.3 million in 2001, a decrease of \$3.9 million, or 39%, from \$10.2 million in 2000. The decreased nutritional supplements gross profit was partially offset by the increase in consumer diagnostics gross profit. Gross profit from consumer diagnostic product sales was \$11.3 million in 2001, an increase of \$1.8 million, or 19%, from \$9.5 million in 2000. Gross profit from our clinical diagnostics product sales was \$6.0 million in 2001, a decrease of \$281,000, or 4%, from \$6.3 million in 2000.

*Purchased In-Process Research and Development.* In the fourth quarter of 2001, we recorded a \$7.0 million noncash charge for an in-process research and development project that we acquired as a part of the Unipath business. This charge represented the portion of the purchase price paid for the Unipath business allocated to this in-process research and development project that had not achieved technological feasibility and did not have future alternative uses. We did not record any such charges in 2000.

*Research and Development Expense.* Research and development expense in 2001 increased \$450,000, or 33%, to \$1.8 million from \$1.4 million in 2000. To date most of our research and development expense was related to clinical diagnostic products. We anticipate an increase in research and development activities and expenses in the future as a result of the acquired Unipath business.

*Sales and Marketing Expense.* Sales and marketing expenses in 2001 increased \$391,000, or 4%, to \$11.0 million from \$10.6 million in 2000. The increase resulted primarily from the addition of the Unipath business since its acquisition date. Sales and marketing expense as a percentage of net product sales increased to 22% in 2001 from 21% in 2000.

*General and Administrative Expense.* General and administrative expense in 2001 increased \$4.6 million, or 65%, to \$11.8 million from \$7.2 million in 2000. General and administrative expense as a percentage of net product sales increased to 24% in 2001 from 14% in 2000. Approximately \$2.5 million of this increase was caused by legal fees incurred in our active defenses of certain litigation matters in 2001. Other

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increases in general and administrative expenses relate to other professional fees, facilities costs due to a relocation of our United States office in 2001, salaries, insurance and the addition of the Unipath business.

*Stock-Based Compensation.* During 2001, we recorded noncash compensation expenses in connection with the sale of restricted stock to our chief executive officer and stock option grants to certain key executives because these securities were sold or granted below the market value of our stock on the measurement date. As a result of a February 2002 amendment to the terms of the chief executive officer's restricted stock award, we will fully amortize the remaining portion of the deferred compensation expense associated with the restricted stock (approximately \$10.1 million) in the first quarter of 2002.

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*Interest Expense.* Interest expense in 2001 remained consistent (a \$49,000, or 3%, decrease) at \$1.9 million compared to 2000. We expect to incur increased interest expense in the future as a result of the new debt issued in connection with the acquisition of the Unipath business.

*Other Expense, Net.* Other expense, net, includes interest income and other income and expenses. Interest income in 2001 increased by \$358,000 to \$385,000 from \$27,000 in 2000. The increase in interest income resulted from higher average cash balances from contributions by IMT in 2001. A significant portion of other income and expense generally represents foreign currency exchange gains and losses. In 2001, we recognized \$727,000 in realized and unrealized foreign exchange transaction losses as compared to losses of \$389,000 in 2000. In 2001, we also settled a lawsuit for which we recorded a loss of \$1.7 million as other expense.

*Income Taxes.* In 2001, we recorded provisions of \$2.1 million for income taxes compared to \$1.8 million in 2000. The increase is primarily due to the write-off of certain deferred tax assets which we do not believe will provide us with future tax benefits as a result of the split-off and merger with IMT and Johnson & Johnson in November 2001.

*(Loss) Income from Continuing Operations.* Loss from continuing operations was \$24.5 million, or \$3.84 per basic and diluted common share, for 2001 compared to income from continuing operations of \$2.8 million, or \$0.59 per basic and diluted common share, for 2000. The significant loss in 2001 resulted from the various factors described above.

*Income (Loss) from Discontinued Operations.* In 2001, we had income from discontinued operations of \$58,000 compared to a loss from discontinued operations of \$598,000 in 2000. The discontinued operations represent the diabetes related segments that were acquired by Johnson & Johnson on November 21, 2001.

*Extraordinary Loss on Early Extinguishment of Debt.* The amount charged to extraordinary loss in 2001 represents the write-off of the remaining unamortized financing costs related to a third-party debt IMT assumed and paid-off at the split-off and merger.

*Net (Loss) Income.* Net loss for 2001 was \$24.7 million as compared to net income of \$2.2 million for 2000. The basic and diluted loss per common share for 2001 was \$3.88 compared to a basic and diluted income per common share of \$0.46 for 2000. The significant loss in 2001 resulted from the various factors described above.

### ***Year Ended December 31, 2000 Compared to Year Ended December 31, 1999***

*Net Product Sales.* Net product sales in 2000 increased \$467,000, or 1%, to \$51.1 million from \$50.6 million in 1999. The primary reason for the increase in product sales was increased sales of our consumer diagnostic products, which are included in our consumer products business segment. Net sales of consumer diagnostic products were \$21.5 million in 2000, an increase of \$3.0 million, or 16%, from \$18.5 million in 1999. The aforementioned increase was partially offset by decreases in the sales of our nutritional supplements, also included in our consumer products business segment, and clinical diagnostic products. Net sales of our nutritional supplements decreased by \$2.2 million, or 10%, to \$18.9 million in 2000 compared to \$21.0 million in 1999. Net sales of our clinical diagnostics products in 2000 decreased \$383,000, or 4%, to \$10.7 million from \$11.1 million in 1999.

*Gross Profit.* Total gross profit for 2000 increased \$2.3 million, or 10%, to \$26.0 million from \$23.7 million in 1999. Gross margin of net product sales was 51% in 2000 compared to 47% in 1999. The gross profit increased primarily as a result of increased sales of pregnancy tests combined with reduced costs to manufacture those tests. This increase was partially offset by a lower gross profit on the sales of nutritional supplements.

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*Research and Development Expense.* Research and development expense remained consistent (decrease of \$36,000 from 1999 to 2000) at \$1.4 million for both years. Most of the research and development expense was related to clinical diagnostic products.

*Sales and Marketing Expense.* Sales and marketing expenses in 2000 decreased \$426,000, or 4%, to \$10.6 million from \$11.0 million in 1999. The decrease resulted primarily from lower selling and marketing expenditures related to our nutritional supplements. Sales and marketing expense as a percentage of net product sales decreased to 21% in 2000 from 22% in 1999.

*General and Administrative Expense.* General and administrative expense in 2000 decreased \$161,000, or 2%, to \$7.2 million from \$7.3 million in 1999. General and administrative expense as a percentage of net product sales decreased to 14% in 2000 from 15% in 1999.

*Interest Expense.* Interest expense in 2000 decreased \$118,000, or 6%, to \$1.9 million from \$2.0 million in 1999. The decrease in interest expense primarily resulted from a lower total average outstanding debt balance during 2000 as compared to 1999.

*Other Expense, Net.* Other expense, net, includes interest income and other income and expenses. Interest income in 2000 decreased by \$3,000 to \$27,000 from \$30,000 in 1999. A significant portion of other income and expense generally represents foreign currency exchange gains and losses. In 2000, we recognized \$389,000 in realized and unrealized foreign exchange transaction losses as compared to losses of \$531,000 in 1999.

*Income Taxes.* In 2000, we recorded provisions of \$1.8 million for income taxes compared to \$1.0 million in 1999. Our effective tax rate is substantially higher than the combined federal and statutory rate due to foreign and divisional losses for which we have not recorded a tax benefit.

*Income from Continuing Operations.* Income from continuing operations was \$2.8 million, or \$0.59 per basic and diluted common share, for 2000 compared to income from continuing operations of \$357,000, or \$0.11 per basic and diluted common share, for 1999. The increase in income was due to greater profits on sales of pregnancy and ovulation tests, partially offset by a decrease in the income on nutritional supplements, and reduced sales and marketing expenditures.

*(Loss) Income from Discontinued Operations.* In 2000, we had a loss from discontinued operations of \$598,000 compared to an income from discontinued operations of \$183,000 in 1999. The discontinued operations represent the diabetes related segments that were acquired by Johnson & Johnson on November 21, 2001.

*Net Income.* Net income for 2000 was \$2.2 million as compared to net income of \$540,000 for 1999. The basic and diluted earnings per common share for 2000 were \$0.46 compared to a basic and diluted earnings per common share of \$0.16 for 1999.

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### Quarterly Financial Information

The following table sets forth unaudited quarterly consolidated operating results for each of our last nine quarters. We prepared this information on a basis consistent with our audited consolidated financial statements and included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the data. These quarterly results are not necessarily indicative of future results of operations. This information should be read in conjunction with our consolidated financial statements and notes included elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus.

	2000				2001				2002
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	First Quarter
(In thousands, except per share data)									
Net revenue	\$ 13,455	\$ 12,743	\$ 12,519	\$ 12,334	\$ 11,812	\$ 12,272	\$ 11,590	\$ 13,711	\$ 38,207
Gross profit	6,908	6,856	6,026	6,186	5,986	6,478	5,591	5,508	20,848
Operating income (loss)	1,983	1,952	1,327	1,591	1,515	1,462	(17)	(21,417)	(22,810)
Income (loss) from continuing operations	835	1,067	317	561	710	151	(288)	(25,035)	(26,934)

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	2000				2001				2002
Income (loss) per share from continuing operations basic and diluted(1)	0.21	0.23	0.06	0.11	0.12	0.02	(0.04)	(3.86)	(4.02)

(1) Computed as described in our historical financial statements and related notes incorporated by reference into this prospectus supplement and the accompanying prospectus.

## Liquidity and Capital Resources

As of March 31, 2002, we had cash and cash equivalents of \$22.4 million, a \$29.6 million decrease from December 31, 2001. We have historically funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities, as well as contributions from IMT, our former parent, and affiliated companies of IMT. We used \$4.7 million in cash for our operating activities during the three months ended March 31, 2002, which was due to a net decrease in accounts payable and accrued expenses of \$3.7 million and an inventory increase of \$2.3 million, offset by \$420,000 in earnings adjusted for noncash expenses and decreases in other current assets of \$865,000. During the three months ended March 31, 2002, we used cash of \$11.7 million for our investing activities, of which \$8.1 million was used for the acquisition of IVC, \$3.4 million was used for restructuring costs and additional acquisition costs related to the Unipath business, and \$384,000 was used for capital expenditure purposes. During the three months ended March 31, 2002, we used cash of \$13.0 million for financing activities, which primarily consisted of principal prepayments of \$20.0 million on the subordinated promissory notes, \$10.0 million on the term loans with The Royal Bank of Scotland plc and \$3.2 million on IVC's bank debt, net of a total of \$20.9 million in proceeds received from issuance of preferred stock and stock option and warrant exercises. We also incurred \$498,000 in financing costs related to various debt instruments. Working capital was \$15.3 million as of March 31, 2002 compared to \$21.0 million as of December 31, 2001.

On March 19, 2002, we acquired IVC, a manufacturer and distributor of vitamins and other nutritional supplements. We intend to consolidate substantially all of our vitamin and nutritional supplement manufacturing at IVC and discontinue most of our outsourced manufacturing arrangements. The aggregate purchase price of IVC was approximately \$27.3 million, which consisted of \$5.6 million in cash representing \$2.50 for each outstanding share of IVC's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of our common stock with an aggregate fair value of \$1.3 million, approximately \$1.6 million in estimated costs to exit certain activities of IVC, primarily severance costs, \$17.4 million in assumed debt, including capital leases, and approximately \$1.4 million in estimated direct acquisition costs. The acquisition was funded by our existing cash. Since the acquisition of IVC, we have made principal payments and prepayments on IVC's debt of \$3.2 million. Of the remaining \$14.2 million of IVC debt outstanding as of March 31,

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2002, \$6.9 million related to a credit agreement with Congress Financial Corporation (Congress), a subsidiary of First Union Corporation, and \$7.3 million related to various notes payable and capital leases. Under the credit agreement with Congress, as amended, IVC can borrow up to \$15.0 million under a revolving credit commitment, subject to borrowing base limitations, as defined in the agreement. IVC also has outstanding \$4.2 million under a term loan commitment. The loans with Congress mature on October 16, 2003. Borrowings under the revolving credit commitment and the term loan bear interest at either 1.50% above the bank's prime rate or, at IVC's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. The notes are collateralized by substantially all of IVC's assets. The credit agreement with Congress requires IVC to maintain minimum tangible net worth and contains various restrictions customary in such financial arrangements, including limitations on the payment of cash dividends. IVC's other notes payable and capital leases mature on various dates through July 2008.

