IGEN INTERNATIONAL INC /DE
Form 424B2
February 07, 2002

PROSPECTUS SUPPLEMENT NO. 1
DATED FEBRUARY 7, 2002
(TO PROSPECTUS DATED JANUARY 3, 2002)

1,018,808 Shares

IGEN INTERNATIONAL, INC.

COMMON STOCK

You should read this prospectus supplement and the accompanying prospectus carefully before you invest. Both documents contain information you should consider carefully before making your investment decision.

INVESTING IN OUR COMMON STOCK INVOLVES CERTAIN RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE S-2 OF THIS PROSPECTUS SUPPLEMENT.

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PROSPECTUS SUPPLEMENT

PROSPECTUS

RISK FACTORS

INVESTING IN OUR COMMON STOCK IS VERY RISKY. YOU SHOULD BE ABLE TO BEAR A COMPLETE LOSS OF YOUR INVESTMENT. YOU SHOULD CAREFULLY CONSIDER THE FOLLOWING FACTORS IN ADDITION TO OTHER INFORMATION CONTAINED ELSEWHERE IN THIS PROSPECTUS OR INCORPORATED BY REFERENCE INTO THIS PROSPECTUS FROM OUR OTHER SEC FILINGS. THE RISKS AND UNCERTAINTIES BELOW ARE NOT THE ONLY ONES FACING IGEN BECAUSE WE ARE ALSO SUBJECT TO ADDITIONAL RISKS AND UNCERTAINTIES NOT PRESENTLY KNOWN TO US. IF ANY OF THESE RISKS ACTUALLY OCCURS, OUR BUSINESS, FINANCIAL CONDITION, OPERATING RESULTS OR CASH FLOWS COULD BE HARMED.

IF THE COMPANIES THAT LICENSE TECHNOLOGY FROM US DO NOT EFFECTIVELY DEVELOP AND MARKET PRODUCTS BASED ON THAT TECHNOLOGY, OUR REVENUE WOULD BE ADVERSELY AFFECTED.

The success of our business depends, in large part, on how effectively the companies to which we have licensed our technology develop and market that technology. If these companies do not effectively develop and market products based on this technology, our revenues would decrease.

We have licensed our technology to Organon Teknika B.V., Eisai Co., Ltd., and Roche Diagnostics GmbH for selected markets and uses. Our license agreements with each of these companies allow each company to develop products using our technology and to manufacture and sell those products in selected markets. In return for the right to use our technology, each of these companies must pay royalties to us based on revenues they receive from sales of products based on our technology. These royalties are a significant part of our overall revenue. For example, they accounted for 52% of our revenue in fiscal year 2001.

We believe that the companies licensing our technology have economic incentives to continue marketing products using our technology. However, we cannot be sure that these companies will diligently and effectively market products that incorporate the technology we have licensed to them. In addition, we have brought a lawsuit against Roche, one of our licensees, in part because we believe Roche has not properly calculated and paid royalties to us and because we believe Roche has not commercialized our technology as diligently as our license agreement with Roche requires. See the risk factor immediately below for a more detailed description of this litigation and the risks it poses to us. We cannot predict whether similar or other problems will arise with other companies to whom we license our technology.

WE ARE SUING THE LARGEST LICENSEE OF OUR TECHNOLOGY, AND THE OUTCOME OF THAT LITIGATION COULD MATERIALLY ADVERSELY AFFECT OUR REVENUES AND FINANCIAL CONDITION.

We have filed a lawsuit in Maryland Federal court against Roche. Roche is the largest licensee of our technology in terms of royalty income, accounting for over 90% of our royalty income in fiscal 2001. The lawsuit centers on disputes over our license agreement with Roche. We cannot provide any assurance that we will ultimately prevail in this litigation. If we do not succeed, our business and revenues could be materially adversely affected.

Our license agreement with Roche gives Roche the exclusive right to manufacture, market and sell immunodiagnostic products using our patented ORIGEN technology to a designated field. The license restricts Roche's rights in the Japanese clinical diagnostic market.

In the lawsuit, we allege that Roche has failed to perform several of its material obligations under the license agreement, including failure to diligently commercialize the licensed technology, selling product outside of its licensed field, failing to provide improvements as required by the agreement and failing to properly compute and pay royalties owed to us. We also claim that Roche engaged in unfair competition. We are seeking both monetary damages as well as a court order declaring that we are entitled to terminate the license agreement. We have voluntarily agreed not to terminate the license agreement until an appellate court determines that we are entitled to do so.

