DIANA SHIPPING INC.
Form 6-K
June 27, 2018

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13A-16 OR 15D-16
OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of June 2018
Commission File Number: 001-32458

DIANA SHIPPING INC.
(Translation of registrant's name into English)
Pendelis 16, 175 64 Palaio Faliro, Athens, Greece
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F [X] Form 40-F [ ]

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): [ ].

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): [ ].

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

INFORMATION CONTAINED IN THIS FORM 6-K REPORT

Attached to this Report on Form 6-K as Exhibit 99.1 is a press release dated June 27, 2018 of Diana Shipping Inc. (the "Company") announcing that, on June 20, 2018, it signed a term sheet with BNP Paribas for a five year loan facility of up to US$75 million, subject to loan documentation.

The information contained in this Report on Form 6-K is hereby incorporated by reference into the Company's registration statement on Form F-3 (File No. 333-205491) filed with the U.S. Securities and Exchange Commission with an effective date of July 21, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DIANA SHIPPING INC.
(registrant)

Dated: June 27, 2018 By: /s/ Anastassis Margaronis
Anastassis Margaronis
President

Exhibit 99.1

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For Immediate Release

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DIANA SHIPPING INC. HAS REACHED AN AGREEMENT WITH
BNP PARIBAS THAT SETS SEVENTEEN VESSELS OF THE FLEET UNENCUMBERED

ATHENS, GREECE, June 27, 2018 – Diana Shipping Inc. (NYSE: DSX), (the "Company"), a global shipping company specializing in the ownership of dry bulk vessels, today announced that on June 20, 2018, it signed a term sheet with BNP Paribas for a five year loan facility of up to US$75 million, subject to loan documentation. The proceeds from the loan facility together with available cash will be used to voluntarily prepay in full the balance of US$130 million of the existing credit facility with BNP Paribas. The new loan facility will result in 17 of the Company's vessels being unencumbered.

Diana Shipping Inc.'s fleet currently consists of 50 dry bulk vessels (4 Newcastlemax, 14 Capesize, 5 Post-Panamax, 5 Kamsarmax and 22 Panamax). As of today, the combined carrying capacity of the Company's fleet is approximately 5.8 million dwt with a weighted average age of 8.84 years. A table describing the current Diana Shipping Inc. fleet can be found on the Company's website, www.dianashippinginc.com. Information contained on the Company's website does not constitute a part of this press release.

About the Company

Diana Shipping Inc. is a global provider of shipping transportation services through its ownership of dry bulk vessels. The Company's vessels are employed primarily on medium to long-term time charters and transport a range of dry bulk cargoes, including such commodities as iron ore, coal, grain and other materials along worldwide shipping routes.

Cautionary Statement Regarding Forward-Looking Statements

Matters discussed in this press release may constitute forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides safe harbor protections for forward-looking statements in order to encourage companies to provide prospective information about their business. Forward-looking statements include statements concerning plans, objectives, goals, strategies, future events or performance, and underlying assumptions and other statements, which are other than statements of historical facts.

The Company desires to take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and is including this cautionary statement in connection with this safe harbor legislation. The words "believe," "anticipate," "intends," "estimate," "forecast," "project," "plan," "potential," "may," "should," "expect," "pending" and similar expressions identify forward-looking statements.

The forward-looking statements in this press release are based upon various assumptions, many of which are based, in turn, upon further assumptions, including without limitation, our management's examination of historical operating trends, data contained in our records and other data available from third parties. Although we believe that these assumptions were reasonable when made, because these assumptions are inherently subject to significant uncertainties and contingencies which are difficult or impossible to predict and are beyond our control, we cannot assure you that we will achieve or accomplish these expectations, beliefs or projections.

In addition to these important factors, other important factors that, in our view, could cause actual results to differ materially from those discussed in the forward-looking statements include the strength of world economies and currencies, general market conditions, including fluctuations in charter rates and vessel values, changes in demand for dry bulk shipping capacity, changes in our operating expenses, including bunker prices, drydocking and insurance costs, the market for our vessels, availability of financing and refinancing, changes in governmental rules and regulations or actions taken by regulatory authorities, potential liability from pending or future litigation, general domestic and international political conditions, potential disruption of shipping routes due to accidents or political events, vessel breakdowns and instances of off-hires and other factors. Please see our filings with the Securities and Exchange Commission for a more complete discussion of these and other risks and uncertainties.

ture 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.

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, MA 02453 and our telephone number is (781) 647-3900.

RECENT DEVELOPMENTS

Acquisition of Unipath

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 (the Unipath business) from Unilever PLC (Unilever) and certain affiliated entities (the Unilever group). 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. The Unipath business is comprised primarily of five former subsidiaries of the Unilever group, specifically Unipath Limited, Unipath Management, Ltd., Unipath Diagnostics GmbH, Unipath Scandinavia A.B. and Unipath B.V., and certain assets. Included in the acquired assets are facilities in Bedford, England, United States marketing and sales operations in Princeton, New Jersey and rights to certain antibody clones and other intellectual property.

The consideration paid to Unilever for the Unipath business was 103 million pounds sterling (approximately 150 million United States dollars or 166 million Euros) in cash, subject to certain adjustments provided for in the sale agreement. We financed the acquisition through a combination of cash on hand and the proceeds from three separate financing transactions, consisting of the private sale of 1,995,000 shares of Series A Convertible Preferred Stock for an aggregate purchase price of $59.85 million, the private sale of approximately $20.0 million of subordinated promissory notes and warrants and the establishment of senior and mezzanine credit facilities with The Royal Bank of Scotland plc and related entities for an aggregate principal amount of $62.5 million. The terms of these financing transactions are described in more detail in Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources and Notes 4 and 6 of the Notes to Consolidated Financial Statements, which are included elsewhere in this report.

Prior to the acquisition, the Unilever group used the assets of the Unipath business for the research, development, manufacturing and distribution of home pregnancy and ovulation testing products and natural family planning products. We intend to continue to use these assets for this purpose. In addition, we intend to use the acquired assets, together with our existing assets, to research, develop and commercialize new products and advanced medical device technologies for the consumer diagnostics and other markets, as well as to supplement our existing product distribution network.

Acquisition of IVC Industries, Inc.

On March 19, 2002, we acquired IVC Industries, Inc. (IVC), a manufacturer and distributor of vitamins and nutritional supplements, in a merger transaction. Under the terms of the merger agreement, each stockholder of IVC received $2.50 in cash for each share of IVC common stock. Accordingly, the aggregate cash payment to IVC's stockholders was approximately $5.6 million, based upon IVC s approximately 2.25 million shares outstanding. In addition, IVC had outstanding debt and capital lease obligations as of closing of approximately $18.7 million. IVC manufactures and sells hundreds of different vitamin and nutritional supplement products under brand names and through private label arrangements with retailers. We intend to continue IVC s present operations. We are in the process of consolidating our vitamin and nutritional supplement manufacturing at IVC and discontinuing most of our outsourced manufacturing arrangements.

BUSINESS SEGMENTS AND GEOGRAPHIC AREA

Our major reportable operating segments are consumer products and clinical diagnostics. Our consumer products are further divisible into self-test diagnostic products and vitamins and nutritional supplements. We further categorize our sales by major geographic areas of the world. Below are discussions of each of our operating segments. Financial information about our business segments is provided in Note 12 of the Notes to Consolidated Financial Statements, which are included elsewhere in this report.

Industry

Consumer Products

Consumer Diagnostic Products. Our current consumer diagnostic products target the women s health market. Home pregnancy detection tests represent approximately 85% and ovulation prediction tests represent approximately 15% of the women's health self-test products available to consumers. 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 part of couples to plan conception with more certainty. The demand for pregnancy test products is growing also, but at a slower pace. We also market Persona®, a diagnostic contraceptive device that is a unique product and does not fit into the traditional women s health or contraceptive market.

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 the total mass retail sales of vitamins and nutritional supplements in the United States during 2000 at $5.7 billion. Growth in the industry is driven by media commentary regarding the quality and efficacy of nutritional supplements. Positive media attention resulting from new scientific studies or announcements can spur rapid growth in demand, 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. These dramatic positive and negative changes generally affect new products and new product segments. 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 (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 pregnancy or disease or the presence of agents that may signal disease.

Customers can be divided into two increasingly polarized 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. Our clinical diagnostics products are rapid result, point-of-care tests that serve this second segment by offering 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 immuno deficiency 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. United States sales of over-the-counter pregnancy and ovulation prediction products were estimated by A.C. Neilson & Co. at approximately $278 million for the 52 weeks ending March 2, 2002. 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 is a smaller player 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 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.

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 an in-vitro 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, which include

Multi-vitamin formulas for both children and adults;

Single-letter vitamins such as A, B-complex, C and E;

Minerals such as calcium, phosphorus, magnesium, potassium and zinc;

Herbal products such as echinacea, St. John s wort, ginko biloba, saw palmetto, garlic and ginseng; and

Non-herbal supplements such as glucosamine-chondroitin, Co-Q10, and MSM.

These products will be marketed under the Inverness Medical tradename, as well as under store brands (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. A 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;

Z-BEC®, a zinc supplement with B-complex vitamins and added antioxidants; and

SoyCare®, a line of soy-based supplements.

We also market the SmartCare® program, which assists consumers in matching their health concerns to the appropriate supplement products that we sell. SmartCare provides the supplement line with a means of linking the various 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.

Many companies in this market are substantially larger than we are and, therefore, may possess greater resources for advertising and promotion. Stresstabs, Ferro-Sequels, Posture, Protegra, ALLBEE, Z-BEC and SoyCare are registered trademarks of Inverness Medical, Inc. and Fields of Nature, LiquaFil, Rybutol Nature s Wonder and Synergy Plus are registered trademarks of IVC.

Clinical Diagnostic Products

Clearview Products. Through our acquisition of the Unipath business, we acquired and currently develop, manufacture and sell 6 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 just 5 minutes, allowing the physician to perform a test during a patient office visit.

Clearview IM. This test is used to diagnose or rule out infectious mononucleosis. Results are available in 5 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 (CDAD) and to monitor the effectiveness of antibiotic treatment. CDAD is a major clinical problem in cancer patients, elderly patients and patients who are on long term antibiotic therapy. 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.

Clearview is a trademark of Inverness Medical Switzerland GmbH.

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 5 minutes and has the advantages of not requiring refrigerated storage or addition of reagents during the test procedure. ImmunoComb, DoubleCheck and ImmunoGold are trademarks of Orgenics Ltd.

Marketing and Sales

Consumer Products

Consumer Diagnostic Products. We market and sell our consumer diagnostic products 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 leading brands both in the United States and globally. With the exception of ClearBlue in the United States, our ClearBlue and ClearPlan products are marketed 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 TV advertising. Within the United States, where our ClearBlue brand has not 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 Walgreen Co., CVS Corporation and Rite Aid Corporation, 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 Walgreen Co., Wal-Mart Stores, Inc. 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 Orgenics 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 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 for distribution in Europe and the United States. 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. For more information regarding our use of the Bedford facility and the risks associated with our arrangement to use this facility see Item 2 Description of Property and the related risk factor on page 30.

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 manufactured all of its softgel requirements 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

We intend to focus our research and development efforts on the development of 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. 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.

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. Orgenics 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.

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. We cannot assure you that we will be able to compete successfully against current or future competitors or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations.

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, Inc., Pfizer, Inc., 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 though supermarkets and other mass retailers are Wyeth, formerly known as American Home Products, Pharmavite, Leiner Health Products, Royal Numico and 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 amplification 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.

Orgenics 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.

We hold certain patent rights and expect to seek patents in the future. 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.

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.

Government Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Most of our self-test products require governmental approvals for commercialization. Future products may require pre-clinical and clinical trials. Manufacturing and marketing of many of our products are subject to the rigorous testing and approval process of the Food and Drug Administration (FDA) and corresponding foreign regulatory authorities. The marketing of our consumer diagnostic products is also subject to regulation by the Federal Trade Commission. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejection as a result of changes in, or additions to, regulatory policies for device marketing authorization during the period of product development and regulatory review. Delays in obtaining such approvals could adversely affect our marketing of products developed and our ability to generate commercial product revenues.

In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice, resulting in our products being banned in certain countries and an associated loss of revenues and income. Foreign regulatory agencies can also introduce test format changes which, if we do not quickly address, can result in restrictions on sales of our products. Such changes are not uncommon due to advances in basic research.

The manufacturing, processing, formulation, packaging, labeling and advertising of our nutritional supplements is subject to regulation by one or more federal agencies, including the FDA, the Federal Trade Commission and the Consumer Product Safety Commission. These activities are also regulated by various agencies of the states, localities and foreign countries in which our nutritional supplements are now sold or may be sold in the future. In

particular, the FDA regulates the safety, manufacturing, labeling and distribution of dietary supplements, including vitamins, minerals and herbs, as well as food additives, over-the-counter and prescription drugs and cosmetics. The Good Manufacturing Practices promulgated by the FDA are different for nutritional supplement, drug and device products. In addition, the FTC has jurisdiction with the FDA to regulate the promotion and advertising of dietary supplements, over-the-counter drugs, cosmetics and foods.

Product Liability and Limited Insurance Coverage

The testing, manufacturing and marketing of consumer and clinical diagnostic devices entail an inherent risk of product liability claims. In addition, the marketing of our vitamins and nutritional supplements may subject us to various product liability claims, including, among others, claims that our products have inadequate warnings concerning side effects and interactions with other substances. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. We cannot be assured that existing insurance can be renewed at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim, against which we are not indemnified or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our business, financial condition and results of operations.

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.

ITEM 2. DESCRIPTION OF PROPERTY

Our principal corporate administrative office, together with the administrative office for most of our United States operations, are housed in approximately 20,600 square feet of leased space located at 51 Sawyer Road, Waltham, Massachusetts at a monthly rent of approximately $74,000. The sublease covering this space expires on May 30, 2003. For transitional purposes, we have agreed to provide Johnson & Johnson with a limited license to occupy a portion of our principal office for up to 9 months following our split-off from IMT on November 21, 2001.

Our European operations, as well as our Unipath business, are currently administered from a 150,000 square foot facility located in Bedford, England. The Bedford facility is also currently providing the manufacturing for our Unipath operations and serving as our research and development center. This facility contains fully automated assembly equipment, and state-of-the-art research laboratories, with excess space and capacity to support potential future expansion. 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 Unilever s lease, Unilever is not permitted to assign the lease to us or sublet the Bedford facility to us without obtaining the prior written consent of the landlord (which consent may not be unreasonably withheld). Unilever is, however, 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. Unilever has also agreed to permit us to use the Bedford facility until such time as the lease is assigned to us or the facility is subleased to us by Unilever for the remaining term of the lease, which expires on December 11, 2021. Under the terms of this agreement, we are required to pay all amounts owed under the lease and otherwise comply with the terms of the lease. The annual rent for the Bedford facility after accounting for the most recent adjustment in September, 2001 is expected to be between £1.3 million and £1.75 million (approximately, $1.85 million and $2.5 million) and is upwardly adjustable every five years. 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 this facility on substantially less favorable terms, seek alternative, more costly means of producing our products or suffer other adverse effects to our business.

We also have manufacturing operations in Freehold, New Jersey, Irvington, New Jersey, Galway, Ireland and Yavne, Israel. We own a 160,000 square foot manufacturing facility in Freehold, New Jersey and lease a 35,000 square foot facility in Irvington, New Jersey. The Irvington lease has a current term of 5 years expiring on December 31, 2006, with an option to extend for an additional 5 years, and the monthly rent is currently approximately $18,100. The New Jersey facilities manufacture the vitamin and nutritional supplement products that we

acquired with IVC and we intend to consolidate manufacturing of substantially all of our vitamin and nutritional supplement products in these facilities. Our facility in Galway, Ireland consists of a 40,000 square foot space. We own half of the Galway facility and lease the other half from a private developer under a lease that expires in 2026. The Galway facility houses the manufacturing and warehousing, as well as some research and development, of Inverness Medical brand and most of our private label pregnancy detection and ovulation prediction test products. Additionally, the Galway facility will for a limited period of time continue to perform certain diabetes-related packaging work for IMT in accordance with our transition services agreement with IMT. Aggregate annual mortgage and lease payments for our Galway facility total approximately $197,000.

The FDA regulates companies that manufacture commercial medical devices and requires that such companies manufacture such devices in a properly designed and validated environment. A registered facility is required to submit to an FDA inspection not less than once every two years. As required by the regulations, each of the above described facilities have been registered with the FDA and are Good Manufacturing Practices compliant. The Bedford facility operates to international standards of Good Manufacturing Practice, Good Laboratory Practice, Good Clinical Practice and Quality Assurance (ISO 9001 and EN 46001). Our Galway facility is a registered FDA facility and is ISO 9001, EN 46001 and ISO 13485 certified.

We also house the administrative offices and development and manufacturing operations of our Orgenics clinical diagnostics business in a leased facility of approximately 10,000 square feet in Yavne, Israel. The lease for this facility expires in 2006 and carries rent of approximately $25,000 per month. The facility includes a number of specialized features and equipment, including environmentally controlled areas, customized production equipment, and computerized systems for purchasing, inventory management and materials tracking. Our Yavne facility is ISO 9001, EN 46001 and Good Manufacturing Practices certified.

We also lease a 130,000 square foot facility in Freehold, New Jersey, which has served as IVC s primary warehouse and distribution facility. This lease expires on July 27, 2008 and the current monthly rent is approximately $43,333. We sublease approximately 30,000 square feet of this facility to a third party. We also have leases or other arrangements for smaller offices and warehouses to support our consumer products business in Princeton, New Jersey, Springfield, New Jersey, Surrey, British Columbia, Sint-Niklaas, Belgium, Quebec, Canada, Koln, Germany, Oxford, England and Lund, Sweden. Our Israeli subsidiary also maintains small sales offices in Paris, France, Sao Paulo, Brazil, St. Petersburg, Russia and Bogota, Columbia, and is in the process of establishing additional sales offices in Nigeria, Kenya and Argentina. We believe that our facilities are adequate to support the operations of our businesses in the foreseeable future. We have insurance coverage for the properties and equipment that we own or lease.