On December 20, 2001, one of our wholly-owned subsidiaries entered into a series of credit agreements (the RBS Credit Agreements) with The Royal Bank of Scotland plc and related entities for credit facilities in the aggregate amount of \$70.0 million, which were amended during the three months ended March 31, 2002. The RBS Credit Agreements consisted of various term loans aggregating \$62.5 million, of which \$10.0 million were denominated in Japanese Yen, and a \$7.5 million multicurrency revolving line of credit. The proceeds of the term loans were used to finance a portion of the cash used to acquire the Unipath business. In March 2002, in connection with the amendments to the RBS Credit Agreements, we elected to make a \$10.0 million principal prepayment on the senior term loans which therefore had a balance of \$42.2 million as of March 31, 2002. The total outstanding loan balance under the RBS Credit Agreements as of March 31, 2002 was \$52.3 million, including capitalized interest, as discussed below. The revolving line of credit is designated for use to cover certain of our liabilities and foreign exchange futures contracts. As of March 31, 2002, there were no outstanding borrowings against the revolving line of credit. We and certain of our subsidiaries are the guarantors of all obligations due under the RBS Credit Agreements. Borrowings under the RBS Credit Agreements are secured by the stock of our European subsidiaries, our intellectual property rights and the assets of our business in the United States. We must make mandatory prepayments on the loans under the RBS Credit Agreements if we meet certain cash flow thresholds, collect insurance proceeds in excess of certain thresholds, receive payments or sell assets not in the ordinary course of our business, or upon a sale or change of control of

our company. The per annum interest rate on the loans is the London Interbank Offered Rate (LIBOR) plus a spread from 1.50% to 3.50% (and an additional 2.00% in case of default), depending on the type of loan (senior or junior) and the interest period. On the loans in which the spread may vary, the spread depends on the ratio of our total debt to EBITDA. Interest at 4.00% per annum is capitalized on the junior loan which, including such capitalized interest, had a principal balance of \$10.1 million at March 31, 2002. Capitalized interest may be paid upon agreement with the lender of our senior debt. The amount of capitalized interest as of March 31, 2002, was \$109,000. In February 2002, we entered into an interest rate swap agreement with the bank, which applies to \$34.8 million to \$41.7 million of the term loans that are denominated in U.S. Dollars, depending upon the interest period, and protects against fluctuations in the LIBOR rate. Under the interest rate swap agreement, the LIBOR rate is set at a minimum of 3.36% and a maximum of 5.00%. Through June 30, 2002, the LIBOR rate under the interest rate swap agreement is set at 3.36%. Under the RBS Credit Agreements, as amended, we must comply with various financial and nonfinancial covenants starting in the second quarter of 2002. The primary financial covenants pertain to, among other things, interest coverage, cash flow coverage, leverage and EBITDA. Failure to comply with these covenants may have a material adverse impact on our financial condition.

On March 6, 2002, we prepaid our then outstanding subordinated promissory notes (Subordinated Notes) having an aggregate principal amount of \$20,000,000 and related accrued interest of \$568,000 using the proceeds from the issuance of Series A Preferred Stock. The original maturity date of the Subordinated Notes was April 1, 2002, with an extension option, and interest accrued at 12% per

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annum, or 18% if and when the maturity date was extended. The Subordinated Notes were convertible into shares of our Series A Preferred Stock at the option of the holder.

During 1999, our CDIL subsidiary financed the purchase of one of the buildings that houses its manufacturing activities through a mortgage loan with the seller. The outstanding balance of the CDIL mortgage was \$176,000 as of March 31, 2002. The CDIL mortgage bears interest at 6% and is payable semiannually through 2003.

Our Organics subsidiary had bank debt balances totaling \$153,000 as of March 31, 2002. Organics' bank debt is collateralized by certain of Organics' assets. The notes bear interest at various rates ranging from 3.43% to 4.25% and are payable on various dates through 2003.

In March 2002, we sold to private investors 531,913 shares of our Series A Preferred Stock at a price of \$39.01 per share for gross proceeds of \$20.75 million for purposes of prepaying the \$20.0 million of Subordinated Notes and related accrued interest. The terms of these shares of Series A Preferred Stock are the same as those shares issued in December 2001. Each share of Series A Preferred Stock accrues dividends on a quarterly basis at \$2.10 per annum, but only on those days when the closing price of our company's common stock is less than \$15.00. As our common stock price did not close below \$15.00 following the issuance of the Series A Preferred Stock, no dividends were recorded during the three months ended March 31, 2002. Dividends accrued are payable only if declared by the Board of Directors. Until December 31, 2003, accrued dividends, if any, must be paid in shares of our common stock. The number of shares of common stock to be issued in payment of any accrued dividends is equal to such number as is determined by dividing the aggregate amount of the accrued dividend then payable by the greater of (i) \$15.00 and (ii) the average market price during the 30 trading day period immediately preceding the date such dividend is declared. Thereafter, we have the option to pay dividends in cash or common stock. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock is equal to such number as is determined by dividing \$30.00 by the conversion price in effect at the time of conversion. The conversion price was initially \$15.00 and is subject to adjustment. The effective purchase price for the shares of common stock underlying the Series A Preferred Stock issued in March 2002 represented a \$2.70 (or 12%) discount to the fair value of our common stock on the issuance date. Starting on December 20, 2003, we may convert the Series A Preferred Stock into common stock in the event that the average closing price of our common stock exceeds \$20.00 for any consecutive 30 trading day period. The Series A Preferred Stock may be redeemed upon a vote by the holders of at least two-thirds of the outstanding Series A Preferred Stock on or after June 30, 2011. The redemption price per share of Series A Preferred Stock will be equal to \$30.00 plus a premium calculated at 5% per annum from the date of issuance.

As of December 31, 2001, we had approximately \$24.8 million of foreign net operating loss carryforwards. These losses are available to reduce foreign taxable income, if any, in applicable jurisdictions in future years. We have recorded a valuation allowance against the portion of the deferred tax assets related to foreign net operating losses and other foreign deferred tax assets to reflect uncertainties that might affect the realization of the deferred tax assets, as these assets can only be realized via profitable foreign operations.

Based on outstanding debt and other commitments as of March 31, 2002, we will be required to use approximately \$11.7 million in cash over the next 12 months to meet debt maturities (approximately \$6.9 million), minimum lease payments (approximately \$3.7 million) and capital expenditure commitments (approximately \$1.1 million). Based upon our current operating plans and business conditions, we believe that our existing capital resources and credit facilities will be adequate to fund our operations, including these outstanding debt and other commitments, for at least the next 12 months. We cannot be certain, however, that our underlying assumed levels of revenues and expenses will be realized. In addition, we may expand our research and development of, and may pursue the acquisition of, new products and technologies, whether through licensing arrangements,

business acquisitions, or otherwise. If we decide to pursue such activities or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed, or, if available, may not be on acceptable terms, which could have a negative effect on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then existing stockholders may result.

### **Critical Accounting Policies**

The consolidated financial statements incorporated by reference into this prospectus supplement and the accompanying prospectus are prepared in accordance with accounting principles generally accepted in the United States. The accounting policies discussed below are considered by our management to be critical to an understanding of our financial statements because their application depends on management's judgment, with financial reporting results relying on estimations and assumptions about the effect of matters that are inherently uncertain. Specific risks for these critical accounting policies are described in the following paragraphs. For all of these policies, management cautions that future events rarely develop exactly as forecast and the best estimates routinely require adjustment. In addition, the "Notes to Consolidated Financial Statements" included in our annual report on Form 10-K, as amended, for the year ended December 31, 2001, which is incorporated by reference herein, include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

#### *Revenue Recognition*

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 101 and its related amendments (collectively, SAB No. 101). SAB No. 101 requires that four basic criteria be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured.

The majority of our revenues are derived from product sales. We recognize revenue upon product shipment to third-party customers, at which time title is transferred, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management's analyses and judgments regarding certain conditions, as discussed below in the critical accounting policy "Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts." Should future changes in conditions prove management's conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

Since the acquisition of the Unipath business in late December 2001, we also receive license and royalty revenue from agreements with third-party licensees. Revenue from fixed fee license and royalty agreements are recognized on a straight-line basis over the license or royalty period. License and royalty fees that are calculated based on the licensees' sales are recognized upon receipt of the license or royalty payments because we would not be able to determine such fees until such time.

#### *Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts*

Sales arrangements with customers for our products generally require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our customers, which generally reduce the sale prices of our products. Against product revenue recognized in any reporting period, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our management analyzes historical returns, current economic trends, and changes in customer demand and acceptance of our

products. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates. Our provision for sales returns and other allowances related to sales incentive arrangements amounted to approximately \$5.9 million for the three months ended March 31, 2002.

Similarly, our management must make estimates of the uncollectibility of our accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms. Our accounts receivable balance was \$27.1 million, net of an allowance for doubtful accounts of \$1.3 million as of March 31, 2002.

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### *Valuation of Goodwill and Other Long-Lived and Intangible Assets*

Our long-lived assets include property, plant and equipment, goodwill and other intangible assets. As of March 31, 2002, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were \$42.6 million, \$74.3 million and \$61.9 million, respectively. For purposes of determining whether there are any impairment losses, our management has historically examined the carrying value of our identifiable long-lived tangible and intangible assets and goodwill when indicators of impairment are present. Effective January 1, 2002, SFAS No. 142 requires that independent impairment reviews be obtained on the carrying values of all goodwill on an annual basis. For all long-lived tangible and intangible assets and goodwill, if an impairment loss is identified based on the fair value of the asset, such loss would be charged to expense in the period we identify the impairment.

*Valuation of Goodwill.* During the three months ended March 31, 2002, we obtained an independent review on the carrying value of our existing goodwill in accordance with SFAS No. 142 which provides specific guidance for determining and measuring impairment of goodwill. Based upon the results of the review, we recorded an impairment charge of \$12.1 million, representing the remaining goodwill related to our reporting unit that comprises the nutritional supplement lines we acquired in 1997. This amount represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) this nutritional supplements business has been experiencing a larger percentage decline in revenues than most of the comparable businesses of other companies. Because future cash flows and operating results used in the independent review are based on management's projections and assumptions, future events can cause actual results to differ from those projections. In such event, the full impairment charge of \$12.1 million taken during the three months ended March 31, 2002 may not be justified.

*Valuation of Other Long-Lived Tangible and Intangible Assets.* Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results; (2) significant changes in the manner of our use of the acquired assets or the strategy for our overall business; (3) underutilization of our tangible assets; (4) discontinuance of product lines by ourselves or our customers; (5) significant negative industry or economic trends; (6) significant decline in our stock price for a sustained period; (7) significant decline

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in our market capitalization relative to net book value; and (8) goodwill impairment identified during an independent review under SFAS No. 142.

Because the independent appraisal of the fair value of the reporting unit underlying our nutritional supplements business indicated an impairment of goodwill related to that reporting unit, as discussed above, we proceeded to also obtain an independent impairment review of the carrying value assigned to related trademarks and brand names. The results of this review also indicated an impairment of the carrying value of such trademarks and brand names because the full carrying amount of these intangible assets was not expected to be recoverable and exceeded its fair value. The carrying amount of these intangible assets was not recoverable because it exceeded the sum of the undiscounted cash flows expected to result from the use and eventual disposition of these assets. The fair value of these intangible assets was determined using a combination of the discounted cash flow approach and the relief from royalty approach, the latter of which valued the brand names as if they were licensed from a third party. Based on these results, we recorded another impairment charge of \$12.7 million to write-off a portion of the carrying value of these trademarks and brand names during the three months ended March 31, 2002. The remaining carrying value of these intangible assets was \$4.2 million at March 31, 2002, which is being amortized over the assets remaining useful lives of 20 years. The impairment was measured partly based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model. Although we believe that the remaining carrying value of our long-lived tangible and intangible assets were realizable as of March 31, 2002, future events could cause us to conclude otherwise.

### *Accounting for Income Taxes*

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure and assessing temporary differences resulting from differing treatment of items, such as reserves and accruals and lives assigned to long-lived and intangible assets, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within our tax provision.



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Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of \$12.3 million as of December 31, 2001, due to uncertainties related to the future benefits from our deferred tax assets, primarily consisting of certain foreign net operating losses and tax credits, before these losses and credits expire. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance which could materially impact our tax provision.

### *Legal Contingencies*

Because of the nature of our business, we may from time to time be subject to consumer product claims or various other lawsuits arising in the ordinary course of our business and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial claims. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us. We are currently involved in certain legal proceedings, as described in our reports filed from time

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to time with the Securities and Exchange Commission, including our quarterly report on Form 10-Q for the quarter ending March 31, 2002. We do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to quantify our potential liability, if any, due to uncertainty as to the nature, extent and validity of the claims against us, uncertainty as to the nature and extent of the damages or other relief sought by the plaintiff and the complexity of the issues involved. Our potential liability, if any, in a particular case may become quantifiable as the case progresses, which will require us to begin accruing for the expected loss.

### **Recently Issued Accounting Standards**

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 142, which addresses changes in the financial accounting and reporting for acquired goodwill and other intangible assets with indefinite lives. Effective January 1, 2002, all existing acquired goodwill and other intangible assets with indefinite lives are no longer amortized to expense, with early adoption required for all goodwill and other intangible assets with indefinite lives acquired subsequent to June 30, 2001. The statement also provides specific guidance for determining and measuring impairment of all goodwill and other intangible assets. We recorded goodwill amortization of approximately \$151,000 for the three months ended March 31, 2001. At March 31, 2002, the total amount of goodwill affected by this statement was \$74.3 million, which was all acquired subsequent to June 30, 2001. Also, at the adoption of SFAS No. 142, we recorded a goodwill impairment charge of \$12.1 million during the three months ended March 31, 2002.

In August 2001, the FASB issued SFAS No. 144, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement requires that a long-lived asset to be abandoned, exchanged for a similar productive asset, or distributed to owners in a spin-off be considered held and used until it is disposed of. The changes in this statement require that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and broaden the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 also provides guidance for determining and measuring impairment of long-lived and intangible assets, which do not materially differ from previous guidance. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years, with early adoption encouraged. The provisions of this statement generally are to be applied prospectively. During the three months ended March 31, 2002, we recorded an impairment charge to our carrying value of certain trademarks and brand names of \$12.7 million in accordance with SFAS No. 144.

