ANTARES PHARMA INC Form 10-K/A September 19, 2002

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

| FORM 10-K/A   |  |
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| [X] ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 15 FOR THE FISCAL YEAR ENDED DECEMBER 35   | 934  |
| [ ] TRANSITION REPORT PURSUANT TO SECTION 1:  THE SECURITIES EXCHANGE ACT OF 1:  For transition period from to  | 934  |
| Commission file number 0-20945  |  |
| ANTARES PHARMA, INC.  |  |
| (Exact name of registrant as specified in :   | its charter)                                     |
| Minnesota   | 41-1350192                                       |
|   | (I.R.S.Identification<br>Number)                 |
| 707 Eagle View Blvd, Suite 414, Exton,  | PA 19341   |
| (Address of principal executive offices)  | (Zip Code)                                       |
| Registrant's telephone number, including area code:   | (610) 458-6200<br>                               |
| SECURITIES REGISTERED PURSUANT TO SECTION 12 (b)  | ) OF THE ACT: None                               |
| SECURITIES REGISTERED PURSUANT TO SECTION 12  Common Stock, \$.01 Par Value   | (g) OF THE ACT:                                  |
| Indicate by check mark whether the registrant (1) has a to be filed by Section 13 or 15(d) of the Securities Exthe preceding 12 months (or for such shorter period the required to file such reports) and (2) has been subject requirements for the past 30 days. | xchange Act of 1934 during at the registrant was |

requirements for the past 90 days.

YES X NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ X ]

Aggregate market value of the voting stock held by nonaffiliates of the registrant as of March 31, 2002, was approximately \$12,981,501\$ (based upon the last reported sale price of \$3.90 per share on March 28, 2002, on the Nasdaq Small Cap Market).

There were 9,161,188 shares of common stock outstanding as of March 31, 2002.

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PART I

Item 1. BUSINESS

General

On January 31, 2001, Antares Pharma, Inc. ("Antares" or the "Company") (formerly known as Medi-Ject Corporation) completed a business combination to acquire the three operating subsidiaries of Permatec Holding AG ("Permatec"), headquartered in Basel, Switzerland. Upon consummation of the transaction, the acquired Permatec subsidiaries were renamed Antares Pharma AG, Antares Pharma IPL AG and Antares Pharma NV. Prior to the closing of the business combination, we did not have sufficient funds to continue our operations, and we had determined that it was necessary to, among other things, either raise more capital or merge with another biopharmaceutical company. Medi-Ject was a company focused on delivery of drugs across the skin using needle free technology, and Permatec specialized in delivery of drugs across the skin using transdermal patch and gel technologies. Given that both groups were focused on delivery of drugs across the skin, but with a focus on different sectors, we believed that a business combination would be attractive to both pharmaceutical partners and to our shareholders. The transaction was accounted for as a reverse acquisition, as Permatec's shareholders initially held approximately 67% of the outstanding stock of Antares. Accordingly, for accounting purposes, Permatec is deemed to have acquired Antares. Upon completion of the transaction we changed our name from Medi-Jet Corporation to Antares Pharma, Inc. The following discussion of our business incorporates the business combination with Permatec.

The U.S. operation develops, manufactures and markets novel medical devices, called jet injectors, that allow people to self-inject drugs without using a needle. The Company makes a small spring-action device and the attached disposable plastic syringes to hold the drug. A liquid drug is drawn up into the syringe through a small hole at the end. When the syringe is held against the body and the spring is released, a piston drives the fluid stream into the tissues beneath the skin. A person may re-arm the device and repeat the process or attach a new sterile syringe between injections. Recently the Company has developed variations of the jet injector by adding a very small hidden needle to a pre-filled, single-use injector as well as a needle free pre-filled, single-use injector.

With the Permatec business combination, Antares is also committed to other methods of drug delivery such as topical gel formulations. Transdermal gels have advantages in cost, cosmetic elegance, ease of application and lack of irritancy compared with better-known transdermal patches and have applications in such therapeutic markets as osteoporosis therapy, cardiovascular therapy, pain management and central nervous system therapy. This drug delivery method will become a material part of the business moving forward.

From inception as a combined business entity, the Company had fifty-three employees with thirty-five research and development personnel, engineers, formulation chemists and technicians, engaged in designing and formulating new products for the pharmaceutical industry. We now have fifty-five full-time and 6 part-time employees.

The Company was a pioneer in the invention of home needle-free injection systems in the late 1970s. Earlier needle-free injection systems were powered by

large air compressors, so their use was limited to vaccinations by the military or school health programs. Early injectors were painful in comparison to today's injectors, and their large size made home use difficult. The first home insulin injector was five times as heavy as the current injector, which weighs five ounces. Today's insulin injector sells at a retail price of \$299 compared to \$799 eight years ago. The first growth hormone injector was introduced in Europe in 1994. This was the first success in achieving distribution through a license to a pharmaceutical manufacturer, and it has resulted in significant market penetration and a very high degree of customer satisfaction. Distribution of growth hormone injectors has expanded to include Japan and other Asian countries.

The Swiss operation developed its first topical products in Argentina in the mid-1990s. This effort resulted in the commercialization of a seven-day estradiol patch in South America in 2000. Over time, the Argentine research effort moved away from the crowded transdermal patch field and focused on topical gel formulations, which allow the delivery of estrogens, progestogens, testosterone and other drugs in a gel base without the need for an occlusive or irritating adhesive bandage. The commercial potential for topical gel therapies is attractive, and several agreements with pharmaceutical companies have led to the early and successful clinical evaluation of Antares' formulations. The Argentine operations were moved to Basel, Switzerland in late 1999.

The Company operates in the specialized drug delivery sector of the pharmaceutical industry. Companies in this sector generally bring technology and know-how in the area of drug formulation and/or delivery devices to pharmaceutical manufacturers through licensing and development agreements. The Company views the pharmaceutical manufacturer as its customer. The Company has negotiated and executed licensing relationships in the growth hormone segment (needle-free devices in Europe and Asia), the hormone replacement segment (transdermal delivery of estradiol

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in South America) and the topical hormone gels segment (several development programs in place worldwide). In addition, the Company continues to market needle-free devices for the home administration of insulin in the U.S. market while seeking a distribution relationship with an insulin manufacturer.

The Company is a Minnesota corporation incorporated in February 1979. Our corporate offices are located at 707 Eagleview Boulevard, Exton, Pennsylvania 19341; telephone (610) 458-6200. We have wholly-owned subsidiaries in Switzerland (Antares Pharma AG and Antares Pharma IPL AG) and the Netherlands Antilles (Antares Pharma NV).

Industry Trends

Based upon previous experience in the industry, the Company believes the following significant trends in healthcare have important implications for the growth of the business.

After a drug loses patent protection, the branded version of the drug often faces competition from generic alternatives. Often market share may be preserved by altering the delivery method, e.g., a single daily controlled release dosage form rather than four pills a day. The Company expects pharmaceutical manufacturers will continue to seek differentiating delivery characteristics to defend against generic competition. The altered delivery method may be an injection device or a novel formulation that offers convenience or improved dosage schedules.

The increasing trend of pharmaceutical companies marketing directly to consumers, as well as the recent focus on patient rights may encourage the use of innovative, user-friendly drug delivery. Part of this trend involves offering patients a wider choice of dosage forms. The Company believes the patient-friendly attributes of our topical gel and jet injection technologies meet these market needs.

The focus on new topical formulations complements our earlier experience with the new injection methods. The Company envisions our program with topical gel formulation as second-generation technology, replacing the older transdermal patch products with more patient-friendly products. Topical gels will offer the patient more choices and added convenience with no compromise of efficacy. Although newer, the gel technology is based upon so-called GRAS ("Generally Recognized as Safe") substances, meaning the toxicology profiles of the ingredients are known and widely used. This approach has a major regulatory benefit and may reduce the cost and time of product development.

Many drugs, including selected hormones and protein biopharmaceuticals, are destroyed in the gastrointestinal tract and may only be administered through the skin, the lung or by injection. Pulmonary delivery is complex and only in the early stages of commercialization, and injection remains the mainstay of protein delivery. Therefore, the growing number of protein biopharmaceuticals requiring injection may compromise patient compliance with treatment programs. The failure to take all prescribed injections can lead to increased health complications for the patient, decreased drug sales for pharmaceutical companies and increased healthcare costs for our society. In addition, conventional syringe needles require special and often costly disposal methods.

In addition to the increase in the number of drugs requiring self-injection, changes in the frequency of insulin injections for the treatment of diabetes also may contribute to an increase in the number of self-injections. For many years, standard treatment protocol was for insulin to be administered once or twice daily for the treatment of diabetes. However, according to recent studies, tightly controlling the disease by, among other things, administration of insulin as many as four to six times a day, can decrease its debilitating effects. The Company believes that as the benefits of tightly controlling diabetes become more widely known, the number of insulin injections self-administered by people with diabetes will increase. The need to increase the number of insulin injections given per day may also motivate diabetics to seek an alternative to traditional needles and syringes.

The importance of vaccines in industrialized and emerging nations is expanding as the prevalence of infectious diseases increases. New vaccines and improved routes of administration are the subject of intense research in the pharmaceutical industry. In the past, the Company had focused only upon the injection of medication in the home, but in 2000 the Company began to research the feasibility of using its devices for vaccines and new vaccine ingredients.

Due to the substantial costs involved, marketing efforts are not currently focused on drug applications administered by healthcare professionals. Jet injection systems, however, may be attractive to hospitals, doctors' offices and clinics, and such applications may be explored in the future. The issues raised by accidental needle sticks and disposal of used syringes have led to the development of syringes with sheathed needles as well as the practice of giving injections

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through intravenous tubing to reduce the number of contaminated needles. In 1998, the State of California banned the use of exposed needles in hospitals and

doctors' offices, and ten additional states have adopted similar legislation. The Company believes that needle-free injection systems may be attractive to healthcare professionals as a further means to reduce accidental needle sticks and the burdens of disposing of contaminated needles. Furthermore, certain drugs, particularly experimental DNA vaccines, may actually be more effective if delivered by jet injection.

Market Opportunity

According to industry sources, an estimated 9 to 12 billion needles and syringes are sold annually worldwide. The Company believes that a significant portion of these are used for the administration of drugs that could be delivered using our injectors, but that only a small percentage of people who self-administer drugs currently use jet injection systems.