ITEM 3. LEGAL PROCEEDINGS

Abbott Laboratories v. Selfcare, Inc. and Princeton BioMeditech Corporation

In April 1998, Abbott commenced a lawsuit against IMT (formerly known as Selfcare, Inc.) and Princeton BioMeditech Corporation (PBM), which manufactured certain products for IMT, in an action filed in the United States District Court for the District of Massachusetts (District Court), asserting patent infringement arising from IMT s and PBM s manufacture, use and sale of products that Abbott claims are covered by one or more of the claims of U.S. Patent Nos. 5,073,484 and 5,654,162 (the Pregnancy Test Patents), to which Abbott asserts that it is the exclusive licensee. Abbott claims that certain of IMT s products relating to pregnancy detection and ovulation prediction (now our products to the extent they are still sold) infringe the Pregnancy Test Patents. Abbott is seeking an order finding that IMT and PBM infringe the Pregnancy Test Patents, an order permanently enjoining IMT and PBM from infringing the Pregnancy Test Patents, compensatory damages to be determined at trial, treble damages, costs, prejudgment and post-judgment interest on Abbott s compensatory damages, attorneys fees, and a recall of all of existing products found to infringe the Pregnancy Test Patents. On August 5, 1998, the court denied Abbott s motion for a preliminary injunction. On March 31, 1999, the District Court granted a motion by IMT, PBM, and PBM-Selfcare LLC (the LLC), a joint venture between PBM and IMT, filed to amend IMT s counterclaim against Abbott, asserting that Abbott is infringing U.S. Patent Nos. 5,559,041 (the 041 patent) and 5,728,587 (the 587 patent), which are owned by the LLC, and seeking a declaration that Abbott infringes the patents and that IMT is entitled to permanent injunctive relief, money damages and attorneys fees. On November 5, 1998, Abbott filed suit in the United States District Court for the Northern District of Illinois seeking a declaratory judgment of non-

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infringement, unenforceability and invalidity of the 041 patent and the 587 patent. The Illinois court granted IMT s motion to transfer the aforementioned Illinois action to Massachusetts. IMT and its co-defendant moved for summary judgment on its defense that the Abbott patents are invalid, and on September 29, 2000, the court granted partial summary judgment, holding that certain key claims in Abbott s patents are invalid as a matter of law. The court refused to grant summary judgment on Abbott s claims of infringement or IMT s remaining claims of invalidity. On December 17, 2001, the court denied a motion by Abbott seeking reconsideration of the court s partial summary judgment in favor of IMT and PBM. Abbott renewed this motion on February 15, 2002. The court has not ruled on this motion. No trial date has been set at this time. In connection with our split-off from IMT, we assumed all obligations and liabilities of IMT arising out of this matter. We believe that we have strong defenses against Abbott s claims and we will continue to defend the case vigorously; however, a final ruling against IMT or us could have a material adverse impact on our sales, operations or financial performance.

Becton, Dickinson and Company v. Selfcare, Inc. et. al.

On January 3, 2000, Becton, Dickinson and Company (Becton Dickinson) filed suit against IMT (formerly known as Selfcare, Inc.) in the U.S. District Court for the District of Delaware (Case No: 00-001) alleging that certain pregnancy and ovulation test kits sold by IMT (and now by us) infringe U.S. Patent Nos. 4,703,017 and 5,591,645. IMT was served with Becton Dickinson s complaint in April 2000 and filed its answer on May 30, 2000, and subsequently added counterclaims alleging violations of state and federal antitrust laws. Becton Dickinson has since lost its rights to U.S. Patent No. 5,591,645 and is no longer asserting claims for infringement of that patent. In August 2001, IMT moved for summary judgment of non-infringement, but that motion was denied. IMT subsequently filed a second motion for summary judgment, which is still pending before the court. In connection with our split-off from IMT, we agreed to assume all obligations and liabilities of IMT arising out of this matter and we have assumed its defense. While a final ruling against IMT or us could have a material adverse impact on our sales, operations or financial performance, we believe that we have strong defenses and we intend to defend this litigation vigorously.

Cambridge Biotech Corporation and Cambridge Affiliate Corporation v. Ron Zwanziger, Selfcare, Inc., Cambridge Diagnostics Ireland, Ltd., Trinity Biotech, plc and Pasteur Sanofi Diagnostics

As of November 19, 2001, the parties to this litigation, (Civil Action No. 99-378) pending in the Middlesex County Massachusetts Superior Court, agreed to settle all claims in connection with this suit brought by Cambridge Biotech Corporation (CBC) and Cambridge Affiliate Corporation (CAC) against IMT, Ron Zwanziger, our subsidiary in Ireland, Cambridge Diagnostics Ireland, Ltd. (CDIL), Trinity Biotech plc (Trinity) and Pasteur Sanofi Diagnostics (Pasteur) arising out of the sale of certain HIV technology to Trinity. The settlement includes releases between the plaintiffs and the defendants and between IMT, CDIL and Ron Zwanziger and Trinity. Under the terms of the settlement IMT and CDIL have paid $500,000 to CBC, and Trinity has paid $50,000 to CBC. IMT and CDIL have also paid $1,500,000 to Trinity. The settlement also includes an agreement for IMT and CDIL to partially indemnify CBC up to a maximum of $1,125,000, and for Trinity to partially indemnify CBC up to a maximum of $75,000. CBC has agreed to partially indemnify IMT, CDIL, Ron Zwanziger and Trinity. Trinity, through a subsidiary, will transfer certain technology to CDIL and has agreed to produce certain antigens for CDIL. In connection with our split-off from IMT, we agreed to assume all obligations and liabilities of IMT arising out of this matter and its settlement.

Intervention, Inc v. Selfcare, Inc. and Companion Cases

In May 1999, Intervention, Inc., a California corporation, filed separate suits, which were subsequently consolidated, in California Contra Costa County Superior Court against IMT (formerly known as Selfcare, Inc.), four of its private label customers (now our customers) and its major competitors (now our competitors) and their private label customers 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. The plaintiff seeks restitution of profits on behalf of the general public, injunctive relief and attorneys fees. Conopco, Inc. (Conopco), predecessor to one of our subsidiaries, Unipath Diagostics, Inc. (Unipath Diagnostics), was also a defendant in this litigation. In connection with our split-off from IMT and our acquisition of the Unipath business

from Unilever, we have assumed the defense of IMT and Unipath Diagnostics and agreed to assume all obligations and liabilities of IMT and Unilever arising out of this matter. More recently the case has been split such that Unipath Diagnostics is a defendant in one case and we and our private label customers are defendants in another case. The case in which we and our private label customers are parties is scheduled for trial in June 2002. No trial date has been established for the case in which Unipath Diagnostics is a party. We are defending our private label customers under agreement. We do not believe that an adverse ruling against our company, our private label customers or Unipath Diagnostics would have a material adverse impact on our sales, operations or financial performance.

Persona Litigation

In April 2001, 69 consumers brought an action in London claiming defects in Unipath s Persona contraceptive device, negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants at or prior to 1998. The case is expected to be ready for trial to a judge in the latter half of 2003. We believe that there are substantial defenses to the claims and we intend to vigorously defend this litigation. Formal documentary and other discovery permitted under the law in the United Kingdom has not yet commenced, but is anticipated to be conducted during the second half of 2002 and into 2003. The case is insured, in the aggregate, by Unilever s product liability insurance up to 50 million British Pounds Sterling or more, depending on when the events giving rise to the consumers suit occurred. As a result, we do not believe that an adverse ruling would have a material adverse impact on our sales, operations or financial performance.

Other Pending and Potential Litigation

Because of the nature of our business, we may be subject at any particular time to consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and we expect that 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 or employment claims. We believe that any adverse ruling in such lawsuits would not have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and often results in counterclaims challenging the validity of our patents and other rights. We are currently a plaintiff in a number of cases filed around the world against competitors who we believe to be selling products that infringe our propriety rights. These outstanding cases do not involve material counterclaims. In particular, on March 7, 2002, we filed suit against Pfizer, Inc. (Pfizer) in the United States District Court for the District of New Jersey alleging that Pfizer s e.p.t ® brand pregnancy tests infringe Unipath s United States Patent Number 6,352,862 and seeking injunctive relief against further infringement as well as damages. This case compliments two existing infringement cases that we have pending against Pfizer based on other Unipath patents.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Set forth below is a summary of the actions taken by our stockholders during the three months ended December 31, 2001. Until November 21, 2001, when we were split off from IMT as a separate publicly traded company, our company was a subsidiary controlled by IMT and the only other stockholder was Ron Zwanziger.

On November 16, 2001, the stockholders approved the matters set forth below by written consent in lieu of special meeting. The stockholders (i) approved a private placement of convertible preferred stock and warrants to purchase common stock for the purpose of raising up to $80 million, (ii) approved a private placement of subordinated convertible capital notes and warrants to purchase common stock for the purpose of raising up to $20 million and (iii) approved a private placement of capital notes and related warrants to purchase common stock for the purpose of raising up to $25 million.

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

On November 23, 2001, our common stock began trading on the American Stock Exchange (AMEX) 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 period indicated, the high and low closing sale prices of our common stock on AMEX.

	High	Low
Year ended December 31, 2001		
4th Quarter (beginning November 23)	$19.35	$15.47

On March 25, 2002, there were 275 holders of record of our common stock. The closing price of our common stock on March 25, 2002 was $21.50.

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.

Recent Sales of Unregistered Securities

Set forth in chronological order below is information regarding unregistered securities issued by our company during the three months ended December 31, 2001, as well as in the first quarter of 2002. No underwriters or underwriting discounts or commissions were involved. There was no public offering in any such transaction and we believe that each transaction was exempt from the registration requirements of the Securities Act of 1933, as amended, by reason of Section 4(2) thereof, based on the private nature of the transactions and the financial sophistication of the purchasers, all of whom had access to complete information concerning our company and acquired the securities for investment and not with a view to the distribution thereof.

On December 20, 2001, we sold an aggregate of 1,995,000 shares of Series A Convertible Preferred Stock (the Series A Preferred Stock) to private investors, including certain of our directors and related persons and entities, at a purchase price of $30.00 per share for an aggregate consideration of $59.85 million. The Series A Preferred Stock is currently convertible into common stock at a 2-for-1 ratio, subject to adjustment. In March 2002, 166,667 of these shares of Series A Preferred Stock were converted into 333,334 shares of common stock. Accordingly, the 1,828,333 of these shares of Series A Preferred Stock that remain outstanding are currently convertible into 3,656,666 shares of common stock. For additional information regarding the identity of the purchasers of the Series A Preferred Stock, see the signature pages to the Stock Purchase Agreement included as Exhibit 10.20 hereto, which information is incorporated herein by reference.

On December 20, 2001, we issued subordinated promissory notes and warrants to private investors, including an entity affiliated with Ron Zwanziger, for an aggregate purchase price of $20.0 million. The notes had an aggregate face value of $20.0 million and were convertible into shares of Series A Preferred Stock at a conversion price of $30.00 per share under certain circumstances. On March 6, 2002, we retired all of the notes using the proceeds from the sale of 531,915 shares of Series A Preferred Stock completed earlier that same day. The warrants are exercisable for an aggregate of 55,189 shares of common stock at a purchase price of $18.12 per share. For additional information regarding the identity of the purchasers of these notes and warrants, see the signature pages to the Note and Warrant Purchase Agreement included as Exhibit 10.21 hereto, which information is incorporated herein by reference.

On December 20, 2001, we issued a warrant to purchase 65,000 shares of common stock at a purchase price of $0.001 per share to RBS Mezzanine Limited (RBS) in connection with the provision by RBS of a $10.0 million mezzanine loan facility (the Mezzanine Loan Facility) to

our company.

On December 20, 2001, we issued a warrant to purchase 385,000 shares of common stock at a purchase price of $17.15 per share to Zwanziger Family Ventures, LLC in consideration of its agreement not to sell or transfer shares of common stock for a specified period of time; such agreement was required by RBS in connection with the Mezzanine Loan Facility.

On March 6, 2002, we sold an aggregate of 531,915 shares of Series A Preferred Stock to private investors at a purchase price of $39.01 per share for an aggregate consideration of approximately $20.75 million. The Series A Preferred Stock is currently convertible into common stock at a 2-for-1 ratio, subject to adjustment. Accordingly, these shares of Series A Preferred Stock are currently convertible into 1,063,830 shares of common stock. For additional information regarding the identity of the purchasers of the Series A Preferred Stock, see the signature pages to the Stock Purchase Agreement included as Exhibit 10.20 hereto, which information is incorporated herein by reference.

In March 2002, we issued 333,334 shares of common stock upon conversion of 166,667 shares of Series A Preferred Stock pursuant to an exemption afforded by Section 3(a)(9) of the Securities Act of 1933, as amended.

ITEM 6. SELECTED FINANCIAL DATA

The following table provides selected historical consolidated financial data of our company as of and for each of the fiscal years in the five-year period ended December 31, 2001 and should be read in conjunction with our consolidated financial statements and notes included elsewhere in this annual report on Form 10-K. The data as of and for each of the fiscal years in the three-year period ended December 31, 2001 have been derived from our consolidated financial statements that have been audited by Arthur Andersen LLP, independent public accountants, and are included elsewhere in this annual report on Form 10-K. The consolidated financial data as of and for the year ended December 31, 1998 has been derived from our audited financial statements not included herein. The consolidated financial data as of and for the year ended December 31, 1997 has been derived from our unaudited financial statements. The unaudited consolidated financial statements for the year ended December 31, 1997 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 that period. The historical consolidated financial information presents our results of operations and financial position as if we had been a separate entity for all periods presented. The historical financial information may not be indicative of our future performance and may not necessarily reflect what our financial position and results of operations would have been if we had been a separate stand-alone entity during the years covered. For a discussion of certain factors that materially affect the comparability of the consolidated financial data or cause the data reflected herein not to be indicative of our future financial condition or results of operation, see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Affecting Future Results.

	Year Ended December 31,				
	2001	2000	1999	1998	1997
	(in thousands, except per share data)				
Consolidated Statements of Operations:					
Net product sales	$ 49,384	$ 51,051	$ 50,584	$ 54,685	$ 50,635
Cost of sales	25,821	25,075	26,890	26,720	24,724
Gross profit	25,563	25,976	23,694	27,965	25,911
Operating expenses:					
Purchased in-process research and development	6,980				
Research and development	1,809	1,360	1,396	2,323	6,210
Sales and marketing	10,976	10,585	11,010	13,169	12,101
General and administrative	11,814	7,178	7,339	9,600	8,998
Other expenses	10,441			4,969	81
Total operating expenses	42,020	19,123	19,745	30,061	27,390
Operating (loss) income	(18,457)	6,853	3,949	(2,096)	(1,479)
Interest and other expenses, net	(3,871)	(2,292)	(2,585)	(2,967)	(2,377)
(Loss) income from continuing operations before income taxes	(22,328)	4,561	1,364	(5,063)	(3,856)
Provision for income taxes	2,134	1,781	1,007	1,115	1,456

(Loss) income from continuing operations	(24,462)	2,780	357	(6,178)	(5,312)
Income (Loss) from discontinued operations	58	(598)	183	(2,882)	(791)
(Loss) income before extraordinary item	$ (24,404)	$ 2,182	$ 540	$ (9,060)	$ (6,103)
Extraordinary loss on early extinguishment of debt	(327)				
Net (loss) income	$ (24,731)	$ 2,182	$ 540	$ (9,060)	$ (6,103)
(Loss) income per common share basic and diluted (1):					
(Loss) income from continuing operations	$ (3.84)	$ 0.59	$ 0.11	$ (2.53)	$ (3.32)
Net (loss) income	$ (3.88)	$ 0.46	$ 0.16	$ (3.71)	$ (3.82)

Balance Sheet Data:

	December 31,				
	2001	**2000**	**1999**	**1998**	**1997**
			(in thousands)		
Cash and cash equivalents	52,024	3,071	661	1,111	5,099
Working capital (deficit)	21,022	(6,464)	(4,060)	(1,986)	(1,401)
Total assets	278,571	74,958	72,210	70,191	67,182
Debt obligations	78,124	12,830	19,076	23,163	26,595
Total stockholders equity	89,614	41,812	34,953	28,932	18,442

(1) Basic and diluted (loss) earnings per share are computed as described in Notes 1, 2(k) and 9 of the Notes to Consolidated Financial Statements.

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

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. (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 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 primarily of its diabetes business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

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.

Recent Developments

Acquisition of Unipath

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 (the Unipath business) from Unilever PLC (Unilever) and certain affiliated entities (the Unilever group). 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. The Unipath business is comprised primarily of five former subsidiaries of the Unilever group, specifically Unipath Limited, Unipath Management, Ltd., Unipath Diagnostics GmbH, Unipath Scandinavia A.B. and Unipath B.V., and certain assets. Included in the acquired assets are facilities in Bedford, England, United States marketing and sales operations in Princeton, New Jersey and 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 or 166 million Euros) in cash, subject to certain adjustments provided for in the sale agreement. We financed the acquisition through a combination of cash on hand and the proceeds from three separate financing transactions, consisting of the private sale of 1,995,000 shares of Series A Convertible Preferred Stock for an aggregate purchase price of $59.85 million, the private sale of approximately $20.0 million of subordinated promissory notes and warrants and the establishment of senior and mezzanine credit facilities with The Royal Bank of Scotland plc and related entities for an aggregate principal amount of $62.5 million. The terms of these financing transactions are described in more detail in Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources and Notes 4 and 6 of the Notes to Consolidated Financial Statements, which are included elsewhere in this report.

Prior to the acquisition, the Unilever group used the assets of the Unipath business for the research, development, manufacturing and distribution of home pregnancy and ovulation testing products and natural family planning products. We intend to continue to use these assets for this purpose. In addition, we intend to use the acquired assets, together with our existing assets, to research, develop and commercialize new products and advanced medical device technologies for the consumer diagnostics and other markets, as well as to supplement our existing product distribution network.

Acquisition of IVC Industries, Inc.

On March 19, 2002, we acquired IVC Industries, Inc. (IVC), a manufacturer and distributor of vitamins and nutritional supplements, in a merger transaction. Under the terms of the merger agreement, each stockholder of IVC received $2.50 in cash for each share of IVC common stock. Accordingly, the aggregate cash payment to IVC's stockholders was approximately $5.6 million, based upon IVC s approximately 2.25 million shares outstanding. In addition, IVC had outstanding debt and capital lease obligations as of closing of approximately $18.7 million. IVC manufactures and sells hundreds of different vitamin and nutritional supplement products under brand names and through private label arrangements with retailers. We intend to continue IVC s present operations. We are in the process of consolidating our vitamin and nutritional supplement manufacturing at IVC and discontinuing most of our outsourced manufacturing arrangements.

Results of Operations

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 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 (See Note 4 of the Notes to Consolidated Financial Statements). 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 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 (see Note 10(c) of the Notes to Consolidated Financial Statements). 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.

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 (see Item 3. Legal Proceedings).

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 (see Note 11 of the Notes to Consolidated Financial Statements).

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 (see Notes 1 and 13 of the Notes to Consolidated Financial Statements).

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 (see Note 6(e) of the Notes to Consolidated Financial Statements).

Net 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 (see Notes 1, 2(k) and 9 of the Notes to Consolidated Financial Statements). 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.

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 (see Note 11 of the Notes to Consolidated Financial Statements).

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 (see Notes 1 and 13 of the Notes to Consolidated Financial Statements).

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 (see Notes 1, 2(k) and 9 of the Notes to Consolidated Financial Statements).

Supplementary Quarterly Financial Information

	2001				2000			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)							
Net product sales	$ 11,812	$ 12,272	$ 11,590	$ 13,711	$ 13,455	$ 12,743	$ 12,519	$ 12,334
Gross profit	5,986	6,478	5,591	5,508	6,908	6,856	6,026	6,186
Operating income (loss)	1,515	1,462	(17)	(21,417)	1,983	1,952	1,327	1,591
Income (loss) from continuing operations	710	151	(288)	(25,035)	835	1,067	317	561
	$ 0.12	$ 0.02	$ (0.04)	$ (3.86)	$ 0.21	$ 0.23	$ 0.06	$ 0.11

Income (loss) per share from continuing operations basic and diluted (1)	

(1) Basic and diluted earnings (loss) per share are computed as described in Notes 1, 2(k) and 9 of the Notes to Consolidated Financial Statements .