### **Quantitative and Qualitative Disclosures about Market Risk**

The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those discussed in the forward-looking statements. We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. We do not use derivative financial instruments for speculative or trading purposes.

#### *Interest Rate Risk*

We are exposed to market risk from changes in interest rates primarily through our investing and financing activities. In addition, our ability to finance future acquisition transactions or fund working capital requirements may be impacted if we are not able to obtain appropriate financing at acceptable rates.

Our investing strategy, to manage interest rate exposure, is to invest in short-term, highly liquid investments. Our investment policy also requires investment in approved instruments with an initial maximum allowable maturity of 18 months and an average maturity of our portfolio that should not exceed 6 months, with at least \$500,000 cash available at all times. Currently, our short-term investments are in money market funds with original maturities of 90 days or less. At March 31, 2002, our short-term investments approximated market value.

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In December 2001, we entered into the RBS Credit Agreements with The Royal Bank of Scotland plc and related entities for credit facilities in the aggregate amount of \$70 million. The RBS Credit Agreements consisted of term loans aggregating \$62.5 million, of which \$10 million were denominated in Japanese Yen, and a \$7.5 million multicurrency revolving line of credit. To date, we have not utilized the revolving line of credit. The aggregate outstanding loan balance under the RBS Credit Agreements as of March 31, 2002 was \$52.3 million, including capitalized interest of approximately \$109,000 but net of a reduction of approximately \$334,000 resulting from a change in the United States Dollar-to-Japanese Yen exchange rate. The term loans and revolving line of credit allow us to borrow at LIBOR plus a spread from 1.5% to 3.5% (and an additional 2% in case of default), depending on the type of loan (senior or junior) and the interest period. On the loans in which the spread may vary, the spread depends on the ratio of our total debt to EBITDA. In February 2002, we entered into an interest rate swap agreement with the bank, as required by the RBS Credit Agreements, which will protect both our company and the bank from interest rate fluctuations. Under the interest rate swap agreement, the LIBOR rate is set at a minimum of 3.36% and a maximum of 5% and applies to \$34.8 million to \$41.7 million of the term loans denominated in United States Dollars, depending upon the interest period. This interest rate swap agreement is effective for the period from February 25, 2002 to December 31, 2004. Had there not been an interest rate swap agreement in place as of March 31, 2002, the LIBOR applicable to the term loans denominated in United States Dollars would have been 1.9%. The LIBOR applicable to the term loan denominated in Japanese Yen was 0.10% at March 31, 2002. If the LIBOR rate increases one percentage point, as compared to the rate at March 31, 2002, taking into consideration the terms of the interest rate swap agreement, we estimate an increase in our interest expense of approximately \$103,000 over the next twelve months. If the LIBOR rate increases two percentage points, as compared to the rate at March 31, 2002, taking into consideration the terms of the interest rate swap agreement, we estimate an increase in our interest expense of approximately \$544,000 over the next twelve months.

Our recently acquired IVC subsidiary has a credit agreement with Congress Financial Corporation, which allows IVC to borrow up to \$15.0 million under a revolving credit commitment, subject to borrowing base limitations, as defined in the agreement. IVC also has outstanding \$4.2 million under a term loan commitment. The loans with Congress mature on October 16, 2003. As of March 31, 2002, total borrowings outstanding under the credit agreement with Congress were \$6.9 million. Borrowings under the revolving credit commitment and the term loan bear interest at either 1.5% above the bank's prime rate or, at IVC's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. As of March 31, 2002, the interest rate on \$5.5 million of the outstanding borrowings was at the Adjusted Eurodollar Rate of 2% plus the spread of 3.75% and the interest rate on the remaining \$1.4 million of the outstanding borrowings was at the prime rate of 4.75% plus the spread of 1.5%. If both the Adjusted Eurodollar Rate and the prime rate increase one percentage point, as compared to the respective rates at March 31, 2002, we estimate an increase in IVC's interest expense of approximately \$60,000 over the next twelve months. If both the Adjusted Eurodollar Rate and the prime rate increase two percentage points, as compared to the respective rates at March 31, 2002, we estimate an increase in IVC's interest expense of approximately \$120,000 over the next twelve months.

#### *Foreign Currency Risk*

We face exposure to movements in foreign currency exchange rates. During the three months ended March 31, 2002, the net impact of foreign currency changes was a gain of \$188,000. We expect this exposure to increase because of our expansion into markets outside of the United States as a result of our recent acquisitions of the Unipath business and IVC. Historically, we have not used derivative financial instruments or other financial instruments to hedge economic exposures or for trading. However, because significant amounts of the revenue and expenses of the Unipath business are denominated in foreign currencies, starting in early 2002 we began utilizing foreign exchange forward contracts to minimize exposure to the risk that the eventual net cash inflows and outflows resulting

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from the sale of products to foreign customers and purchases from foreign suppliers will be adversely affected by changes in exchange rates. Our goal is to utilize foreign exchange forward contracts for recognized receivables and payables and firmly committed cash inflows and outflows. The use of these derivative financial instruments allows us to reduce our overall exposure to exchange rate movements, since the gains and losses on these contracts are expected to substantially offset losses and gains on the assets, liabilities and transactions to which these contracts relate. Cash inflows and outflows denominated in the same foreign currency are netted on a legal entity basis and the corresponding net cash flow exposure is appropriately hedged. As of March 31, 2002, we did not have outstanding foreign exchange forward contracts.

Additionally, as described above, in December 2001 we entered into a series of credit agreements with The Royal Bank of Scotland plc and related entities pursuant to which we borrowed \$10.0 million denominated in Japanese Yen (or 1,283 million Japanese Yen). As of March 31, 2002, the outstanding balance of this loan was \$8.1 million, net of a reduction of approximately \$334,000 resulting from a change in the

dollar-to-yen exchange rate. We have not entered into a foreign exchange forward contract to hedge this loan; however, if we do not expect to collect sufficient payments in yen from our royalty contracts recently acquired as part of the Unipath business, we may do so in the future. As of March 31, 2002, the dollar-to-yen exchange rate was approximately 132.77. If the dollar-to-yen exchange rate decreased by ten percent, as compared to the rate at March 31, 2002, we estimate that the outstanding principal amount owed by us under this loan would have been higher by approximately \$900,000 on that date. If the dollar-to-yen exchange rate decreased by twenty percent, as compared to the rate at March 31, 2002, we estimate that the outstanding amount owed by us under this loan would have been higher by approximately \$2.0 million on that date. If, on the maturity dates over the next twelve months, the dollar-to-yen exchange rate was lower by ten percent, as compared to the rate at March 31, 2002, we would have to pay approximately \$118,000 more in principal repayments during that period. If, on the maturity dates over the next twelve months, the dollar-to-yen exchange rate was lower by twenty percent, as compared to the rate at March 31, 2002, we would have to pay approximately \$265,000 more in principal repayments during that period.

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## BUSINESS

*The description herein of our business has been derived from a more complete description thereof contained in our annual report on Form 10-K, as amended, for the year ended December 31, 2001 and other filings with the Securities and Exchange Commission incorporated by reference into this prospectus supplement and the accompanying prospectus. As a result, it may not include all information that is important to you. You should read this entire prospectus supplement and the accompanying prospectus, including the documents incorporated by reference, carefully before deciding whether to invest in our common stock.*

### Overview

We develop, manufacture and market consumer health care 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 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 health care 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.

On November 21, 2001, Johnson & Johnson acquired Inverness Medical Technology, Inc., or IMT, our former parent, in a merger transaction and, simultaneously, our company was split off from IMT as a separate publicly traded company. Immediately prior to the consummation of these transactions, IMT restructured its operations so that we would hold all of IMT's non-diabetes businesses (women's health, nutritional supplements and clinical diagnostics). At the closing of the transaction, all of the shares of our common stock held by IMT were split-off from IMT in a pro rata distribution to IMT's stockholders (the Split-Off), and IMT merged with and became a wholly-owned subsidiary of Johnson & Johnson.

On December 20, 2001, we acquired Unipath Limited, a global leader in home pregnancy and ovulation testing and natural family planning, and its associated companies and assets from Unilever plc and certain entities affiliated with Unilever. The Unipath acquisition provides us with leading brand name consumer diagnostic products that complement our existing value branded and private label home pregnancy detection and ovulation prediction products. Together with the acquisition of the Unipath business, we also acquired rights to certain antibody clones and other intellectual property rights. The consideration paid to Unilever for the Unipath business was 103 million pounds sterling (approximately 150 million United States dollars) in cash, subject to certain adjustments provided for in the sale agreement.

On March 19, 2002, we acquired IVC Industries, Inc., a manufacturer and distributor of hundreds of different vitamin and nutritional supplement products sold under brand names and through private label arrangements with retailers. With the addition of IVC, we intend to consolidate substantially all of our vitamin and nutritional supplement manufacturing at IVC and discontinue most of our outsourced manufacturing arrangements. The aggregate purchase price of IVC was approximately \$27.3 million, which included \$17.4 million in assumed debt.

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## Strategy

Our objective is to become the leading provider of innovative products in the areas of women's health and chronic disease self-management. The key elements of our strategy for achieving this goal are to:

*Continue developing innovative diagnostic products.* Prior to the split-off of our company as an independent public company in November 2001, our management team developed the first electrochemical blood glucose monitoring system and commercialized a system that measures blood glucose in the fastest time available with a small blood sample. In addition, our Unipath subsidiary, acquired in December 2001, was the first to develop a one-step home pregnancy test, a one-step ovulation test and an estrogen-based fertility monitor. We intend to leverage our collective experience in the rapid test diagnostic sector and our significant intellectual property portfolio to develop superior and innovative products in the areas of women's health and chronic disease self-management.

*Expand the application of our technology to develop products in other focus areas.* Currently, our diagnostic products are primarily used to detect pregnancy and predict ovulation. However, we believe there are additional market opportunities for us to pursue, both in women's health and in other areas. For example, we believe that the aging population may provide opportunities in other areas of women's health, such as osteoporosis and menopause, creating demand for consumer diagnostic products in those areas. We plan to continue investing in research and development and intend to begin commercially launching new products in our targeted areas by 2004, with a goal of launching at least one significant new product each year.

*Selectively acquire complementary product lines, companies and technologies.* We plan to pursue selective acquisitions that could advance our technologies, establish new products and increase market penetration and breadth of our product offerings. We have significant experience in evaluating and completing acquisitions of businesses, technologies and intellectual property and in integrating acquired businesses and commercializing acquired technology. We have recently completed and are integrating two acquisitions, Unipath and IVC.

*Maximize market penetration of our products.* We will continue to leverage our global marketing and sales force to further penetrate our existing markets through our relationships with leading retailers, including Walgreens, CVS, RiteAid and Boots, as well as with drug wholesalers and mass merchandisers. We believe that our high level of service and ability to provide a wide range of high quality consumer products, which include premium and value-oriented brands and private label products, enhances our existing customer relationships and helps us develop new relationships.

*Manufacture high quality products at low cost.* One of the most significant contributors to our growth will be to leverage and enhance manufacturing operations for our products. We produce nearly all of our disposable consumer diagnostic products at our facilities in Bedford, England and Galway, Ireland, both of which are ISO and FDA registered establishments that employ modern production techniques to produce consistent, high quality products at low cost.

## Industry

### Consumer Products

*Consumer Diagnostic Products.* Our current consumer diagnostic products target the women's health market. A.C. Neilson & Co. estimates total United States retail sales of pregnancy and ovulation prediction tests at approximately \$278 million for the 52 weeks ending March 30, 2002, approximately 85% of which represents sales of pregnancy detection tests and approximately 15% of which represents sales of ovulation prediction tests. We believe that the demand for ovulation prediction products is growing steadily because of increased awareness of the incidence of infertility, as well as a desire on the

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part of couples to plan conception with more certainty. The demand for pregnancy test products is growing also, but at a slower pace.

There are numerous pregnancy self-tests on the market, which are typically urine-based tests and provide results in less than five minutes. Ovulation prediction urine-based tests inform women of the best time to conceive a baby by detecting the surge of the luteinizing hormone, which precedes ovulation. Ovulation prediction tests are generally easy to use and are becoming widely accepted by professional fertility care providers and the general public.

*Vitamins and Nutritional Supplements.* The Dietary Supplement Information Bureau estimates that the total mass merchandise retail sales of vitamins and nutritional supplements in the United States during 2000 was \$5.7 billion. Growth in the industry is primarily driven by media commentary regarding the quality and efficacy of nutritional supplements. Well-established market segments, where competition is greater and

media commentary less frequent, generally experience relatively slow and stable growth. There has been little or no growth in the overall nutritional supplements industry over the last year, as the decline of the herbal supplement segment, which was extremely active in the past, has offset the growth in particular new mineral and non-herbal supplements. Slow growth has resulted in retailers reducing shelf space for nutritional supplements and forced many under-performing items out of distribution, including several broad product lines. Sales growth of store brand, or private label, products has outpaced the overall industry growth, as retailers continue to add to the number of private label nutritional products on their shelves.