Our focus is on the market for the delivery of self-administered injectable drugs. The largest and most mature segments of this market consist of the delivery of insulin for diabetics and human growth hormone for children with growth retardation. In the U.S., over 3.2 million people inject insulin for the treatment of diabetes, resulting in an estimated 2.3 billion injections annually, and we believe that the number of insulin injections will increase with time as the result of new diabetes management techniques which recommend more frequent injections. A second attractive market has developed with growth hormone; children suffering from growth retardation take daily hormone injections for an average of five years. The numbers of children with growth retardation are small relative to diabetes, but most children are exceptionally needle adverse. Our distributors in Europe, Japan and Asia have made significant inroads using our injectors in their markets. Other injectable drugs that are presently self-administered and may be suitable for injection with our systems include therapies for the prevention of blood clots and the treatment of multiple sclerosis, migraine headaches, impotence, hormone therapy, AIDS and hepatitis. We also believe that many injectable drugs currently under development will be administered by self-injection once they reach the market.

According to one industry publication, industry worldwide hormone replacement revenues, the initial focus of our transdermal patch and topical gel formulation program, are expected to grow to \$4.0 billion by 2002. As of 1998, only 15% of these sales were composed of transdermal delivery systems in the U.S. However, the Company believes that the industry is shifting away from oral systems, as evidenced in Europe, more specifically France, the leading country in the usage of transdermal hormone replacement therapy. According to an industry report, 64.8% of treated menopausal women in France used either patch (44.7%) or gel (20.1%) therapy. In the future, products may be formulated to address equally large opportunities in other sectors of the pharmaceutical industry, including cardiovascular, osteoporosis, addiction and central nervous system therapies.

Products and Technology

Current Needle-Free Injection Systems

The Medi-Jector Vision(R), a smaller, easier to use insulin injector, was introduced in October 1999, replacing the Medi-Jector Choice(R). The Vision replaced the Choice in the U.S. insulin market and will gradually replace the Choice in international growth hormone markets. Each injector model is operated by first compressing a coil spring mechanism and then filling the attached disposable plastic syringe from a multi-use medication vial. The proper dosage is displayed in the dosage window. An injection is given by holding the injector perpendicular to the skin in a location appropriate for the injection and pressing the trigger button. Each injector is recommended to be used for 2 years, and the needle-free plastic syringes are recommended for a one-week usage. The U.S. retail price of the Vision insulin device (excluding the

needle-free syringe) is \$299. The total annual cost to the end user of needle-free syringes and related supplies is approximately \$250 per year (based upon an average of two injections per day). Based in part upon the results of marketing and clinical studies performed by us, the Company believes that injections using an Antares injection system are considered more comfortable and more discreet than injections using a conventional needle and syringe. The needle-free syringes used with any of the injector systems do not require special disposal. Once a needle-free syringe is removed from the device portion of the system, it cannot pierce the skin; consequently, the risk of cross-infection from discarded needle-free syringes is reduced significantly from the risk associated with needles.

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#### New Device Development

The Company is currently developing three new injector platforms. One platform, code named the MJ-8, represents a new concept in needle-free delivery, incorporating a smaller power pack with a self-contained medicinal cartridge. This device has been designed to compete with cartridge-based pen-like devices, which use replaceable needles, common in the European insulin market and rapidly replacing conventional syringes in the U.S. insulin market. A second platform, referred to as the AJ-1, combines a very low energy power source with a small hidden needle to offer a totally disposable, single injection system best suited for high volume doses or medications that require infrequent injections. A modification of this device is being developed to deliver vaccines to the very superficial layers of skin, a popular direction of vaccine research. A third platform, referred to as the MJ-10, is a needle-free version of the disposable pre-filled injector. This diverse development program will offer pharmaceutical manufacturers a broad and attractive array of delivery choices while providing consumers with less expensive and more user-friendly injectors.

MJ-8 Injector. The major obstacle to widespread market acceptance of needle-free injection systems has been the lack of a suitably compact and easy-to-use injector. Although the size and complexity of injectors has been reduced over the years, further reduction in size is possible by limiting delivery of a single dose to 0.25ml or less. To this end, we have targeted the insulin market where most people in Europe and a growing number in the U.S. take four injections daily of 0.10ml to 0.15ml. Smaller doses require less energy and smaller energy sources. The space conserved by reducing the energy source is used to store a vial cartridge within the device, adding further user convenience. Prototypes of this platform were tested in clinical trials during the fourth quarter of 2001.

AJ-1 Injector. The coil springs of the commercial needle-free injectors limit injection volume to 0.5ml; larger fluid volumes require larger springs and are therefore impractical. Nevertheless, injection volumes of 1.0ml or more are not uncommon. In 1998, our engineers found that they could greatly reduce the size of the coil spring by adding a very short, hidden needle (mini-needle). They concluded that breaking the very outer layers of the skin with a small needle allows very low energy jet injection. At lower energies, the devices could hold the drug in small, standard, single dose glass cartridges. The Company built and successfully tested a small, pre-filled, totally disposable mini-needle injector during 1999, and we have continued to refine this platform for the needs of interested pharmaceutical companies. Engineers with Elan Corporation plc ("Elan"), a drug delivery company based in Ireland, developed additional proprietary technologies that complement the AJ-1 design, and in November 1998, the Company licensed the Elan technology for certain applications.

MJ-10 Injector. Several needle-free injection companies and pharmaceutical manufacturers are pursuing needle-free versions of the AJ-1 device with only limited success. Our engineers believe that they have identified unique opportunities in this field, and we are proceeding with product development in this area.

The Company expended approximately \$1,647,000, \$939,000 and \$3,556,000 on research and development efforts during fiscal years 1999, 2000 and 2001, respectively. Of these amounts, approximately \$1,352,000, \$560,000 and \$729,000, respectively, were funded by third-party sponsored development programs and licensing fees, which were reflected in revenues.

### Current Transdermal Patch Technology

The Company markets a seven-day estradiol patch for hormone replacement therapy in Brazil and Chile. Patches are small adhesive structures applied to the skin. The patch allows for the diffusion of one or more active compounds through the skin during an extended period of time. These patches are based upon the second generation of technology known as matrix patches where the active material is dispersed in the adhesive polymer. The seven-day estradiol patches are manufactured by contract in Germany. The Company commenced sales of the seven-day estradiol patches in the fourth quarter of 2000.

#### New Formulation Products

Antares Combi Gel(TM) product containing estradiol and norethindrone acetate ("NETA") was licensed to Solvay in Europe in 1999 and has progressed successfully through Phase II clinical evaluation. Phase III studies are scheduled to commence in 2002. In 2000, the Company signed an exclusive agreement with BioSante, an early stage U.S. pharmaceutical company, and began clinical studies of four Combi Gel(TM) hormone formulations for commercialization in the U.S. and other countries.

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#### Patents

When appropriate, the Company actively seeks protection for its products and proprietary information by means of U.S. and international patents and trademarks. With the injection device technology, we currently hold 24 patents and have an additional 40 applications pending in the U.S. and other countries. With the Company's drug formulation technology we hold 34 patents and an additional 39 applications, in various countries, are pending. The patents have expiration dates ranging from 2002 to 2019.

Some of the Company's technology is developed on its behalf by independent outside contractors. To protect the rights of its proprietary know-how and technology, our policy requires all employees and consultants with access to proprietary information to execute confidentiality agreements prohibiting the disclosure of confidential information to anyone outside the Company. These agreements also require disclosure and assignment to the Company of discoveries and inventions made by such individuals while devoted to Company-sponsored activities. Companies with which we have entered into development agreements have the right to certain technology developed in connection with such agreements.

#### Manufacturing

The Company operates a U.S. device manufacturing facility in compliance with current Quality System Regulations ("QSR") established by the Food and Drug

Administration ("FDA") and by the centralized European regulatory authority (ISO 9001 and EN 46001). Injector and disposable parts are manufactured by third-party suppliers and assembled at the facility in Minneapolis, Minnesota. Quality control and final packaging are performed on-site. The Company may need to invest in automated assembly equipment if volume increases in the future. The Company is obligated to allow Becton Dickinson to bid on manufacturing our disposable plastic components of certain injector systems. The Company is obligated to negotiate with Becton Dickinson before any other company for exclusive rights to manufacture our disposable plastic components of certain injector systems. If the Company and Becton Dickinson are unable to agree on the terms and conditions of an agreement, the Company is free to negotiate with any third party on terms no more favorable in the aggregate than those that were offered to Becton Dickinson. The Company pays Becton Dickinson royalties on sales of plastic components of certain injector systems.

The Company's transdermal estradiol patches are manufactured in Germany through a contract arrangement. The Combi Gel(TM) formulations for clinical studies are currently manufactured by contract under our supervision. The Company has approximately 3,000 square feet of undeveloped space reserved in its Basel facility for pilot manufacturing of gel products.

#### Marketing

The Company's basic business strategy is to develop and manufacture new products specific to certain pharmaceutical applications and to market through the existing distribution systems of pharmaceutical and medical device companies.

During 2001, our international revenue accounted for 62% of our total revenue. Europe (primarily Germany) accounted for 85% of international revenue with the remainder coming primarily from Asia. The following three customers accounted for 71% of the Company's worldwide revenue in 2001: Ferring Pharmaceutical NV (38%), BioSante Pharmaceuticals, Inc. (28%) and Solvay Pharmaceuticals B.V. (5%). Revenue from Ferring resulted from sales of injection devices and related disposable components. Revenue from BioSante and Solvay resulted from license fees, milestone payments and clinical testing supplies for hormone replacement therapy transdermal gel formulations.

## Injection Devices

The Company markets needle-free injectors for insulin and growth hormone delivery through pharmaceutical companies and medical products distributors in over 20 countries. Device and related disposable product sales in 2001 were approximately \$1.8 million. Historical product development alliances, from which licensing and development fees were obtained, include those with Becton Dickinson and Company, Schering-Plough Corporation and the Organon division of Akzo Nobel.