Liquidity and Capital Resources

At December 31, 2001, we had cash and cash equivalents of $52.0 million, a $49.0 million increase from December 31, 2000. We have historically funded our business through operating cash flows, proceeds from borrowings and the issuance of common and preferred stock, as well as contributions from IMT and affiliated companies. We had a positive cash flow of $15.4 million from our operating activities during the year ended December 31, 2001 due largely to an increase in accrued expenses and other liabilities of $15.1 million. We had a loss of $2.3 million adjusted for noncash expenses and net income from discontinued operations. During 2001, cash used in our discontinued operations was $1.2 million. In December 2001, we used cash of $146.2 million to purchase the Unipath business from Unilever (see Note 4 of the accompanying Notes to Consolidated Financial Statements). Approximately $3.3 million relating to the Unipath acquisition will be paid in 2002. Also during the

year ended December 31, 2001, we used $3.5 million for capital expenditures and we had a decrease in non-current assets of $129,000. During the year ended December 31, 2001, we raised cash of $184.1 million from financing activities. During 2001, we received proceeds of $59.85 million from the issuance of preferred stock (see Note 10(b) of the accompanying Notes to Consolidated Financial Statements) and $0.6 million from the issuance of common stock upon the exercise of options and warrants. We also received $62.5 million from borrowings pursuant to credit agreements with The Royal Bank of Scotland plc and affiliated entities (see Note 6(a) of the accompanying Notes to Consolidated Financial Statements) and $20 million of proceeds from the issuance of subordinated promissory notes and warrants (see Note 6(b) of the accompanying Notes to Consolidated Financial Statements). Additionally, during 2001, we received cash contributions of $47.7 million from IMT, including $41.4 million at the time of our split-off from IMT. During 2001, we used $4.3 million for principal repayments on loans from The Chase Manhattan Bank (Chase) and various other debt and $2.2 million for deferred financing costs. Working capital was $21.0 million on December 31, 2001 compared to a deficit of $6.5 million on December 31, 2000.

On December 20, 2001, one of our wholly-owned subsidiaries entered into a series of credit agreements (the Credit Agreements) with The Royal Bank of Scotland plc and related entities for credit facilities in the aggregate amount of $70,000,000, which were amended in the first quarter of 2002. The Credit Agreements consist of term loans aggregating $62,500,000, of which $10,000,000 are denominated in Japanese Yen and a $7,500,000 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. The revolving line of credit is designated for use by our company to cover certain of our liabilities and future foreign exchange contracts. At December 31, 2001, there were no outstanding borrowings on the revolving line of credit. We and certain of our subsidiaries are the guarantors of all obligations due under the Credit Agreements. Borrowings under the Credit Agreements are secured by the stock of our European subsidiaries, our intellectual property rights, and the assets of our United States businesses. We must make mandatory prepayments on the loans under the Credit Agreements if we meet certain cash flow thresholds, collect insurance proceeds in excess of certain thresholds, receive payments and sell assets not in the ordinary course of business, or upon a sale or change of control of our company. The per annum interest rate on the loans will be the London Interbank Offered Rate (LIBOR) plus a spread from 1.5% to 3.5% (and an additional 2.0% 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 earnings before interest expense, taxes, depreciation and amortization (EBITDA). In February 2002, we entered into an interest rate swap agreement with the bank, which applies to $41.7 million of the term loans that are denominated in United States Dollars and protects both parties 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%. Interest at 4.0% per annum is capitalized on the junior loan. Capitalized interest may be paid upon agreement with the lender of our senior debt. The amount of capitalized interest during 2001 was approximately $9,000. Under the 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 affect on us.

In connection with the Credit Agreements, our chief executive officer and an entity controlled by our chief executive officer were required to enter into a lock up agreement with the bank, pursuant to which they are restricted in the trading of our securities for various specified periods and amounts. In consideration of their entry into this lock up agreement, we issued our chief executive officer an option to purchase 115,000 shares of our common stock and the entity a warrant to acquire 385,000 shares of our common stock, in each case, at $17.15 per share (the fair value of our common stock on the date of issuance).

On December 20, 2001, we sold to private investors 1,995,000 shares of Series A Preferred Stock at $30 per share for gross proceeds of $59,850,000 for purposes of funding part of our acquisition of the Unipath business. The private investors include certain of our directors and entities affiliated with such directors and our chief executive officer, who in the aggregate purchased 626,666 of such shares. 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. As our stock price had not been below $15 following the issuance of the Series A Preferred Stock, no dividends were recorded in 2001. 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 (using the same conversion ratio as described below in connection with a voluntary conversion of shares of Series A Preferred Stock). Thereafter, we have the option to pay dividends in cash or common stock, if such dividends are declared by the board of directors. 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. The conversion price was initially $15 and is subject to adjustment. The conversion price for the Series A Preferred Stock represents a $2 (or 11.8%) discount to the fair value of the 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 for any consecutive 30 trading day period. The Series A Preferred Stock may be redeemed upon a vote by the holders of at least 66% of the outstanding shares on or after June 30, 2011. 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. In March 2002, we sold to private investors an additional 531,915 shares of Series A Preferred Stock at $39.01 per share for gross proceeds of $20,750,000 for purposes of repaying the subordinated promissory notes that we issued on December 20, 2001. The terms of these new shares of Series A Preferred Stock are substantially the same as the terms of the shares issued in December 2001 and each share is currently convertible into two shares of our common stock.

We entered into a note and warrant purchase agreement pursuant to which, on December 20, 2001, we issued subordinated promissory notes (Subordinated Notes) having an aggregate principal amount of $20.0 million for the purpose of funding our acquisition of the Unipath business. Interest accrued at 12% per annum on the outstanding principal amount and was payable on the first day of each calendar quarter starting April 1, 2002 and on the maturity date, if extended as described herein. We had an option to make interest payments in the form of cash or our common stock at a value of 95% of the ten-day average closing price of our common stock prior to the interest payment due date. The Subordinated Notes were set to mature on April 1, 2002; however, we had an option to extend the maturity date to any date prior to the original maturity date of the term loans under the Credit Agreements, subsequent to which interest would accrue at 18% per annum. As part of the note and warrant purchase agreement, in addition to the Subordinated Notes, we also issued 10-year warrants to purchase a total of 55,189 shares of our common stock at an exercise price of $18.12 per share. On March 6, 2002, we prepaid the Subordinated Notes plus accrued interest in full using the proceeds from the issuance of Series A Preferred Stock on that date. The warrants issued in connection with the Subordinated Notes remain outstanding.

In February 1998, our subsidiary, Inverness Medical, Inc. (IMI), acquired Can-Am, a leading supplier of diabetes care products, for a combination of cash, notes and shares of IMT common stock. At the time, IMI entered into a $42 million credit agreement with Chase, with IMT as guarantor, to fund the cash portion of the purchase price and to repay outstanding indebtedness under a prior credit facility. The Chase credit agreement consisted of a $37 million term loan and a $5 million revolving line of credit. Borrowings under the Chase credit agreement were secured by the capital stock of a subsidiary of IMT, our assets and the assets of our subsidiaries. IMI was required to make quarterly principal payments on the term portion of the loan ranging from $1.4 million to $1.7 million through December 31, 2003. IMI was also required to make mandatory prepayments on the term loan if it met certain cash flow thresholds, sold assets outside of the ordinary course of business, issued or sold indebtedness or issued stock. During the year ended December 31, 2001, IMI made quarterly principal payments and a mandatory prepayment totaling $3.5 million. Immediately prior to the consummation of the split-off and merger, the balance of this debt was discharged.

During 1999, our subsidiary in Ireland, Cambridge Diagnostics Ireland Ltd. (CDIL), financed the purchase of one of its manufacturing buildings through a mortgage loan (the CDIL Mortgage) with the seller. The outstanding balance of the CDIL Mortgage was $237,000 at December 31, 2001. The CDIL Mortgage bears interest at 6% and is payable semiannually through 2003.

Our subsidiary in Israel, Orgenics Ltd. (Orgenics), had bank debt balances totaling $230,000 at December 31, 2001. Orgenics bank debt is collaterized by certain of Orgenics assets. The notes bear interest at rates ranging from 3.43% to 4.25% and are payable on various dates through 2003.

On March 19, 2002, we acquired IVC, a manufacturer and distributor of vitamins and other nutritional supplements. The purchase price for IVC consisted of $2.50 in cash for each outstanding share of IVC s common stock (an aggregate cost of approximately $5.6 million), assumed stock options having a fair value of approximately $540,000, certain employee costs and benefits related to a restructuring of activities upon the acquisition and direct acquisition costs. In addition, IVC had outstanding debt and capital lease obligations as of closing of approximately

$18.7 million. We are accounting for this acquisition as a purchase in accordance with Statement of Financial Accounting Standards No. 141 and are in the process of determining the purchase price allocation.

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 in future years, if any. 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 December 31, 2001, we will be required to use approximately $28.7 million in cash during 2002 to meet debt maturities (approximately $24.3 million), minimum lease payments (approximately $3.5 million) and capital expenditure commitments (approximately $0.8 million). Based upon 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 revenue 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 available 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 included elsewhere in this annual report on Form 10-K 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. Note 2 of the Notes to Consolidated Financial Statements includes 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.

For 2001, our revenues were derived solely 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.

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 amounted to approximately $2.7 million in 2001.

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 $21.7 million, net of allowance for doubtful accounts of $0.8 million as of December 31, 2001.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include property, plant and equipment and goodwill and other intangible assets. As of December 31, 2001, the balances of property, plant and equipment and goodwill and other intangible assets, net of accumulated depreciation and amortization, were $20.5 million and $160.8 million, respectively. For purposes of determining whether there are any impairment losses, our management examines the carrying value of our identifiable long-lived and intangible assets when indicators of impairment are present. 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.

Factors we generally consider important which could trigger an impairment review 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; and (7) our market capitalization relative to net book value.

When we determine that the carrying value of long-lived tangible and intangible assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment 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 carrying value of our long-lived tangible and intangible assets were realizable as of December 31, 2001, future events could cause us to conclude otherwise.

During 2002, Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, became effective. As a result, we will cease to amortize approximately $12.1 million of goodwill. Annual amortization of this goodwill balance had been approximately $603,000. In the fourth quarter of 2001, we recorded $73.2 million in goodwill and other intangible assets with indefinite lives, relating to which we had not recorded and will not record any amortization in accordance with SFAS No. 142. In lieu of amortization, we are required to obtain an independent initial impairment review of our goodwill in 2002 and annual impairment reviews thereafter. We expect the independent initial review to be completed during the early part of 2002. Depending on the findings of the initial review, we may be required to record a material impairment charge.

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.

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 discussed in Item 3. Legal Proceedings in this annual report on Form 10-K. As of December 31, 2001, we have not accrued for potential losses on legal proceedings where our company is the defendant because we are currently 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.

In addition, in Item 3 of this report, we have reported as to certain legal proceedings that we do not believe a final ruling against us could have a material adverse impact on our financial position and operations. To the extent that unanticipated facts or circumstances arise that cause us to change this assessment with respect to any matter, our future results of operations and financial position could be materially affected.

Certain Factors Affecting Future Results

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 with respect to 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 pages 1 and 39 of this report.

Risks Related to the Split-Off

On November 21, 2001, we were split-off from IMT and became an independent, publicly owned company as part of a transaction by which IMT was acquired by Johnson & Johnson. Prior to that time, we had been a majority owned subsidiary of IMT, and the businesses that we acquired in connection with the restructuring that preceded the split-off represented approximately 20% of IMT s net product sales during the calendar quarter concluded immediately prior to the split-off. 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.

The historical financial information included in this annual report on Form 10-K 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 this 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:

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 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 on March 19, 2002, we assumed additional debt and capital lease obligations totaling approximately $18.7 million. Our substantial level of debt affects our future operations in several important ways, including the following:

our ability to obtain additional financing may be impaired;

our flexibility to adjust to market conditions is limited, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in which we operate;

we may need to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and other business activities 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 $15.9 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 the Unipath business. 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.

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 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.

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.

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 United States 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 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.

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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. Orgenics 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.

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

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

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.

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.

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

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

As of March 25, 2002, there were 2,360,248 shares of Series A Preferred Stock outstanding. Pursuant to the terms of the certificate of designation creating the Series A Preferred Stock, upon a liquidation or a deemed liquidation of our company, the holders of the shares of our Series A Preferred Stock are entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is $30 per share of Series A Preferred Stock (or $40.50 per share in certain circumstances), plus the amount of any dividends that have accrued on those shares, subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting our Series A Preferred Stock. Dividends accrue on the shares of our Series A Preferred Stock at the rate of up to $2.10 per share per annum based on the percentage of trading days on which the closing market price of our common stock is less than $15.00. As a

result of these terms, the holders of our common stock may be disproportionately affected by any reduction in the value of our assets or fluctuations in the market price of our common stock.

The ability of our stockholders to control our policies and effect a change of control of our company is limited, which may not be in your best interests.

There are provisions in our certificate of incorporation and by-laws which may discourage a third party from making a proposal to acquire us, even if some of our stockholders might consider the proposal to be in their best interests. These provisions include the following:

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

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

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

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

We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of your investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value after the offering or even maintain the price at which you purchased your shares.

Recently Issued Accounting Standards

In June 2001, the FASB issued SFAS No. 141, *Business Combinations*. SFAS No. 141 addresses changes in the financial accounting and reporting for business combinations and supersedes Accounting Principles Board (APB) Opinion No. 16, Business Combinations, and SFAS No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises*. Effective July 1, 2001, all business combinations should be accounted for using only the purchase method of accounting. We do not believe the adoption of this statement will have a material effect on our financial position, results of operations or cash flows.

In June 2001, the FASB issued SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 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 will no longer be 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 $603,000, $603,000 and $762,000 during 2001, 2000 and 1999, respectively. We have determined the full impact of not amortizing goodwill on our consolidated financial statements. The total amount of goodwill and intangible assets, net of accumulated amortization, expected to be effected by this statement was approximately $85,375,000 at December 31, 2001, of which approximately $73,227,000 was acquired between June 30, 2001 and December 31, 2001. We are currently assessing whether our existing goodwill has been impaired in accordance with SFAS No. 142.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS 144 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 spinoff 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 by broadening the presentation of discontinued operations to include more disposal transactions. 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 application encouraged. The provisions of this statement generally are to be applied prospectively. We adopted SFAS No. 144 in 2002 and have not yet determined the impact of this statement on our financial position, results of operations or cash flows.

SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K 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 shou contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this annual report on Form 10-K. These differences may be the result of various factors, including those factors described in the Certain Factors Affecting Future Results section of this annual report. 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;

significant litigation adverse to us including product liability claims, patent infringement claims and antitrust claims;

product efficacy or safety concerns resulting in product recalls or declining sales;

the impact of business combinations, including acquisitions and divestitures, and organizational restructuring consistent with evolving business strategies;

our ability to satisfy the financial covenants and other conditions contained in our credit facilities;

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

the issuance of new or revised accounting standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board or the Securities and Exchange Commission.

The foregoing list sets forth many, but not all, of the factors that could impact upon our ability to achieve results described in any forward-looking statements. Readers should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events

described in the Certain Factors Affecting Future Results section and elsewhere in this annual report 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.

ITEM 7A. 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 December 31, 2001, our short-term investments approximated market value.

In December 2001, we entered into a series of credit agreements with The Royal Bank of Scotland plc and related entities for credit facilities in the aggregate amount of $70 million. These credit agreements consisted of term loans aggregating $62.5 million, of which $10 million are 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 balance of the term loans as of December 31, 2001 was $62.2 million, net of a reduction of approximately $300,000 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 the London Interbank Offered Rate (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 earnings before interest expense, taxes, depreciation and amortization. In February 2002, we entered into an interest rate swap agreement with the bank, as required by the 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 $41.7 million of the term loans denominated in United States Dollars. This interest rate swap agreement is effective for the period from February 25, 2002 to December 31, 2004. As of December 31, 2001, the LIBOR applicable to the term loans denominated in United States Dollars was 1.92% and the LIBOR applicable to the term loan denominated in Japanese Yen was 0.10%. If the LIBOR rate increases one percentage point, as compared to the rate at December 31, 2001, we estimate an increase in our interest expense of approximately $271,000 in 2002. If the LIBOR rate increases two percentage points, as compared to the rate at December 31, 2001, we estimate an increase in our interest expense of approximately $610,000 in 2002.

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates. In 2001, the net impact of foreign currency changes was a loss of $727,000. 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 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 December 31, 2001, 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 million denominated in Japanese Yen. As of December 31, 2001, the outstanding balance of this loan was $9.7 million, net of a reduction of approximately $300,000 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 December 31, 2001, the dollar-to-yen exchange rate was approximately 131.67. If the dollar-to-yen exchange rate decreased by ten percent, as compared to the rate at December 31, 2001, we estimate that the outstanding principal amount owed by us under this loan would have been higher by approximately $1.1 million on that date. If the dollar-to-yen exchange rate decreased by twenty percent, as compared to the rate at December 31, 2001, we estimate that the outstanding amount owed by us under this loan would have been higher by $2.5 million on that date. If, on the 2002 maturity dates, the dollar-to-yen exchange rate was lower by ten percent, as compared to the rate at December 31, 2001, we would have to pay approximately $119,000 more in principal repayments during 2002. If, on the maturity dates in 2002, the dollar-to-yen exchange rate was lower by twenty percent, as compared to the rate at December 31, 2001, we would have to pay approximately $267,000 more in principal repayments during 2002.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data are listed under Item 14(a) and have been filed as part of this report on the pages indicated.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information regarding our directors, executive officers and significant employees included in our definitive Proxy Statement to be filed pursuant to Regulation 14A in connection with our 2002 Annual Meeting of Shareholders (the Proxy Statement) is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information regarding executive compensation included in the Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information regarding security ownership of certain beneficial owners and management included in the Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information regarding certain relationships and related transactions included in the Proxy Statement is incorporated herein by reference.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) 1. Financial Statements.

The financial statements listed below have been filed as part of this report on the pages indicated:

2. Financial Statement Schedules.

None.