#### *Clinical Diagnostics*

The clinical diagnostics market consists of products designed to assist medical professionals in analyzing human body fluids or other materials for markers of medical conditions, including pregnancy or disease, or the presence of agents that may signal disease.

Customers can be divided into two segments. One segment consists of centralized laboratories that increasingly benefit from computerization and automation. The second segment consists of small and medium-sized non-centralized laboratories and testing locations, including small blood banks, doctors' offices and some rapid response laboratories in larger medical centers. Clinical diagnostics products that serve this second segment are rapid result, point-of-care tests that offer an alternative to traditional high volume, multi-step immunoassays (which use antibodies to measure hormone levels) that require skilled operators and centralized processing.

We believe that the demand for infectious disease diagnostic products is growing faster than demand in other segments of the point-of-care immunoassay market due to the increasing incidence of certain diseases or groups of diseases, including viral hepatitis, acquired immunodeficiency syndrome, tuberculosis, as well as chlamydia and other sexually transmitted diseases.

We also believe there is a growing demand in the clinical diagnostics market for fast, high-quality, inexpensive, self-contained diagnostic kits resulting in part from efforts in many nations to control health care expenditures.

### **Products**

#### *Consumer Products*

*Consumer Diagnostics.* Our consumer diagnostics business currently develops, manufactures and markets home pregnancy and ovulation prediction tests under our own brands and under various private labels. Our ClearBlue brand of home pregnancy detection tests and our ClearPlan brand of ovulations prediction tests are global leaders in terms of both sales and technology, though ClearBlue has a smaller presence in the United States. Our Inverness Medical branded products are marketed to value-oriented consumers in the United States. In addition, we are a major United States supplier of

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private label home pregnancy detection and ovulation prediction products. We also sell Persona, a contraceptive monitoring device sold overseas, primarily in Germany and the United Kingdom.

*Pregnancy Test Products.* We market our pregnancy self-test kits in both stick and cassette versions. The stick version has an exposed wick which absorbs urine when placed in the urine stream. The cassette version requires the user to first collect a urine sample in a cup and then use an enclosed dropper to place the urine sample in the test well. Both versions employ identical technology enabling the display of visual results in approximately three minutes. We manufacture our pregnancy test kits at our facilities in Bedford, England and Galway, Ireland and sell them over-the-counter through drug store chains, grocery chains and mass merchandisers under their own store brand label as well as under our own brand names.

*Ovulation Prediction Products.* We market our ovulation prediction self-test kits in stick and cassette versions, each of which operates in a manner similar to the comparable version of our pregnancy self-test kits. We market our ovulation prediction test kits under our own brand names and under various store brand labels of retail drugstore chains, grocery stores and mass merchandisers. Our ovulation prediction test kit provides 24 to 48 hours notice of when ovulation is likely to occur. By identifying the days when a woman is most fertile, these products assist couples in their family planning. Clinically accurate results are available in approximately three minutes.

## Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 424B2

We also market an advanced ovulation prediction self-test device called the ClearPlan Easy Fertility Monitor. The Fertility Monitor not only detects the surge of the luteinizing hormone, which causes ovulation, but it also identifies additional days when a woman can conceive by detecting a rise in estrogen levels. The Fertility Monitor is comprised of a hand held monitoring device and disposable urine test sticks. This product is sold primarily in the United States and Canada.

Our ovulation prediction products are primarily manufactured at our facilities in Bedford, England and Galway, Ireland, except for the Fertility Monitor hand held monitoring device which we purchase from third party suppliers.

*Persona.* Persona is a diagnostic monitoring device that serves as a natural method of contraception by allowing the user to monitor her menstrual cycle. Persona is comprised of a hand held monitoring device and disposable urine test sticks. Persona is sold in Europe, primarily in Germany and the United Kingdom, where it is classed as a contraceptive device. Persona does not currently have regulatory approval in the United States.

*Vitamins and Nutritional Supplements.* As a result of our recent acquisition of IVC, we now market a wider variety of vitamins and nutritional supplements through retail drug store chains, mass merchandisers, food stores and warehouse clubs. Through IVC, we acquired a comprehensive assortment of vitamin, mineral and nutritional supplement products. These products will be marketed under the Inverness Medical tradename, as well as under private label and are positioned as high quality, lower priced alternatives to nationally advertised brands. The acquired IVC branded products are high quality products sold at moderate prices through national and regional drug store, club stores, supermarket and mass merchandising chains. Our Synergy Plus line of products is sold primarily in health food stores. The acquisition of IVC also expands our vitamin and nutritional supplements business outside of United States for the first time because the products we acquired from IVC are marketed internationally.

Our nutritional supplement products that predate our acquisition of IVC include Stresstabs, a B-complex vitamin with added antioxidants; Ferro-Sequels, a time release iron supplement; Protegra, an antioxidant vitamin and mineral supplement; Posture, a calcium supplement; ALLBEE, a line of B-complex vitamins; and Z-BEC, a zinc supplement with B-complex vitamins and added antioxidants.

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We also market our products under the SmartCare program, which assists consumers in matching their health concerns to the appropriate supplement products that we sell. SmartCare provides a means of linking our various nutritional supplement products, allowing for greater efficiencies in advertising, promotion and merchandising. We have not yet determined whether we will be able to expand this program to include products that we acquired from IVC.

### *Clinical Diagnostic Products*

*Clearview Products.* Through our acquisition of the Unipath business, we acquired and currently develop, manufacture and sell six qualitative, visually-interpreted rapid diagnostic tests for use by medical professionals. These products, which are primarily sold under the Clearview label, are used in point-of-care environments where a rapid response is desired or where the volume of testing is too low to warrant high volume methods.

The six Clearview products are:

*Clearview HCG II and Easy HCG.* These tests are used to confirm pregnancy and also to rule out pregnancy in patients with abdominal pain, late menses and spotting.

*Clearview Chlamydia MF.* This test provides a protocol to rapidly detect chlamydia trachomatis infection in men (urine specimen) and women (endocervical swab). The test delivers comparable performance of laboratory immunoassays, but takes only 30 minutes to achieve a result. In the United States, this product is approved for evaluation of females only.

*Clearview Strep A.* The test is used to detect streptococcal group A in pharyngeal swabs from patients with sore throat and other symptoms. The test gives results in five minutes.

## Edgar Filing: INVERNESS MEDICAL INNOVATIONS INC - Form 424B2

*Clearview IM.* This test is used to diagnose or rule out infectious mononucleosis. Results are available in five minutes for serum plasma specimen and 15 minutes for whole blood. This test is not sold in the United States.

*Clearview C Diff A.* This test is used to diagnose clostridium difficile-associated diarrhea and to monitor the effectiveness of antibiotic treatment. The test is sold under the Clearview brand in the United States. We also manufacture and supply this test to an unrelated third party for sale outside the United States.

*Listeria.* This test is used to detect the presence of listeria monocytogenes, a microorganism, in foods and raw materials used in the food industry. We manufacture and supply this test for an unrelated third party who markets it globally under its own brand name.

*Orgenics Products.* Our wholly-owned subsidiary, Orgenics Ltd., which is located in Yavne, Israel, develops, manufactures and sells clinical diagnostic products based on several proprietary technological platforms. These platforms are used to detect a wide variety of infectious diseases, including HIV-1, HIV-2, hepatitis, chlamydia and TORCH. The products are designed to enable small to medium-sized laboratories to economically analyze low volumes of test specimens.

Our Orgenics clinical diagnostic products are based on three primary platforms: ImmunoComb, DoubleCheck and ImmunoGold. ImmunoComb is our main platform and currently serves as the basis for 25 diagnostic products. The platform is based upon a plastic "comb" with twelve projections upon which antigens or antibodies are applied and which is inserted into a vessel containing a patient's specimen. This manual testing platform provides the sensitivity, accuracy and versatility of more expensive automated testing platforms at lower prices. DoubleCheck is a single test device through which a specimen migrates to a reaction zone where it filters through and subsequently binds to immobilized antigens or antibodies. DoubleCheck produces results in less than 15 minutes. ImmunoGold consists of a strip containing antigens or antibodies immobilized along a line to which a pad containing gold conjugate is attached. When rehydrated by the liquid specimen the gold particles migrate laterally along the strip where they react with immobilized reagents to produce a sharp red line. ImmunoGold produces results in about five minutes and has the advantages of not requiring refrigerated storage or addition of reagents during the test procedure.

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### Marketing and Sales

#### *Consumer Products*

*Consumer Diagnostic Products.* We market and sell our consumer diagnostic products worldwide through third party brokers and our sales force under our own trade and brand names as well as under store brands. Our customers include retail drug store chains, drug wholesalers, grocery retailers and mass merchandisers in North America and Europe. Our ClearBlue and ClearPlan brand products are global leaders in terms of both sales and technology, though ClearBlue has a smaller presence in the United States. Our ClearBlue and ClearPlan products are generally marketed globally as premium products and compete intensively with other premium brand name products. Persona is also marketed as a premium product in Europe. Marketing of premium branded products focuses on brand awareness and feature and performance differentiation. This is achieved primarily through mass media television advertising. Within the United States, where our ClearBlue brand has not yet established the high level of brand awareness and brand loyalty typical of a premium brand, we are attempting to build market share by offering value-oriented pricing as well as by aggressively advertising the brand. Our Inverness Medical branded products compete primarily based on price and are not heavily advertised. Private label arrangements accounted for 63% of our consumer diagnostics revenues during 2001 without reference to the Unipath business, which was not acquired until December 20, 2001. Our three largest customers are Walgreens, CVS and Rite Aid, each of which sells both branded and private label products purchased from us.

*Vitamins and Nutritional Supplements.* We primarily market and sell our vitamins and nutritional supplements under our own brand names to retail drug store chains, drug wholesalers, grocery retailers and mass merchandisers in the United States and Canada. We also have distribution agreements in place to support the sale of certain of our products in the Middle East, Mexico, South Africa, Europe and the Pacific Rim. Our three largest customers during 2001 were Walgreens, Wal-Mart and McKesson Corporation. IVC's largest customer has historically been Costco Wholesale, which accounted for 57% of IVC's sales during its fiscal year ending July 31, 2001. Our rights to the trademarks Stresstabs, Ferro-Sequels, Posture, Protegra, ALLBEE and Z-BEC are limited to use in North America, but we are not restricted from marketing the formulations sold under those brand names in North America under other brand names outside of North America.

#### *Clinical Diagnostic Products*

Our Clearview products are sold worldwide through third party distributors and in Germany by our own sales force. However, we sell our C Diff A test under our Clearview brand only in the United States. We otherwise manufacture and sell our C Diff A test, as well as our Listeria test product, to an unaffiliated company who markets the products under its own brands. That arrangement prohibits us from selling these tests

directly or to other resellers. Five countries, the United States, Germany, the United Kingdom, Japan and China, represent 80% of our sales of Clearview products. Our Organics business has sales offices in Israel, France, Russia, Brazil, Nigeria and Colombia which market our clinical diagnostics products to smaller laboratories, blood banks, physicians' offices and other patient point-of-care sites in more than 90 countries, principally in Europe, Latin America, Africa and Asia.

## **Manufacturing**

### *Consumer Products*

*Consumer Diagnostic Products.* We produce nearly all of our disposable consumer diagnostic products at our facilities in Bedford, England and Galway, Ireland. Both facilities are ISO 9001 and EN 46001 certified, FDA registered establishments that employ modern production techniques to produce consistent, high quality components. A significant portion of our products produced and assembled at our Galway plant are subsequently packaged by a third party in the United States. We rely on third

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parties for nearly all our production materials. We purchase our electronic consumer diagnostic products, the Fertility Monitor and Persona, to our specifications from third party suppliers in Europe. We also purchase a small number of low cost, disposable products from third party suppliers for distribution in Europe. Because most components of our diagnostic products are produced to our specifications, some of our suppliers are single source suppliers with few, if any, alternative sources immediately available.

We own one-half and lease one-half of our Galway facility and are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business.

*Vitamins and Nutritional Supplements.* Through our acquisition of IVC, we acquired manufacturing facilities in Freehold and Irvington, New Jersey. IVC manufactured substantially all of its products at these locations. The facilities located in Freehold, New Jersey are equipped with large-volume blending, tableting and coating equipment, high-speed packaging equipment, including "cartoning," "stretch carding" and "blister carding" equipment, and testing and quality control laboratories. IVC internally manufactures all of its softgel products at the Irvington facility. We intend to consolidate manufacturing of substantially all of our vitamin and nutritional supplement products in these acquired facilities, both of which currently have substantial additional capacity. These facilities have been certified by an independent auditing firm to be in compliance with Good Manufacturing Practices. We currently manufacture our non-IVC nutritional supplement products domestically through third parties.

### *Clinical Diagnostics Products.*

Our clinical diagnostic products are manufactured at our facilities in Bedford, England, which is described above, and in Yavne, Israel. The Yavne manufacturing facility is ISO 9001 and EN 46001 certified, as well as Good Manufacturing Practices certified by the Israeli Ministry of Health.

## **Research and Development**

Our research and development efforts are currently focused on developing new products and enhanced features for our lines of women's health and clinical diagnostics products, as well as the development of product lines targeting new markets. Our research and development staff consists of approximately 70 people, many of whom have extensive experience in the consumer diagnostics industry. Most of our research and development activities are carried out in Bedford, England, Galway, Ireland and Yavne, Israel. We may, from time to time, supplement our internal research and development efforts with third parties' efforts either through co-development or licensing arrangements, or through product or technology acquisitions. In connection with co-development or licensing activities that we may enter into in the future, we may provide financial development assistance to these parties and may also utilize our own research and development resources to design certain portions of such products. We expect research and development expenses to continue to increase as we seek to enhance our existing products and develop additional products.