Roche has filed a counterclaim against us in the lawsuit, alleging, among

other things, that we breached the Roche license by permitting Eisai Co., Ltd., another of our licensees, to market some ORIGEN-based products in Japan.

On January 10, 2002, a jury awarded us $505 million in damages in our case against Roche including $105 million in compensatory damages and $400 million in punitive damages. The jury also confirmed our right to Roche's Elecysy(R)diagnostics product line, which was developed by Roche using our proprietary ORIGEN biological detection technology, as well as to other improvements. In addition, the jury's findings that Roche materially breached the license agreement, if affirmed on appeal, would permit the Company to terminate the agreement with Roche. Following termination, Roche would not be able to use ORIGEN in its diagnostics products. The jury also found in our favor and against Roche on all of Roche's counterclaims, except for one in which we were ordered to pay $500,000.

We expect post-trial motions will be filed by Roche to set aside some or all of the jury's findings and that Roche will appeal various decisions in this case. The jury's decisions, including its finding that Roche materially breached the license agreement, would be effective if affirmed on appeal. During an appeal process, which we expect could take approximately 18 months, we would continue to receive royalties on Roche's sales of royalty-bearing products under the license.

While we expect to vigorously oppose any appeal filed by Roche, there can be no assurance that the jury's verdict will not be overturned in whole or in part or that the district court or an appellate court will not order a new trial

on some or all of the jury's findings. The risks involved in the litigation include:

- The district court or an appellate court may modify or overturn some or all of the jury's findings that were favorable to us including the finding that Roche materially breached the license agreement, the scope and extent of the improvements awarded to us, the amount of compensatory and punitive damages, or the jury's favorable findings relating to Roche's counterclaims against us.

- The district court or an appellate court could overturn some or all of the jury's findings and order a new trial on those issues. For example, if the court orders a new trial on whether or not Roche miscalculated and underpaid royalties, breached its duty of good faith and fair dealing, or engaged in unfair competition against us, the amount of damages awarded in a new trial could be lower than the amount already awarded to us.

- If the court orders a new trial on any of the issues, we might need to continue expending significant amounts of money and management time in pursuing our claims against Roche. This time and money will then be unavailable for use in the development of our business.

- If the appellate court upheld the jury's finding that Roche materially breached the license agreement, and we were able to and did terminate the agreement, our royalty revenues would suffer unless and until we were able to introduce new products and generate revenues on our own or find one or more comparable replacements for Roche.

- There are no assurances that we could find a suitable replacement for Roche or successfully introduce new products on our own if we terminate the license. Our ability to successfully commercialize new products, including products based on the improvements awarded to us in this litigation, is subject to numerous risks and uncertainties including risks relating to:

  - the need for governmental approvals;

  - our ability to compete effectively;

  - our ability to effectively manufacture and market new products;

  - our ability to attract and retain employees;

  - our need for additional financing;

  - our dependence on suppliers; and

  - the other risks applicable to our business as more completely described below and in findings with the SEC.

- While an appeal is pending, Roche may divert its attention from selling the licensed products that generate royalties to us and focus its energies instead to find alternative products to develop and market, especially if Roche believes we may be successful in obtaining the right to terminate the license agreement.

- While an appeal is pending, Roche may continue to market and sell other Roche products that compete with its ORIGEN-based products, thereby lowering the royalty revenues that we would have otherwise received if Roche had sold more ORIGEN-based products instead of its other competing products.

OUR ROYALTY INCOME COULD SUFFER AS A RESULT OF OUR LITIGATION AGAINST HITACHI.

We are suing Hitachi Ltd. in Japan. Hitachi develops and manufactures diagnostic equipment based on ORIGEN technology for Roche, to whom we license our technology. We believe that Hitachi's actions in Japan violate rights that we originally granted to Eisai Co., Ltd. to develop, manufacture and sell products using ORIGEN technology to the Japanese clinical diagnostic market. We have asked the Japanese court to prohibit Hitachi from manufacturing, using or selling in Japan the Elecsys 2010 Instrument, which Hitachi developed for Roche based on our technology.

If we lose our lawsuit against Hitachi and Hitachi continues Japanese manufacturing of products covered by our license with Eisai, Eisai's ability to sell products based on our technology in Japan could suffer, and the royalty income we receive from Eisai could decrease as a result. If, on the other hand, we win the lawsuit against Hitachi, Roche will either have to find a new manufacturer to make equipment based on ORIGEN technology or make arrangements for Hitachi to manufacture the equipment outside of Japan. Our royalty income could suffer if Roche cannot effectively make alternate arrangements.