3. Exhibits

2.1 Sale Agreement, dated December 20, 2001, between Inverness Medical Innovations, Inc. (the Company) and Unilever U.K. Holdings Limited (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K dated December 20, 2001)

2.2 Amended and Restated Agreement and Plan of Merger, made and entered into as of December 21, 2001 and amended and restated as of January 22, 2002, by and among the Company, Nutritionals Acquisition Corporation and IVC Industries, Inc. (IVC) (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K dated March 29, 2002)

+*2.3 Restructuring Agreement, dated as of November 21, 2001, by and among Inverness Medical Technology, Inc. (IMT), the Company and certain subsidiaries of IMT

*3.1 Amended and Restated Certificate of Incorporation of the Company

3.2 Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K dated December 20, 2001)

*3.3 Amended and Restated By-laws of the Company

4.1

Specimen certificate for shares of Common Stock of the Company (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

*10.1 Post-Closing Covenants Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT, the Company, certain subsidiaries of IMT and certain subsidiaries of the Company

*10.2 Tax Allocation Agreement, dated as of November 21, 2001, by and among Johnson &

Johnson, IMT and the Company

*10.3 Supply of Goods Agreement, dated July 28, 1998, between Schleicher & Schuell GmbH and Unipath Limited

10.4 Trademark License Agreement, dated as of February 19, 1997, by and among American Cyanamid Company and Selfcare Acquisition Corporation (incorporated by reference to Exhibit 10.5 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

10.5 Lease, dated as of March 19, 1992, by and among Cambridge Diagnostics Ireland Limited and George Conroy, Brendan Conroy and Patrick Conroy (incorporated by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

10.6 Lease, dated as of January 12, 1999, by and among Cambridge Diagnostics Ireland Limited and the Industrial Development Agency (Ireland) (incorporated by reference to Exhibit 10.4 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

10.7 Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

10.8 Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

*10.9 Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan First Amendment

*10.10 Lease Agreement, dated July 28, 1998, between 569 Halls Mill Road, L.L.C. and IVC

*10.11 Restricted Stock Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Ron Zwanziger

*10.12 Promissory Note, dated August 16, 2001, from Ron Zwanziger to the Company

*10.13 Pledge Agreement, dated as of August 16, 2001, between Ron Zwanziger and the Company

*10.14 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Jerry McAleer

*10.15 Promissory Note, dated December 4, 2001, from Jerry McAleer to the Company

*10.16 Pledge Agreement, dated as of December 4, 2001, between Jerry McAleer and the Company

*10.17 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and David Scott

*10.18 Promissory Note, dated December 4, 2001, from David Scott to the Company

*10.19 Pledge Agreement, dated as of December 4, 2001, between David Scott and the Company

10.20 Stock Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K dated March 14, 2002)

10.21

Note and Warrant Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.3 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.22 Form of Subordinated Promissory Note issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.4 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.23 Form of Warrant for the Purchase of Shares of Common Stock of the Company issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.5 to the Company s Current Report on Form 8-K

dated December 20, 2001)

10.24 Credit Agreement, dated December 20, 2001, between the Company, Inverness Medical Switzerland GmbH, the Banks listed on Schedule 1 thereto, The Royal Bank of Scotland plc, as Facility Agent, The Royal Bank of Scotland plc, as Issuing Bank, The Royal Bank of Scotland plc, as Overdraft Bank, and The Royal Bank of Scotland plc, as Lead Arranger (incorporated by reference to Exhibit 99.6 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.25 Mezzanine Loan Agreement, dated December 20, 2001, between the Company, Inverness Medical Switzerland GmbH, the Lenders listed on Schedule 1 thereto, RBS Mezzanine Limited, as Facility Agent, and RBS Mezzanine Limited, as Lead Arranger (incorporated by reference to Exhibit 99.7 to the Company s Current Report on Form 8-K dated December 20, 2001)

*10.26 Warrant Agreement, dated as of December 20, 2001, by and between the Company and RBS Mezzanine Limited

*10.27 Warrant to Purchase Common Stock of the Company, dated December 20, 2001, issued to RBS Mezzanine Limited in connection with the Mezzanine Loan Agreement

*10.28 Warrant for the Purchase of Shares of Common Stock of the Company, dated as of December 20, 2001, issued to Zwanziger Family Ventures, LLC

*10.29 Loan and Security Agreement, dated as of October 16, 2000, between IVC and Congress Financial Corporation

*10.30 Amendment No. 1 to Loan and Security Agreement, dated June 13, 2001, by and between Congress Financial Corporation and IVC

*10.31 Amendment No. 2 to Loan and Security Agreement, dated as of June 14, 2001, by and between Congress Financial Corporation and IVC

*10.32 Amendment No. 3 to Loan and Security Agreement, dated as of March 19, 2002, by and between Congress Financial Corporation and IVC

*10.33 Agreement, dated December 1, 1986, between Bernard Levere, Zelda Levere, Pioneer Pharmaceuticals, Inc. and Essex Chemical Corp. and Unconditional Guarantee by Essex Chemical Corp.

*10.34 Option to Assume and Extend Lease, dated as of February 1995, between Bernard Levere, Zelda Levere and International Vitamin Corporation

10.35 Inverness Medical Innovations, Inc. Executive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

*10.36 Amendment to Mezzanine Loan Agreement, dated March 28, 2002, between RBS Mezzanine Limited, for and on behalf of the Finance Parties, and the Company, for and on behalf of itself and Inverness Medical Switzerland GmbH

*10.37 Licensing Agreement, dated March 14, 1988, between Unilever Plc and Behringwerke AG

*10.38 Supplemental Agreement, dated October 16, 1994, between Unilever Plc, Unilever NV and Behringwerke AG

*10.39 Amendment to Credit Agreement, dated March 28, 2002, between The Royal Bank of Scotland plc, for and on behalf of the Finance Parties, and the Company, for and on behalf of itself and Inverness Medical Switzerland GmbH

*21.1 List of Subsidiaries of the Company as of April 1, 2002

23.1 Consent of Arthur Andersen LLP

*99.1 Letter from the Company to the Securities and Exchange Commission regarding Arthur Andersen LLP representations

Filed herewith.

* Previously filed.

+ The Company agrees to furnish supplementally to the Securities and Exchange Commission (the Commission) a copy of any omitted schedule or exhibit to this agreement upon request by the Commission.

(b) *Reports on Form 8-K*

On December 31, 2001, we filed a Current Report on Form 8-K dated December 21, 2001 (Item 5) in connection with our entry into a definitive agreement to acquire IVC Industries, Inc.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVERNESS MEDICAL INNOVATIONS, INC.

Date: April 2, 2002

By: /s/ Ron Zwanziger

Ron Zwanziger

Chairman, President and Chief Executive Officer

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Inverness Medical Innovations, Inc.:

We have audited the accompanying consolidated balance sheets of Inverness Medical Innovations, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inverness Medical Innovations, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Boston, Massachusetts

March 28, 2002

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2001	**2000**	**1999**
Net product sales	$ 49,384,795	$ 51,050,574	$ 50,583,854
Cost of sales	25,821,331	25,074,536	26,890,187
Gross profit	23,563,464	25,976,038	23,693,667
Operating expenses:			
Purchased in-process research and development	6,980,221		
Research and development	1,809,508	1,359,500	1,395,401
Sales and marketing	10,975,572	10,584,680	11,010,381
General and administrative	11,814,342	7,178,429	7,339,290
Stock-based compensation (1)	10,440,588		
Total operating expenses	42,020,231	19,122,609	19,745,072
Operating (loss) income	(18,456,767)	6,853,429	3,948,595
Interest expense, including amortization of original issue discount and beneficial conversion feature (Note 6)	(1,855,353)	(1,904,696)	(2,022,974)
Other expense, net	(2,015,723)	(387,884)	(562,298)
(Loss) income from continuing operations before income taxes	(22,327,843)	4,560,849	1,363,323
Provision for income taxes	2,134,359	1,781,244	1,006,709
(Loss) income from continuing operations	(24,462,202)	2,779,605	356,614
Income (loss) from discontinued operations, net of taxes (Note 13)	57,895	(597,784)	183,089
(Loss) income before extraordinary item	(24,404,307)	2,181,821	539,703
Extraordinary loss on early extinguishment of debt (Note 6(e))	(326,580)		
Net (loss) income	$ (24,730,887)	$ 2,181,821	$ 539,703
(Loss) income per common share basic and diluted (Notes 2(k) and 9)**:**			
(Loss) income from continuing operations	$ (3.84)	$ 0.59	$ 0.11
Net (loss) income	$ (3.88)	$ 0.46	$ 0.16
Weighted average shares	6,368,000	4,726,000	3,364,000

(1) Stock-based compensation expense by statements of operations classifications is as follows:

Research and development	$ 9,345,528	$	$
General and administrative	1,095,060		
Total stock-based compensation	$ 10,440,588	$	$

The accompanying notes are an integral part of these consolidated financial statements.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2001	**2000**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,023,531	$ 3,071,477
Accounts receivable, net of allowances of $2,595,000 and $1,742,000 at December 31, 2001 and 2000, respectively	21,661,185	8,606,144
Inventory	14,781,990	4,297,626
Deferred income taxes	1,466,786	1,539,489
Prepaid expenses and other current assets	4,938,373	356,141
Total current assets	94,871,865	17,870,877
Property, plant and equipment, net	20,526,228	3,122,681
Goodwill, trademarks and other intangible assets, net	160,765,613	34,845,522
Deferred financing costs and other assets, net	2,407,134	773,528
Net assets of discontinued operations (Note 13)		18,345,835
Total assets	$ 278,570,840	$ 74,958,443
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 20,819,383	$ 5,309,666
Accounts payable	10,264,023	5,418,894
Accrued expenses and other current liabilities	42,766,464	6,157,308
Due to Inverness Medical Technology, Inc. and affiliates (Note 5(a))		7,449,364
Total current liabilities	73,849,870	24,335,232
Long-term liabilities:		
Long-term debt	57,304,834	7,520,487
Deferred income taxes	2,044,019	1,120,674
Other liabilities	3,863,550	170,000
Total long-term liabilities	63,212,403	8,811,161
Commitments and contingencies (Note 8)		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized 2,666,667 shares		
Issued and outstanding 1,995,000 shares at December 31, 2001	51,894,435	
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 8,681,744 and 5,827,715 shares at December 31, 2001 and 2000, respectively		8,682		5,828
Additional paid-in capital		147,410,812		54,839,225
Notes receivable from stockholders		(14,691,097)		
Deferred compensation		(10,144,937)		
Accumulated deficit		(34,636,572)		(13,798,883)
Accumulated other comprehensive income		1,667,244		765,880
Total stockholders equity		89,614,132		41,812,050
Total liabilities and stockholders equity	$	278,570,840	$	74,958,443

The accompanying notes are an integral part of these consolidated financial statements.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock Number of Shares	Common Stock $0.001 Par Value	Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders Equity	Comprehensive (Loss) Income
BALANCE, DECEMBER 31, 1998	3,021,728	$3,022	$49,442,130	$	$	$(20,353,389)	$(159,846)	$28,931,917	$
Common stock issued by IMT effected by exchange ratio and related stock split (Note 2(k))	620,128	620	(620)						
Capital contribution from IMT related to income taxes for Inverness Medical, Inc.			2,796,851					2,796,851	
Capital contribution from IMT related to acquisition of minority interest in Orgenics, Ltd.			44,259					44,259	
Net cash contributed by IMT			1,864,202					1,864,202	
Changes in cumulative translation adjustment							776,084	776,084	776,084
Net (loss) income			(1,563,147)			2,102,850		539,703	539,703
Total comprehensive income									1,315,787
BALANCE, DECEMBER 31, 1999	3,641,856	3,642	52,583,675			(18,250,539)	616,238	34,953,016	
Common stock issued by IMT effected by exchange ratio and related stock split (Note 2(k))	2,185,859	2,186	(2,186)						
Capital contribution from IMT related to			2,558,517					2,558,517	

income taxes for Inverness Medical, Inc								
Net cash contributed by IMT			1,969,054				1,969,054	
Changes in cumulative translation adjustment						149,642	149,642	149,642
Net (loss) income			(2,269,835)		4,451,656		2,181,821	2,181,821
Total comprehensive income								2,331,463
BALANCE, DECEMBER 31, 2000	5,827,715	5,828	54,839,225		(13,798,883)	765,880	41,812,050	
Common stock issued by IMT effected by exchange ratio and related stock split (Note 2(k))	756,859	757	(757)					
Capital contribution from IMT related to income taxes for Inverness Medical, Inc.			986,694				986,694	
Capital contribution from IMT in connection with split-off (Note 1)			46,712,368				46,712,368	
Issuance of common stock from stock option and warrant exercises	279,598	279	567,571				567,850	
Issuance of stock for notes receivable	1,817,572	1,818	14,689,929	(14,691,097)			650	
Deferred compensation related to issuance of restricted stock (Notes 1 and 10(c))			20,585,525		(20,585,525)			
Amortization of deferred compensation expense (Notes 1 and (10(c))					10,440,588		10,440,588	
Beneficial conversion feature on issuance of series A redeemable convertible preferred stock			7,927,889				7,927,889	

(Note 10(b))									
Amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 10(b))						(24,429)		(24,429)	
Original issue discount and beneficial conversion feature on issuance of debt (Notes 6(a) and (b))			5,019,995					5,019,995	
Changes in cumulative translation adjustment							901,364	901,364	901,364
Net loss			(3,917,627)			(20,813,260)		(24,730,887)	(24,730,887)
Total comprehensive loss									$(23,829,523)
BALANCE, DECEMBER 31, 2001	8,681,744	$8,682	$147,410,812	$(14,691,097)	$(10,144,937)	$(34,636,572)	$1,667,244	$89,614,132	

The accompanying notes are an integral part of these consolidated financial statements.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2001	**2000**	**1999**
Cash Flows from Operating Activities:			
Net (loss) income	$ (24,730,887)	$ 2,181,821	$ 539,703
(Income) loss from discontinued operations	(57,895)	597,784	(183,089)
Net (loss) income, excluding discontinued operations	(24,788,782)	2,779,605	356,614
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Noncash interest expense related to amortization of original issue discount and beneficial conversion feature	430,721		
Noncash stock-based compensation expense	10,440,588		
Charge for in-process research and development	6,980,221		
Noncash extraordinary loss on early extinguishment of debt	296,105		
Depreciation and amortization	3,352,727	2,864,765	2,969,615
Deferred income taxes	418,815	(69,311)	19,570
Other noncash losses	546,058		19,680
Capital contribution from Inverness Medical Technology, Inc. related to income taxes for Inverness Medical, Inc.	986,694	2,558,517	2,796,851
Changes in assets and liabilities, net of acquisition:			
Accounts receivable, net	1,671,613	(966,724)	(203,239)
Inventory	(223,137)	(619,960)	809,859
Prepaid expenses and other current assets	(1,782,155)	627,429	55,817
Accounts payable	(736,138)	597,340	(32,053)
Accrued expenses and other current liabilities	15,145,392	1,684,817	(1,414,767)
Due to Inverness Medical Technology, Inc. and affiliates	2,649,018	(455,037)	1,669,914
Net cash provided by continuing operations	15,387,740	9,001,441	7,047,861
Net cash used in discontinued operations	(1,170,123)	(1,293,325)	(4,404,230)
Cash Flows from Investing Activities:			
Purchases of property, plant and equipment, net of proceeds from disposals	(3,452,866)	(780,791)	(1,476,117)
Cash paid for purchase of Unipath businesses, net of cash acquired	(146,154,237)		
Decrease in other assets	129,054	3,571	
Net cash used in investing activities	(149,478,049)	(777,220)	(1,476,117)
Cash Flows from Financing Activities:			
Cash paid for deferred financing costs	(2,196,309)	(103,750)	

Proceeds from issuance of common and preferred stock	60,366,399		
Proceeds from borrowings under notes payable	82,552,000	4,762,514	3,831,574
Repayments of notes payable	(4,307,097)	(11,006,501)	(7,775,410)
Contribution from Inverness Medical Technology, Inc.	47,659,616	1,969,054	1,864,203
Net cash provided by (used in) financing activities	184,074,609	(4,378,683)	(2,079,633)
Foreign exchange effect on cash and cash equivalents	137,877	(141,293)	461,986
Net increase (decrease) in cash and cash equivalents	48,952,054	2,410,920	(450,133)
Cash and cash equivalents, beginning of year	3,071,477	660,557	1,110,690
Cash and cash equivalents, end of year	$ 52,023,531	$ 3,071,477	$ 660,557

The accompanying notes are an integral part of these consolidated financial statements.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	Years Ended December 31,		
	2001	**2000**	**1999**
Supplemental Disclosure of Cash Flow Information:			
Interest paid	$ 895,408	$ 1,535,558	$ 1,816,909
Taxes paid	$ 45,458	$ 30,000	$ 71,926
Supplemental Disclosure of Noncash Activities:			
Net assets of discontinued operations (Note 13)	$ (19,400,109)	$	$
Long-term debt discharged (Note 6(e))	$ 8,084,126	$	$
Forgiveness of due to Inverness Medical Technology, Inc. and affiliates, net (Note 5(a))	$ 10,368,735	$	$
On December 20, 2001, the Company acquired the Unipath businesses (Note 4)			
Accounts receivable	$ 15,835,304	$	$
Inventory	9,187,651		
Other current assets	2,356,972		
Property and equipment	15,255,088		
Intangible assets	134,869,189		
Cash paid for purchase of Unipath businesses, net of cash acquired	(146,154,237)		
	31,349,967		
Unfunded pension liability	(3,685,000)		
Other accrued direct acquisition cost	(3,265,581)		
Assumed liabilities	$ 24,399,386	$	$

The accompanying notes are an integral part of these consolidated financial statements.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2001

(1) Description of Business and Basis of Presentation

Inverness Medical Innovations, Inc. and its subsidiaries (Innovations or the Company) 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, the Company develops, manufactures and markets clinical diagnostic products for use by medical professionals.

On November 21, 2001, pursuant to an Agreement and Plan of Split-Off and Merger dated May 23, 2001 (the Merger Agreement), Johnson & Johnson acquired Inverness Medical Technology, Inc. (IMT) in a merger transaction and, simultaneously, Innovations, a then subsidiary of IMT, was split-off from IMT as a separate publicly traded company. Pursuant to the terms of the Merger Agreement and related agreements, immediately prior to the consummation of the transaction, IMT restructured its operations so that all of IMT s non-diabetes businesses (women s health, nutritional supplements and clinical diagnostics) were held by Innovations and Innovations subsidiaries. At the closing of the transaction, all of the shares of Innovations common stock held by IMT were split-off from IMT in a pro rata distribution to IMT stockholders and IMT (which then consisted primarily of its diabetes care business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

Innovations was incorporated on May 11, 2001 for the purpose of receiving IMT s contribution of its women s health, nutritional supplements and clinical diagnostics businesses in connection with the transactions described in the Merger Agreement and related agreements. Innovations consolidated financial statements include IMT subsidiaries and businesses that were contributed to Innovations for all periods presented as if such subsidiaries and businesses were historically organized in a manner consistent with the restructuring set forth in the Merger Agreement and related agreements. The primary subsidiaries and businesses that were contributed to Innovations by IMT are as follows:

Inverness Medical, Inc. (IMI), a U.S. corporation, and its wholly-owned subsidiary, Can-Am Care Corporation (Can-Am), a U.S. corporation

Cambridge Diagnostics Ireland Ltd. (CDIL), an Irish corporation

Orgenics, Ltd. (Orgenics), an Israeli corporation

The women s health business of Inverness Medical Europe GmbH (IME), a German corporation

Inverness Medical Benelux Bvba (IMB), a Belgian corporation

The women s health assets held by IMT, plus allocations to Innovations of IMT common expenditures

Innovations has consolidated the financial statements of the above individual legal entities and the newly acquired entities and businesses, as discussed below, along with the assets, liabilities, revenues and expenses of the businesses. For all periods prior to the split-off and merger, the financial statements were combined in a manner consistent with the consolidated financial statements. All material intercompany transactions and balances have been eliminated. Amounts due to IMT and IMT affiliates that are not part of Innovations are reflected as amounts due to Inverness Medical Technology, Inc. and affiliates in the accompanying consolidated balance sheets (see below and Note 5). Innovations equity accounts for all periods presented reflect the par value of Innovations stock at the date of incorporation, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Note 2(k)); the historical equity accounts of the legal entities that comprise Innovations are consolidated as if such subsidiaries and businesses were historically organized in a manner consistent with the restructuring set forth in the Merger Agreement and related agreements.