## **Foreign 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.



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## Competition

### *General*

We have existing competitors, as well as a number of potential new competitors, who have greater name recognition, and significantly greater financial, technical and marketing resources than we do. These strengths may allow them to devote greater resources than we can to the development, marketing and sales of products. These competitors may also engage in more extensive research and development, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies and make more attractive offers to existing and potential employees, customers and clients.

We expect that industry forces will impact us and our competitors. Our competitors will likely strive to improve their product offerings and price competitiveness. We also expect our competitors to develop new strategic relationships with providers, referral sources and payors, which could result in increased competition. The introduction of new and enhanced services, acquisitions and industry consolidation, and the development of strategic relationships by our competitors could cause a decline in sales or loss of market acceptance of our products, intensify price competition or make our products less attractive.

### *Consumer Products*

*Consumer Diagnostic Products.* Competition in the pregnancy detection and ovulation prediction market is intense. Our competitors in the United States, and worldwide, are numerous and include, among others, large medical and consumer products companies as well as numerous private label manufacturers. Our competitors for the sale of pregnancy test products include Abbott Laboratories, Acon Laboratories, Advanced Biotechnologies, Becton Dickinson, Biotech Atlantic, Armkel, London International Holdings, Pfizer, Princeton BioMeditech Corporation, Syntron Bioresearch and Quidel Corp. Our competitors for the sale of ovulation predictors include Becton Dickinson, Armkel, Princeton Biomeditech, Syntron and Quidel. Competition among branded consumer diagnostics products is based on brand recognition and price. Products sold under well-established or "premium" brand names can demand higher prices and maintain high market shares due to brand loyalty. Outside of the United States, ClearBlue is a premium brand and is a market leader. In the United States, where ClearBlue is less well-established, although still a leading brand, the premium brands can demand higher pricing than we can. Our ClearPlan ovulation prediction products qualify as premium brands worldwide and are market leaders both in the United States and globally. Our Inverness Medical-branded consumer products compete based on price and do not attempt to compete based on brand recognition. For private label manufacturers, competition is based primarily on the delivery of products at lower prices that have substantially the same features and performance as brand name products. ClearPlan Fertility Monitor and Persona are unique products, and their competitors or markets are not easily defined.

Many of our competitors have substantially greater financial, production, marketing and distribution resources than we do. However, we believe that we can continue to compete effectively in the consumer diagnostics market based on our research and development capabilities, advanced manufacturing expertise, diversified product positioning, global market presence and established wholesale and retail distribution networks.

*Vitamins and Nutritional Supplements.* In the branded nutritional supplements industry, competition is based principally upon brand name recognition, price, quality, customer service and marketing support. There are numerous companies in this industry selling products to retailers. A number of these companies, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources. Among the major competitors of our branded products that are sold through supermarkets and other mass retailers are Wyeth, formerly known as American Home Products, Pharmavite, Leiner Health Products, Royal Numico and

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SmithKline Beecham. There are also several manufacturers that produce store brand nutritional supplements with formulations very similar to those of nationally marketed brands, including ours. Major competitors of our Synergy Plus brand, which is sold through health food stores and independent drug stores, include Twinlab Corporation, Wyeth and Weider Nutritional International.

The market for private label vitamins and nutritional supplements is extremely price sensitive, with quality, customer service and marketing support also being important. Many of the companies listed above as competitors of our mass marketed branded vitamins and nutritionals also sell to private label customers and constitute our major competitors for private label business. In addition, there are several companies, such as

Perrigo and Contract Pharmacal, that compete only in the private label business.

#### *Clinical Diagnostic Products*

*Clearview Products.* Our main competitors in the point-of-care immunoassay market are Abbott Laboratories and Quidel Corporation. Other notable competitors in all or some product segments are Thermo Biostar, Biosite Diagnostics, Beckman Coulter, Becton Dickinson, and a host of small but aggressive companies such as Syntron Bioresearch, Princeton BioMeditech Corporation, Applied Biotech, Vedalab and Trinity Biotech. Some automated immunoassay systems can be considered as competitors when labor shortages force laboratories to automate or when the costs of such systems are lower. Such systems are provided by Abbott, Bayer, Roche Diagnostics, Beckman and other large diagnostic companies. In the infectious disease area, new technologies utilizing simplification techniques for analyzing molecular DNA gene sequences such as lygase chain reaction or polymerase chain reaction from Abbott, Roche and Gen-Probe are making in-roads into this market.

*Organics Products.* The main competitors of our ImmunoComb products are standard enzyme linked immuno sorbent assay, or ELISA, systems, such as those produced by Organon, Inc., Bio-Rad, Abbott, Ortho, Roche and others. ELISA tests are generally used by high-volume batch processors such as blood banks and other centralized laboratories. The primary competitors of our other rapid test platforms also include multinational corporations that tend to concentrate their efforts on sales of automated diagnostic systems to centralized laboratories. These multinational corporations have greater resources and more extensive sales networks than we have. Other competitors include Trinity Biotech, Savyon, Gull Laboratories and SDS, which are smaller companies operating primarily in our niche market. Some of these companies do not have the international sales network or the number of products that we have.

#### **Patents and Proprietary Technology; Trademarks**

The medical products industry, including the diagnostic testing industry, places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability to obtain patent protection for our products and manufacturing processes to preserve our trade secrets and to avoid infringing the proprietary rights of third parties.

However, we cannot assure you as to the success or timeliness in obtaining any such patents or as to the breadth or degree of protection that any such patents might afford us. The patent position of medical products and diagnostic testing firms is often highly uncertain and usually involves complex legal and factual questions. There is a substantial backlog of patents at the United States Patent and Trademark Office and in other patent registration offices around the world. No consistent policy has emerged regarding the breadth of claims covered in medical product patents. Accordingly, we cannot assure you that patent applications relating to our products or technology will result in patents being issued, that, if issued, such patents will afford adequate protection to our products or that our competitors will not be able to design around such patents.

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The medical products industry, including the diagnostic testing industry, historically has been characterized by extensive litigation regarding patents, licenses and other intellectual property rights. We could and have incurred substantial costs in defending ourselves against patent infringement claims and in asserting such claims against others. To determine the priority of inventions, we may also have to participate in interference proceedings declared by the United States Patent and Trademark Office or foreign patent and trademark authorities, which could also result in substantial costs to us. If the outcome of any such litigation is adverse to us, our business could be materially adversely affected.

In addition, we sometimes obtain licenses to patents or other proprietary rights of third parties to manufacture and market our products. We cannot assure you that licenses required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions while we attempt to design around such patents or other rights, or we may be unable to develop, manufacture or sell such products in certain countries, or at all.

We also seek to protect our proprietary technology, including technology that may not be patented or patentable, in part through confidentiality agreements and, if applicable, inventors' rights agreements with collaborators, advisors, employees and consultants. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our trade secrets will not otherwise be disclosed to, or discovered by, competitors or potential competitors. Moreover, we may from time to time conduct research through academic advisors and collaborators who are prohibited by their academic institutions from entering into confidentiality or inventors' rights agreements.

Finally, we believe that certain of our trademarks in our consumer products product lines are valuable assets and are important to the marketing of our products. Substantially all of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate. We cannot assure you, however, that registrations will afford us adequate protection and will not be challenged as unenforceable or invalid, or will not be infringed. In addition, we could incur substantial costs in defending suits brought against us or in

prosecuting suits in which we assert rights under such registrations.

## Employees

As of March 25, 2002, we had a total of 1,171 full-time employees, of which 454 employees are located in the United States. In addition, we utilize the services of a number of consultants specializing in research and development in our targeted markets, regulatory compliance, strategic planning, marketing and legal matters.

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## MANAGEMENT

The following biographical descriptions set forth certain information regarding our directors, executive officers and other key employees.

Name	Age	Position
Ron Zwanziger	48	Chairman of the Board, President and Chief Executive Officer
David Scott, Ph.D.	45	Director and Chief Scientific Officer
Anthony J. Bernardo	50	Vice President and Chief Operating Officer President of Inverness Medical, Inc.
Jerry McAleer, Ph.D.	47	Vice President, Research and Development Managing Director of Unipath Ltd.
David Toohey	45	Vice President, European Operations
Duane L. James	42	Vice President, Finance and Treasurer
John Yonkin	42	Vice President, U.S. Sales & Marketing
Doug Shaffer	44	Vice President, U.S. Operations
Paul T. Hempel	53	General Counsel and Secretary
Ernest A. Carabillo, Jr.	63	Director
Carol R. Goldberg	71	Director
Robert P. Khederian	49	Director
John F. Levy	55	Director
Peter Townsend	67	Director
Alfred M. Zeien	72	Director

**Ron Zwanziger** has served as our Chairman, Chief Executive Officer and President since May 11, 2001. Prior to the Split-Off, Mr. Zwanziger served as Chairman, Chief Executive Officer and President of Inverness Medical Technology since its inception in 1992. From 1981 to 1991, he was Chairman and Chief Executive Officer of MediSense, a medical device company.

**David Scott, Ph.D.** has served on the Board since July 31, 2001 and is our Chief Scientific Officer. Prior to the Split-Off, Dr. Scott served as chairman of Inverness Medical Limited, a subsidiary of Inverness Medical Technology, since July 1999 and served as a managing director of Inverness Medical Limited from July 1995 to July 1999. Dr. Scott served as Managing Director of Great Alarm Limited, a consulting company, from October 1993 to April 1995. Between October 1984 and September 1993, he held several positions at MediSense UK, most recently as managing director where he was responsible for managing product development, as well as the mass manufacture of one of its principal products, ExacTech.

**Anthony J. Bernardo** has served as a Vice President since the Split-Off and on February 19, 2002 was appointed our Vice President & Chief Operating Officer. He has also served as President and Chief Operating Officer of Inverness Medical, Inc., our primary U.S. operating subsidiary, since the Split-Off. Prior to the Split-Off, Mr. Bernardo served as Vice President of New Business Development of Inverness Medical Technology since April 2000. Prior to April 2000, Mr. Bernardo served as Vice President and Senior Director of Operations for a division of Polaroid Corporation from April 1997. From 1991 to 1997, he held several executive management positions with Dade International Inc., most recently as Vice President of Site Operations for the Paramax Chemistry unit where he was responsible for the integration of the diagnostics business unit acquired from DuPont.

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**Jerry McAleer, Ph.D.** has served as our Vice President, Research and Development since the Split-Off. Prior to the Split-Off, Dr. McAleer served as Vice President of Research and Development of Inverness Medical Technology and Inverness Medical Limited, one of its subsidiaries, since 1999. From 1995 to 1999, Dr. McAleer served as Director of Development of Inverness Medical Limited and headed the development of Inverness Medical Technology's electrochemical glucose strips. Prior to joining Inverness Medical Technology, Dr. McAleer held senior research and development positions at MediSense from 1985 to 1993 and more recently, at Ecosensors, Inc., an environmental research company, where he was responsible for the development of electrochemically based assay systems.

**David Toohey** was appointed Vice President, European Operations on February 19, 2002 and had served as our Vice President, New Products since the Split-Off. He was also appointed Managing Director of Unipath Ltd. when we acquired the Unipath businesses on December 20, 2001. Prior to the Split-Off, Mr. Toohey was employed by Inverness Medical Technology as its Vice President, New Products since May 2001. Prior to joining Inverness Medical Technology, Mr. Toohey served as Vice President of Operations at Boston Scientific Corporation's Galway, Ireland facility. Between 1995 and 2001, he oversaw the growth of that facility initially as General Manager, later as Managing Director and finally as Vice President of Operations. Prior to that time he held various executive positions at Bausch & Lomb, Inc., Digital Equipment Corp. and Mars, Inc.

**Duane L. James** has served as our Vice President, Finance since the Split-Off and as our Treasurer since our company's inception. Prior to the Split-Off, Mr. James served as Vice President, Finance and Treasurer of Inverness Medical Technology since October 2000. Prior to October 2000, Mr. James served as Inverness Medical Technology's Chief Accounting Officer since August 1998 and as its Corporate Controller from February 1996 until August 1998. From June 1991 to February 1996, he held positions at Aquila Biopharmaceuticals, Inc. ranging from Accounting Manager to Corporate Controller.

**John Yonkin** has served as our Vice President, U.S. Sales & Marketing since the Split-Off. Prior to the Split-Off, Mr. Yonkin served as Inverness Medical Technology's Vice President of U.S. sales since October 1998 and General Manager since January 2000. He also served as Manager of Product Development for Inverness Medical Technology from October 1997 until October 1998. From January 1995 to September 1997, Mr. Yonkin was Director of National Accounts for Genzyme Genetics, a subsidiary of Genzyme, Inc., a leader in Genetic testing services for hospitals, physicians and managed healthcare companies. Previously, he worked for MediSense, a medical device company, in a number of marketing and sales capacities.