In connection with our ongoing litigation against Roche, Roche has attempted to sue us for interfering with its contract with Hitachi because we filed this lawsuit. That claim was dismissed by the district court. If we lose our lawsuit against Hitachi, Roche may try to bring this claim against us again.

There can be no assurance that we will be able to successfully dismiss this claim if reinstated.

FAILURE TO MEET OUR DEBT OBLIGATIONS COULD ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION; IN ADDITION, OUR DEBT SERVICE OBLIGATIONS COULD IMPAIR OUR OPERATING FLEXIBILITY.

We have a substantial amount of indebtedness, and there is a possibility that we may be unable to generate cash or arrange financing sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due, or in the event any of our indebtedness is accelerated. In addition, our substantial leverage may require that we dedicate a substantial portion of our expected cash flow from operations to service our indebtedness, which would reduce the amount of our expected cash flow available for other purposes, including working capital and capital expenditures.

In March 1999, we entered into a debt financing with John Hancock Mutual Life Insurance Company under a note purchase agreement in which we received $30 million, and we issued 8.5% senior secured notes due 2006. Principal and interest installments of $1.7 million are due quarterly through March 2006. The notes are secured by, among other things, royalty payments and our right to

receive monies due under our license agreement with Roche and a restricted cash balance account. If we are unable to meet our obligations under the notes, the note holders could require us to repay the principal amount of, and accrued interest on, the subordinated convertible debentures, and we may not have sufficient financial resources or be able to arrange sufficient financing to make those payments when required.

In addition, covenants in the note purchase agreement for our 8.5% senior secured notes require us to comply with annual and quarterly royalty payment coverage ratios that are tied to royalty payments and debt service. The note purchase agreement also contains covenants that limit our ability to take specified actions, including incurring additional secured debt and amending our license agreement with Roche, which could affect our ability to resolve issues that are being litigated through an amendment to the existing license agreement with Roche. These restrictions may limit our operating flexibility, as well as our ability to raise additional capital.

In January 2000, we sold $35 million in aggregate principal amount of 5% subordinated convertible debentures due 2005. Unless and until holders of the debentures convert their debentures into Common Stock, we are required to make semi-annual interest payments of $875,000 through 2005. If we are unable to meet our obligations under the subordinated convertible debentures, the debenture holders could require us to repay the principal amount of, and accrued interest on, the subordinated convertible debentures, and we may not have sufficient financial resources or be able to arrange sufficient financing to make those payments when required.

WE HAVE A HISTORY OF OPERATING LOSSES, EXPECT TO INCUR FUTURE LOSSES AND CANNOT BE CERTAIN THAT WE WILL BECOME A PROFITABLE COMPANY.

We have experienced significant operating losses in most years since our inception, and we expect those losses to continue. We also have an accumulated deficit and negative net worth. Our losses have resulted principally from costs incurred in research and development and from litigation costs, selling costs and other general and administrative costs. We expect to incur additional operating losses as a result of increases in expenses for manufacturing,

marketing and sales capabilities, litigation costs and expenses, research and product development, general and administrative costs and our share of losses in Meso Scale Diagnostics (MSD). We cannot assure you that we will ever achieve profitability in the future. Our ability to become profitable in the future will depend on, among other things, our ability to:

- expand the commercialization of our existing products;
- upgrade and enhance the M SERIES product capabilities;
- introduce new products into the market;
- develop our marketing capabilities cost-effectively;
- develop sales and distribution capabilities cost-effectively; and

- establish successful collaborations with corporate partners to develop and commercialize products that incorporate our technologies.

OUR QUARTERLY OPERATING RESULTS MAY FLUCTUATE SIGNIFICANTLY, AND THESE FLUCTUATIONS MAY CAUSE OUR STOCK PRICE TO FALL.

Our quarterly operating results depend upon:

- the volume and timing of orders for M-SERIES or other products;
- the timing of instrument deliveries and installations;
- the success of M-SERIES upgrades and enhancements;
- variations in revenue recognized from royalties and other contract revenues;
- our mix of products sold;
- whether our instruments are sold to or placed with customers;
- the timing of our introduction of new products;
- our competitors' introduction of new products;
- variations in expenses we incur in connection with the operation of our business, including legal fees, research and development costs, and sales and marketing costs, including costs for upgrading the M-SERIES products;
- our share of losses in MSD;
- our manufacturing capabilities; and
- the volume and timing of product returns and warranty claims.