Pursuant to the Merger Agreement and related agreements, on November 21, 2001, immediately prior to the split-off and merger, Innovations transferred to IMT those entities or businesses that conduct business in the diabetes segment, principally the Can-Am subsidiary of IMI and the diabetes businesses of CDIL and IMB. As a result, Innovations has presented the historical diabetes operations of its subsidiaries as discontinued operations in the accompanying consolidated financial statements under Accounting Principles Board (APB) Opinion No. 30, *Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*.

The discontinuation of the diabetes businesses is one of a number of transactions that occurred upon the closing of the transactions set forth in the Merger Agreement and related agreements that had a significant impact on Innovations financial statements. Prior to the split-off and merger, IMT capitalized Innovations with approximately $41.4 million in cash in connection with the restructuring of the businesses as described herein. IMT also assumed or discharged all of Innovations third-party and related-party debt, except for the third-party debt maintained by CDIL and Orgenics (Notes 5(a) and 6(e)). At the closing of the transactions set forth in the Merger Agreement and related agreements, IMT distributed to its stockholders one Innovations share for every five IMT shares held. In order for IMT to do so, Innovations declared a stock split, effected as a dividend. Accordingly, earnings per share information for all periods presented represents the actual number of shares of Innovations common stock outstanding as of the date of its incorporation, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Notes 2(k) and 9).

Innovations consolidated financial statements for all periods prior to the split-off and merger also reflect the allocation of IMT s common expenditures. Such allocations have been made in accordance with Staff Accounting Bulletin (SAB) No. 55, *Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity*.

The accompanying consolidated financial statements reflect substantially all costs of doing business, including those incurred by IMT on Innovations behalf. Costs that are clearly identifiable as being applicable to an Innovations subsidiary or business have been allocated to Innovations. The most significant costs included in this category include salary and benefits of certain employees and legal and other professional fees. Costs of centralized departments and corporate operations that serve all operations have been allocated, where such allocations would be material, using relevant allocation measures, such as estimated percentage of time worked for salary and benefits of certain executives and employees and square feet occupied for occupancy costs in shared facilities. Corporate costs that clearly relate to businesses or subsidiaries that were retained by IMT or that do not provide any significant direct or indirect benefit to Innovations have not been allocated to Innovations. For all periods prior to the split-off and merger, Innovations accounted for income taxes using the separate return method, pursuant to Statement of Financial Accounting Standard (SFAS) No. 109, *Accounting for Income Taxes*. IMT has historically charged interest on loans made to its subsidiaries. Accordingly, Innovations consolidated statements of operations reflect interest expense on amounts due to entities not included in Innovations consolidated financial statements (primarily to IMT) (Note 5(a)). Interest expense also reflects amounts recorded on third-party notes payable when such notes relate specifically to Innovations operations. Interest expense does not include amounts recorded on general corporate borrowings of IMT. Innovations believes that the allocation methods described herein are reasonable and fairly reflect its financial position and results of operations.

Immediately prior to the split-off and merger, each IMT option or warrant was split into a new IMT option or warrant and an Innovations option or warrant (the new IMT options and warrants were subsequently converted into Johnson & Johnson options or warrants in the merger). The option or warrant split was accomplished in such a manner that the aggregate intrinsic value of the two options or warrants equals the intrinsic value of the IMT option or warrant before the split. The option or warrant split also required that the ratio of intrinsic value to market value for each option or warrant be the same. Concurrent with the option split, (1) the vesting for all Innovations options was accelerated and (2) the period of exercisability for IMT employees who did not become Innovations employees was extended. Such actions are deemed to be award modifications pursuant to Financial Accounting Standards Board (FASB) Interpretation (FIN) No. 44, *Accounting for Certain Transactions Involving Stock Compensation*. Under FIN No. 44, Innovations measured compensation at the date of the award modifications based on the intrinsic value of the option and recognized (or will recognize in the future) such compensation if, absent the modifications, the award would have been forfeited pursuant to the award s original terms. For IMT employees who did not become employees of Innovations, the recognition of this charge, approximately $645,000, was immediate and recorded as compensation expense in the accompanying consolidated statements of operations during 2001. For IMT employees who became Innovations employees, the Company has measured this potential charge, approximately $1,173,000 at the date of the modification, but will not record the related compensation charge unless and until such time as these Innovations employees terminate their employment with the Company. At this time, the portion of the award that, absent the modification, would have forfeited under the award s original terms, would be recognized as compensation expense. The Company did not recognize any compensation expense related to these Innovations employees in 2001. The total number of shares of common stock underlying stock options and warrants Innovations issued in the split-off was 929,456 and 117,950, respectively.

In addition to the businesses contributed by IMT, as described above, on December 20, 2001, Innovations acquired certain entities and businesses (the Unipath businesses) of Unilever Plc (Unilever) that are in the business of manufacturing and distributing women s health and clinical diagnostics products (Note 4). The acquired Unipath businesses, that are included in the consolidated financial statements of Innovations since December 20, 2001, are as follows:

Unipath Ltd. (Unipath UK), a British corporation, and its wholly-owned subsidiary, Unipath Management Ltd. (UML), also a British corporation

The women s health business of Unipath conducted in the United States (Unipath US)

Unipath Diagnostics GmbH (Unipath Germany), a German corporation

Unipath Scandinavia AB (Unipath Scandinavia), a Swedish corporation

Unipath B.V. (Unipath Netherlands), a Dutch corporation

Unipath assets, primarily intellectual property, held by Unilever, along with the related license revenue

(2) Summary of Significant Accounting Policies

(a) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from

those estimates.

The Company considers the following to be critical accounting policies: (a) revenue recognition, (b) use of estimates for sales returns and other allowances and allowance for doubtful accounts, (c) valuation of goodwill and other long-lived and intangible assets, (d) accounting for income taxes, and (e) legal contingencies.

(b) Foreign Currencies

The Company follows the provisions of SFAS No. 52, *Foreign Currency Translation*. All assets and liabilities of the Company s foreign subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date while income and expense accounts are translated using the average rates of exchange during each reporting period. Foreign currency exchange transaction losses of approximately $727,000, $389,000 and $531,000 during 2001, 2000 and 1999, respectively, are included as a component of other expense, net, in the accompanying consolidated statements of operations.

(c) Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents consisted of money market funds at December 31, 2001 and 2000.

(d) Inventories

Inventories are stated at the lower of cost (first in, first out) or market.

(e) Depreciation and Amortization

The Company records property, plant and equipment at historical cost. Depreciation and amortization are computed using the straight-line method based on the following estimated useful lives of the related assets: machinery, laboratory equipment and tooling (3-16 years), buildings (20 years), leasehold improvements (lesser of term of lease or useful life of asset), furniture and fixtures (3-10 years) and computer equipment (1-6 years).

(f) Goodwill, Trademarks and Other Intangible Assets

The Company amortizes its goodwill and trademarks related to the acquisition of certain nutritional supplement lines using the straight-line method over their estimated useful lives of 25 years. The intangible asset pertaining to the Company s acquired core immuno-assay technology (used in the women s health business) is being amortized over 15 years. The acquired intangible assets with finite lives, core technology, patents

and license agreements, related to the purchase of the Unipath businesses are being amortized over 7 to 13 years. Effective January 1, 2002, under SFAS No. 142, *Goodwill and Other Intangible Assets,* all existing acquired goodwill and other intangible assets with indefinite lives will no longer be amortized to expense, with early adoption required for all goodwill and other intangible assets with indefinite lives acquired subsequent to June 30, 2001 (Note 2(o)). The Company recorded amortization expense of approximately $1,981,000, $1,882,000 and $2,018,000 during 2001, 2000 and 1999, respectively, related to goodwill and other intangible assets. This amortization expense is allocated to cost of sales, research and development and general and administrative expenses in the accompanying consolidated statements of operations.

(g) Impairment of Long-Lived and Intangible Assets

The Company periodically examines the carrying value of its long-lived and intangible assets to determine whether there are any impairment losses. If indicators of impairment were present in long-lived and intangible assets used in operations and discounted future cash flows were not expected to be sufficient to recover the assets carrying amount, an impairment loss would be charged to expense in the period the impairment is identified based on the fair value of the asset. The Company believes that the remaining carrying value of these assets were realizable as of December 31, 2001 and 2000.

(h) Income Taxes

The Company provides for income taxes in accordance with the provisions of SFAS No. 109. The Company s income tax provisions mainly represent those recorded by its U.S. subsidiary, IMI. Most of the Company s foreign subsidiaries have been in net loss positions and, accordingly, have paid virtually no income taxes in their jurisdictions. For federal and some state income tax filing purposes, the results of IMI s operations were consolidated with IMT prior to the split-off and merger. For the periods prior to the split-off and merger, IMI had stand-alone tax filing responsibilities in some states and the tax accounts of the Company were computed using the separate return method. Accordingly, a deferred tax asset or liability is determined based on the difference between the financial reporting and tax bases of assets and liabilities, as measured by the enacted tax rates expected to be in effect when these differences reverse as if each of the Company s subsidiaries filed its own separate tax return. The Company s primary temporary differences which give rise to the deferred tax asset and liability are nondeductible reserves and accruals and different lives assigned to long-lived and intangible assets (Note 11).

(i) Revenue Recognition

The Company s revenues are derived from product sales. The Company follows SAB No. 101, *Revenue Recognition,* which sets forth provisions for revenue recognition on multiple-element arrangements and acceptance and delivery criteria, among other items, and recognizes revenue upon product shipment to customers, at which time title is transferred, less a reserve for estimated product returns and allowances. The adoption of SAB No. 101 did not have a material impact on the Company s consolidated financial statements.

(j) Employee Stock-Based Compensation Arrangements

The Company adopted an employee stock option plan in 2001 (Note 10(c)). The Company accounts for its employee stock-based compensation arrangements under the provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and FIN No. 44. The Company has elected to use the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and in accordance with FIN No. 44, has included in these disclosures all IMT options held by those individuals who became Innovations employees at the split-off and merger, retroactively converted into Innovations options as if such options had historically been granted by Innovations (Note 10(c)).

(k) Net (Loss) Income per Common Share

Net (loss) income per common share, computed in accordance with SFAS No. 128, *Earnings per Share*, is based upon the actual number of common shares issued and outstanding upon incorporation of Innovations, for all periods presented, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Notes 1 and 9).

The following table reconciles the number of IMT weighted average common shares outstanding, giving effect to the exchange ratio, to Innovations weighted average common shares used for the computation of net (loss) income per common share (Note 9).

	Years Ended December 31,		
	2001 (i)	**2000**	**1999**
Number of IMT weighted average shares	31,814,000	23,632,000	16,820,000
Exchange ratio to effect the exchange of IMT shares for Innovations shares 5:1	0.2	0.2	0.2
Number of Innovations weighted average shares used for the computation of net income per common share in 2000 and 1999	6,363,000	4,726,000	3,364,000
Weighted average shares issued after the split-off	5,000		
Number of Innovations weighted average shares used for the computation of net loss per common share in 2001	6,368,000		

(i) IMT weighted average shares are through date of split-off and merger.

(l) Pension and Postretirement Benefits

As part of the acquisition of the Unipath businesses (Notes 1 and 4), Innovations assumed responsibility of the pension obligations for the United Kingdom-based Unipath employees and has accounted for the projected benefit obligation in excess of plan assets transferred from Unilever on the date of the acquisition as part of the purchase price of the Unipath businesses under SFAS No. 141, *Business Combinations*, and SFAS No. 87, *Employer s Accounting for Pensions* (Note 7(a)). In addition, Orgenics provides certain severance benefits (Note 7(b)).

(m) Concentration of Credit Risk

Financial instruments that potentially subject Innovations to concentration of credit risk primarily consist of cash and cash equivalents and accounts receivable. Innovations invests its excess cash primarily in high quality securities and limits the amount of credit exposure to any one financial institution. Innovations does not require collateral or other securities to support customer receivables; however, it performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses. There were no accounts receivable balances outstanding at December 31, 2001 and 2000 that were in excess of 10% of the total gross accounts receivable balances on those dates. Innovations had one significant customer representing 14%, 12% and 12% of net revenues during 2001, 2000 and 1999, respectively.

Innovations has no significant off-balance-sheet or other concentration of credit risks such as foreign exchange contracts, option contracts or other foreign hedging arrangements at December 31, 2001 and 2000. See Note 12 for financial information by geographic area and business segment.

(n) Financial Instruments and Fair Value of Financial Instruments

Innovations financial instruments at December 31, 2001 and 2000 consist of cash equivalents, accounts receivable and debt. The estimated fair value of these financial instruments approximates their carrying value at those dates. The estimated fair values have been determined through information obtained from market sources. Innovations does not have any material derivative or other financial instruments outstanding at December 31, 2001 and 2000. In February 2002, the Company entered into an interest rate swap agreement, which protects it and the bank from interest rate fluctuations related to a portion of its long-term debt to the bank (Note 6(a)). The Company also uses foreign exchange forward contracts starting in 2002. The Company will account for these derivatives in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* and related amendments.

(o) Recent Accounting Pronouncements

In June 2001, the FASB issued SFAS No. 141, which addresses changes in the financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, *Business Combinations*, and SFAS No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises*. Effective July 1, 2001, all business combinations should be accounted for using only the purchase method of accounting. The adoption of this statement did not have a material effect on the Company s financial position, results of operations or cash flows.

In June 2001, the 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 will no longer be 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. The Company recorded goodwill amortization of approximately $603,000, $603,000 and $762,000 during 2001, 2000 and 1999. The Company has estimated the impact of not amortizing goodwill on its consolidated financial statements. The total amount of goodwill and intangible assets, net of accumulated amortization, expected to be affected by this statement was approximately $85,375,000 at December 31, 2001, of which approximately $73,227,000 was acquired between June 30, 2001 and December 31, 2001. The Company is currently assessing whether its existing goodwill has been impaired in accordance with SFAS No. 142.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long*-Lived Assets. SFAS No. 144 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. 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 application encouraged. The provisions of this statement generally are to be applied prospectively. The Company adopted SFAS No. 144 in 2002 and has not yet determined the impact of this statement on its financial position, results of operations or cash flows.

(p) Reclassifications

Certain prior-year account balances have been reclassified to be consistent with the current year s presentation.

(3) Other Balance Sheet Information

Components of other selected captions in the consolidated balance sheets consist of:

	December 31,	
	2001	**2000**
Inventories:		
Raw materials	$ 6,895,192	$ 1,401,589
Work-in-process	1,378,503	204,579
Finished goods	6,508,295	2,691,458
	$ 14,781,990	$ 4,297,626
Property, plant and equipment:		
Machinery, laboratory equipment and tooling	$ 14,640,938	$ 3,653,894
Leasehold improvements	4,899,956	674,490
Buildings	676,843	628,812
Furniture and fixtures	1,448,687	648,091
Computer equipment	3,324,296	1,391,592
	24,990,720	6,996,879
Less: Accumulated depreciation and amortization	4,464,492	3,874,198
	$ 20,526,228	$ 3,122,681
Goodwill, trademarks and other intangible assets:		
Goodwill	$ 88,307,476	$ 15,080,464
Trademarks	46,758,014	21,059,405
Other intangible assets	34,438,505	5,463,465
	169,503,995	41,603,334
Less: Accumulated amortization	8,738,382	6,757,812
	$ 160,765,613	$ 34,845,522
Accrued expenses and other current liabilities:		
Compensation and compensation-related	$ 16,460,802	$ 1,482,031
Advertising and marketing	10,324,041	2,548,019
Other	15,981,621	2,127,258
	$ 42,766,464	$ 6,157,308

(4) Acquisition of Unipath Businesses

On December 20, 2001, the Company acquired the Unipath entities and businesses from Unilever (Note 1). The aggregate purchase price of approximately $158,135,000 consisted of $149,807,000 in cash, $4,974,000 in costs to exit certain activities of the acquired businesses, primarily severance costs in accordance with Emerging Issues Task Force ("EITF") Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*, and the assumption of the portion of Unilever s unfunded pension liability for the benefit of the Unipath UK employees, and $3,354,000 in direct acquisition costs. The acquisition was funded by the issuance of 1,995,000 shares of series A convertible redeemable preferred stock (Series A Preferred Stock) with aggregate proceeds of $59,850,000 (Note 10(b)), $62,500,000 in loans under a series of credit agreements with a bank and entities related to this bank (Note 6(a)), the issuance of subordinated promissory notes and warrants for aggregate proceeds of $20,000,000 (Note 6(b)) and the Company s existing cash.

The aggregate purchase price of the Unipath entities and businesses was allocated to the acquired assets and assumed liabilities as follows:

Cash and cash equivalents	$	5,030,000
Accounts receivable		15,835,000
Inventory		9,188,000
Other current assets		2,357,000
Property and equipment		15,255,000
Goodwill and trademarks		98,914,000
In-process research and development		6,980,000
Other intangible assets		28,975,000
Liabilities assumed		(24,399,000)
	$	158,135,000

The acquisition of the Unipath businesses was accounted for as a purchase under SFAS No. 141. Accordingly, the results of the Unipath businesses have been included in the accompanying consolidated financial statements since the date of acquisition. The Company is amortizing the portion of the purchase price allocated to other intangible assets with finite lives (approximately $28,975,000), which are comprised of core technology, patents and license agreements, on a straight-line basis over lives ranging from 7 to 13 years. The weighted average amortization period for these assets is 11.2 years. The allocation of the purchase price to the assets acquired is based upon the results of an independent appraisal of the fair value of the assets. The Company has not yet assigned the amount allocated to goodwill to specific reporting units as of December 31, 2001. The Company intends to complete this analysis in 2002.

At the time of the acquisition, the research and development staff of the Unipath businesses was seeking to develop a new technology. However, the technology being sought under this specific in-process research and development project (IPRD Project) had not yet reached technological feasibility and had no alternative future use at the date of acquisition, and therefore, the portion of the purchase price allocated to this IPRD Project was charged to expense upon the acquisition. Management believes that many of the complex technical issues have been resolved. However, the technology does not have Food and Drug Administration approval. Therefore, the risk of not achieving commercialization is not only one of development, but also a regulatory challenge. The work of a full project, which includes demonstrating feasibility, defining the project, design, development, verification and clinical testing, and regulatory submission and approval will all need to be completed prior to launch. As these hurdles are crossed, new complexities are likely to arise. The Company anticipates that this IPRD Project will take one to one and a half years to complete. The Company estimates that it will cost approximately $2.7 million in additional research and development costs to complete this IPRD Project. Based upon time and costs incurred, this IPRD Project is estimated to be approximately 92% complete. The amount of the purchase price allocated to this IPRD Project represents its estimated fair value determined using the income approach, whereby projected future cash flows are discounted to value the technology. An estimated royalty rate of 4% was applied to projected revenues to calculate pretax royalty savings attributed to completed technology. A 30% tax rate was used and then a risk-adjusted discount rate of 24% was applied.

The following table presents selected unaudited financial information of the Company and the Unipath businesses as if the acquisition had occurred on January 1, 2001 and 2000, respectively. The unaudited pro forma results are not necessarily indicative of the results that would have occurred had the acquisition been consummated on January 1, 2001 and 2000, respectively, or future results.