**Douglas Shaffer** has served as our Vice President, U.S. Operations since the Split-Off. Prior to the Split-Off, Mr. Shaffer served as Vice President, U.S. Operations of Inverness Medical Technology since January 2001. Prior to January 2001, he served as Inverness Medical Technology's Controller, U.S. Operations since December 1996. Before joining Inverness Medical Technology, Mr. Shaffer served as a division controller for several different divisions of MKS Instruments, Inc., a leading producer of gas management instrumentation.

**Paul T. Hempel** has served as General Counsel and Secretary since the inception of our company. Prior to the Split-Off, Mr. Hempel served as General Counsel and Assistant Secretary of Inverness Medical Technology since October 1, 2000. He was a founding stockholder and Managing Director of Erickson Schaffer Peterson Hempel & Israel PC from 1996 to 2000. Prior to 1996, Mr. Hempel was a partner and managed the business practice at Bowditch & Dewey LLP.

**Ernest A. Carabillo, Jr.** has served on the Board since May 30, 2001. Prior to the split-off, Mr. Carabillo served as a director of Inverness Medical Technology since May 2000. He is the founder and President of EXPERTech Associates, Inc., which provides regulatory, clinical and quality management consulting services to medical device companies, where he has served as President since 1990. He has also served in management positions at Baxter Healthcare, C.R. Bard and the medical

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device/pharmaceutical division of Union Carbide. Mr. Carabillo has served as the head of three different divisions of the Food and Drug Administration and Department of Justice and as Associate Director of Regulatory Affairs for the President's Office of Drug Abuse Policy.

**Carol R. Goldberg** has served on the Board since May 30, 2001. Prior to the Split-Off, Ms. Goldberg served as a director of Inverness Medical Technology since August 1992. Since December 1989, she has served as President of The AVCAR Group, Ltd., an investment and management consulting firm in Boston, Massachusetts. Ms. Goldberg is a director and serves on the compensation committee of the board of directors of America Service Group, Inc., a managed healthcare company, The Gillette Company, a consumer products company, and Konover Property Trust, Inc., a real estate investment trust. Ms. Goldberg is a member of the Board's Compensation Committee.

**Robert P. Khederian** has served on the Board since July 31, 2001. Mr. Khederian is the Chairman of Belmont Capital, a venture capital firm he founded in 1996. From 1984 through 1996, he was founder and Chairman of Medical Specialties Group, Inc., a nationwide distributor of medical products which was acquired by Bain Capital. Since 1998, Mr. Khederian has served as the Managing Partner of Provident Capital

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Partners and First Healthcare Partners, both of which are investment banking firms based in Boston, Massachusetts. Mr. Khederian is also a director of Cambridge Heart, Inc. Mr. Khederian is a member of the Board's Audit Committee.

**John F. Levy** has served on the Board since May 30, 2001. Prior to the Split-Off, Mr. Levy served as a director of Inverness Medical Technology since August 1996. Since 1993, he has been an independent consultant. Mr. Levy served as President and Chief Executive Officer of Waban, Inc., a warehouse merchandising company, from 1989 to 1993. Mr. Levy is a member of the Board's Audit Committee.

**Peter Townsend** has served on the Board since May 30, 2001. Prior to the Split-Off, Mr. Townsend served as a director of Inverness Medical Technology since August 1996. From 1991 to 1995, when he retired, Mr. Townsend served as Chief Executive Officer and a director of Enviromed plc, a medical products company currently known as Theratase plc. Mr. Townsend is a member of the Board's Audit Committee.

**Alfred M. Zeien** has served on the Board since July 31, 2001. From 1991 until his retirement in 1999, Mr. Zeien served as Chairman and Chief Executive Officer of The Gillette Company, a consumer products company. Mr. Zeien currently serves on the boards of EMC Corporation, Massachusetts Mutual Life Insurance Company, Raytheon Company, Polaroid Corporation and Bernard Technologies. Mr. Zeien is a member of the Board's Compensation Committee.

### Board of Directors

Our Board of Directors is currently comprised of eight members. The eight directors are divided into three classes as follows: two Class I Directors (Messrs. Carabillo and Levy), three Class II Directors (Ms. Goldberg and Messrs. Zeien and Zwanziger) and three Class III Directors (Messrs. Khederian, Scott and Townsend). The members of each class serve for a staggered three-year term and, at each annual meeting of stockholders, a class of directors is elected for a three-year term to succeed the directors of the same class whose terms are expiring. The current terms of the Class I Directors, Class II Directors and Class III Directors will expire at the annual meetings of stockholders held following the end of calendar years 2001, 2002 and 2003, respectively.

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### PRINCIPAL STOCKHOLDERS

The following table furnishes information as to shares of our common stock and Series A Preferred Stock beneficially owned by:

each person or entity known by us to beneficially own more than five percent of either our common stock or the Series A Preferred Stock;

each of our directors;

each of our five most highly compensated executive officers for the last fiscal year; and

all of our directors and executive officers as a group.

Unless otherwise stated, beneficial ownership is calculated as of March 31, 2002. For the purpose of this table, a person, group or entity is deemed to have "beneficial ownership" of any shares that such person, group or entity has the right to acquire within 60 days after such date through the exercise of options or warrants or the conversion of convertible securities.

Name and Address of Beneficial Owner (2)	Common Stock		Series A Preferred Stock(1)	
	Amount and Nature of Beneficial Ownership(3)	Percent(4)	Amount and Nature of Beneficial Ownership(3)	Percent(4)
Deutsche Bank AG(5)	705,600	7.73%		
Zwanziger Family Ventures, LLC(6)	1,686,283	16.00%	500,000	21.18%

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	Common Stock		Series A Preferred Stock(1)	
Orit Goldstein(7)	909,832	9.29%	333,333	14.12%
Leroy Schechter(8)	479,336	5.07%	166,667	7.06%
Cooper Hill Partners(9)	333,334	3.52%	166,667	7.06%
Goldman, Sachs & Co.(10)	333,332	3.52%	166,666	7.06%
Galleon Group(11)	589,678	6.28%	128,172	5.43%
Oxford Bioscience Partners(12)	384,600	4.04%	192,300	8.15%
Perry Capital(13)	662,949	6.83%	292,613	12.40%
Ron Zwanziger(14)	3,226,609	30.33%	500,000	21.18%
David Scott, Ph.D.(15).	573,516	6.17%		
Kenneth D. Legg, Ph.D.(16)	96,212	1.05%		
Jerry McAleer, Ph.D.(17)	420,319	4.52%		
David Toohey(18)	10,000	*		
Ernest A. Carabillo, Jr.(19)	25,549	*	10,000	*
Carol R. Goldberg(20)	81,905	*	16,666	*
Robert P. Khederian(21)	210,000	2.25%	100,000	4.24%
John F. Levy(22)	109,693	1.20%		
Peter Townsend	10,285	*		
Alfred M. Zeien				
All current executive officers and directors (15 persons)(23)	4,719,057	41.75%	626,666	26.55%

\*

Represents less than 1%

(1)

Each share of Series A Preferred Stock is currently convertible into two shares of common stock.

(2)

The address of each director or executive officer (and any related persons or entities) is c/o the Company at its principal office.

(3)

Unless otherwise indicated, the stockholders identified in this table have sole voting and investment power with respect to the shares beneficially owned by them.

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(4)

The number of shares outstanding used in calculating the percentage for each person, group or entity listed includes the number of shares underlying options, warrants and convertible securities held by such person or group that were exercisable or convertible within 60 days from March 31, 2002, but excludes shares of stock underlying options, warrants or convertible securities held by any other person.

(5)

The address of Deutsche Bank AG is Taunusanlage 12, D-60325, Frankfurt am Main, Federal Republic of Germany. The information for Deutsche Bank AG contained herein is based upon information contained in a Schedule 13G filed with the Securities and Exchange Commission on February 1, 2002.

(6)

Consists of 273,689 shares of common stock, 412,594 shares of common stock underlying warrants exercisable within 60 days from March 31, 2002, and 500,000 shares of Series A Preferred Stock which are currently convertible into 1,000,000 shares of common stock, all of which are owned by Zwanziger Family Ventures, LLC (Zwanziger Family Ventures). Ron Zwanziger, our Chairman, Chief Executive Officer and President, and Janet M. Zwanziger, his spouse, are the managers of Zwanziger Family Ventures and each have shared voting and investment power over these securities.

(7)

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Orit Goldstein is the sister of Ron Zwanziger, our Chairman, Chief Executive Officer and President. Of the shares of common stock attributed to her, Ms. Goldstein disclaims beneficial ownership of (i) 4,894 shares owned by her husband, (ii) 900 shares held in her husband's IRA, and (iii) 100,230 shares owned by the Zwanziger Family Trust, of which Ms. Goldstein is a trustee.

- (8) Consists of 146,002 shares of common stock and 166,667 shares of Series A Preferred Stock which are currently convertible into 333,334 shares of common stock. The address of Leroy Schechter is 55 Passaic Ave., Kearny, NJ 07032.
- (9) Consists of 166,667 shares of Series A Preferred Stock which are currently convertible into 333,334 shares of common stock held in the name of several private investment funds controlled by Cooper Hill Partners, LLC and Cooper Hill Partners, L.P., two institutional investment managers under the common control of Jeffrey Casdin and Casdin Capital, LLC. The address of Cooper Hill Partners is 230 Park Avenue, 20<sup>th</sup> Floor, New York, NY 10169.
- (10) Consists of 166,666 shares of Series A Preferred Stock which are currently convertible into 333,332 shares of common stock held in the name of several private investment funds managed by Goldman, Sachs & Co.'s Private Equity Group. The address of Goldman, Sachs & Co. is 32 Old Slip, 21<sup>st</sup> Floor, New York, NY 10005.
- (11) Consists of 333,334 shares of common stock and 128,172 shares of Series A Preferred Stock which are currently convertible into 256,344 shares of common stock held in the name of two private investment funds managed by The Galleon Group. The address of The Galleon Group is 135 East 57<sup>th</sup> Street, 16<sup>th</sup> Floor, New York, NY 10022.
- (12) Consists of 192,300 shares of Series A Preferred Stock which are currently convertible into 384,600 shares of common stock held in the name of two private investment funds managed by Oxford Bioscience Partners. The address of Oxford Bioscience Partners is 31 St. James Avenue, #905, Boston, MA 02116.
- (13) Consists of 77,723 shares of common stock and 292,613 shares of Series A Preferred Stock which are currently convertible into 585,226 shares of common stock held in the name of several private investment funds managed by Perry Capital. The address of Perry Capital is 599 Lexington Avenue, 36<sup>th</sup> Floor, New York, NY 10022.
- (14) Consists of 1,714,530 shares of common stock, 512,079 shares of common stock underlying options and warrants exercisable within 60 days from March 31, 2002, and 500,000 shares of Series A

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Preferred Stock which are currently convertible into 1,000,000 shares of common stock. Of the shares attributed to Mr. Zwanziger, 273,689 shares of common stock, 412,594 shares of common stock underlying warrants exercisable within 60 days from March 31, 2002 and all of the shares of Series A Preferred Stock listed are owned by Zwanziger Family Ventures, a limited liability company managed by Mr. Zwanziger and his spouse. Of the other shares attributed to him, Mr. Zwanziger disclaims beneficial ownership of (i) 2,600 shares owned by his wife, Janet Zwanziger and (ii) 7,600 shares owned by the Zwanziger Goldstein Foundation, a charitable foundation where Mr. Zwanziger and his spouse, along with three others, serve as directors.

- (15) Consists of 411,554 shares of common stock and 161,962 shares of common stock underlying options or warrants exercisable within 60 days from March 31, 2002.
- (16) Consists of 52,712 shares of common stock and 43,500 shares of common stock underlying options or warrants exercisable within 60 days from March 31, 2002. Dr. Legg disclaims beneficial ownership of 1,079 shares of common stock owned by his son and 3,960 shares held in trust for the benefit of his son. Dr. Legg retired on February 15, 2001.
- (17) Consists of 250,059 shares of common stock and 170,260 shares of common stock underlying options or warrants exercisable within 60 days from March 31, 2002.

- (18) Consists of common stock underlying options exercisable within 60 days from March 31, 2002.
- (19) Consists of 5,549 shares of common stock and 10,000 shares of Series A Preferred Stock which are currently convertible into 20,000 shares of common stock.
- (20) Consists of 21,413 shares of common stock, 27,160 shares of common stock underlying options or warrants exercisable within 60 days from March 31, 2002, and 16,666 shares of Series A Preferred Stock which are currently convertible into 33,332 shares of common stock. Ms. Goldberg disclaims beneficial ownership of 8,333 shares of Series A Preferred Stock owned by the Avram J. Goldberg and Carol R. Goldberg Charitable Remainder Unitrust.
- (21) Consists of 10,000 shares of common stock and 100,000 shares of Series A Preferred Stock which are currently convertible into 200,000 shares of common stock.
- (22) Consists of 100,977 shares of common stock and 8,716 shares of common stock underlying options or warrants exercisable within 60 days from March 31, 2002. Mr. Levy disclaims beneficial ownership of warrants to purchase 1,007 shares of common stock owned by a charitable remainder unitrust.
- (23) Includes 923,756 shares of common stock underlying options or warrants exercisable within 60 days from March 31, 2002 and 626,666 shares of Series A Preferred Stock which are currently convertible into 1,253,332 shares of common stock.

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#### UNDERWRITING

We and the underwriter, SG Cowen Securities Corporation, have entered into an underwriting agreement with respect to the shares being offered. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase from us 1,600,000 shares at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus supplement.