With respect to current injection device selling efforts, our relationship with Ferring GmbH best reflects this basic strategy. Ferring is selling human growth hormone throughout Europe with a marketing campaign tied exclusively to the Medi-Ject needle-free delivery system. Ferring has been successful in establishing a user base of more than 1,000 children for its drug using the Medi-Ject needle-free system. In the Netherlands, where Ferring enjoys its largest market share, 22% of children taking growth hormone use our injector. During the past five years, a Japanese pharmaceutical company, JCR, has distributed small numbers of growth hormone injectors to hospital-based physicians. In 1999, SciGen Pte Ltd. began distribution in Asia of our growth hormone injectors along with their drug.

The table below summarizes our current collaborative and distribution agreements in the injection device sector.

| Company                            | Market   |
|------------------------------------|--|
| Eli Lilly Company                  | Feasibility and option agreem several products         |
| Pharmacia                          | AJ1 Evaluation<br>(worldwide)                          |
| Organon, a division of Akzo Nobel  | Undisclosed Development Pro                            |
| Becton Dickinson and Company(1)    | Manufacturing - All Applicat<br>(worldwide)            |
| Ferring Pharmaceuticals NV         | Growth Hormone<br>(Europe)                             |
| JCR Pharmaceuticals Co., Ltd       | Growth Hormone<br>(Japan)                              |
| SciGen Pte Ltd.                    | Growth Hormone<br>(Asia/Pacific)                       |
| Bio-Technology General Corporation | Growth Hormone<br>(United States)                      |
| drugstore.com                      | Insulin -E-Commerce<br>(United States)                 |
| Direct Trading International       | Insulin - Distribution<br>(Czech Republic)             |
| Comar Cardio Technology srl        | Insulin - Distribution<br>(Italy)                      |
| McKesson Corporation               | Insulin - Distribution<br>(United States)              |
| Care Service (Diabetic Express)    | Insulin - Distribution - E-C<br>(United States/Canada) |

(1) Becton Dickinson has certain manufacturing bid rights to our disposable needle-free syringes.

Feasibility studies are those in which the Company's collaborative partner is assessing the potential value of the Company's technology with a specific product or products. Such studies often include a small fee to the Company, and the subjects of the studies are often kept confidential for competitive reasons (as with the Eli Lilly and Company agreement). Generally, any costs incurred in a feasibility study are borne by the Company's partner. The Company's current feasibility studies have not provided the Company with substantial revenue. The goal upon successful completion of a feasibility study is to move to a full

licensing agreement with the partner. All of the registrant's feasibility studies remain in process and have not yet progressed to the licensing agreement stage.

Distribution agreements are arrangements under which the Company's products are supplied to end-users through the distributor. The Company provides the distributor with injection devices, and the distributor often receives a margin on sales. The Company currently has five distribution agreements under which the distributors sell the Company's injector devices and related components for use with insulin. To date, the revenue received from these agreements has been immaterial.

Under the Company's growth hormone agreements, the Company sells its injection devices to partners who manufacture and/or market human growth hormone directly. The partner then markets the Company's devices with its human growth hormone. The Company receives benefit from these agreements in the form of manufacturing margins and royalties on end-sales of the Company's products.

Under the Company's December 1993 agreement with Ferring, the Company granted Ferring exclusive rights to use and market, throughout Europe and the former Soviet Union, the Company's injector device for use with the administration of human growth hormone. The Company also agreed to supply Ferring with all of its requirements of injector devices. Under the agreement, Ferring was required to pay the Company upon the occurrence of certain events, such as completion of certain clinical studies and receipt of regulatory approvals. All such payments have been received by the Company, and currently, the Company receives payment from Ferring for the supplied injectors. Unless Ferring exercises its option to renew the agreement for two-year periods, the agreement will terminate ten years following Ferring's receipt of technical and regulatory approvals to market the Company's injector devices in France, Germany, Italy and Spain. The Company expects the last of such approvals to be received by the end of 2002. In 2001, revenue from Ferring accounted for 48% of the Company's product sales. Revenue from the remaining three growth hormone agreements accounted for less than 3% of product sales in 2001.

Over the past year, the Company has taken several steps to increase its U.S. insulin injector distribution while lowering the associated expense. The Company has succeeded in lowering expenses, but with no material increase in sales volumes. In February 1999, the Company established an E-commerce distribution channel that allows purchase of its products through the Internet, and in October 1999, the Company began E-commerce distribution with drugstore.com, a leading Internet pharmacy. The effort to market through the Internet has proven unsatisfactory. In April 1999, the FDA granted permission to sell our insulin injectors without requiring a prescription. In February 2000, the Company transferred responsibility for the majority of our direct sales to the Home Service Medical division of Chronimed, and more recently, in March 2001, the Company again transferred U.S. distribution to Diabetic Express, a division of Care Services, Inc. Antares has concluded that the successful distribution of insulin devices will require additional physician support and the marketing power of a major insulin manufacturer. However, our current effort will continue because our devices provide a vital service to the needle-phobic diabetic and provide the Company with considerable information regarding the needs of people required to self-administer drugs by injection.

### Topical Delivery Products

Currently the Company markets the transdermal estradiol patch in Brazil and Chile. Market introduction was recent but we estimate that the markets for our products will remain small because of intense competition in this field. Over the short term, the majority of revenues generated from topical drug formulation will be through the fees generated by licensing and development agreements.

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The following table describes existing pharmaceutical relationships in the topical delivery sector.

| Pharmaceutical Company Partner | Compound                                | Market Segment  |
|--------------------------------|---|---|
| Solvay                         | NETA/Estradiol                          | Hormone replacement therapy (Europe)                        |
| Segix                          | Estradiol                               | Hormone replacement therapy<br>(Italy)                      |
| Sigmapharma/Novaquimica        | Estradiol                               | Hormone replacement therapy<br>(Brazil)                     |
| Recalcine                      | Estradiol                               | Hormone replacement therapy (Chile)                         |
| BioSante                       | Progesterone/Estradiol/<br>Testosterone | Hormone replacement therapy (U.S., Canada, other countries) |
| SciTech                        | Estradiol/Testosterone                  | Hormone replacement therapy (Asia, Australia & Oceania)     |
| Pharmacia                      | Ibuprofen Gel                           | Pain<br>(Sweden)  |
|                                |   |   |

Currently, the only agreement in the above table under which the Company markets its topical delivery products is with Recalcine in Chile, for whom the Company supplies its transdermal estradiol patch product. This product has also been approved in Brazil, but has not yet been marketed there. The remaining agreements in the table are license agreements under which the Company's partners are conducting clinical evaluations of the Company's products. For competitive reasons, the Company's partners usually do not divulge the exact stage of clinical development. The two major agreements in the topical delivery sector are with Solvay Pharmaceuticals and BioSante Pharmaceuticals, Inc. Under the Company's June 1999 agreement with Solvay, the Company granted an exclusive license to Solvay for the Company's transdermal gel technology for delivery of an estradiol/progestin combination for hormone replacement therapy. The exclusive license applies to all countries and territories in the world, except for the United States, Canada, Japan and Korea. The agreement contains a development plan under which the Company and Solvay collaborate to bring the product to market. Solvay must pay the Company a license fee of \$5 million in four separate payments, all of which are due upon completion of various phases of the development plan. To date, the Company has received \$1.5 million of this fee. Once commercial sale of the product begins, Solvay is required to, on a quarterly basis, pay the Company a royalty based on a percentage of sales. The royalty payments will be required for a period of 15 years or when the last patent for the product expires, whichever is later.

In June 2000, the Company granted an exclusive license to BioSante to allow BioSante to develop and commercialize four of the Company's gel technology products for use in hormone replacement therapy in the United States, Canada and other countries. BioSante paid the Company \$1 million upon execution of the agreement and is also required to pay the Company royalty payments once commercial sales of the products have begun. The royalty payments are based on a percentage of sales of the products and must be paid for a period of 10 years following the first commercial sale of the products, or when the last patent for the products expires, whichever is later. The agreement also provides for milestone payments to the Company upon the occurrence of certain events.

#### Competition

Competition in the injectable drug delivery market is intensifying. The Company faces competition from traditional needle syringes, newer pen-like and sheathed needle syringes and other needle-free injection systems as well as alternative drug delivery methods including oral, transdermal and pulmonary delivery systems. Nevertheless, the vast majority of injections are currently administered using needles. Because injection is typically only used when other drug delivery methods are not feasible, the needle-free injection systems may be made obsolete by the development or introduction of drugs or drug delivery methods which do not require injection for the treatment of conditions the Company has currently targeted. In addition, because the Company intends to enter into collaborative arrangements with pharmaceutical companies, the Company's competitive position will depend upon the competitive position of the pharmaceutical company with which we collaborate for each drug application.

Three companies currently sell injectors to the U.S. insulin market. Antares believes that it retained the largest market share in 2001, and competes on the basis of device size, price and ease of use. In 1998, Bioject, Inc., the manufacturer of a needle-free vaccine injector, purchased the insulin injector business of Vitajet, and after some months of redesign, they entered the U.S. insulin injector market. Equidyne, Inc. entered the worldwide insulin injector market in mid-2000. Powderject Pharmaceuticals, plc, a British research company, is developing a needle-free injection system based upon the principle of injecting a fine dry powder, and Weston Medical Ltd., another U.K. based company, is developing a single-use needle-free system. Both Powderject and Weston Medical compete actively and successfully for licensing agreements with pharmaceutical manufacturers and have accumulated large cash resources.

The Company expects the needle-free injection market to expand, even though improvements continue to be made in needle syringes, including syringes with hidden needles and pen-like needle injectors. The Company expects to compete with existing needle injection methods as well as new delivery methods yet to be commercialized. For example, Inhale Therapeutic Systems, Inc., in partnership with Pfizer, Inc. and Aventis Pharmaceuticals, is completing Phase III clinical testing of inhaled insulin which, if successful, could replace the use of injection in some patients.

Competition in the formulation sector differs in that the market is considerably larger, more mature and dominated by much larger companies like ALZA Corporation and Elan Corporation plc. Other large competitors include SkyePharma plc and Alkermes, Inc. These companies have substantially greater capital resources, more experienced research teams, larger facilities and a broader range of products and technologies. Nevertheless, ALZA and Elan have focused in recent years on growth through the acquisition and sales of traditional pharmaceutical products.