	2001	2000
	(unaudited)	
Pro forma net product sales	$ 151,214,000	$ 149,356,000
Pro forma loss from continuing operations	(24,635,000)	(9,772,000)
Pro forma net loss	(24,904,000)	(10,369,000)
Pro forma loss per common share:		
Pro forma loss from continuing operations	$ (3.87)	$ (2.07)
Pro forma net loss	(3.91)	(2.19)

(5) Related Party Transactions

(a) Due to Inverness Medical Technology, Inc. and Affiliates

Due to Inverness Medical Technology, Inc. and Affiliates as of December 31, 2000 consisted of the following:

Payable to IMT and affiliates	$ 3,241,090
Note payable to IMT by IMI	2,000,000
Note payable to IMT by CDIL	2,208,274
	$ 7,449,364

As discussed in Note 1, upon the split-off and merger, IMT and its affiliates forgave all outstanding balances due from Innovations. The forgiveness of this indebtedness, approximately $10,369,000, was recorded as a component of the capital contribution from IMT.

The amount in Payable to IMT and affiliates mostly represent funding, net of repayments, from IMT and its affiliates to Innovations and Innovations subsidiaries prior to the split-off and merger. Also included in Payable to IMT and affiliates are operating expenses allocated to IMI by IMT. These allocations include, among other things, support services such as financial, computer, legal, sales, marketing, customer support and accounting, as well as rent and administrative costs (Note 1). IMI recorded expenses of approximately $3,033,000, $2,733,000 and $3,257,000 relating to these allocations during 2001, 2000 and 1999, respectively, which it believes approximates arm s-length costs.

The expenses allocated by IMT to IMI, which are included in the respective captions in the accompanying consolidated statements of operations, are made up of the following:

	Years Ended December 31,		
	2001 (i)	2000	1999
Cost of sales	$ 208,000	$ 246,000	$ 200,000
Research and development	23,000	37,000	116,000
Sales and marketing	1,365,000	1,495,000	1,769,000
General and administrative	1,437,000	955,000	1,172,000
	$ 3,033,000	$ 2,733,000	$ 3,257,000

(i) Through the date of split-off and merger

In February 1997, in connection with IMI s purchase of the nutritional supplement product line from American Home Products (now known as Wyeth), IMI borrowed $2,000,000 from IMT. Interest was accruing at an annual rate of 6.5%. Interest expense on this note was approximately $115,000, $130,000 and $130,000 during 2001, 2000 and 1999, respectively.

At December 31, 2000, CDIL had a note payable balance plus accrued interest totaling approximately $2,208,000 due to IMT under a loan agreement originally dated July 1, 1997, as amended. Interest was accruing at an annual rate of 9%. Interest expense on this note was approximately $183,000, $165,000 and $119,000 during 2001, 2000 and 1999, respectively.

(b) Transition Services Agreement with IMT

Prior to the split-off and merger, Innovations entered into a transition services agreement, whereby Innovations would provide certain transition services to IMT and IMT affiliates for an agreed-upon period of time and service fee. Transition services include, but are not limited to, operational services provided by IMI and CDIL related to certain diabetes products. Since the split-off and merger through December 31, 2001, the Company has charged approximately $181,000 in transition service fees to IMT, which it believes to approximate arm s-length costs.

(6) Long-term Debt

The Company had the following long-term debt balances outstanding:

	December 31,	
	2001	2000

Term loans	$	61,145,997	$	
Subordinated promissory notes		16,511,390		
Bank debt Orgenics		230,000		868,000
Mortgage loan CDIL		236,830		365,201
IMI bank loan				11,596,952
		78,124,217		12,830,153
Less: Current portion		20,819,383		5,309,666
	$	57,304,834	$	7,520,487

The following describes each of the above listed debt instruments:

(a) Term Loans and Revolving Line of Credit

On December 20, 2001, a wholly-owned subsidiary of Innovations entered into a series of credit agreements (the Credit Agreements) with a bank and entities related to this bank for credit facilities in the aggregate amount of $70,000,000, which were amended in the first quarter of 2002. The Credit Agreements consist of term loans aggregating $62,500,000, of which $10,000,000 are denominated in Japanese Yen (JPY), and a $7,500,000 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 businesses (Note 4). The revolving line of credit is designated for use by the Company to cover certain of its liabilities and future foreign exchange contracts. Innovations, the parent company, and certain of its subsidiaries are the guarantors of all obligations due under the Credit Agreements. Borrowings under the Credit Agreements are secured by the stock of the Company s European subsidiaries, the Company s intellectual property rights, and the assets of the Company s U.S. businesses.

The terms of each facility aggregating the $70,000,000 Credit Agreements are summarized as follows:

	Senior Term A1	**Senior Term A2**	**Senior Term B**	**Junior Term Loan**	**Revolving Line of Credit**
Loan amount (in millions)	$26.5	JPY 1,283 ($10.0)	$16.0	$10.0	$7.5 (i)
Principal repayment dates	On June 30th and December 31st from 2002 through 2008	On June 30th and December 31st from 2002 through 2008	On June 30 and December 31, 2009	On June 30 and December 31, 2010	On the interest due date relating to each advance
Periodic principal repayment amounts (in millions) **(ii)**	Varies from $1.5 to $2.5	Varies from $0.5 to $1.0	$8.0	$5.0	In full
Per annum interest rate **(iii)**	LIBOR plus 2.25%	LIBOR plus 2.25%	LIBOR plus 2.75%	LIBOR plus 3.50%	LIBOR plus 2.25%
Interest rate on December 31, 2001	4.17%	2.35%	4.67%	5.42%	4.17%
Interest period	1, 3 or 6 months duration	1, 3 or 6 months duration	1, 3 or 6 months duration	6 months duration	1, 3 or 6 months duration
Interest payment date	In arrears on the last day of each interest period	In arrears on the last day of each interest period	In arrears on the last day of each interest period	In arrears on the last day of each interest period	In arrears on the last day of each interest period
Per annum rate for capitalized interest	Not applicable	Not applicable	Not applicable	4.00% (iv)	Not applicable
Per annum interest rate on default payments **(iii)**	LIBOR plus 4.25%	LIBOR plus 4.25%	LIBOR plus 4.75%	LIBOR plus 5.50%	LIBOR plus 4.25%

(i) At December 31, 2001, there were no outstanding borrowings on the Revolving Line of Credit.

(ii) The Company must make mandatory prepayments on the loans under the Credit Agreements if it meets certain cash flow thresholds, collects insurance proceeds in excess of certain thresholds, receives payments and sells assets not in the ordinary course of business, or upon a sale or change of control of the Company.

(iii) With the commencement of the quarter beginning January 1, 2003, the per annum interest rate of Term A1, Term A2 and the Revolving Line of Credit will be the London Interbank Offered Rate (LIBOR) plus a spread from 1.50% to 2.00% (and an additional 2.00% in case of default). The spread depends on the ratio of total debt of the Company to earnings before interest expense, taxes, depreciation and amortization (EBITDA). In February 2002, the Company entered into an interest rate swap agreement with the bank, which applies to two-thirds of the combined Senior and Junior Loans that are denominated in U.S. Dollars and protects both the Company and the bank against fluctuation 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%.

(iv) Capitalized interest may be paid upon agreement with the lender of senior debt. The amount of capitalized interest during 2001 was approximately $9,000.

The Credit Agreements, as amended, require compliance with various financial and nonfinancial covenants for the Company starting in the second quarter of 2002. The primary financial covenants pertain to, among other things, interest coverage, cash flow coverage, leverage and EBITDA.

As part of the Credit Agreements, the Company issued the bank a warrant to acquire 65,000 shares of the Company s common stock at nominal cost. The Company allocated $1,105,000 of the loan proceeds to this warrant as original issuance discount, which represented the fair value of the warrant at the date of issuance, and is amortizing this discount over the life of the Credit Agreements. The total amount amortized to interest expense in 2001 was approximately $4,000.

(b) Subordinated Promissory Notes

The Company entered into a note and warrant purchase agreement pursuant to which, on December 20, 2001, it issued subordinated promissory notes (Subordinated Notes) having an aggregate principal amount of $20,000,000 for the purpose of funding its acquisition of the Unipath businesses (Note 4). Interest accrued at 12% per annum on the outstanding principal amount and was payable on the first day of each calendar quarter starting April 1, 2002 and on the maturity date, if extended as described herein. The Company had an option to make interest payments in the form of cash or its common stock at a value of 95% of the ten-day average closing price of its common stock prior to the interest payment due date. The Subordinated Notes were set to mature on April 1, 2002; however, the Company had an option to extend the maturity date to any date prior to the original maturity date of the term loans under the Credit Agreements described in Note 6(a), subsequent to which interest would accrue at 18% per annum. In accordance with SFAS No. 133 and related amendments, this extension option represents a premium paid by the Company at the date of issuance of the Subordinated Notes in the form of additional interest, which should be bifurcated from the Subordinated Notes and recognized as interest expense over the initial term of the notes. The value of this derivative asset was not material to the Company s consolidated financial statements. The Company did not exercise its option to extend the maturity of the Subordinated Notes, as it raised additional funding through the issuance of Series A Preferred Stock in March 2002 (Note 10(b)).

As part of the note and warrant purchase agreement, in addition to the Subordinated Notes, the Company also issued 10-year warrants to purchase a total of 55,189 shares of the Company s common stock at an exercise price of $18.12 per share. The Company allocated $672,000 of the aggregate proceeds from the Subordinated Notes to the warrants as original issuance discount, which represented the relative fair value of the warrants at the date of issuance, and was amortizing the discount to interest expense over the life of the Subordinated Notes. The total amount amortized to interest expense in 2001 was approximately $73,000.

The holders of the Subordinated Notes had the option to convert all or part of their notes into shares of the Company s Series A Preferred Stock on April 1, 2002 if the Company s aggregate proceeds from the issuance of its Series A Preferred Stock through March 15, 2002 was less than $80,000,000. Due to the convertible nature of the Subordinated Notes, the Company recorded a discount on the notes in the form of a beneficial conversion feature of $3,243,000 in accordance with EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF Issue No. 00-27, *Application of EITF Issue No. 98-5 to Certain Convertible Instruments*. The value of the beneficial conversion feature was measured using the intrinsic value and was being amortized to interest expense over the life of the Subordinated Notes. The amount amortized to interest expense in 2001 was approximately $353,000. On March 6, 2002, the Company prepaid the Subordinated Notes plus accrued interest in full using the proceeds from the issuance of Series A Preferred Stock on that date (Note 10(b)). Consequently, on that date, the remaining amounts of unamortized original issue discount and beneficial conversion feature totaling approximately $969,000 were charged as an extraordinary item due to the early extinguishment of debt. The warrants issued in connection with the Subordinated Notes remain outstanding.

An entity controlled by the Company s chief executive officer (CEO) was a holder of a $10,000,000 Subordinated Note, which was paid in full in March 2002, and holds a warrant to purchase 27,594 shares of the Company s common stock at $18.12 per share.

(c) Bank Debt Orgenics

Orgenics has approximately $230,000 of notes payable to certain financial institutions outstanding as of December 31, 2001. The outstanding balance is collateralized by certain of Orgenics assets. The notes bear interest at rates ranging from 3.43% to 4.25% and are payable on various dates through 2003.

(d) Mortgage Loan CDIL

In 1999, CDIL financed the purchase of one of its manufacturing buildings through a mortgage loan (the Mortgage) with the seller. The outstanding balance on the Mortgage is collateralized by the building. The Mortgage bears interest at 6% and is payable semiannually through 2003.

(e) IMI Bank Loan

In 1998, IMI entered into a credit agreement with a bank for purposes of financing its acquisition of Can-Am and refinancing the then existing bank debt which resulted from the earlier acquisition of certain nutritional supplement lines. As part of the Merger Agreement and related

agreements, in November 2001, the outstanding balance under this credit agreement was discharged as discussed in Note 1. The Company recorded the remaining amount of unamortized deferred financing costs related to this loan as an extraordinary loss for the early extinguishment of debt in 2001.

(f) Maturities of Long-Term Debt

The following is a summary of the maturities of all long-term debt outstanding on December 31, 2001:

2002	$	24,307,993
2003		4,158,837
2004		4,500,000
2005		5,000,000
2006		5,500,000
Thereafter		39,246,661
		82,713,491
Less: Unamortized original issuance discount and beneficial conversion feature		(4,589,274)
	$	78,124,217

(7) Pension and Other Postretirement Benefit Plans

(a) Multi-Employer Defined Benefit Pension Plan

Unilever offers a non-contributory defined benefit pension plan to its United Kingdom-based employees, including those of Unipath UK. As part of the acquisition of the Unipath businesses and in accordance with SFAS No. 87 and SFAS No. 88, *Employer s Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits*, the Company assumed the liability of such pension benefits related to the employees of Unipath UK. Accordingly, the Company recorded an unfunded pension liability of approximately $3,685,000 in purchase accounting, which represents the excess of the projected benefit obligation (approximately $20,485,000) over the fair value of the plan assets (approximately $16,800,000) that were allocated by Unilever to the pension benefits for the employees of Unipath UK at the date of the acquisition. Also, pursuant to the purchase and sale agreement between the Company and Unilever, the Company agreed to maintain this benefit for a period of three years and the agreement provides that employees of Unipath UK can remain in the Unilever plan for up to one year after the date of acquisition, at which time the Company must establish its own plan. As the Company s assumption of these pension benefits was on December 20, 2001, the acquisition date of the Unipath businesses, the Company has recorded virtually no pension costs in 2001.

The assets of the pension plan consist of investments in fixed-income and equity securities. The Company made no contributions to the pension plan in 2001.

(b) Orgenics Severance Obligations

Israeli law provides that employers have certain severance obligations to employees in Israel. Orgenics liability for severance pay pursuant to such law is provided by insurance policies and severance pay funds. Severance expenses were approximately $12,000, $68,000 and $156,000

during 2001, 2000 and 1999, respectively. The balance of unfunded severance liability was approximately $141,000 and $170,000 at December 31, 2001 and 2000, respectively, which the Company has accrued for on those dates.

France has a government-run mandatory pension plan to which contributions are made monthly by both the employee and employer based on the employee s gross monthly salary. Orgenics liability for its employees in France is fully covered by these contributions. In addition, pursuant to industry employment agreements, a lump sum severance is payable upon retirement to employees still in the service of Orgenics French subsidiary at the date of retirement. There were no such obligations outstanding as of December 31, 2001 and 2000.

(8) Commitments and Contingencies

(a) Operating Leases

The Company has operating lease commitments for certain of its facilities and equipment that expire through 2021, except as noted below. The following schedule outlines future minimum annual rental payments under these leases at December 31, 2001:

2002	$	3,530,000
2003		3,444,000
2004		2,728,000
2005		2,330,000
2006		2,161,000
Thereafter		36,623,000
	$	50,816,000

Rent expense relating to these operating leases was approximately $1,029,000, $486,000 and $569,000 during 2001, 2000 and 1999, respectively.

The Unipath UK businesses are currently occupying a 150,000 square foot manufacturing, research and development and office facility in Bedford, United Kingdom. The lease of this facility is between Unilever and a third party landlord and Unipath UK is using the facility pursuant to an agreement with Unilever in connection with the acquisition. Future minimum annual rent payments under this facility lease range from 1,300,000 British Pounds Sterling to 1,750,000 British Pounds Sterling (approximately $1,850,000 to $2,500,000) with upward adjustments every 5 years. The lease expires in December 2021. Unilever has agreed to use its best efforts to obtain the landlord s consent, as required under the lease agreement, so it may assign the lease to the Company for its remaining term. If Unilever is unable to successfully assign the lease to the Company, the Company may be forced to renegotiate a lease of this facility on substantially less favorable terms, seek alternative, more costly means of producing its products or suffer other adverse effects to its business. Because the Company is required to pay all amounts owed under the lease, as agreed upon at the acquisition, it has included in the table above all future minimum lease payments under this facility lease.

(b) Capital Expenditure Commitments

At December 31, 2001, Unipath UK had total outstanding non-cancelable equipment purchase commitments of approximately 570,000 British Pounds Sterling (approximately $830,000).

(c) Legal Proceedings

Because of the nature of its business, the Company may from time to time be subject to consumer product claims or various other lawsuits arising in the ordinary course of its business and expects that 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, the Company aggressively defends its 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 the Company.

As part of the Merger Agreement and related agreements, IMT retained liability arising from litigation pertaining to diabetes-related matters and Innovations assumed liabilities relating to the women s health and clinical diagnostics-related matters. In each of the following legal proceedings, the Company is currently not able to estimate the range of potential losses due to the early stages and complexity of these proceedings.

In April 2001, 69 consumers brought an action in London claiming defects in Unipath s Persona contraceptive device, negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants at or prior to 1998. The case is expected to be ready for trial to a judge in the latter half of 2003. The Company believes that there are substantial defenses to the claims and intends to vigorously defend this litigation. Formal documentary and other discovery permitted under the law in the United Kingdom has not yet commenced, but is anticipated to be conducted during the second half of 2002 and into 2003. The case is insured by Unilever s product liability insurance up to 50 million British Pounds Sterling (approximately $72,700,000) or more, depending on when events giving rise to the consumers suit occurred. As a result, the Company does not believe that an adverse ruling would have a material adverse impact on its sales, operations or financial performance.

On January 3, 2000, Becton, Dickinson and Company (Becton Dickinson) (Note 8(e)) filed suit against IMT alleging that certain pregnancy and ovulation test kits sold by IMT infringe two U.S. patents. Becton Dickinson has since lost its rights to one of the two U.S. patents and is no longer asserting claims for infringement of that patent. A pretrial conference is scheduled for June 18, 2002, but no trial date has been established. While a final ruling against Innovations, as successor to IMT, could have a material adverse impact on its sales, operations or financial performance, the Company believes that it has strong defenses and intends to defend this litigation vigorously.

In May 1999, Intervention, Inc., a California corporation, filed separate suits against IMT, Unipath US and certain of their competitors alleging that the defendants labeling on their home pregnancy tests is misleading as to the level of accuracy under certain conditions. The plaintiff seeks restitution of profits on behalf of the general public, injunctive relief and attorneys fees. Innovations, as a successor to IMT, is defending its private label customers under its agreements with these customers. A trial on this matter against Innovations, the parent company, and its private label customers, is scheduled for April 2002, while a trial against Unipath US has not yet been scheduled. The Company believes that the actions are without merit and intends to continue its vigorous defense. The Company does not believe that an adverse ruling would have a material adverse impact on its sales, operations or financial performance.

On January 22, 1999, in connection with CDIL s sale of its infectious disease business, Cambridge Biotech Corporation (CBC) and Cambridge Affiliate Corporation (CAC) filed suit against IMT, IMT s CEO, CDIL, Trinity and Pasteur Sanofi Diagnostic (Pasteur) alleging, among other things, that the sale of the business was not properly authorized and, as a result, CBC may lose the benefit of certain patent licenses from Pasteur. CBC requested that the sale agreement be declared null and void, the license between Pasteur and CBC be declared to be in full force and that it be awarded damages caused by the actions of IMT, its CEO and Pasteur. Innovations, as a successor to IMT, agreed to assume the liabilities under this litigation at the split-off and merger. In November 2001, the parties to the litigation agreed to settle all claims brought by CBC and CAC, including releases between the plaintiffs and the defendants. Under the terms of the settlement, Innovations and CDIL have paid a total of $2,000,000 to CBC and Trinity. Of this $2,000,000, the Company charged approximately $1,700,000 to other expenses in the accompanying consolidated statements of operations in 2001. The Company had accrued for the remaining $300,000 in prior years. The settlement also includes an agreement for Innovations and CDIL to partially indemnify CBC up to a maximum of $1,125,000. CBC has agreed to partially indemnify Innovations and its CEO (formerly also IMT s CEO), CDIL and Trinity. Trinity, through a subsidiary, will transfer certain technology to CDIL and has agreed to produce certain antigens for CDIL.