These factors may cause our quarterly operating results to fluctuate significantly, which in turn, may cause our stock price to fall. In addition, because our revenues and operating results are volatile and difficult to predict, we believe that period-to-period comparisons of our results of operations are not a good indication of our future performance.

WE MAY NOT BE ABLE TO RAISE SUFFICIENT ADDITIONAL CAPITAL TO SUCCESSFULLY DEVELOP OUR BUSINESS.

We need substantial amounts of money to fund our operations. We currently anticipate that our existing capital resources, together with revenue from product sales and royalties, will be adequate to fund our operations through calendar year 2002. Our access to funds could be negatively impacted by

many factors, including the results of pending litigation, the volatility of the price of Common Stock, continued losses from operations and other factors.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including the following:

- for research and development in order to successfully develop our technologies;
- to obtain regulatory approval for some of our products;
- to file and prosecute patent applications in order to protect our technologies;
- to respond to innovations that our competitors develop;
- to continue to aggressively pursue our ongoing litigations against Roche and Hitachi;
- to retain qualified employees, particularly in light of intense competition for qualified scientists and engineers;
- to make new arrangements to market our technology, especially if we terminate our license agreement with Roche;
- to continue to fund investments in MSD;
- to manufacture products ourselves or through a third party; and
- to market different products to different markets, either through building our own sales and distribution capabilities or relying on a third party.

We cannot be certain that we will have access to enough funds to successfully develop our business.

We may try to raise necessary additional capital by issuing additional debt or equity securities. Holders of debt securities would have priority over our equity holders with respect to the proceeds from the sale of our assets in the event of liquidation of our business, and any debt financings we obtain may contain restrictive terms that limit our operating flexibility. If, on the other hand, we raise additional capital by selling more common or preferred stock, the holdings of existing stockholders would be diluted. On December 7, 2001, we entered into agreements to sell up to $30 million of Common Stock. Pursuant to those agreements, we sold 1,018,808 shares of Common Stock at an aggregate purchase price of $29.45 per share.

If we are unable to raise additional capital, we may have to scale back, or

even eliminate, some programs. Alternatively, we may have to consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures. These arrangements could require that we give up substantial rights to technology or products.

WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY AGAINST MORE ESTABLISHED COMPANIES AND INSTITUTIONS, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

We are a relatively young company in a highly competitive industry. We compete against established companies and research and academic institutions, and we expect this competition to intensify. Many of these companies and institutions have one or more competitive advantages over us, including:

- more money to invest;
- greater expertise and resources in developing, manufacturing, marketing and selling products;
- a larger, more experienced workforce; and
- more experience in obtaining regulatory approval for clinical diagnostic products.

As a result, we may not be able to compete successfully against our current or future competitors. This could have a material adverse effect on our business, financial condition and revenue.

WE DEPEND ON CONTINUING PRODUCT DEVELOPMENT.

The market for our products is characterized by rapidly changing technology, evolving industry standards, the need for updated and effective technology and new product introduction. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new or enhanced products. There can be no assurance that we will be able to avoid the obsolescence of our products due to rapid technological change and evolving industry standards. In general, the development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends as well as precise technological execution. We have and may continue to experience design, development, implementation and other difficulties that could delay or prevent our introduction of new or enhanced products or affect the performance of existing products. These difficulties and delays have caused, and may continue to cause, our expenses to increase and our product sales to fluctuate.

WE DEPEND ON HIGHLY TRAINED AND SKILLED EMPLOYEES AND MANAGEMENT, AND WE CANNOT BE SURE THAT WE WILL BE ABLE TO ATTRACT AND RETAIN SUFFICIENT PERSONNEL.

We need to hire additional staff and to retain existing staff, both of which are difficult in today's competitive marketplace. Because we are a technology company, we depend heavily on scientists and engineers to develop products and to build a successful business. Research and development efforts

could suffer if we are not able to hire and retain enough qualified scientists and engineers.

We cannot be sure that we will succeed in our hiring and retention efforts. We compete with other technology companies and research and academic institutions for experienced scientists. Many of these companies and institutions have greater resources than we do and thus may be in a better position to attract desirable candidates.

In addition to scientists, we will also need to hire managers as the business grows. We will need managers who are able to address the need for regulatory, manufacturing and marketing capabilities. If we are not able to hire managers with these skills, or develop expertise in these areas, our business prospects could suffer.