### Government Regulation

Antares' products and manufacturing operations are subject to extensive government regulations, both in the United States and abroad. In the United

States, the Food & Drug Administration ("FDA") administers the Federal Food Drug

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and Cosmetic Act (the "FDC Act") and has adopted various regulations affecting our business, including those governing the introduction of new medical devices, the observation of certain standards and practices with respect to the manufacturing and labeling of medical devices, the maintenance of certain records and the reporting of device-related deaths, serious injuries and certain malfunctions to the FDA. Manufacturing facilities and certain company records are also subject to FDA inspections. The FDA has broad discretion in enforcing the FDC Act and the regulations thereunder, and noncompliance can result in a variety of regulatory steps ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal actions or penalties.

Drug delivery systems such as injectors may be approved or cleared for sale as a medical device or may be evaluated as part of the drug approval process in connection with a new drug application ("NDA") or a Product License Application ("PLA"). To the extent permitted under the FDC Act and current FDA policy, the Company intends to seek the required approvals and clearance for the use of our new injectors, as modified for use in specific drug applications under the medical device provisions, rather than under the new drug provisions, of the FDC Act.

Products regulated as medical devices may not be commercially distributed in the United States unless they have been cleared or approved by the FDA, unless otherwise exempted from the FDC Act and regulations thereunder. There are two methods for obtaining such clearance or approvals. Under Section 510(k) of the FDC Act ("510(k) notification"), certain products qualify for a pre-market notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish in the 510(k) notification that the product to be marketed is substantially equivalent to another legally marketed product (that is, that it has the same intended use and that it is as safe and effective as a legally marketed device and does not raise questions of safety and effectiveness that are different from those associated with the legally marketed device). Marketing may commence when the FDA issues a letter finding substantial equivalence to such a legally marketed device. The FDA may require, in connection with a 510(k) notification, that it be provided with animal and/or human test results. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a pre-market approval ("PMA") application under Section 515 of the FDC Act. A PMA must show that the device is safe and effective and is generally a much more complex submission than a  $510\,(k)$ notification, typically requiring more extensive pre-filing testing and a longer FDA review process. The Company believes that injection systems, when indicated for use with drugs or biologicals approved by the FDA, will be regulated as medical devices and are eligible for clearance through the  $510\,(k)$  notification process. There can be no assurance, however, that the FDA will not require a PMA in the future.

In addition to submission when a device is being introduced into the market for the first time, a  $510\,(k)$  notification is also required when the manufacturer makes a change or modification to a previously marketed device that could significantly affect safety or effectiveness, or where there is a major change or modification in the intended use or in the manufacture of the device. When any change or modification is made in a device or its intended use, the manufacturer is expected to make the initial determination as to whether the change or modification is of a kind that would necessitate the filing of a new  $510\,(k)$  notification. The FDA's regulations provide only limited guidance in making this determination. The Company has received  $510\,(k)$  marketing clearance

from the FDA to allow marketing of the Medi-Jector Choice and the Medi-Jector Vision systems. In the future we or our partners will submit  $510\,(k)$  notifications with regard to further device design improvements and uses with additional drug therapies.

If the FDA concludes that any or all of our new injectors must be handled under the new drug provisions of the FDC Act, substantially greater regulatory requirements and approval times will be imposed. Use of a modified new product with a previously unapproved new drug likely will be handled as part of the NDA for the new drug itself. Under these circumstances, the device component will be handled as a drug accessory and will be approved, if ever, only when the NDA itself is approved. Our injectors may be required to be approved as part of the drug delivery system under a supplemental NDA for use with previously approved drugs. Under these circumstances, our device could be used with the drug only if and when the supplemental NDA is approved for this purpose. It is possible that, for some or even all drugs, the FDA may take the position that a drug-specific approval must be obtained through a full NDA or supplemental NDA before the device may be labeled for use with that drug.

To the extent that our modified injectors are handled as drug accessories or part of a drug delivery system, rather than as medical devices, they are subject to all of the requirements that apply to new drugs. These include drug manufacturing requirements, drug adverse reaction reporting requirements, and all of the restrictions that apply to drug labeling and advertising. In general, the drug requirements under the FDC Act are more onerous than medical device

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requirements. These requirements could have a substantial adverse impact on our ability to commercialize our products and our operations.

In the European Union, a drug delivery device that is an integral combination with the drug to be delivered is considered part of the medicinal product and is regulated as a drug. Gels and transdermal patches are drug delivery devices which are, therefore, regulated as drugs and must comply with the requirements described in the Medicinal Products Directive 85/65/EEC.

The FDC Act also regulates our quality control and manufacturing procedures by requiring the Company and its contract manufacturers to demonstrate compliance with the current Quality System Regulations ("QSR"). The FDA's interpretation and enforcement of these requirements have been increasingly strict in recent years and seem likely to be even more stringent in the future. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA and by conducting periodic FDA inspections of manufacturing facilities. If the inspector observes conditions that might violate the QSR, the manufacturer must correct those conditions or explain them satisfactorily. Failure to adhere to QSR requirements would cause the devices produced to be considered in violation of the FDA Act and subject to FDA enforcement action that might include physical removal of the devices from the marketplace.

The FDA's Medical Device Reporting Regulation requires companies to provide information to the FDA on the occurrence of any death or serious injuries alleged to have been associated with the use of their products, as well as any product malfunction that would likely cause or contribute to a death or serious injury if the malfunction were to recur. In addition, FDA regulations prohibit a device from being marketed for unapproved or uncleared indications. If the FDA believes that a company is not in compliance with these regulations, it could institute proceedings to detain or seize company products, issue a recall, seek injunctive relief or assess civil and criminal penalties against the company or

its executive officers, directors or employees.

The Company is also subject to the Occupational Safety and Health Act ("OSHA") and other federal, state and local laws and regulations relating to such matters as safe working conditions, manufacturing practices, environmental protection and disposal of hazardous or potentially hazardous substances.

Sales of medical devices outside of the U.S. are subject to foreign legal and regulatory requirements. The Company's transdermal and injection systems have been approved for sale only in certain foreign jurisdictions. Legal restrictions on the sale of imported medical devices and products vary from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. We rely upon the companies marketing our injectors in foreign countries to obtain the necessary regulatory approvals for sales of our products in those countries. Generally, products having an effective 510(k) clearance or PMA may be exported without further FDA authorization.

The Company has obtained ISO 9001/EN 46001 qualification for its manufacturing systems. This certification shows that our procedures and manufacturing facilities comply with standards for quality assurance and manufacturing process control. Such certification, along with European Medical Device Directive certification, evidences compliance with the requirements enabling the Company to affix the CE Mark to current products. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all European Union ("EU") countries. Semi-annual audits by the British Standards Institute are required to demonstrate continued compliance.

#### Forward Looking Statements

We and our representatives may from time to time make written or oral forward-looking statements with respect to our annual or long-term goals, including statements contained in our filings with the Securities and Exchange Commission and in our reports to shareholders.

The words or phrases "will likely result," "are expected to," "will continue to," "is anticipated," "estimate," "project" or similar expressions identify "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical earnings and those presently anticipated or projected. We wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date made.

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In connection with the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, we are identifying the important risk factors below that could affect our financial performance and could cause our actual results for future periods to differ materially from any opinions or statements expressed with respect to future periods in any current statements.

We undertake no obligation to publicly revise any forward-looking statements to reflect future events or circumstances.

#### Risk Factors

The following "risk factors" contain important information about us and our business and should be read in their entirety.

Risks Related to Our Business

We will require additional capital to continue operations

Our cash position will be insufficient to fund working capital requirements and will not be sufficient for us to reach profitability. We expect our working capital needs over the next twelve months to approximate \$10.0 million. This amount consists of approximately \$7.0 million for research and development, \$500,000 for business development, \$1.2 million for marketing and sales, \$600,000 for regulatory and quality assurance and \$5.7 million for general and administrative expenses, all of which is offset by approximately \$5.1 million of projected license fees and net product margins. We are currently seeking funds through additional equity or debt offerings, equity investments by our strategic partners/customers and divestment of non-core technologies. There can be no assurance that sufficient additional equity or debt financing will be available. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail development of new drug technologies or expansion of manufacturing capacity or cease operations altogether.

We have incurred significant losses to date, and for our last fiscal year we received an opinion from our accountants expressing doubt on our ability to continue as a going concern

The report of our independent accountants in our 10-K for the fiscal year ended December 31, 2001, contains an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern as a result of recurring losses and negative cash flows from operations. We had negative working capital of (\$2,439,577) and (\$11,712) at December 31, 2000 and 2001, respectively. We incurred net losses of (\$3,967,366), (\$5,260,387) and (\$9,499,101) in 1999, 2000 and 2001, respectively. The costs for research and product development of our drug delivery technologies along with marketing and selling expenses and general and administrative expenses have been the principal causes of our losses. We expect to report a net loss for the year ending December 31, 2002, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products. Our ability to achieve and/or sustain profitable operations depends on a number of factors, many of which are beyond our control. These factors include the following:

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- o the demand for our technologies;
- our ability to manufacture products efficiently and with the required quality;
- o our ability to increase manufacturing capacity;
- o the level of product and price competition;
- o our ability to develop additional commercial applications for our products;
- o our ability to obtain regulatory approvals;
- o our ability to control costs; and
- o general economic conditions.

We depend on a limited number of customers for the majority of our revenue, and the loss of any one of these customers could substantially reduce our revenue

During 2001, we derived 71% of our revenue from the following three

#### customers:

- o Ferring Pharmaceutical NV (38%)
- o BioSante Pharmaceuticals, Inc. (28%)
- o Solvay Pharmaceuticals B.V. (5%)

The loss of any one of these customers could cause revenues to decrease significantly, resulting in, or increasing, our losses from operations. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenues. We may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues. If that occurs, our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability.

We have limited manufacturing experience and may experience manufacturing difficulties related to the use of new materials and procedures, which could increase our production costs and, ultimately, decrease our profits

Our past assembly, testing and manufacturing experience for certain of our technologies has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future drug delivery technologies necessitate significant changes and additions to our manufacturing and assembly process to accommodate new components. These systems must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In addition, our plans call for significantly increased levels of production and a shift to performing more manufacturing functions internally rather than relying on third-party suppliers, which will require us to eventually expand beyond our current facilities. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment, component supplies and shortages of personnel, any of which could result in significant delays in production. There can be no assurance that we will be able to successfully produce and manufacture our drug delivery technology. Any failure to do so would negatively impact our business, financial condition and results of operations.