The underwriting agreement provides that the obligations of the underwriter to purchase the shares of common stock offered hereby are conditional and may be terminated at its discretion based on its assessment of the state of the financial markets. The obligations of the underwriter may also be terminated upon the occurrence of other events specified in the underwriting agreement. The underwriter is committed to purchase all of the shares of common stock being offered by us if any shares are purchased.

The underwriter proposes to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus supplement. The underwriting fee is an amount equal to the offering price to the public less the amount paid per share by the underwriter to us. The underwriter may offer the common stock to securities dealers at the price to the public less a concession not in excess of \$0.76 per share. Securities dealers may reallow a concession not in excess of \$0.10 per share to other dealers. After the shares of common stock are released for sale to the public, the underwriter may vary the offering price and other selling terms from time to time.

We have granted to the underwriter an option, exercisable not later than 30 days after the date of this prospectus supplement, to purchase up to an aggregate of 240,000 additional shares of common stock at the public offering price set forth on the cover page of this prospectus supplement less the underwriting discounts and commissions. The underwriter may exercise this option only to cover over-allotments, if any, made in connection with the sale of the common stock offered hereby.

The following table shows the underwriting discounts and commissions that we are to pay to the underwriter in connection with this offering. These amounts are shown assuming no exercise and full exercise of the underwriter's option to purchase additional shares of common stock.

**Payable by Inverness Medical  
Innovations, Inc.**

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	Payable by Inverness Medical Innovations, Inc.	
	No Exercise	Full Exercise
Per share	\$ 1.265	\$ 1.265
Total	\$ 2,024,000	\$ 2,327,600

We estimate that the total expenses of this offering, excluding underwriting discounts and commissions, will be approximately \$309,000.

We have agreed to indemnify the underwriter against certain civil liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, and to contribute to payments the underwriter may be required to make in respect of any such liabilities.

We, and our directors and executive officers, have agreed with the underwriter that, for a period of 90 days following the date of this prospectus supplement, we, and our directors and executive officers, will not dispose of or hedge any shares of common stock or any securities convertible into or exchangeable for shares of common stock. Notwithstanding the foregoing, we are permitted to issue up to 500,000 shares of our common stock in connection with the acquisition of a business, product line or technology or in connection with a strategic alliance, provided that the recipients of such shares agree to restrictions substantially similar to those described in this paragraph. The underwriter may, in its sole discretion, at any time without prior notice, release all or any portion of the shares from the

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restrictions described in this paragraph. In connection with this offering, we expect that Ron Zwanziger, our Chairman, Chief Executive Officer and President, will purchase approximately 100,000 shares of the common stock being offered hereby at the public offering price. Such shares will be subject to the restrictions described above.

The underwriter has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority. The underwriter is delivering this prospectus supplement only in printed form.

The underwriter may engage in over-allotment, stabilizing transactions, syndicate covering transactions, penalty bids and passive market making in accordance with Regulation M under the Securities Exchange Act. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate covering transactions involve purchases of the shares of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the shares of common stock originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Penalty bids may have the effect of deterring syndicate members from selling to people who have a history of quickly selling their shares. In passive market making, market makers in the shares of common stock who are underwriters or prospective underwriters may, subject to certain limitations, make bids for or purchases of the shares of common stock until the time, if any, at which a stabilizing bid is made. These stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the shares of common stock to be higher than it would otherwise be in the absence of these transactions. These transactions may be effected on the American Stock Exchange or otherwise and, if commenced, may be discontinued at any time.

Our common stock is traded on the American Stock Exchange under the symbol "IMA."

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## 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. Brown Raysman Millstein Felder & Steiner LLP is acting as counsel for the underwriter in connection with various legal matters relating to the shares of common stock offered hereby. 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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**PROSPECTUS****5,000,000 Shares****INVERNESS MEDICAL INNOVATIONS, INC.****Common Stock**

(par value \$0.001 per share)

This prospectus provides you with a general description of common stock that Inverness Medical Innovations, Inc. may offer and sell from time to time. Each time we sell securities we will provide a prospectus supplement that will contain specific information about the terms of that sale and may add to or update the information in this prospectus. You should read this prospectus and any prospectus supplement carefully before you invest in our securities.

Our common stock is listed on the American Stock Exchange under the symbol "IMA." On April 26, 2002, the last reported sale price of our common stock on the American Stock Exchange was \$25.40.

This prospectus may not be used to sell securities unless accompanied by the applicable prospectus supplement.

See **"Risk Factors"** beginning on page 2 for a discussion of certain factors that you should consider before you invest in our common stock.

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

**The date of this Prospectus is May 8, 2002**

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**PROSPECTUS SUMMARY**

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*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 16 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 This Prospectus**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission utilizing a shelf registration process. Under this shelf registration process, we may sell up to 5,000,000 shares of common stock in one or more offerings. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that specific offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading "Where You Can Find More Information."

### **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 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."

### **Plan of Distribution**

We may sell the securities through agents, dealers or underwriters, directly to investors or any combination of these methods of sale. The distribution of securities may be effected in one or more transactions at fixed prices, at market prices prevailing at the time of sale, at prices related to such prevailing market prices, or at negotiated prices. See "How We Plan to Offer and Sell the Securities."

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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 16 of this prospectus.

***Risks Related to the Split-Off***

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 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.**

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The historical financial information included in our annual report on Form 10-K, as amended, for the year ended December 31, 2001 reports on time periods prior to the split-off and reflect 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 the periods presented. 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, but also because:

various adjustments and allocations were made to the financial statements in our annual report on Form 10-K because IMT did not account for us as a single stand-alone business for any period presented; 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 our financial information may not appropriately reflect our operations during the periods presented as if we had operated as a stand-alone company.

### **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 the price of our common stock from time to time.**

Our common stock recently became listed on the American Stock Exchange. An active trading market in our common stock, however, may not 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

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 does not have a proven 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:

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

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

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

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

government regulation in the health care industry;

changes in other areas such as tax laws;

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

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

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claims, the amount could be substantial. In such an event, we may not have sufficient funds available to satisfy our potential indemnification obligations. In addition, we may be unable to obtain the funds on terms satisfactory to us, if at all. If we are unable to obtain the necessary funds, we will need to consider other alternatives, including sales of assets, to raise necessary funds.

### ***Risks Related to our Business***

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

As of December 31, 2001, we had approximately \$82.7 million of outstanding indebtedness under our credit facilities, subordinated promissory notes and other debt-related instruments. With our acquisition of IVC Industries, Inc. (IVC) on March 19, 2002, we assumed additional debt and capital lease obligations totaling approximately \$17.4 million. Our substantial level of debt affects our future operations in several important ways, including the following:

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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 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 December 31, 2001, we had approximately \$62.4 million of outstanding indebtedness under our various credit facilities, substantially all of which was owed to The Royal Bank of Scotland plc and related entities. IVC, which we acquired on March 19, 2002, has additional credit facilities under which approximately \$14.6 million was owed at the closing of the acquisition. 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 are executive officers of our company, are currently serving on our board of directors, however, there is not assurance that they will continue to do so.

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

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

**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 the Unipath business and IVC may not be profitable or successfully integrated and will result in significant charges against earnings.**

On December 20, 2001, we acquired Unipath Limited and its associated companies and assets (the Unipath business) from Unilever PLC (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*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived 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.

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**We could experience significant manufacturing delays, disruptions to our ongoing research and development and increased production costs if Unilever is unable to successfully assign the lease for the primary operating facility of the Unipath business which is located in Bedford, England to us.**

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 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 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). Unilever has not yet obtained the landlord's consent to assign the lease to us or sublet the property to us. Although Unilever is obligated to use its best efforts to obtain the landlord's consent to assignment and then to pursue the assignment, and, if necessary, a sublease, through the courts, there are no assurances that Unilever will be successful. If Unilever is unable to successfully assign the lease to us 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.**



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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;
- 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.

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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.

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 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

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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.

**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® 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 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 Organics clinical diagnostics products to small and medium sized customers in more than 92 countries at considerable cost that reduces the operating margins in our Organics clinical diagnostics business.**

Because small and medium sized laboratories are the principal customers of our Organics clinical diagnostic products, we sell these products worldwide in order to maintain sufficient sales volume. Our Organics clinical diagnostics products are marketed in more than 92 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 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 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.

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

Our wholly-owned subsidiary, Orgenics 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 Orgenics business are located in Yavne, Israel. Although most of Orgenics' sales currently are to customers outside of Israel, political, economic and military conditions in Israel could nevertheless directly affect its operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Despite its history of avoiding adverse effects, our Orgenics business could be adversely affected by any major hostilities involving Israel, 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 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.

**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.**

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

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

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

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

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

Substantial litigation over intellectual property rights exists in both the consumer and 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 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.

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

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

- assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

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

Currently, we have initiated a number of lawsuits against competitors who we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, our stock price could decline.

**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.

**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 Convertible 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 Convertible Preferred Stock outstanding. Pursuant to the terms of the certificate of designation creating the Series A Convertible Preferred Stock, upon a liquidation or a deemed liquidation of our company, the holders of the shares of our Series A Convertible 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 Convertible 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 Convertible Preferred Stock. Dividends accrue on the shares of our Series A Convertible 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.

**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



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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 in this prospectus and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Some important additional factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;

competitive factors, including technological advances achieved and patents attained by competitors and generic competition;

domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and government laws and regulations relating to sales and promotion, reimbursement and pricing generally;

government laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products and licensing;

manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products;

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;

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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 above and elsewhere in this prospectus could harm our business, prospects, operating results and financial condition. We do not undertake any obligation to update any forward-looking statements as a result of future events or developments.

### HOW WE INTEND TO USE THE PROCEEDS

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We currently intend to use the net proceeds from the sale of any securities under this prospectus for general corporate purposes, which may include:

the repayment of debt;

the possible repurchase of our common stock;

the financing of potential investments;

working capital; and

other purposes as mentioned in any prospectus supplement.

Pending such use, we may temporarily invest the net proceeds. The precise amounts and timing of the application of proceeds will depend upon our funding requirements and the availability of other funds. Except as mentioned in any prospectus supplement, specific allocations of the proceeds to such purposes will not have been made at the date of that prospectus supplement.

Based upon our historical and anticipated future growth and our financial needs, we may engage in additional financings of a character and amount that we determine as the need arises.

### DESCRIPTION OF CAPITAL STOCK

The following summary describes the material terms of our capital stock. To fully understand the actual terms of our capital stock you should refer to our certificate of incorporation and by-laws, each as amended to date, which are filed as exhibits to the registration statement of which this prospectus is a part.

#### *Authorized and Outstanding Capital Stock*

Our authorized capital stock consists of 50,000,000 shares of common stock, par value \$.001 per share, and 5,000,000 shares of preferred stock, par value \$.001 per share, of which 2,666,667 shares have been designated as Series A Convertible Preferred Stock, par value \$.001 per share (Series A

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Preferred Stock). As of March 31, 2002, we had 9,126,588 shares of common stock and 2,360,246 shares of Series A Preferred Stock issued and outstanding.

#### *Common Stock*

*Voting Rights.* The holders of our common stock have one vote per share. Holders of our common stock are not entitled to vote cumulatively for the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority, or, in the case of the election of directors, by a plurality, of the votes cast at a meeting at which a quorum is present, voting together as a single class, subject to any voting rights granted to holders of any then outstanding preferred stock.

*Dividends.* Holders of common stock will share ratably in any dividends declared by our board of directors, subject to the preferential rights of any preferred stock then outstanding. We may pay dividends consisting of shares of common stock to holders of shares of common stock.

*Other Rights.* Upon the liquidation, dissolution or winding up of our company, all holders of common stock are entitled to share ratably in any assets available for distribution to holders of shares of common stock, subject to the preferential rights of any preferred stock then

outstanding. No shares of common stock are subject to redemption or have preemptive rights to purchase additional shares of common stock.

### ***Preferred Stock***

Our certificate of incorporation provides that we may issue shares of preferred stock from time to time in one or more series. Our board of directors is authorized to fix the voting rights, if any, designations, powers, preferences, qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our board of directors may, without stockholder approval issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of the common stock and could have anti-takeover effects, including preferred stock or rights to acquire preferred stock in connection with implementing a shareholder rights plan. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of our company or the removal of existing management.

### ***Series A Preferred Stock***

As noted above, there are currently 2,360,246 shares of Series A Preferred Stock issued and outstanding. The general terms of the Series A Preferred Stock are as follows:

*Voting Rights.* Except as described below, the holders of Series A Preferred Stock generally vote with the holders of common stock, as a single class, on an as converted basis. As of March 31, 2002, each share of Series A Preferred Stock was convertible into two shares of common stock and, accordingly, had two votes.

With respect to the election of directors, the holders of Series A Preferred Stock, other than officers, directors and certain related persons and entities, are entitled to elect one or more directors as a separate class unless these holders do not own at least 5% of the issued and outstanding common stock, assuming that all shares of Series A Preferred Stock or other convertible securities, if any, options and warrants have been fully converted into, or exercised for, shares of common stock. If these holders are entitled to elect one or more directors as a separate class, then the shares of Series A Preferred Stock may not be voted with the common stock for the election of any other members of the board of directors. If these holders are not entitled to elect one or more directors as a separate class,

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then the shares of Series A Preferred Stock may be voted with the common stock for the election of all of the directors.