In April 1998, Abbott Laboratories (Abbott) commenced a patent infringement lawsuit against IMT and Princeton BioMeditech Corporation (PBM) (Note 8(d)). Abbott claims that certain of IMT s pregnancy detection and ovulation prediction products infringe patents that Abbott claims to have rights to in the United States. Abbott is seeking an order finding that IMT and PBM infringe on the patents and enjoining such infringement, reimbursement of certain damages and a recall of all of IMT s existing products found to infringe such patents. IMT and PBM moved for summary judgment on their defense that the Abbott patents are invalid, and the court granted partial summary judgment, holding that certain key claims on Abbott s patents are invalid as a matter of law. The court refused to grant summary judgment on Abbott s claims of infringement or IMT s remaining claims of invalidity. No trial date has been set at this time. As a successor to IMT, Innovations believes that Abbott s claims will be proven to be without merit and will continue to defend the case vigorously. However, a final ruling of this suit against the Company could have a material adverse impact on its sales, operations or financial performance.

(d) Agreement with PBM

On August 6, 1997, IMT and PBM, along with wholly-owned subsidiaries of each, formed a limited liability company, PBM Selfcare LLC (the LLC), in which each party owns a 50% interest, and entered into a joint venture and a series of related technology transfer and licensing agreements to develop a comprehensive strategy to commercially exploit products and related intellectual property in the area of pregnancy detection and ovulation prediction (collectively, the Joint Venture Agreement). Under the Joint Venture Agreement, PBM contributed intellectual property and Innovations, as a successor of IMT, agreed to fund up to $2,000,000, of which approximately $539,000 remained outstanding at December 31, 2001, on an as-needed basis to cover expenses incurred by the LLC in enforcing the rights of the LLC in the intellectual property.

(e) License Agreements with Becton Dickinson

IMT entered into two women s health-related patent license agreements with Becton Dickinson, effective from April 1, 1998 until the date on which the last of the patents expire. The agreements grant Innovations, as a successor of IMT, the right to manufacture and sell products using certain patented technology as set forth in the agreement. Innovations was to pay royalties on the net sales of products using the licensed technology at a rate of 6% until December 31, 1998, 6.25% on the first $108,000,000 of net sales beginning January 1, 1999, and 5.25% thereafter, extending through the expiration of the patents.

During 2000 and 1999, Innovations paid royalties of approximately $576,000 and $1,001,000, respectively, under this agreement and had approximately $544,000 and $416,000 accrued at December 31, 2001 and 2000, respectively. Innovations did not make any such royalty payments during 2001. In December 1999, IMT gave Becton Dickinson a written notice to terminate these license agreements effective January 1, 2000, prior to the expiration of the patents. As a result of this early termination, Becton Dickinson filed suit against IMT (Note 8(c)). Innovations, as a successor to IMT, agreed to assume the liabilities under this litigation.

(f) Orgenics Royalty Commitment

Orgenics has received participation payments in programs sponsored by the Chief Scientist of the Ministry of Industry and Commerce of Israel (the "Chief Scientist") for the support of its research and development projects. In the event that development of the products in which the Chief Scientist participates is successful, Orgenics will be obligated to pay royalties at the rate of 2.0% to 3.5% of the sales of products developed with funds provided by the Chief Scientist, up to an amount equal to 100% of the Chief Scientist s participation payments to such projects. The balance of the maximum contingent royalty as of December 31, 2001 and 2000 was approximately $2,200,000. Orgenics does not have any liability to the State of Israel for amounts received in support of unsuccessful programs or unsaleable products. During 2001, 2000 and 1999, Orgenics paid approximately $169,000, $206,000 and $196,000, respectively, in royalties to the Chief Scientist.

(9) Earnings Per Share

The following table sets forth the computation of basic and diluted (loss) income per share:

	2001	2000	1999
Numerator:			
(Loss) income from continuing operations	$ (24,462,202)	$ 2,779,605	$ 356,614
Income (loss) from discontinued operations	57,895	(597,784)	183,089
(Loss) income before extraordinary item	(24,404,307)	2,181,821	539,703
Extraordinary item	(326,580)		
Net (loss) income	$ (24,730,887)	$ 2,181,821	$ 539,703
Denominator:			
Weighted average shares (Note 2(k))	6,368,000	4,726,000	3,364,000
(Loss) income per share basic and diluted:			
(Loss) income from continuing operations	$ (3.84)	$ 0.59	$ 0.11
Income (loss) from discontinued operations	0.01	(0.13)	0.05
(Loss) income before extraordinary item	(3.83)	0.46	0.16
Extraordinary item	(0.05)		
Net (loss) income	$ (3.88)	$ 0.46	$ 0.16

The Company had options, warrants and Series A Preferred Stock outstanding at December 31, 2001 exercisable for or convertible into approximately 1,955,000, 621,000 and 3,990,000 shares of its common stock, respectively. The weighted average common stock equivalents of these securities were not included in the computation of diluted net loss per share for 2001 because the inclusion of such potential common stock would have an antidilutive effect on net loss per share. There were no dilutive securities outstanding during 2000 and 1999.

(10) Stockholders Equity

In this Note, all amounts pertaining to shares and share prices for all securities have been restated assuming the stock split described in Note 1, as if the split-off and merger had occurred on the dates such securities were issued.

(a) Common Stock

As of December 31, 2001, the Company had 50,000,000 shares of common stock, $0.001 par value, authorized, of which 8,681,744 shares were issued and outstanding, 3,990,000 shares were reserved for issuance upon conversion of outstanding Series A Preferred Stock, 2,658,866 shares were reserved for issuance upon grant and exercise of stock options under current stock option plans and 620,880 shares were reserved for issuance upon exercise of outstanding warrants.

(b) Preferred Stock

As of December 31, 2001, the Company had 5,000,000 shares of preferred stock, $0.001 par value, authorized, of which 2,666,667 shares were designated as Series A Preferred Stock, $0.001 par value. As of December 31, 2001, there were 1,995,000 shares of Series A Preferred Stock issued and outstanding.

In December 2001, the Company sold to private investors 1,995,000 shares of Series A Preferred Stock at $30 per share for gross proceeds of $59,850,000 for purposes of funding part of its acquisition of the Unipath businesses (Note 4). The private investors include certain directors of the Company and entities and persons affiliated with such directors and the CEO, who in the aggregate purchased 626,666 shares of Series A Preferred Stock. 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 the Company s common stock is less than $15. As the Company s stock price did not close below $15 following the issuance of the Series A Preferred Stock, no dividends were recorded in 2001. Dividends accrued are payable only if declared by the board of directors. Until December 31, 2003, accrued dividends, if any, must be paid in the Company s common stock (using the same conversion ratio as described below in connection with a voluntary conversion of Series A Preferred Stock). Thereafter, the Company has 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 by the conversion price in effect at the time of conversion. The conversion price was initially $15 and is subject to adjustment. The conversion price for the Series A Preferred Stock represents a $2 (or 11.8%) discount to the fair value of the common stock on the issuance date. In accordance with EITF Issue No. 98-5 and EITF Issue No. 00-27, the Company recorded a beneficial conversion feature in the form of a discount on the Series A Preferred Stock of approximately $7,980,000, which is being amortized to accumulated deficit over the redemption period (as discussed below). The amortization of this discount reduces earnings available to common stockholders in the computation of earnings per share. The total amount of the discount amortized in 2001 was not material to the Company's consolidated financial statements. Starting on December 20, 2003, the Company may convert the Series A Preferred Stock into common stock in the event that the average closing price of its common stock exceeds $20 for any consecutive 30 trading day period.

Because the Series A Preferred Stock may be redeemed upon a vote by the holders of at least $66^{2}/_{3}$% of the outstanding shares on or after June 30, 2011, the Company has classified the outstanding Series A Preferred Stock outside of stockholders equity in the accompanying consolidated balance sheet as of December 31, 2001. 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.

In March 2002, the Company sold to private investors an additional 531,915 shares of Series A Preferred Stock at $39.01 per share for gross proceeds of $20,750,000 for purposes of repaying the Subordinated Notes (Note 6(b)). The terms of these new Series A Preferred Stock are the same as those issued in December 2001 and each share is currently convertible into two shares of the Company s common stock.

(c) Stock Options and Awards

In 2001, Innovations adopted the 2001 Stock Option and Incentive Plan (the 2001 Plan) which allows for the issuance of up to 3,824,081 shares of common stock and other awards. The 2001 Plan is administered by a compensation committee in order to select the individuals eligible to receive awards, determine or modify the terms and conditions of the awards granted, accelerate the vesting schedule of any award and generally administer and interpret the 2001 Plan. The key terms of the 2001 Plan permit the granting of incentive or nonqualified stock options with a term of up to ten years and the granting of stock appreciation rights, restricted stock awards, unrestricted stock awards, performance share awards and dividend equivalent rights. The 2001 Plan also provides for option grants to nonemployee directors and automatic vesting acceleration of all options and stock appreciation rights upon a change in control, as defined by the 2001 Plan.

On August 15, 2001, Innovations sold to its CEO 1,168,191 shares of restricted common stock at a price of $9.13 per share. Two-thirds of the restricted stock, or 778,794 shares, vest ratably over 36 months; the remaining one-third, or 389,397 shares, vests ratably over 48 months. Except for the par value of the common stock, which was paid in cash, the CEO purchased the restricted stock with a five-year promissory note which, for accounting purposes, was treated as a non-recourse note. The balance of the promissory note is recorded as a note receivable and is classified in stockholders equity in the accompanying consolidated balance sheet as of December 31, 2001. The note bears interest at an annual rate of 4.99%. Under the terms of the original restricted stock agreement, Innovations could repurchase unvested shares at cost in certain circumstances. Innovations accounted for this arrangement under FIN No. 44, EITF Issue No. 95-16, *Accounting for Stock Compensation Arrangements with Employer Loan Features under APB Opinion No. 25*, and EITF Issue No. 00-23, *Issues Related to Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44*. Accordingly, on November 20, 2001, the date on which this arrangement was approved by the stockholders, the Company measured total compensation expense to be approximately $10,595,000 based on the intrinsic value of the stock on that date. The amount of compensation expense is deferred and amortized ratably over the vesting periods of the restricted stock. Amortization of deferred compensation related to this restricted stock arrangement was approximately $451,000 in 2001, which was recorded as stock-based compensation in the accompanying consolidated statements of operations. In February 2002, the terms of the restricted stock agreement were amended, pursuant to which the Company may repurchase unvested shares at the then fair value in certain circumstances. Also, in connection with this amendment, the CEO surrended 50,000 shares of his nonqualified stock options in the Company. Because the repurchase rights on unvested shares are now at fair value, the Company will fully amortize the remaining portion of the deferred compensation expense associated with the restricted stock in the first quarter of 2002.

In August 2001, Innovations granted two nonqualified stock options to purchase an aggregate of 778,794 shares of common stock at an exercise price of $6.20 per share to two other key executive officers. These options were set to expire on January 31, 2002. In December 2001, the executive officers exercised these options (one fully; one partially) by paying cash in the amount of par value and delivering promissory notes for the difference, as permitted pursuant to the terms of the original grant. For accounting purposes, the promissory notes were treated as non-recourse notes. The balance of the promissory notes is recorded as a note receivable and classified in stockholders equity in the accompanying consolidated balance sheet as of December 31, 2001. The notes bear interest at an annual rate of 3.97%, the applicable federal rate for a five-year note in effect during the month of exercise. Shares issued upon exercise vest ratably over 36 months. Under certain circumstances, Innovations may repurchase unvested shares at the then fair value. One of these executive officers exercised part of the option for only a portion of the underlying shares; as a result, in accordance with the terms of the original option agreement, Innovations granted a replacement option to this executive officer for the remaining unexercised shares with an exercise price equal to the fair value of the common stock on the date of grant. Innovations accounted for these arrangements under FIN No. 44, EITF Issue Nos. 95-16 and 00-23. Accordingly, on November 20, 2001, the date on which these arrangements were approved by the stockholders, the Company measured total compensation expense to be approximately $9,345,000 based on the intrinsic value of the stock on that date. Because the repurchase rights on unvested shares are at fair value, the Company recorded the full intrinsic value as stock-based compensation in the accompanying consolidated statements of operations in 2001.

Innovations also granted immediately after the effective date of the split-off and merger options to purchase an additional 389,397 shares of common stock to these two key executive officers. These options will become exercisable ratably over four years and expire 10 years from the date of grant. The exercise price per share was equal to the fair value of the Company s common stock on the date of grant. The options permit exercise for cash, Innovations shares paid for at least 6 months prior to the exercise date or with proceeds from a promissory note which will contain terms that are substantially the same as those described above.

In connection with the Credit Agreements (Note 6(a)), the Company s CEO was required to enter into a lock up agreement with the bank, pursuant to which he is restricted in the trading of the Company s securities for various specified periods and amounts. In consideration of his entry into this lock up agreement, the Company granted him an option to acquire 115,000 shares of the Company s common stock at $17.15 per share (the fair value of the Company s common stock on the date of grant). Simultaneously, an entity controlled by the Company s CEO also received a warrant to purchase 385,000 shares of the Company s common stock (Note 10(d)).

Upon the split-off and merger, each outstanding IMT stock option (IMT Option) was exchanged for an option to purchase Innovations common stock (Innovations Option) at an exchange ratio of 0.20 and an option to purchase Johnson & Johnson common stock at an exchange ratio of 0.5395. The new exercise prices of the Innovations Options and the Johnson and Johnson options were determined based on the relative fair values of the Johnson & Johnson common stock and Innovations common stock on the first trading day immediately after the split-off and merger, taking into consideration the relative exchange ratios. The per share numbers and exercise prices of stock options granted prior to the split-off and merger date in the following tables have been restated to reflect the exchange of IMT Options for Innovations Options, as if the exchange occurred on the date of grants.

The following summarizes all stock option activity during each of the years ended December 31:

	2001		2000		1999	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	886,153	$ 2.06	1,048,433	$ 1.93	909,765	$ 2.49
Granted	2,335,347	12.68	46,335	4.34	345,036	2.06
Exercised	(1,120,857)	12.04	(155,669)	1.49	(43,589)	0.74
Terminated	(145,716)	6.55	(52,946)	2.88	(162,779)	5.65
Outstanding at December 31	1,954,927	$ 12.77	886,153	$ 2.06	1,048,433	$ 1.93
Exercisable at December 31	775,229	$ 7.55	747,874	$ 1.94	619,236	$ 1.57

The following represents additional information related to stock options outstanding and exercisable at December 31, 2001:

	Outstanding			Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.56-0.75	35,351	1.78	$ 0.69	35,351	$ 0.69
1.16-1.71	203,466	5.50	1.42	203,466	1.42
1.80-2.68	159,567	6.97	2.35	159,567	2.35
2.89-4.32	20,644	5.84	4.02	20,644	4.02
4.38-6.03	39,151	5.92	4.80	39,151	4.80
6.67-9.03	13,134	5.94	7.19	13,134	7.19
11.68-17.49	1,328,689	8.70	15.79	298,991	15.62
17.91-24.14	151,061	9.87	18.73	1,061	18.05
27.34-29.41	3,864	4.52	27.87	3,864	27.87
	1,954,927	8.08	$ 12.77	775,229	$ 7.55

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees who remained Innovations employees after the split-off and merger during 2001, 2000 and 1999 were $10.35, $8.39 and $2.16, respectively.

The Company has computed the pro forma disclosures required under SFAS No. 123 for stock options granted after January 1, 1995 to those employees who remained Innovations employees after the split-off and merger, using the Black-Scholes option pricing model prescribed by SFAS No. 123. The assumptions used during each of the three years ended December 31, 2001 were as follows:

	2001	2000	1999
Risk-free interest rate	4.3 - 4.8%	5.7%	5.9%
Expected dividend yield			

Expected lives	0.3 - 7 years	5 years	6 years
Expected volatility	54 - 82%	82%	78%

Had compensation expense for stock options granted to those employees who remained Innovations employees after the split-off and merger been determined based on the fair values at the grant dates for awards under the stock option plans consistent with the method of accounting prescribed by SFAS No. 123, the Company s net (loss) income would have been (increased) decreased to the pro forma amounts indicated as follows:

	2001	2000	1999
Net (loss) income			
As reported	$ (24,730,887)	$ 2,181,821	$ 539,703
Pro forma	(30,949,746)	1,857,441	139,035
Basic and diluted net (loss) income per share			
As reported	$ (3.88)	$ 0.46	$ 0.16
Pro forma	(4.86)	0.39	0.04

(d) Warrants

Upon the split-off and merger, each outstanding IMT warrant (IMT Warrant) was exchanged for a warrant to purchase Innovations common stock (Innovations Warrant) at an exchange ratio of 0.20 and a warrant to purchase Johnson and Johnson common stock at an exchange ratio of 0.5935. The new exercise prices of the Innovations Warrants and the Johnson and Johnson warrants were determined based on the relative fair values of the Johnson & Johnson common stock and Innovations common stock on the first trading day immediately after the split-off and merger, taking into consideration the relative exchange ratios. The per share numbers and exercise prices of warrants issued prior to the split-off and merger date in the following tables have been restated to reflect the exchange of IMT Warrants for Innovations Warrants, as if the exchange occurred on the date of issuance.

The following is a summary of all warrant activity during the three years ended December 31, 2001:

	Number of Shares	Exercise Price	Weighted Average Exercise Price
Warrants outstanding and exercisable, December 31, 1998	202,853	$ 0.75-6.80	$ 3.26
Exercised	(29,778)	1.24	1.24
Cancelled	(25,739)	1.24-4.93	4.30
Warrants outstanding and exercisable, December 31, 1999	147,336	0.75-6.80	3.49
Granted	23,687	3.81-7.55	5.25
Exercised	(22,553)	3.02-6.80	6.52
Cancelled	(8,236)	4.93-6.80	5.52
Warrants outstanding and exercisable, December 31, 2000	140,234	0.75-7.55	3.18
Granted	524,564	0.001-21.28	15.06
Exercised	(43,918)	3.02-7.55	5.06
Warrants outstanding and exercisable, December 31, 2001	620,880	$ 0.75-21.28	$ 13.09

The following represents additional information related to warrants outstanding and exercisable at December 31, 2001:

Exercise Price	Number of Shares	Outstanding and Exercisable Weighted Average Remaining Contract Life	Weighted Average Exercise Price
$0.001-0.75	65,000	9.97	$ 0.001
0.75	55,900	11.88	0.75
3.02-4.52	20,184	2.97	3.61
4.54-6.27	18,041	7.31	5.13
7.37-7.55	2,191	8.66	7.48
11.55-17.15	399,714	4.97	17.02
18.12-21.28	59,850	9.35	18.37
	620,880	6.51	$ 13.09

In connection with the Credit Agreements (Note 6(a)), an entity controlled by the Company s CEO was required to enter into a lock up agreement with the bank, pursuant to which it is restricted in the trading of the Company s securities for various specified periods and amounts. In consideration of its entry into this lock up agreement, the Company issued this entity a warrant to acquire 385,000 shares of the Company s common stock at $17.15 per share (the fair value of the Company s common stock on the date of issuance). The Company s CEO also received an option to purchase 115,000 shares of the Company s common stock (Note 10(c)).