WE DEPEND ON A LIMITED NUMBER OF SUPPLIERS FOR MATERIALS USED IN MANUFACTURING OUR PRODUCTS, AND ANY INTERRUPTION IN THE SUPPLY OF THOSE MATERIALS COULD HAMPER OUR ABILITY TO MANUFACTURE PRODUCTS AND MEET CUSTOMER ORDERS.

We depend on vendors to supply key materials that we use in our products. Some of these materials are available only from limited sources. In the event of a reduction in, interruption of, or degradation in the quality of the supply of any of our required materials, or an increase in the cost of obtaining those materials, we would be forced to locate an alternative source of supply. If no alternative source were available or if an alternative source were not available on a timely basis or at a reasonable cost or otherwise on acceptable terms, our ability to manufacture one or more of our products would be delayed or halted. Any changes in sources of supply may require additional engineering or technical development in order to ensure consistent and acceptable performance of the products. If any of these events occur, product costs may increase, we might be unable to deliver products timely, we could lose sales as well as customers, and our business would be significantly harmed as a result.

WE MUST OBTAIN FDA APPROVAL TO MARKET OUR CLINICAL DIAGNOSTIC PRODUCTS, WHICH IS OFTEN COSTLY AND TIME CONSUMING, AND IF WE DO NOT OBTAIN THE NECESSARY APPROVAL OUR BUSINESS PROSPECTS WOULD SUFFER.

The FDA regulates many areas in which we conduct research and in which we develop, produce and market products. In particular, we must obtain FDA approval before we can market clinical diagnostic products such as those we are currently developing for the patient care market. The approval process is often costly and time consuming. In addition, we cannot assure you that we will be successful in obtaining FDA approval for any of our clinical diagnostic products, which would materially adversely affect our future prospects.

In order to obtain FDA approval in the United States, we, or the companies with whom we work, will need to either obtain pre-market application approval or pre-market notification clearance from the FDA. In order to obtain pre-market notification clearance, we must submit data from clinical trials demonstrating that new clinical diagnostic systems are substantially equivalent to diagnostic

systems that the FDA has already approved. If a product is subject to the substantial equivalence requirement, neither we, nor any of our licensees can sell that system for clinical use in the United States until the FDA determines that a new ORIGEN-based system is substantially equivalent to a previously approved system. Typically, the FDA review process takes 90 days, but the FDA's review could take longer. In addition, we cannot be sure that we will be able to demonstrate substantial equivalence for future diagnostic systems.

If we do not successfully demonstrate substantial equivalence, or if we are required to obtain pre-market application approval as an initial matter, we will

have to conduct extensive clinical testing of these products, which could take years to complete. Extensive testing could involve substantial additional costs and might delay bringing clinical diagnostic products to market, weakening our competitive position. If we fail to obtain FDA approval for new products altogether, we will be unable to market our ORIGEN-based systems at all for clinical use in the United States.

WE ARE SUBJECT TO EXTENSIVE, ONGOING GOVERNMENT REGULATION, WHICH MAY INVOLVE SIGNIFICANT COSTS AND MAY RESTRICT OUR ABILITY TO CONDUCT BUSINESS.

We expect that we may need to spend a substantial amount of money to comply on an ongoing basis with the regulations of the FDA and other government agencies. Government agencies, such as the FDA and the Environmental Protection Agency, regulate manufacturers of diagnostic products and the manufacturing process itself. The costs of complying with governmental regulations and any restrictions that government agencies might impose could have a significant impact on our business. As we increase our manufacturing, these costs will increase.

Whether we manufacture products ourselves or contract with another company to manufacture products based on our technology, the FDA will continually review and periodically inspect the manufacturing process. If the FDA were to discover a problem with our products, the manufacturing process or the manufacturing facility, the FDA could place restrictions on these products and on the manufacturer. For example, the FDA could require us to recall, or even totally withdraw, a product from the market or close a manufacturing facility. In addition to FDA regulations, the process of manufacturing products is subject to a variety of environmental and safety laws and regulations, including laws and regulations governing the use and disposal of hazardous materials. If we fail to comply with these laws or regulations, our business and financial condition could be materially adversely affected.

WE HAVE LIMITED MANUFACTURING AND MARKETING EXPERIENCE, WHICH PUTS US AT A COMPETITIVE DISADVANTAGE.