The holders of Series A Preferred Stock have class voting rights which require us to obtain the affirmative vote of the holders of two-thirds of the outstanding shares of Series A Preferred Stock before taking certain actions, such as creating a series of preferred stock which is senior to the Series A Preferred Stock with respect to liquidation or dividends.

*Liquidation.* Upon any voluntary or involuntary liquidation, dissolution or winding up of our company, the holders of the then outstanding shares of Series A Preferred Stock will be entitled to receive, prior to any payments to the holders of common stock, a liquidation preference of \$30 per share, or \$40.50 per share in certain circumstances relating to a sale of our company or a transaction resulting in a change in control of our board of directors, plus accrued but unpaid dividends, if any.

*Dividends.* Each share of Series A Preferred Stock accrues dividends on a quarterly basis at \$2.10 per annum, but only on those days when the closing price of our common stock is less than \$15. Accrued dividends, if any, are payable only if declared by the board of directors. Until December 31, 2003, accrued dividends, if any, must be paid in shares of our common stock. The number of shares of common stock to be issued in payment of any accrued dividends is equal to such number as is determined by dividing the aggregate amount of the accrued dividends then payable by the greater of (i) \$15.00 and (ii) the average market price during the 30 trading day period immediately preceding the date such dividend is declared. Thereafter, we have the option to pay dividends in cash or common stock, if such dividends are declared by our board of directors.

*Conversion.* Each share of Series A Preferred Stock is convertible into common stock at any time upon the election the holder of such share. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock is equal to such number as is determined by dividing \$30 by the conversion price in effect at the time of the conversion. As of March 31, 2002, the conversion price was \$15, subject to adjustment. Accordingly, each share of Series A Preferred Stock is currently convertible into two shares of common stock.

Starting on December 20, 2003, we may convert all of the outstanding shares of Series A Preferred Stock into common stock in the event that the average closing price of our common stock exceeds \$20 for any consecutive 30 trading day period.

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*Redemption.* On or after June 30, 2011, the Series A Preferred Stock may be redeemed upon a vote by the holders of at least two-thirds of the outstanding shares of Series A Preferred Stock. The redemption price per share of Series A Preferred Stock will be equal to \$30 plus accrued interest calculated at 5% per annum from the date of issuance.

### ***Indemnification Matters***

Our certificate of incorporation contains a provision permitted by Delaware law that generally eliminates the personal liability of directors for monetary damages for breaches of their fiduciary duty, including breaches involving negligence or gross negligence in business combinations, unless the director has breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or a knowing violation of law, paid a dividend or approved a stock repurchase in violation of the Delaware General Corporation Law or obtained an improper personal benefit. This provision does not alter a director's liability under the federal securities laws and does not affect the availability of equitable remedies, such as an injunction or rescission, for breach of fiduciary duty. Our by-laws provide that directors and officers shall be, and in the discretion of our board of directors, non-officer employees may be, indemnified by us to the fullest extent authorized by Delaware law, as it now exists or may in the future be amended, against all expenses and liabilities reasonably incurred in connection with service for or on behalf of us. Our by-laws also provide for the advancement of expenses to

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directors and, in the discretion of our board of directors, officers and non-officer employees. In addition, our by-laws provide that the right of directors and officers to indemnification shall be a contract right and shall not be exclusive of any other right now possessed or hereafter acquired under any by-law, agreement, vote of stockholders or otherwise. We also have directors' and officers' insurance against certain liabilities. We believe that the limitation of liability and indemnification provisions of our certificate of incorporation and by-laws and directors' and officers' insurance, will assist us in attracting and retaining qualified individuals to serve as our directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be provided to our directors or officers, or persons controlling our company as described above, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. At present, there is no pending material litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted.

### ***Provisions of Our Certificate of Incorporation and By-Laws that May Have Anti-Takeover Effects***

Certain provisions of our certificate of incorporation and by-laws described below, as well as the ability of our board of directors to issue shares of preferred stock and to set the voting rights, preferences and other terms thereof, may be deemed to have an anti-takeover effect and may discourage takeover attempts not first approved by our board of directors, including takeovers which particular stockholders may deem to be in their best interests.

These provisions also could have the effect of discouraging open market purchases of our common stock because these provisions may be considered disadvantageous by a stockholder who desires subsequent to such purchases to participate in a business combination transaction with us or elect a new director to our board.

*Classified Board of Directors.* Our board of directors is divided into three classes serving staggered three-year terms, with one-third of the board being elected each year. Our classified board, together with certain other provisions of our certificate of incorporation authorizing the board of directors to fill vacant directorships or increase the size of the board, may prevent a stockholder from removing, or delay the removal of, incumbent directors and simultaneously gaining control of the board of directors by filling vacancies created by such removal with its own nominees.

*Director Vacancies and Removal.* Our certificate of incorporation provides that the affirmative vote of a majority of the remaining directors is necessary to fill vacancies in our board of directors, except for any directorship that is to be filled exclusively by holders of Series A Preferred Stock. Our certificate of incorporation provides that directors, other than those elected exclusively by the holders of Series A Preferred Stock, may be removed from office only with cause and only by the affirmative vote of holders of at least seventy-five percent of the shares then entitled to vote in an election of directors.

*No Common Stockholder Action by Written Consent.* Our certificate of incorporation provides that any action required or permitted to be taken by the holders of our common stock at an annual or special meeting of stockholders must be effected at a duly called meeting and may not be taken or effected by a written consent of stockholders.

*Special Meetings of Stockholders.* Our certificate of incorporation and by-laws provide that only our board of directors may call a special meeting of stockholders. Our by-laws provide that only those matters included in the notice of the special meeting may be considered or acted upon at that special meeting unless otherwise provided by law.

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*Advance Notice of Director Nominations and Stockholder Proposals.* Our by-laws include advance notice and informational requirements and time limitations on any director nomination or any new proposal which a stockholder wishes to make at an annual meeting of stockholders. A stockholder's notice of a director nomination or proposal will be timely if delivered to our corporate secretary at our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting.

*Amendment of the Certificate of Incorporation.* As required by Delaware law, any amendment to our certificate of incorporation must first be approved by a majority of our board of directors and, if required by law, thereafter approved by a majority of the outstanding shares entitled to vote with respect to such amendment, except that any amendment to the provisions relating to common stockholder action by written consent, directors (other than those provisions contained in the certificate of designation of Series A Preferred Stock), limitation of liability and the amendment of our certificate of incorporation must be approved by not less than seventy-five percent of the outstanding shares entitled to vote with respect to such amendment.

*Amendment of By-laws.* Our certificate of incorporation and by-laws provide that our by-laws may be amended or repealed by our board of directors or by the stockholders. Such action by the board of directors requires the affirmative vote of a majority of the directors then in office. Such action by the stockholders requires the affirmative vote of at least seventy-five percent of the shares present in person or represented by proxy at an annual meeting of stockholders or a special meeting called for such purpose unless our board of directors recommends that the stockholders approve such amendment or repeal at such meeting, in which case such amendment or repeal only requires the affirmative vote of a majority of the shares present in person or represented by proxy at the meeting.

#### ***Statutory Business Combination Provision***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly held Delaware corporation from completing a "business combination," except under certain circumstances, with an "interested stockholder" for a period of three years after the date such person became an "interested stockholder" unless:

before such person became an interested stockholder, the board of directors of the corporation approved the transaction in which the interested stockholder became an interested stockholder or approved the business combination;

upon the closing of the transaction that resulted in the interested stockholder becoming such, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares held by directors who are also officers of the corporation and shares held by employee stock plans; or

following the transaction in which such person became an interested stockholder, the business combination is approved by the board of directors of the corporation and authorized at a meeting of stockholders by the affirmative vote of the holders of at least two-thirds of the outstanding voting stock of the corporation not owned by the interested stockholder.

The term "interested stockholder" generally is defined as a person who, together with affiliates and associates, owns, or, within the prior three years, owned, 15% or more of a corporation's outstanding voting stock.

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The term "business combination" includes mergers, consolidations, asset sales involving 10% or more of a corporation's assets and other similar transactions resulting in a financial benefit to an interested stockholder. Section 203 makes it more difficult for an "interested stockholder" to effect various business combinations with a corporation for a three-year period. A Delaware corporation may "opt out" of Section 203 with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from an amendment approved by holders of at least a majority of the outstanding voting stock. Neither our certificate of incorporation nor our by-laws contain any such exclusion.

*Trading on the American Stock Exchange*

Our common stock is listed on the American Stock Exchange under the symbol "IMA."

*Transfer Agent and Registrar*

The transfer agent and registrar for our common stock is EquiServe Trust Company.

**HOW WE PLAN TO OFFER AND SELL THE SECURITIES**

We may sell the securities in any one or more of the following ways:

directly to investors;

to investors through agents;

to dealers;

through underwriting syndicates led by one or more managing underwriters; and

through one or more underwriters acting alone.

Any underwritten offering may be on a best efforts or a firm commitment basis. We may also make direct sales through subscription rights distributed to our stockholders on a pro rata basis, which may or may not be transferable. In any distribution of subscription rights to stockholders, if all of the underlying securities are not subscribed for, we may then sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers or agents, including standby underwriters, to sell the unsubscribed securities to third parties.

The distribution of the securities may be effected from time to time in one or more transactions:

at a fixed price or prices, which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

Any of the prices may represent a discount from the prevailing market prices.

In the sale of the securities, underwriters or agents may receive compensation from us or from purchasers of the securities, for whom they may act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities may be deemed to be underwriters under the Securities Act of 1933, and any discounts or commissions they receive from us and any profit on the

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resale of securities they realize may be deemed to be underwriting discounts and commissions under the Securities Act of 1933. The applicable prospectus supplement will, where applicable:

identify any such underwriter or agent;

describe any compensation in the form of discounts, concessions, commissions or otherwise received from us by each such underwriter or agent and in the aggregate to all underwriters and agents;

identify the amounts underwritten; and

identify the nature of the underwriter's obligation to take the securities.

Common stock sold pursuant to a prospectus supplement will be listed on the American Stock Exchange, subject to the American Stock Exchange's approval of the listing of the additional shares of common stock sold.

Until the distribution of the securities is completed, rules of the Securities and Exchange Commission may limit the ability of any underwriters and selling group members to bid for and purchase the securities. As an exception to these rules, underwriters are permitted to engage in some transactions that stabilize the price of the securities. Such transactions consist of bids or purchases for the purpose of pegging, fixing or maintaining the price of the securities.

If any underwriters create a short position in the securities in an offering in which they sell more securities than are set forth on the cover page of the applicable prospectus supplement, the underwriters may reduce that short position by purchasing the securities in the open market.

The lead underwriters may also impose a penalty bid on other underwriters and selling group members participating in an offering. This means that if the lead underwriters purchase securities in the open market to reduce the underwriters' short position or to stabilize the price of the securities, they may reclaim the amount of any selling concession from the underwriters and selling group members who sold those securities as part of the offering.

In general, purchases of a security for the purpose of stabilization or to reduce a short position could cause the price of the security to be higher than it might be in the absence of such purchases. The imposition of a penalty bid might also have an effect on the price of a security to the extent that it discourages resales of the security before the distribution is completed.

We do not make any representation or prediction as to the direction or magnitude of any effect that the transactions described above might have on the price of the securities. In addition, we do not make any representation that underwriters will engage in such transactions or that such transactions, once commenced, will not be discontinued without notice.

Under agreements into which we may enter, underwriters, dealers and agents who participate in the distribution of the securities may be entitled to indemnification by us against some liabilities, including liabilities under the Securities Act.

Underwriters, dealers and agents may engage in transactions with us, perform services for us or be our customers in the ordinary course of business.

If indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by particular institutions to purchase securities from us at the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in such prospectus supplement. Each delayed delivery contract will be for an amount no less than, and the aggregate principal amounts of securities sold under delayed delivery contracts shall be not less nor more than, the respective amounts stated in the applicable prospectus supplement. Institutions with which such contracts, when authorized,

may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others, but will in all cases be subject to our approval. The obligations of any purchaser under any such contract will be subject to the conditions that (a) the purchase of the securities shall not at the time of delivery be prohibited under the laws of any jurisdiction in the

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United States to which the purchaser is subject, and (b) if the securities are being sold to underwriters, we shall have sold to the underwriters the total principal amount of the securities less the principal amount thereof covered by the contracts. The underwriters and such other agents will not have any responsibility in respect of the validity or performance of such contracts.

To comply with applicable state securities laws, the securities offered by this prospectus will be sold, if necessary, in such jurisdictions only through registered or licensed brokers or dealers. In addition, securities may not be sold in some states unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

### 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 we sell all of the securities registered hereunder or otherwise terminate the offering of the securities:

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;

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; 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.

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. We are not making an offer of these securities in any state where the offer is not permitted. 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., Washington, D.C.



20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site that contains reports, proxy and information statements and other information regarding registrants, including Inverness Medical Innovations, Inc., that file electronically with the Securities and Exchange Commission. You may access the Securities and Exchange Commission's web site at <http://www.sec.gov>.

#### **EXPERTS**

The consolidated financial statements of Inverness Medical Innovations, Inc. 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 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.

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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**1,600,000 Shares**

**Common Stock**

**PROSPECTUS SUPPLEMENT**

**SG COWEN**

May 21, 2002

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