Our technologies have achieved only limited acceptance by patients and physicians, which could have a negative effect on our revenue

Our revenues depend on ultimate patient and physician acceptance of our needle-free injectors, gels, patches and our other potential drug delivery technologies as an alternative to more traditional forms

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of drug delivery including injections using a needle, tablets and liquid formulas. To date, these delivery technologies have achieved only limited acceptance from such parties. If our drug delivery technologies are not accepted in the marketplace, the pharmaceutical company partners may be unable to successfully market and sell our products, which would limit our ability to generate revenues and to achieve and/or sustain profitability. The degree of acceptance of our drug delivery systems depends on a number of factors. These factors include the following:

- o demonstrated clinical efficacy and safety;
- o cost-effectiveness;
- o convenience and ease of administration of injectors, transdermal gels

and patches;

- o advantages over alternative drug delivery systems; and
- o marketing and distribution support.

Physicians may refuse to prescribe products incorporating our drug delivery technologies if the physicians believe that the active ingredient is better administered to a patient using alternative drug delivery technologies or the physicians believe that the delivery method will result in patient noncompliance. Factors such as allergic reactions, patient perceptions that a gel is inconvenient and cosmetic considerations about patches may cause patients to reject our drug delivery technologies.

In addition, we expect that the pharmaceutical company partners will price products incorporating their drug delivery technologies slightly higher than conventional methods, which may impair their acceptance. Because only a limited number of products incorporating our drug delivery technologies are commercially available, we cannot yet assess the level of market acceptance of our drug delivery technologies.

Our success depends on the market acceptance of alternative drug delivery technologies, and the failure to obtain such acceptance could substantially reduce our revenue

Our success will, in large part, depend upon increasing market acceptance of our drug delivery technologies as an alternative to traditional delivery systems. During the time period since initial commercial introduction, our products have had only limited success competing with traditional drug delivery systems for a variety of reasons, including the size, cost and complexity of use and maintenance of our drug delivery technologies and the relatively small number of drugs that have been self-administered. In order to increase market acceptance, we believe that we must successfully develop improvements in the design and functionality of future drug delivery technology that will reduce cost and increase appeal to users, thereby making these technologies desirable despite their premium cost over traditional drug delivery systems. Projected improvements in functionality and design may not adequately address the actual or perceived complexity of using our drug delivery technologies or adequately reduce cost. In addition, we believe that our future success depends upon our ability to enter into additional collaborative agreements with drug and medical device manufacturers, as discussed below. There can be no assurance that we will be successful in these efforts or that our drug delivery technologies will ever gain sufficient market acceptance to achieve and/or sustain profitable operations.

Although transdermal patches are a well-accepted method of drug delivery, many other companies compete in this sector. Because the cost of manufacturing equipment for transdermal patches is high, most manufacturing is done by a limited number of contract manufacturers. Therefore, our costs will remain high and our pricing options will be limited. We may develop a superior patch, but we may not be able to price it competitively, or our margins may not justify maintaining the business if our market share is low. Patches are not central to our business strategy and may suffer from lack of attention. There can be no assurance that we will be successful in the transdermal patch market.

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Because transdermal gels are a newer, less understood method of drug delivery, our potential consumers, the pharmaceutical manufacturers, have little experience with manufacturing costs or pricing parameters. Our assumption of higher value may not be shared by the consumer. To date, transdermal gels have

gained successful entry into only a limited number of markets. There can be no assurance that transdermal gels will ever gain sufficient market acceptance in those or other markets to achieve and/or sustain profitable operations.

Although the injectable gel research field is active, there is essentially no data regarding consumer acceptance. Regulatory compliance and approvals can take a substantial amount of time due to clinical evaluations that are required for this type of method but not for other drug delivery methods. There can be no assurance that injectable gels will ever obtain the necessary regulatory approvals or gain sufficient market acceptance to achieve and/or sustain profitable operations.

A recent FDA study questioned the safety of hormone replacement therapy for menopausal women, and our female hormone replacement therapy business may suffer as a result

In July 2002, the Federal Drug Administration halted a study being conducted on oral female hormone replacement therapy (HRT) because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking HRT. The study looked at only one brand of oral HRT, and there is no information on whether other brands with different levels of hormones would carry the same risks. Because the FDA's findings are very recent, we cannot assess what impact, if any, they will have on the HRT market as a whole, or on our own HRT product line. Additionally, there is no information at this point regarding whether the transdermal gels and patches that we market for HRT will be shown to carry the same risks as those found in the study.

We rely on third parties to supply components for our products, and any failure to retain relationships with these third parties could negatively impact our ability to manufacture our products

Certain of our technologies contain a number of customized components manufactured by various third parties. Regulatory requirements applicable to medical device and transdermal patch manufacturing can make substitution of suppliers costly and time-consuming. In the event that we could not obtain adequate quantities of these customized components from our suppliers, there can be no assurance that we would be able to access alternative sources of such components within a reasonable period of time, on acceptable terms or at all. The unavailability of adequate quantities, the inability to develop alternative sources, a reduction or interruption in supply or a significant increase in the price of components could have a material adverse effect on our ability to manufacture and market our products.

We may be unable to successfully expand into new areas of drug delivery technology, which could substantially reduce our revenue and negatively impact our business as a whole

We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery technologies. Even if enhanced or additional technologies appear promising during various stages of development, we may not be able to develop commercial applications for them because

- o the potential technologies may fail clinical studies;
- o we may not find a pharmaceutical company to adopt the technologies;
- o it may be difficult to apply the technologies on a commercial scale;
- o the technologies may be uneconomical to market; or
- o we may not receive necessary regulatory approvals for the potential technologies.

We have not yet completed research and development work or obtained regulatory approval for any technologies for use with any drugs other than insulin, human growth hormone and estradiol. There can be no assurance that any newly developed technologies will ultimately be successful or that unforeseen difficulties will not occur in research and development, clinical testing, regulatory submissions and approval, product manufacturing and commercial scale up, marketing, or product distribution related to any such improved technologies or new uses. Any such occurrence could materially delay the commercialization of such improved technologies or new uses or prevent their market introduction entirely.

As health insurance companies and other third-party payors increasingly challenge the products and services for which they will provide coverage, our individual consumers may be unable to afford to use our products, which could substantially reduce our revenues

Our injector device products are currently sold in the European Community (EC) and in the United States for use with human growth hormone or insulin. In the United States the injector products are only available for use with insulin. A transdermal patch containing estradiol for hormone replacement therapy is sold in Chile. Although it is impossible for us to identify the amount of sales of our products that our customers will submit for payment to third-party insurers, at least some of these sales may be dependent in part on the availability of adequate reimbursement from these third-party healthcare payors. Currently, insurance companies and other third-party payors reimburse the cost of certain technologies on a case-by-case basis and may refuse reimbursement if they do not perceive benefits to the technologies' use in a particular case. Third-party payors are increasingly challenging the pricing of medical products and services, and there can be no assurance that such third-party payors will not in the future increasingly reject claims for coverage of the cost of certain of our technologies. Insurance and third party payor practice vary from country to country, and changes in practices could negatively affect our business if the cost burden for our technologies were shifted more to the patient. Therefore, there can be no assurance that adequate levels of reimbursement will be available to enable us to achieve or maintain market acceptance of our technologies or maintain price levels sufficient to realize profitable operations. There is also a possibility of increased government control or influence over a broad range of healthcare expenditures in the future. Any such trend could negatively impact the market for our drug delivery technologies.

The loss of any existing licensing agreements or the failure to enter into new licensing agreements could substantially affect our revenue  $\frac{1}{2}$ 

We believe that the introduction and broad acceptance of our drug delivery technologies is in part dependent upon the success of our current and any future development and licensing arrangements with pharmaceutical and medical device companies covering the development, manufacture, use and marketing of drug delivery technologies with specific parenteral drug therapies. We anticipate that under these arrangements the pharmaceutical or medical device company will assist in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. The pharmaceutical or medical device company also will be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements. There can be no assurance that we will be successful in executing additional agreements with pharmaceutical or medical device companies or that existing or future agreements will result in increased sales of our drug delivery technologies. If we do not enter into additional agreements in the future, or if our current or future agreements do not result in successful marketing of our products, our business, results of operations and

financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of these arrangements, we are dependent upon the development, data collection and marketing efforts of such pharmaceutical and medical device companies. The amount and timing of

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resources such pharmaceutical and medical device companies devote to these efforts are not within our control, and such pharmaceutical and medical device companies could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology.

Additional risks that we face related to our collaborative agreements include the following:

- o other pharmaceutical and biotechnology companies may not consider our technology the most appropriate to provide the additional benefit such companies require in order for them to justify investment in our technology, and as a result we may be unable to enter into collaborative agreements to develop additional products using drug delivery technologies;
- o any existing or future collaborative agreements may not result in additional commercial products;
- o additional commercial products that we may develop may not be successful;
- o although none of our collaborative agreements have been terminated for failure to meet milestones, we may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees; and
- o we may not be able to develop successful new drug delivery technologies that will be attractive to potential pharmaceutical company partners.

The failure of any of our third party licensees to develop, obtain regulatory approvals for, market, distribute and sell our products could substantially reduce our revenue

Pharmaceutical company partners help us develop, obtain regulatory approvals for, manufacture and sell our products. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of the products as planned, our revenues and gross profits may not reach expectations or may decline. We may not be able to control the timing and other aspects of the development of products because pharmaceutical company partners may have priorities that differ from ours. Therefore, commercialization of products under development may be delayed unexpectedly. Further, we may incorporate certain of our drug delivery technologies into the oral dosage forms of products marketed and sold by pharmaceutical company partners. We do not have a direct marketing channel to consumers for drug delivery technologies. Therefore, the success of the marketing organizations of the pharmaceutical company partners, as well as the level of priority assigned to the marketing of

the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies.

Because the barriers to entry in our product market are low, we face increasing competition which could force us to reduce our prices and, consequently, decrease our planned profits

Our current competition comes primarily from traditional hypodermic needles and syringes that are used for the vast majority of injections administered today and from transdermal patch and gel products marketed by others. Currently, competition in the needle-free injection market is limited to small companies with limited financial and other resources, but the barriers to entry are currently low, and additional competitors may enter the needle-free injection systems market, including companies with substantially greater resources and experience than us. There can be no assurance that we will be able to

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compete effectively against our current or potential competitors in the drug delivery market, or that such competitors will not succeed in developing or marketing products that will be more accepted in such market. Competition in this market could also force us to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

We have applied for, and have received, several patents, and we may be unable to protect our intellectual property, which would negatively affect our ability to compete

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

Currently, we have been granted 23 patents in the United States and 23 patents in other countries. We have also made application for a total of 44 patents, both in the United States and other countries. Any patent applications we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. Further, we may not have the necessary financial resources to enforce our patents.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information.