We lack experience in large-scale manufacturing, which could hamper our ability to manufacture existing products or new products that we develop. We have two options to address this issue. First, we could expand our internal ability to manufacture products. Second, we could contract with a third party to manufacture for us products based on our technology. If, however, we are unable to expand our own manufacturing capability or find a suitable manufacturer on

acceptable terms we may be unable to meet demand for existing products and could be delayed in introducing new products to the market. Failure to meet demand for existing products or delays in introducing new products could put us at a competitive disadvantage and could harm our financial condition or our business prospects.

We will also need to develop greater selling, marketing and distribution capabilities. To market clinical diagnostic products directly to customers, and not through a licensee, we need to develop a substantial sales force with technical expertise. We also need to establish a distribution system to support the sales force. Alternatively, we could license or contract with another company to provide sales and distribution services for products, in much the same way as we have done with Roche, Eisai and Organon Teknika. We cannot be sure, however, that we will be able to develop a sufficient sales and distribution force or that we will be able to find a suitable company to fill that role for us.

THE SUCCESS OF OUR BUSINESS DEPENDS ON PATENTS THAT WILL EXPIRE AND THAT MUST BE ACTIVELY PURSUED AND PROTECTED.

Our business depends heavily on patents that will expire over time and may be challenged or circumvented by competitors. Patents allow us to prevent others, for a time, from using our inventions to compete against us. Our business success or failure will depend, in part, on our ability to obtain and maintain adequate patent protection for the ORIGEN technology. We cannot be certain that current patents or future patents will adequately protect our technology from being used by our competitors.

Because there is no consistent policy governing the scope of claims in medical patents, patent protection is uncertain. Companies may, for example, challenge and invalidate patents or circumvent valid claims in patents, all of which could make it necessary for us to defend our patents in litigation. Litigation over patents poses the following risks to our business:

- Litigation costs can be extremely high, which could drain our financial resources.

- Litigation over our patents could discourage other companies from working with us to develop and market new products based on technology covered by these disputed patents.

- If we lose some patent protection as a result of litigation, our competitive advantage could be eroded.

OUR BUSINESS WOULD BE HARMED IF WE VIOLATE THE PATENT RIGHTS OF OTHERS.

Our business success or failure will also depend, in part, on the patent rights of others. We license technology from other companies and academic institutions. Because access to this technology is necessary to our business, we must be certain that we comply with these license agreements. Our business could be harmed if we breached any of these license agreements and lost the rights to use this patented technology or if we were unable to renew existing licenses on acceptable terms or get additional licenses that we may need on acceptable terms.

We must also make sure that we do not infringe the patent rights of others. If we were to infringe others' patent rights we could be exposed to the following risks:

- We could be required to alter, or abandon, our products or processes.

- We could be required to obtain a license from the patent holder.

- We could lose customers that are reluctant to continue using our products or doing business with us.

- We could be forced to abandon development work that we had begun with respect to these products.

- We could be required to pay damages that could be substantial.

We cannot be sure that we would be able to alter products or processes or that we could obtain a license at a reasonable cost, if at all. Our business could be damaged if we were unable to make necessary alterations or obtain a

necessary license on acceptable terms.

In addition, we may need to litigate the scope and validity of patents held by others and such litigation could be a substantial cost for us.

WE RELY ON TRADE SECRETS AND OTHER INFORMATION THAT CANNOT BE PROTECTED BY PATENTS, AND WE FACE RISKS THAT THIS INFORMATION WILL BE DISCLOSED TO OTHERS.

In addition to patents, we also rely in our business on trade secrets, know-how and other proprietary information. If this information were disclosed to competitors, our business would suffer. We seek to protect this information, in part, by entering into confidentiality agreements with licensees, employees and consultants, which prohibit these parties from disclosing our confidential information. Despite our entering into these agreements, we cannot be sure that the agreements will provide adequate protection for our trade secrets, know-how and other proprietary information or that the information we share with others during the course of our business will remain confidential. We also cannot be certain that we would have sufficient legal remedies to correct or compensate for unauthorized disclosures or sufficient resources to seek redress.

RESTRICTIONS ON HEALTH CARE COSTS AND HEALTH CARE AND INSURANCE FINANCING PRACTICES COULD LIMIT DEMAND FOR OUR PRODUCTS.