The majority of the warrants included in the table above were issued in connection with debt and equity financings, or amendments thereto, of which warrants to purchase an aggregate of 441,291 shares of the Company s common stock were issued to officers and directors of the Company or entities controlled by these officers and directors and were outstanding at December 31, 2001. The value of warrants issued in connection with debt financings have yielded original issue discounts and additional interest expense of $77,000 for the period from the split-off and merger date through December 31, 2001. The Company believes that its equity classification is appropriate for all outstanding warrants, pursuant to the provisions of EITF Issue No. 00-19, *Determination of Whether Share Settlement Is within the Control of the Issuer for Purposes of Applying EITF Issue No. 96-13, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock*.

(e) Employee Stock Purchase Plan

In 2001, Innovations adopted the 2001 Employee Stock Purchase Plan under which eligible employees will be allowed to purchase shares of Innovations common stock at a discount through periodic payroll deductions. Purchases may occur at the end of every six month offering period at a purchase price equal to 85% of the market value of Innovations common stock at either the beginning or end of the offering period, whichever is lower. Innovations may issue up to 500,000 shares of common stock under this plan. At December 31, 2001, no shares had been issued under this plan.

(f) Executive Bonus Plan

In 2001, Innovations adopted a stockholder approved executive bonus plan (the Executive Bonus Plan) pursuant to which certain key executives of Innovations would have been entitled to receive annual cash bonuses if shares of Innovations common stock attain certain targeted prices per share. Performance determinations were to be made at the end of each calendar year, starting with December 31, 2002 and ending with December 31, 2005. Payments under the Executive Bonus Plan, if any, were to be paid in cash in January of the following year. The maximum amount that could have been earned under the Executive Bonus Plan was $21,650,000. In February 2002, the Executive Bonus Plan was amended, pursuant to which cash bonuses were replaced with option grants to be awarded at fair value on the date performance targets are achieved. The maximum number of shares for which options may be granted under the Executive Bonus Plan, as amended, is 712,600.

(11) Income Taxes

Innovations income tax provisions mainly represent those recorded by its U.S. subsidiary, IMI. For federal and some state income tax filing purposes, the results of IMI s operations were consolidated with IMT s through the date of the split-off and merger (November 21, 2001). IMI has stand-alone tax filing responsibilities in some states. Prior to the split-off and merger, the tax accounts maintained by IMI and other Innovations subsidiaries were computed using the separate return method. IMT had been in a net loss position and, accordingly, paid virtually no income taxes in any jurisdiction. IMI had a tax sharing agreement with IMT, under which IMT agreed to pay all of IMI s tax liabilities (or offset these liabilities via IMT s net operating loss carryforwards) until IMI s cumulative taxable income (beginning January 1, 1998) exceeded $15,500,000. Once IMI s cumulative taxable income passed this threshold, IMI was required to pay a dividend to IMT equal to 40% of the amount that exceeds the threshold. During 2000, IMI surpassed the threshold and IMI has accrued a dividend to IMT of approximately $1,187,000 as of December 31, 2000. Pursuant to this agreement, IMI recorded a capital contribution from IMT for taxes paid by IMT or offset via IMT s net operating loss carryforward. Upon the split-off and merger, this agreement was cancelled.

The Company provides for income taxes in accordance with the provisions of SFAS No. 109. Accordingly, a deferred tax asset or liability is determined based on the difference between the financial statement and tax bases of assets and liabilities, as measured by the enacted tax rates expected to be in effect when these differences reverse. The Company s primary temporary differences that give rise to the deferred tax asset and liability are nondeductible reserves and accruals and different lives assigned to the tangible assets. The income tax effect of these temporary differences are as follows:

	December 31,	
	2001	**2000**
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$ 4,741,851	$ 4,703,240
Nondeductible reserves	1,564,403	1,155,584
Nondeductible accruals	1,803,519	663,221
Nondeductible stock-based compensation	4,169,910	
Nondeductible write-off of tangible assets	1,466,786	
Difference between book and tax bases of tangible assets		20,684
Valuation allowance	(12,279,683)	(5,003,240)
Deferred tax asset	$ 1,466,786	1,539,489
Deferred tax liabilities:		

Difference between book and tax bases of tangible assets	$	2,044,019		
Difference between book and tax bases of intangibles				1,120,674
Deferred tax liability	$	2,044,019	$	1,120,674

At December 31, 2001, Innovations has available foreign net operating loss carryforwards of approximately $24,760,000 to reduce future foreign taxable income, if any. These carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The valuation allowance related to Innovations net operating losses and other foreign deferred tax assets is due to uncertainty surrounding their realizability, as these assets can only be realized via profitable foreign operations.

The following table presents the components of Innovations provision for income taxes:

	2001	2000	1999
Current			
Federal	$ 1,061,695	$ 1,399,050	$ 844,394
State	620,642	431,946	260,701
Foreign	33,207	18,000	(98,386)
	1,715,544	1,848,996	1,006,709
Deferred			
Federal	320,013	(51,763)	
State	98,802	(15,989)	
	418,815	(67,752)	
Total tax provision	$ 2,134,359	$ 1,781,244	$ 1,006,709

The following table presents a reconciliation from the statutory tax rate to Innovations effective tax rate from continuing operations:

	2001	2000	1999
Statutory rate	(34%)	34%	34%
Foreign and divisional losses not benefited	5	17	56
Rate differential on foreign losses	2	(4)	(14)
State income taxes, net of federal benefit	2	6	10
Change in valuation allowance	34	(14)	(12)
	9%	39%	74%

(12) Financial Information by Segment

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. Innovations chief operating decision making group is composed of the CEO and members of senior management. Innovations reportable operating segments are Consumer Products (comprised of consumer diagnostic products and vitamins and nutritional supplements), Clinical Diagnostics Products, and Corporate and Other.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies. Innovations evaluates performance based on EBITDA. Revenues are attributed to geographic areas based on where the customer is located. Segment information for 2001, 2000 and 1999 are as follows:

2001	Consumer Products	Clinical Diagnostics Products	Corporate and Other	Total
Net product sales to external customers	$ 38,794,021	$ 10,590,774	$	$ 49,384,795
EBITDA	5,626,102	(1,464,345)	(3,860,711)	301,046
Depreciation and amortization	2,186,781	430,998	734,948	3,352,727
Charge for in-process research and development	6,980,211			6,980,211
Stock compensation			10,440,588	10,440,588
Interest income:				
External	89,030		296,099	385,129
Interest expense:				
External	686,716	205,223	694,957	1,586,896
To IMT	115,397		153,060	268,457
Total interest expense	802,113	205,223	848,017	1,855,353
Provision for income taxes	1,966,359	18,000	150,000	2,134,359
Income from discontinued operations			57,895	57,895
Extraordinary loss from early extinguishment of debt	326,580			326,580
Assets	194,372,340	42,023,783	42,174,717	278,570,840
Expenditures for property, plant and equipment	2,291,137	334,000	827,729	3,452,866

2000	Consumer Products	Clinical Diagnostics Products	Corporate and Other	Total
Net product sales to external customers	$ 40,345,433	$ 10,681,000	$ 24,141	$ 51,050,574
EBITDA	9,346,572	1,239,000	(1,255,262)	9,330,310
Depreciation and amortization	2,087,373	398,000	379,392	2,864,765
Interest income:				
External	12,442	15,000		27,442
Interest expense:				
External	1,344,675	265,000		1,609,675
To IMT	130,356		164,665	295,021
Total interest expense	1,475,031	265,000	164,665	1,904,696
Provision for income taxes	1,763,244	18,000		1,781,244
Loss from discontinued operations			597,784	597,784
Assets from continuing operations	46,239,592	6,423,591	3,949,425	56,612,608
Expenditures for property, plant and equipment	457,277	246,000	77,514	780,791

1999	Consumer Products	Clinical Diagnostics Products	Corporate and Other	Total
Net product sales to external customers	$ 39,518,805	$ 11,063,488	$ 1,561	$ 50,583,854
EBITDA	6,465,067	902,006	(1,013,253)	6,353,820
Depreciation and amortization	2,029,951	545,379	394,285	2,969,615
Interest income:				
External	15,160	15,000		30,160
Interest expense:				
External	1,498,396	252,000	23,547	1,773,943
To IMT	130,356		118,675	249,031
Total interest expense	1,628,752	252,000	142,222	2,022,974
Provision for income taxes	956,709	50,000		1,006,709
Income from discontinued operations			183,089	183,089
Assets from continuing operations	44,585,518	5,721,158	4,252,783	54,559,459
Expenditures for property, plant and equipment	1,317,727	127,000	31,390	1,476,117

	Years Ended December 31,		
	2001	2000	1999
Reconciliation of EBITDA to (Loss) Income from Continuing Operations			
EBITDA	$ 301,046	$ 9,330,310	$ 6,353,820
Depreciation and amortization expense	(3,352,727)	(2,864,765)	(2,969,615)
Interest expense	(1,855,353)	(1,904,696)	(2,022,974)
Income taxes	(2,134,359)	(1,781,244)	(1,006,709)
Other noncash items	(17,420,809)		2,092
(Loss) income from continuing operations	$ (24,462,202)	$ 2,779,605	$ 356,614
Revenue by Geographic Area			
United States	$ 35,615,307	$ 38,819,170	$ 37,900,174
Europe	6,342,151	4,417,330	5,204,245
Other	7,427,337	7,814,074	7,479,435
	$ 49,384,795	$ 51,050,574	$ 50,583,854

	December 31,	
	2001	2000
Long-lived Tangible Assets by Geographic Area		
United Kingdom	$ 14,993,888	$
Ireland	2,559,877	1,520,186
United States	1,609,574	345,330
Other	1,362,889	1,257,165
	$ 20,526,228	$ 3,122,681

(13) Discontinued Operations

Pursuant to the Merger Agreement and related agreements, Innovations transferred to IMT those entities or businesses that conduct business in the diabetes segment, principally the Can-Am subsidiary of IMI and the diabetes business of IMB. As discussed in Note 1, the accompanying consolidated financial statements reflect the transfer of the diabetes businesses by Innovations as discontinued operations.

The net assets of discontinued operations in the accompanying balance sheet as of December 31, 2000 are composed of the following:

Current assets	$	8,795,653
Property, plant and equipment		59,919
Other non-current assets, primarily goodwill		24,139,581
		32,995,153
Current liabilities		(8,763,630)
Long-term liabilities		(5,885,688)
Net assets of discontinued operations	$	18,345,835

The accompanying consolidated statements of operations include income (losses) from discontinued operations as follows:

	2001 (i)	2000	1999
Net product sales	$ 30,748,823	$ 33,478,566	$ 28,709,993
Cost of sales	**22,605,542**	**23,108,414**	**18,644,151**
Gross profit	**8,143,281**	**10,370,152**	**10,065,842**
Operating expenses	**6,634,612**	**8,755,407**	**6,956,967**
Operating income	**1,508,669**	**1,614,745**	**3,108,875**
Other expenses, net	**415,929**	**1,083,989**	**1,139,002**
Income before income taxes and extraordinary item	**1,092,740**	**530,756**	**1,969,873**
Provision for income taxes	**761,613**	**1,128,540**	**1,786,784**
Income (loss) before extraordinary item	**331,127**	**(597,784)**	**183,089**
Extraordinary loss from early extinguishment of debt	**273,232**		
Net income (loss) from discontinued operations	**$ 57,895**	**$ (597,784)**	**$ 183,089**

(i) Through date of the split-off and merger

(14) Valuation and Qualifying Accounts

Innovations has established reserves against accounts receivable for doubtful accounts, product returns, discounts and other allowances. The activity in the table below includes all accounts receivable reserves. Provisions for doubtful accounts are recorded as a component of general and administrative expenses. Provisions for returns, discounts and other allowances are charged against net product sales. The following table sets forth activities in Innovations accounts receivable reserve accounts:

	Balance at Beginning of Period	Provision	Amounts Charged Against Reserves	Balance at End of Period
Year ended December 31, 1999	$ 1,920,000	$ 5,419,000	$ (5,104,000)	$ 2,235,000
Year ended December 31, 2000	2,235,000	9,340,000	(9,833,000)	1,742,000
Year ended December 31, 2001	1,742,000	10,591,000	(9,738,000)	2,595,000

(15) Acquisition of IVC Industries, Inc.

On March 19, 2002, the Company acquired IVC Industries, Inc. (IVC), a manufacturer and distributor of vitamins and other nutritional supplements. The purchase price for IVC consisted of $2.50 in cash for each outstanding share of IVC s common stock (an aggregate cost of approximately $5,619,000), assumed stock options having a fair value of approximately $540,000, certain employee costs and benefits related to a restructuring of activities upon the acquisition, direct acquisition costs and assumed liabilities. As of the acquisition date, IVC had outstanding debt of approximately $18,700,000. The Company is accounting for this acquisition as a purchase in accordance with SFAS No. 141 and is in the process of determining the purchase price allocation.

EXHIBIT INDEX

2.1	Sale Agreement, dated December 20, 2001, between Inverness Medical Innovations, Inc. (the Company) and Unilever U.K. Holdings Limited (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K dated December 20, 2001)
2.2	Amended and Restated Agreement and Plan of Merger, made and entered into as of December 21, 2001 and amended and restated as of January 22, 2002, by and among the Company, Nutritionals Acquisition Corporation and IVC Industries, Inc. (IVC) (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K dated March 29, 2002)
+*2.3	Restructuring Agreement, dated as of November 21, 2001, by and among Inverness Medical Technology, Inc. (IMT), the Company and certain subsidiaries of IMT
*3.1	Amended and Restated Certificate of Incorporation of the Company
3.2	Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K dated December 20, 2001)
*3.3	Amended and Restated By-laws of the Company
4.1	Specimen certificate for shares of Common Stock of the Company (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))
*10.1	Post-Closing Covenants Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT, the Company, certain subsidiaries of IMT and certain subsidiaries of the Company
*10.2	Tax Allocation Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT and the Company
*10.3	Supply of Goods Agreement, dated July 28, 1998, between Schleicher & Schuell GmbH and Unipath Limited
10.4	Trademark License Agreement, dated as of February 19, 1997, by and among American Cyanamid Company and Selfcare Acquisition Corporation (incorporated by reference to Exhibit 10.5 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))
10.5	Lease, dated as of March 19, 1992, by and among Cambridge Diagnostics Ireland Limited and George Conroy, Brendan Conroy and Patrick Conroy (incorporated by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))
10.6	Lease, dated as of January 12, 1999, by and among Cambridge Diagnostics Ireland Limited and the Industrial Development Agency (Ireland) (incorporated by reference to Exhibit 10.4 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))
10.7	Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))
10.8	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

*10.9 Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan First Amendment

*10.10 Lease Agreement, dated July 28, 1998, between 569 Halls Mill Road, L.L.C. and IVC

*10.11 Restricted Stock Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Ron Zwanziger

*10.12 Promissory Note, dated August 16, 2001, from Ron Zwanziger to the Company

*10.13 Pledge Agreement, dated as of August 16, 2001, between Ron Zwanziger and the Company

*10.14 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and

Jerry McAleer

*10.15 Promissory Note, dated December 4, 2001, from Jerry McAleer to the Company

*10.16 Pledge Agreement, dated as of December 4, 2001, between Jerry McAleer and the Company

*10.17 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and David Scott

*10.18 Promissory Note, dated December 4, 2001, from David Scott to the Company

*10.19 Pledge Agreement, dated as of December 4, 2001, between David Scott and the Company

10.20 Stock Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K dated March 14, 2002)

10.21 Note and Warrant Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.3 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.22 Form of Subordinated Promissory Note issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.4 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.23 Form of Warrant for the Purchase of Shares of Common Stock of the Company issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.5 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.24 Credit Agreement, dated December 20, 2001, between the Company, Inverness Medical Switzerland GmbH, the Banks listed on Schedule 1 thereto, The Royal Bank of Scotland plc, as Facility Agent, The Royal Bank of Scotland plc, as Issuing Bank, The Royal Bank of Scotland plc, as Overdraft Bank, and The Royal Bank of Scotland plc, as Lead Arranger (incorporated by reference to Exhibit 99.6 to the Company s Current Report on Form 8-K dated December 20, 2001)

10.25 Mezzanine Loan Agreement, dated December 20, 2001, between the Company, Inverness Medical Switzerland GmbH, the Lenders listed on Schedule 1 thereto, RBS Mezzanine Limited, as Facility Agent, and RBS Mezzanine Limited, as Lead Arranger (incorporated by reference to Exhibit 99.7 to the Company s Current Report on Form 8-K dated December 20, 2001)

*10.26 Warrant Agreement, dated as of December 20, 2001, by and between the Company and RBS Mezzanine Limited

*10.27 Warrant to Purchase Common Stock of the Company, dated December 20, 2001, issued to RBS Mezzanine Limited in connection with the Mezzanine Loan Agreement

*10.28 Warrant for the Purchase of Shares of Common Stock of the Company, dated as of December 20, 2001, issued to Zwanziger Family Ventures, LLC

*10.29 Loan and Security Agreement, dated as of October 16, 2000, between IVC and Congress Financial Corporation

*10.30 Amendment No. 1 to Loan and Security Agreement, dated June 13, 2001, by and between Congress Financial Corporation and IVC

*10.31 Amendment No. 2 to Loan and Security Agreement, dated as of June 14, 2001, by and between Congress Financial Corporation and IVC

*10.32

Amendment No. 3 to Loan and Security Agreement, dated as of March 19, 2002, by and between Congress Financial Corporation and IVC

*10.33 Agreement, dated December 1, 1986, between Bernard Levere, Zelda Levere, Pioneer Pharmaceuticals, Inc. and Essex Chemical Corp. and Unconditional Guarantee by Essex Chemical Corp.

*10.34 Option to Assume and Extend Lease, dated as of February 1995, between Bernard Levere,

Zelda Levere and International Vitamin Corporation

10.35 Inverness Medical Innovations, Inc. Executive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Company s Registration Statement on Form S-4, as amended (File No. 333-67392))

*10.36 Amendment to Mezzanine Loan Agreement, dated March 28, 2002, between RBS Mezzanine Limited, for and on behalf of the Finance Parties, and the Company, for and on behalf of itself and Inverness Medical Switzerland GmbH

*10.37 Licensing Agreement, dated March 14, 1988, between Unilever Plc and Behringwerke AG

*10.38 Supplemental Agreement, dated October 16, 1994, between Unilever Plc, Unilever NV and Behringwerke AG

*10.39 Amendment to Credit Agreement, dated March 28, 2002, between The Royal Bank of Scotland plc, for and on behalf of the Finance Parties, and the Company, for and on behalf of itself and Inverness Medical Switzerland GmbH

*21.1 List of Subsidiaries of the Company as of April 1, 2002

23.1 Consent of Arthur Andersen LLP

*99.1 Letter from the Company to the Securities and Exchange Commission regarding Arthur Andersen LLP representations

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Filed herewith.

* Previously filed.

+ The Company agrees to furnish supplementally to the Securities and Exchange Commission (the Commission) a copy of any omitted schedule or exhibit to this agreement upon request by the Commission.