Others may bring infringement claims against us, which could be time-consuming and expensive to defend

Third parties may claim that the manufacture, use or sale of our drug delivery technologies infringe their patent rights. If such claims are asserted, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in court. If we cannot obtain required licenses, are

found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, United States or foreign patents that pose a risk of potential infringement claims.

Additionally, the drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical companies or third parties. If those patents or other forms of protection expire, become ineffective or are subject to the control of third parties, sales of the drugs by the collaborating pharmaceutical company may be restricted or may cease. Our revenues, in that event, may decline.

We may incur significant costs seeking approval for our products, which could delay the realization of revenue and, ultimately, decrease our revenues from such products

The design, development, testing, manufacturing and marketing of pharmaceutical compounds, medical nutrition and diagnostic products and medical devices are subject to regulation by governmental authorities, including the FDA and comparable regulatory authorities in other countries. The approval

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process is generally lengthy, expensive and subject to unanticipated delays. Currently, we, along with our partners, are actively pursuing marketing approval for a number of products from regulatory authorities in other countries and anticipate seeking regulatory approval from the FDA for products developed pursuant to the agreement with BioSante. Our revenue and profit will depend, in part, on the successful introduction and marketing of some or all of such products by us or our partners. There can be no assurance as to when or whether such approvals from regulatory authorities will be received.

Applicants for FDA approval often must submit extensive clinical data and supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new drug application also may cause delays or rejection of an approval. Even if the FDA approves a product, the approval may limit the uses or "indications" for which a product may be marketed, or may require further studies. The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if unforeseen problems follow initial marketing.

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies, must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues would be reduced. We may not be able to obtain all necessary regulatory approvals. We may be required to incur significant costs in obtaining or maintaining regulatory approvals.

Our business could be harmed if we fail to comply with regulatory requirements and, as a result, are subject to sanctions

If we, or pharmaceutical companies with whom we are developing technologies, fail to comply with applicable regulatory requirements, we, and the pharmaceutical companies, may be subject to sanctions, including the following:

- o warning letters;
- o fines;
- o product seizures or recalls;
- o injunctions;
- o refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;
- o total or partial suspension of production;
- o withdrawals of previously approved marketing applications; or
- o criminal prosecutions.

Our revenues may be limited if the marketing claims asserted about our products are not approved

Once a drug product is approved by the FDA, the Division of Drug Marketing, Advertising and Communication, the FDA's marketing surveillance department within the Center for Drugs, must approve marketing claims asserted by our pharmaceutical company partners. If a pharmaceutical company partner fails to obtain from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug technologies, our revenues from that product may be limited. Marketing claims are the basis for a product's labeling, advertising and promotion. The claims the pharmaceutical company partners are asserting about our drug delivery technologies, or the drug product itself, may not be approved by the Division of Drug Marketing.

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Product liability claims related to participation in clinical trials or the use or misuse of our products could prove to be costly to defend and could harm our business reputation

The testing, manufacturing and marketing of products utilizing our drug delivery technologies may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with whom we are developing drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of the product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. As the result either of adverse claim experience or of medical device or insurance industry trends, we may in the future have difficulty in obtaining product liability insurance or be forced to pay very high premiums, and there can be no assurance that insurance coverage will continue to be available on commercially reasonable terms or at all.

Our business could suffer if our competitors develop a superior drug delivery technology, and we are unable to effectively compete with that technology

Our success depends, in part, upon maintaining a competitive position in the development of products and technologies in a rapidly evolving field. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Drug delivery companies that compete with our technologies include Bioject Medical Technologies, Inc., Weston Medical Group plc, Equidyne Corporation, Bentley Pharmaceuticals, Inc., Cellegy Pharmaceuticals, Inc., Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc. and Novavax, Inc., along with other companies. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do, and, therefore, represent significant competition.

In general, injection is used only with drugs for which other drug delivery methods are not possible, in particular with biopharmaceutical proteins (drugs derived from living organisms, such as insulin and human growth hormone) that cannot currently be delivered orally, transdermally (through the skin) or pulmonarily (through the lungs). Transdermal patches and gels are also used for drugs that cannot be delivered orally. Many companies, both large and small, are engaged in research and development efforts on novel techniques aimed at delivering such drugs through the skin, either without needle injection or by patch and gel. The successful development and commercial introduction of such a non-injection technique would likely have a material adverse effect on our business, financial condition, results of operations and general prospects.

Competitors may succeed in developing competing technologies or obtaining governmental approval for products before we do. Competitors' products may gain market acceptance more rapidly than our products. Developments by competitors may render our products, or potential products, noncompetitive or obsolete.

We expect our quarterly revenues and operating results to fluctuate for a number of reasons, which could cause our stock price to fluctuate

Our operating results may vary significantly from quarter to quarter, in part because of changes in consumer buying patterns, aggressive competition, the timing of the recognition of licensing or development fee payments and the timing of, and costs related to, any future technology or new drug use introductions. Our operating results for any particular quarter are not necessarily indicative of any future results. The uncertainties associated with the introduction of any new technology or drug use and with general market trends may limit management's ability to forecast short-term results of operations accurately. Fluctuations caused by variations in quarterly operating results or our failure to meet analysts' projections or public expectations as to results may adversely affect the market price of our Common Stock.

Our business may suffer if we lose certain key officers or employees

The success of our business is materially dependent upon the continued services of certain of our key officers and employees. The loss of such key personnel could have a material adverse effect on our business, operating results or financial condition. We plan on hiring personnel to work in the areas of regulatory/clinical, device production and administrative support. Competition for such personnel is intense, and there can be no assurance that we will be successful in attracting and retaining key personnel in the future.

We are involved in many international markets, and this subjects us to

additional business risks

We have offices and a research facility in Basel, Switzerland, and we also license and distribute our products in the European Community and the United States. These geographic localities provide economically and politically stable environments in which to operate. However, in the future, we intend to introduce products through partnerships in other countries. As we expand our geographic market, we fill face additional ongoing complexity to our business and may encounter the following additional risks:

- o increased complexity and costs of managing international operations;
- o protectionist laws and business practices that favor local companies;
- o dependence on local vendors;
- o multiple, conflicting and changing governmental laws and regulations;
- o difficulties in enforcing our legal rights;
- o reduced or limited protections of intellectual property rights; and
- o political and economic instability.

A significant portion of our international revenues is denominated in foreign currencies. An increase in the value of the U.S. dollar relative to these currencies may make our products more expensive and, thus, less competitive in foreign markets.

Future Terrorist Attacks Could Substantially Harm Our Business

On September 11, 2001, the United States was the target of terrorist attacks of unprecedented scope. The U.S. government and media agencies were also subject to subsequent acts of terrorism through the distribution of anthrax through the mail. Such attacks and the U.S. government's ongoing response may lead to further acts of terrorism, bio-terrorism and financial and economic instability. The precise effects of these attacks, future attacks or the U.S. government's response to the same are difficult to determine, but they could have an adverse effect on our business, profitability and financial condition.

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### Risks Related to our Common Stock

Our stock price has been, and is likely to continue to be, volatile, which may result in a loss to our shareholders

The market price for our common stock has been volatile. The trading prices of our common stock could be subject to wide fluctuations in response to events or factors, many of which are beyond our control. These could include, without limitation (i) quarter to quarter variations in our operating results, (ii) announcements by us or our competitors regarding the results of regulatory approval filings, clinical trials or testing, (iii) developments or disputes concerning proprietary rights, (iv) technological innovations or new commercial products, (v) material changes in our collaborative arrangements and (vi) general conditions in the medical technology industry. Moreover, the stock market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical technology and device companies and which have often been unrelated to the operating performance of such companies.

All decisions affecting our company are under the control of a single shareholder who owns a majority of the voting power of our common stock, and this could lower the price of our common stock

As a result of our reverse business combination with Permatec in January 2001, Permatec Holding AG and its controlling shareholder, Dr. Jacques Gonella own a majority of (currently 63.8%) the outstanding shares of our common stock. Because of Permatec's and Dr. Gonella's control of the Company, investors will be unable to affect or change the management or the direction of the Company. As a result, some investors may be unwilling to purchase our common stock. If the demand for our common stock is reduced because of Permatec's and Dr. Gonella's control of the Company, the price of our common stock could be materially depressed.

Because Permatec and Dr. Gonella own more than 50% of the combined voting power of our stock, they will be able to generally determine the outcome of all corporate actions requiring shareholder approval. As a result, Permatec and Dr. Gonella will be in a position to control all matters affecting our Company, including decisions as to our corporate direction and policies; future issuances of our common stock or other securities; our incurrence of debt; amendments to our articles of incorporation and bylaws; payment of dividends on our common stock; and acquisitions, sales of our assets, mergers or similar transactions, including transactions involving a change of control.

Sales of our common stock by our officers and directors may lower the market price of our common stock  $\,$ 

As of December 31, 2001, our officers and directors beneficially owned in excess of 60% of our common stock, including stock options exercisable within 60 days. If our officers and directors, or other shareholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

We do not expect to pay dividends in the foreseeable future

We intend to retain all earnings in the foreseeable future for our continued growth and, thus, do not expect to declare or pay any cash dividends in the foreseeable future.

Anti-takeover effects of certain by-law provisions and Minnesota law could discourage, delay or prevent a change in control

Our articles of incorporation and bylaws along with Minnesota law could discourage, delay or prevent persons from acquiring or attempting to acquire us. Our articles of incorporation authorize our board of directors, without action by our shareholders, to designate and issue preferred stock in one or more series, with such rights, preferences and privileges as the board of directors shall determine. In addition, our bylaws grant our board of directors the authority to adopt, amend or repeal all or any of our bylaws, subject to the power of the shareholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our shareholders.

As a public corporation, we are prohibited by the Minnesota Business Corporation Act, except under certain specified circumstances, from engaging in any merger, significant sale of stock or assets or business combination with any shareholder or group of shareholders who own at least 10% of our common stock.