In the United States and elsewhere, demand for clinical diagnostic testing is dependent, in part, on consumers' ability to be reimbursed for the cost of the tests by third-party payors, such as government agencies, health maintenance organizations and private insurers. Medicaid and other third-party payors are increasingly challenging the prices charged for medical services, including clinical diagnostic tests. They are also attempting to contain costs by limiting

their coverage of, and the amount they will reimburse for, clinical diagnostic tests and other health care products. We cannot be certain that insurers will provide coverage for clinical diagnostic tests in the future. Without adequate coverage and reimbursement, consumer demand for clinical diagnostic tests may decrease. Decreased demand would likely cause sales of our clinical diagnostic products, and sales by our licensees, to fall since fewer tests would be performed or prices would be lowered, or both. Reduced sales or royalty income would hurt our business and our business prospects.

In many foreign markets, governments directly set the prices that clinical diagnostic companies may charge for their products and services. In the United States, a number of legislative and regulatory proposals aimed at changing the health care system have been proposed in recent years. We cannot predict whether these proposals will be adopted or the effect that these proposals or managed care efforts may have.

WE ARE EXPOSED TO PRODUCT LIABILITY RISKS.

We may not be able to adequately insure against risk of product liability. As we begin marketing products, we may face product liability for claims and lawsuits brought by customers. Damages awarded in product liability cases can be very large. While we have product liability insurance, this coverage is limited. We cannot assure you that our current product liability insurance would be adequate to cover us against our potential liabilities or that we will be able to maintain current levels of product liability insurance on acceptable terms, if at all. Claims or losses in excess of our current or future product liability insurance coverage could have a material adverse effect on our financial condition.

MANAGEMENT EXERCISES SIGNIFICANT CONTROL OVER IGEN.

Our management has significant control over IGEN through its stock ownership. Our officers and directors own, or have the right to purchase, about 30% of Common Stock and our Chief Executive Officer owns approximately 23% of Common Stock at September 30, 2001. Our officers and directors have significant influence over the election of directors and other stockholders actions.

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We have grown rapidly and expect to continue to grow by hiring new employees in all areas of our operations, increasing our presence in existing markets and introducing new products we develop into new potential high-growth markets. Our growth has placed, and continues to place, a strain on our management and our operating and financial systems.

As we grow, our personnel, systems, manufacturing capabilities and resources, procedures and controls may be inadequate to support future operations. In order to accommodate the increased operations for sales and marketing, research and development, facilities and administration, we will need to hire, train and retain the appropriate personnel. We may also need to improve

our financial and management controls, reporting systems and operating systems. We may encounter difficulties in developing and implementing other new systems.

In response to our growth, we have recently implemented a new enterprise resource planning system in order to automate all of our accounting, manufacturing, sales and purchasing. If the enterprise resource planning system fails to operate as we expect or experiences delays or interruptions, our operations, as well as our ability to manage our increased growth, could be materially adversely affected.

PROVISIONS OF OUR GOVERNING DOCUMENTS MAY DETER OTHERS FROM ATTEMPTING TO ACQUIRE US.

Our governing documents contain provisions designed to prevent hostile takeovers, which may limit the ability of stockholders to sell their stock at a premium in a takeover. According to our governing documents, stockholders can only act at annual meetings or at special meetings of stockholders. Stockholders are not allowed to act by written consent. In addition, stockholders are not allowed to call for a special meeting. Only our board of directors, the chairman of the board or the president may call a special meeting. These provisions may make it difficult for stockholders to force us to hold special meetings. These provisions may also limit the ability of stockholders to consider transactions that they may want to approve, such as a hostile takeover of us.

Our governing documents also contain other provisions that could make it more difficult for a change in control to be effected. Our board of directors can issue preferred stock and can determine the rights of those preferred stockholders without the approval of holders of Common Stock. For example, our board of directors could give preferred stockholders one or more votes on issues on which holders of Common Stock vote. This could have the effect of diluting the voting rights of holders of Common Stock, which might further discourage other companies from trying to acquire us.

In addition, our certificate of incorporation contains provisions dividing our board of directors into three classes. Each class serves until the third succeeding annual meeting, and one class is elected at each annual meeting of stockholders. As a result, even if our stockholders might prefer to effect a

change sooner, it could take at least two annual meetings of stockholders to change a majority of the members of the board of directors.

Furthermore, our certificate of incorporation authorizes, and we have adopted, a preferred share purchase rights plan, commonly referred to as a "poison pill." Under the rights plan, we made a dividend distribution to the stockholders of record on November 6, 1996 of one right to purchase from us one one-hundredth of a share of our preferred stock for each outstanding share of Common Stock. The terms of the rights and the circumstances under which they may be exercised are contained in a rights agreement, which has been filed with the SEC.