### Employees

As of March 31, 2002, we employed 37 full-time and 2 part-time employees in Minnesota and Pennsylvania, and the subsidiaries employed 18 full-time and 4 part-time employees in Switzerland. None of our employees are represented by any labor union or other collective bargaining unit. We believe that our relations with our employees are good.

#### EXECUTIVE OFFICERS OF THE REGISTRANT

| Name                    | Age | Position   |
|-------------------------|-----|--|
| Roger G. Harrison, Ph.D | 54  | Chief Executive Officer,<br>President and Director,<br>from March 12, 2001   |
| Franklin Pass, M.D      | 65  | Chief Executive Officer,<br>Chairman of the Board<br>of Directors and President<br>until March 12, 2001;<br>currently Vice Chairman<br>of the Board of Directors |
| Lawrence Christian      | 59  | Chief Financial Officer,<br>Secretary and Vice<br>President - Finance  |
| Dario Carrara, Ph.D     | 38  | Managing Director -<br>Formulations Group  |
| Peter Sadowski, Ph.D    | 54  | Vice President -<br>Devices Group  |

Roger G. Harrison, Ph.D., joined us as Chief Executive Officer, President and a member of our Board of Directors in March 2001. Prior to that time, Dr. Harrison was Director of Alliance Management at Eli Lilly and Company. In this role he helped to create a renewed focus on generating value from corporate alliances as part of the company's core business strategy. In his 25-years at Eli Lilly and Company, his roles also included Global Product Team Leader and Director, Development Projects Management and Technology Development and Planning. He is the author of twelve publications, has contributed to four books and holds nine patents. Dr. Harrison earned a Ph.D. in organic chemistry and a B.Sc. in chemistry from Leeds University in the United Kingdom and conducted postdoctoral research work at Zurich University in Switzerland.

Franklin Pass, M.D., joined us as a director and consultant in January 1992 and served as Chief Executive Officer, President and Chairman of the Board of Directors from February 1993 to January 2001. From 1990 to 1992, Dr. Pass served as President of International Agricultural Investments, Ltd., an agricultural technology consulting and investment company. Dr. Pass, a physician and scientist, was Director of the Division of Dermatology at Albert Einstein College of Medicine from 1967 to 1973, Secretary and Treasurer of the American Academy of Dermatology from 1978 to 1981 and the co-founder and Chief Executive Officer of Molecular Genetics, Inc., now named MGI Pharma, Inc., from 1979 to 1986. He is the author of more than 40 published medical and scientific articles.

Lawrence Christian is currently Chief Financial Officer, Secretary and Vice President - Finance. He joined us in March 1999 as Vice President, Finance & Administration, Chief Financial Officer and Secretary. Mr. Christian took

been 3M Financial Director - World-Wide Corporate R&D and Government Contracts involved in organizing new business venture units and commercialization of new technologies. Prior to 1996 Mr. Christian served as Financial Manager - Government Contracts, European Controller and Division Controller within 3M. Prior to joining 3M in 1982, Mr. Christian was Vice President/CFO of APC Industries, Inc., a closely-held telecommunications manufacturing company in Texas.

Dario Carrara, Ph.D. is currently Managing Director - Formulations Group, located in Basel, Switzerland. He served as General Manager of Permatec's Argentinean subsidiary from 1995 until its liquidation in 2000. Prior to joining Permatec, Dr. Carrara worked as Pharmaceutical Technology Manager for Laboratorios Beta, a pharmaceutical laboratory in Argentina that ranks among the top ten pharmaceutical companies in Argentina, between 1986 and 1995. Dr. Carrara has extensive experience in developing transdermal drug delivery devices. He earned a double degree in Pharmacy and Biochemistry, as well as a Ph.D. in Pharmaceutical Technology from the University of Buenos Aires.

Peter Sadowski, Ph.D., is currently Vice President - Devices Group, located in Minneapolis, Minnesota. He joined us in March 1994 as Vice President, Product Development. He was promoted to Executive Vice President and Chief Technology Officer in 1999. From October 1992 to February 1994, Dr. Sadowski served as Manager, Product Development for GalaGen, Inc., a biopharmaceutical company. From 1988 to 1992, he was Vice President, Research and Development for American Biosystems, Inc., a medical device company. Dr. Sadowski holds a Ph.D. in microbiology.

#### Liability Insurance

Our business entails the risk of product liability claims. Although we have not experienced any material product liability claims to date, any such claims could have a material adverse impact on our business. We maintain product liability insurance with coverage of \$1 million per occurrence and an annual aggregate maximum of \$5 million. We evaluate our insurance requirements on an ongoing basis.

#### Item 2. DESCRIPTION OF PROPERTY.

We lease approximately 3,000 square feet of office space in Exton, Pennsylvania for our corporate headquarters facility. The lease will terminate in November 2004. We believe this facility will be sufficient to meet our Exton requirements through the lease period.

We lease approximately 23,000 square feet of office, manufacturing and warehouse space in Plymouth, a suburb of Minneapolis, Minnesota. The lease will terminate in April 2004. We believe these facilities will be sufficient to meet our Minneapolis requirements through the lease period.

We also lease approximately 1,000 square meters of facilities in Basel, Switzerland, with 300 square meters of laboratories (formulation and analytical) and an additional 300 square meters in expansion reserve. The lease will terminate in September 2008. We believe the facilities will be sufficient to meet our Switzerland requirements through the lease period.

#### Item 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

#### Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of shareholders during the quarter ended December 31, 2001.

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#### PART II

#### Item 5. MARKET FOR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS.

Our Common Stock has traded on the Nasdaq Small Cap Market of the Nasdaq Stock Market since March 8, 1999. Prior to that time, the Common Stock traded on the Nasdaq National Market of the Nasdaq Stock Market. Our Common Stock is traded under the symbol ANTR. The following table sets forth the per share high and low sales prices of our Common Stock for each quarterly period during the two most recent fiscal years. Sale prices are as reported by the Nasdaq Stock Market.

|                | High     | Low      |
|----------------|----------|----------|
|                |          |          |
| 2000:          |          |          |
| First Quarter  | \$ 7.875 | \$ 3.250 |
| Second Quarter | 5.969    | 3.500    |
| Third Quarter  | 5.438    | 3.250    |
| Fourth Quarter | 6.125    | 3.656    |
| 2001:          |          |          |
| First Quarter  | 5.000    | 2.250    |
| Second Quarter | 5.650    | 2.880    |
| Third Quarter  | 4.300    | 1.590    |
| Fourth Quarter | 4.050    | 1.900    |

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Common Shareholders

As of March 31, 2002, we had 106 holders of record of our common stock, with another estimated 2,960 shareholders whose stock is held in nominee name.

#### Dividends

We have not paid or declared any cash dividends on our common stock during the past six years. We have no intention of paying cash dividends in the foreseeable future on common stock. We are obligated to pay semi-annual dividends on Series A Convertible Preferred Stock ("Series A") at an annual rate of 10%, payable on May 10 and November 10 each year. In addition to the stated 10% dividend, we are also obligated to pay foreign tax withholding on the dividend payment, if paid in cash, which equates to an effective dividend rate of 14.2%. Such foreign tax withholding payments have been reflected as dividends, when paid in cash, since they are non-recoverable. The Series A agreement has a provision which allows us to pay the dividend by issuance of the same stock when funds are not available. We have exercised this provision for the last five dividend payments.

#### Sales of Unregistered Securities

On November 10, 1998, Medi-Ject sold 1,000 shares of Medi-Ject Series A and warrants to purchase 56,000 shares of common stock to Elan International Services, Ltd., for total consideration of \$1,000,000. Series A remains outstanding after the Permatec business combination. The Series A carries a 10% dividend which is payable semi-annually. In addition to the stated 10% dividend, we are also obligated to pay foreign tax withholding on the dividend payment, which equates to an effective dividend rate of 14.2%. Such foreign tax withholding payments have been reflected as dividends since they are non-recoverable. The Series A is redeemable at our option at any time and is convertible into common stock for sixty days following the 10th anniversary of

the date of issuance at the lower of \$7.50 per share or 95% of the market price of the common stock. The warrants to purchase common stock may be exercised at any time prior to November 10, 2005, at a price of \$4.51 per share.

On December 22, 1999, the Company sold 250 shares of Series B Convertible Preferred Stock ("Series B") to Bio-Technology General Corporation for total consideration of \$250,000. The Series B did not carry a dividend rate. Series B was automatically converted on June 30, 2001, into 100,000 shares of common stock pursuant to the terms of the Series B stock agreement.

On February 5, 2001 Antares issued 1,194,537 shares of common stock for \$7,000,000, and on March 5, 2001, we issued 511,945 shares of common stock for \$3,000,000 in connection with a private placement of Units. Each Unit, at a

2.2.

price of \$23.44, consisted of (i) four shares of our common stock, \$0.01 par value, and (ii) a warrant to purchase one share of our common stock. Each of the four warrants, to purchase in the aggregate 426,621 shares of common stock, issued in the private placement is exercisable for a period of five years at an exercise price of \$7.03. The proceeds from the sale of these securities have been primarily used for working capital. There was no underwriter involved and no fees were paid to any other parties, except legal and accounting fees, in connection with this transaction. These securities were exempt from registration because they were issued to four accredited investors in a private placement in reliance on Rule 506 of Regulation D under the Securities Act of 1933.