These terms have been designed to deter hostile takeovers of us, even though our stockholders might favor a takeover, especially if it were to afford them an opportunity to sell their stock at a price above the prevailing market rate.

OUR STOCK PRICE IS VOLATILE AND COULD DROP PRECIPITOUSLY AND UNEXPECTEDLY.

Our Common Stock currently trades on The Nasdaq National Market. The prices of publicly traded stock often fluctuate. The price of our stock may rise or fall dramatically, even though our business performance has not changed. In the past, the stock price of technology companies has been especially volatile. We expect that this will continue to be the case.

In addition to these fluctuations, an investment in our stock could be affected by a wide variety of factors that relate to our business and industry, many of which are outside of our control. For example, the value of Common Stock could be affected by:

- new product introductions;
- innovations by competitors;
- our competitors' announcements of their financial results;
- the failure of our operating results to meet or exceed the expectations of investors and analysts;
- changes in financial estimates and recommendations by security analysts;
- general economic conditions;
- disputes over patents or other proprietary rights;
- new or existing litigation, including our litigation with Roche;
- publicity;
- regulations;
- market conditions; and
- fluctuations in our performance and the performances of our licensees.

WE DO NOT PLAN TO PAY ANY CASH DIVIDENDS ON OUR COMMON STOCK.

We have never paid cash dividends on Common Stock. We have no plans to pay cash dividends in the foreseeable future.

THE VALUE OF THE COMMON STOCK MAY BE DILUTED IN THE FUTURE.

Our officers, directors, employees and consultants have options to purchase a significant aggregate amount of Common Stock. If they exercise their options and purchase Common Stock, Common Stock will be diluted. In addition, we currently have preferred stockholders and convertible debenture holders who have the right to convert their preferred shares and debentures, as the case may be, to Common Stock. Common Stock would be diluted if these preferred stockholders or convertible debenture holders decide to convert their securities in the future. Moreover, Common Stock could be further diluted if we issue additional Common Stock or securities convertible into Common Stock in the future, which we may need to do to raise funds for our business. Sales of additional shares of Common Stock or the conversion of securities into Common Stock could cause the market price of Common Stock to decrease.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus supplement and the accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a Registration Statement on Form S-3 under the Securities Act of 1933 with the SEC with respect to the Common Stock being offered pursuant to this prospectus supplement and the accompanying prospectus. This prospectus supplement omits certain information contained in the Registration Statement, as permitted by the SEC. You should refer to the Registration Statement, including the exhibits, for further information about us and the Common Stock being offered pursuant to this prospectus supplement. Statements in this prospectus supplement regarding the provisions of certain documents filed with, or incorporated by reference in, the Registration Statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the Registration Statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until we sell all of our shares of Common Stock covered by the registration statement. The documents we are incorporating by reference are:

- Annual Report on Form 10-K for the year ended March 31, 2001;
- Quarterly Reports on Form 10-Q for the quarters ended June 30, and September 30, 2001;
- Proxy Statement filed July 30, 2001;
- Supplement filed September 5, 2001 to the Proxy Statement filed July 30, 2001;
- Current Report on Form 8-K, dated August 15, 2001;

- Amendment No. 1 to the Current Report on Form 8-K, dated August 15, 2001;

- Current Report on Form 8-K, dated December 7, 2001;

- Current Report on Form 8-K, dated January 10, 2002; and

- The description of Common Stock contained in our Registration Statement on Form 8-A filed with the SEC on December 10, 1996 including any amendments or reports filed for the purpose of updating such description.

Upon request, we will provide without charge to each person to whom a copy of this prospectus has been delivered a copy of any information that was incorporated by reference in the prospectus (other than exhibits to documents, unless the exhibits are specifically incorporated by reference into the prospectus). We will also provide upon request, without charge to each person to whom a copy of this prospectus has been delivered, a copy of all documents filed by us from time to time with the SEC pursuant to the Securities Exchange Act of 1934. Requests for copies should be directed to:

IGEN International, Inc.
16020 Industrial Drive
Gaithersburg, MD 20877
Attention: George Migausky, Chief Financial Officer
Telephone: (301) 869-9800

GENERAL

You should rely only on the information provided or incorporated by reference in this prospectus supplement and the prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date on the front of these documents.

NEITHER THE SECURITIES EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS OR PROSPECTUS SUPPLEMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

THE DATE OF THIS PROSPECTUS SUPPLEMENT IS FEBRUARY 7, 2002