#### Item 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL DATA (In thousands, except per share data)

|  |                           |    |                       | Αt  | Dece    |
|--|---------------------------|----|-----------------------|-----|---------|
|  | <br>1997                  |    | 1998<br>              |     |         |
| Balance Sheet Data:  |                           |    |                       |     |         |
| Cash and cash equivalents  | \$<br>332<br>114<br>1,656 | ·  | 492<br>(109)<br>2,671 | \$  | (<br>2, |
| Long-term liabilities, less current maturities Accumulated deficit               | 3,328<br>(3,767)          |    | •                     |     | 10,     |
| Total shareholders' equity (deficit)   | \$<br>(2,204)             | \$ | (6,518)               | \$  | (9,     |
|  |                           |    | Year                  | End | ded D   |
|  | <br>1997                  |    | 1998<br>              |     | 199     |
| Statement of Operations Data:  |                           |    |                       |     |         |
| Sales  Licensing and product development  Contract research with related parties | \$<br>-<br>-<br>145       | \$ | -<br>68<br>179        | \$  | 1,      |
| Revenues   | <br>145                   |    | 247                   |     | 1,      |

| Cost of sales                                      | _                    | _                    |                 |
|--|----------------------|----------------------|-----------------|
| Research and development                           | 796                  | 1,750                | 1,              |
| Sales and marketing                                | 70                   | 179                  |                 |
| General and administrative                         | 1226                 | 2,431                | 3,              |
| Operating expenses                                 | 2 <b>,</b> 092       | 4,360                | 5 <b>,</b>      |
| Net operating loss                                 | (1,947)              | (4,113)              | (3,             |
| Net other income (expense)                         | (55)                 | (124)                | (               |
| Income tax expense                                 | (54)                 | (33)                 |                 |
| Loss before cumulative effect of change in         |                      |                      |                 |
| accounting principle                               | (2,056)              | (4,270)              | (3,             |
| principle  |                      | _                    |                 |
| Net loss In-the-money conversion feature-preferred | (2,056)              | (4,270)              | (3,             |
| stock dividend                                     | _                    | _                    |                 |
| Preferred stock dividends                          | _                    |                      |                 |
| Net loss applicable to common shares               | \$ (2,056)<br>====== | \$ (4,270)<br>====== | \$ (3,<br>===== |
| Net loss per common share (1), (2)                 | \$ (.48)             | \$ (.99)             | \$ (            |
| Weighted average number of                         |                      |                      |                 |
| common shares                                      | 4,302                | 4,321                | 4,              |
|  | ======               | =======              |                 |

- (1) Basic and diluted loss per share amounts are identical as the effect of potential common shares is anti-dilutive.
- (2) We have not paid any dividends on our Common Stock since inception.

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

#### General

In July 2000, Medi-Ject Corporation, now known as Antares Pharma, Inc. entered into a Purchase Agreement with Permatec Holding AG to purchase three subsidiaries from Permatec. Pursuant to the Purchase Agreement, Antares purchased all of the outstanding shares of each subsidiary. As consideration for the transaction, Antares issued 2,900,000 shares of Antares common stock to Permatec (the "Share Transaction"). The Share Transaction was consummated on January 31, 2001, and was accounted for as a reverse acquisition because Permatec held approximately 67% of the outstanding common stock of Antares immediately after the Share Transaction. Effective with the consummation of the Share Transaction the financial statements and related disclosures for all periods that were previously reported as Medi-Ject's were replaced with the Permatec financial statements and disclosures.

The Medi-Ject operations, which were acquired by Permatec, consisted primarily of the development, marketing and sale of needle-free injection devices and disposables. These operations, including all manufacturing and

substantially all administrative activities, are located in Minneapolis, Minnesota and are referred to below as Antares/Minnesota. The Permatec operations are located primarily in Basel, Switzerland and consist of administration and facilities for the research and development of transdermal and transmucosal drug delivery products. Permatec's operations have historically been focused on research and development. In the past two years Permatec has signed a number of license agreements with pharmaceutical companies for the application of its drug delivery systems. Permatec generated revenue starting in 1999 with the recognition of license revenues and commenced the sale of licensed products in 2000. Permatec's operations are referred to below as Antares/Switzerland.

In December 2001, the Company opened its new corporate headquarters in Exton, Pennsylvania. The Company's headquarters were formerly located in its Minneapolis, Minnesota, facility. After the move to Exton, the Minneapolis location has maintained research facilities and many of the administrative functions. Certain executives have relocated to the Exton office, while most other employees have remained at the Company's research facilities in Minneapolis and Basel, Switzerland.

We expect to report a net loss for the year ending December 31, 2002 as we continue to incur marketing and development costs related to bringing future generations of products to market. Our long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products.

Results of Operations

Critical Accounting Policies

In preparing the financial statements in conformity with accounting principles generally accepted in the United States of America, management must make decisions which impact reported amounts and related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, management applies judgment based on its understanding and analysis of relevant circumstances. Note 1 to the financial statements provides a summary of the significant accounting policies followed in the preparation of the financial statements. The following accounting policies are considered by management to be the most critical to the presentation of the consolidated financial statements because they require the most difficult, subjective and complex judgments.

Revenue Recognition - The majority of the Company's revenue relates to product sales for which revenue is recognized upon shipment, with limited judgment required related to product returns. Licensing revenue recognition requires management to estimate effective terms of agreements and identify points at which performance is met under the contracts such that the revenue earnings process is complete. Revenue related to up-front, time-based and performance-based payments is recognized over the entire contract performance period. For major licensing contracts, this results in the deferral of significant revenue amounts (approximately \$1,500,000 at December 31, 2001) where non-refundable cash payments have been received, but the revenue is not immediately recognized due to the long-term nature of the respective agreements. Subsequent factors affecting the initial estimate of the effective terms of agreements could either increase or decrease the period over which the deferred revenue is recognized.

Inventory Reserves - The Company records reserves for inventory shrinkage and for potentially excess, obsolete and slow moving inventory. The amounts of these reserves are based upon inventory levels, expected product lives and forecasted sales demand. Although management believes the likelihood to be relatively low, results could be materially different if demand for the Company's products decreased because of economic or competitive conditions, or if products became obsolete because of technical advancements in the industry or by the Company. The Company has recorded inventory reserves of approximately \$105,000 at December 31, 2001.

Years Ended December 31, 1999, 2000, 2001

#### Revenues

Revenues decreased by 59% from \$1,351,607 in 1999 to \$560,043 in 2000 and increased \$2,938,481 to \$3,498,524 in 2001, or 525%. The increase in 2001 revenues was largely due to commencement of product sales in 2001. In 2001, Antares realized product sales of \$2,769,591 of which \$1,776,159 and \$993,432, respectively, were attributable to the Antares/Minnesota and Antares/Switzerland operations.

Antares/Minnesota product sales include sales of injector devices, related parts, disposable components, and repairs. Since the acquisition of Antares/Minnesota on January 31, 2001, a total of 2,326 devices were sold at an average price of approximately \$245 per unit. Sales of disposable components in 2001 totaled approximately \$1,040,000. Antares/Switzerland product sales include sales of topical gel and transdermal patch drug delivery products. The gel product sales were made to licensees in connection with clinical studies and other development activities under license agreements.

The decrease in revenues in 2000 from 1999 resulted from lower license fees paid to Antares/Switzerland. In 1999, Antares/Switzerland received a \$1,000,000 licensing fee in connection with a licensing agreement with BioSante. All revenue from this fee was recognized in 1999. However, effective January 1, 2000, the Company adopted the cumulative deferral method of accounting which substantially altered the timing under which the Company recognizes its licensing revenue. Accordingly, the Company deferred recognition of \$1,059,622 of previously recognized license milestone payments, including a portion of the \$1,000,000 license fee recognized in 1999. For the years ended December 31, 2000 and 2001, the Company recognized \$277,200 and \$267,180, respectively, of license revenues that were deferred at January 1, 2000, as a result of the adoption of the cumulative deferral method. Development revenues recognized during 2000 were \$387,807 and license fees were \$172,236.

Licensing and product development revenue increased in 2001 by \$168,890 to \$728,933, primarily due to a \$150,000 payment received by Antares/Minnesota under a research agreement. The research agreement was effective in April 2000, had an original term of 2 years and contained potential milestone payments. The \$150,000 payment related to the Company's completion of various milestones related to the design and evaluation of materials for pre-filled needle-free syringes. The Company had no further obligations under the agreement following the achievement of this milestone. Therefore, the \$150,000 payment was immediately recognized as revenue.

In April 2001, the Company entered into an exclusive agreement to license certain drug-delivery technology to SciTech Medical Product Pte Ltd ("SciTech") in various Asian countries with options to other countries if certain conditions are met. The Company will receive an aggregate license fee of \$600,000 upon the achievement of certain milestones, such milestones being structured around successful completion of clinical trials, subsequent submission to and/or approval by various regulatory authorities, and product commercialization. In

addition to the license fees, the Company will receive a 5% royalty from the sale of licensed products. At June 30, 2001 \$200,000 had been recorded in accounts receivable and deferred revenue in connection with the SciTech agreement. In the third quarter the agreement was amended to change the due date of the initial \$200,000 payment from June 30, 2001 to December 31, 2001. The agreement was amended a second time to change the due date for this payment from December 31, 2001 to June 30, 2002. The Company recorded no deferred license fee revenue at December 31, 2001 and recognized no license fee revenue in 2001 in connection with this agreement.

Cost of Sales

Cost of sales in 2001 of \$1,862,955 is 67% of total product sales. Cost of sales for Antares/Minnesota was \$1,579,836 or 89% of its product sales, and cost of sales for Antares/Switzerland was \$283,119 or 28% of its product sales. Cost of sales for Antares/Minnesota is relatively high compared to product sales primarily because production volume was lower than anticipated resulting in a higher than expected amount of unabsorbed manufacturing overhead.

Research and Development

Research and development expenses decreased by 43% from \$1,647,059 in 1999 to \$938,562 in 2000 and, excluding the write-off of acquired in-process research and development in 2001, increased to \$3,555,874 in 2001, an

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increase of 279%. The decrease from 1999 to 2000 was attributable to the closing in 1999 of operations in Argentina and France. The 2001 increase is primarily due to research employee additions at Antares/Switzerland for increased research activities and research costs of \$2,191,999 incurred by Antares/Minnesota since January 31, 2001. The 2001 expense amount includes a write off of certain molds and tooling totaling approximately \$400,000 after a determination was made by management late in the fourth quarter of 2001 that these developmental molds would not be used in future production.

In-Process Research and Development

In connection with the business combination with Permatec, the Company acquired in-process research and development ("IPR&D") projects having an estimated fair value of \$948,000, which had not yet reached technological feasibility and had no alternative future use. Accordingly, the \$948,000 was immediately expensed in the consolidated statement of operations. The fair value of in-process research and development was determined using discounted forecasted cash flows directly related to the products expected to result from the research and development projects. The discount rates used in the valuation take into account the stage of completion and the risks surrounding the successful development and commercialization of each of the purchased in-process technology projects that were valued. The weighted-average discount rate used in calculating the present value of the in-process technology was 65%. Projects included in the valuation were all within the injection technology area, which covers injection technology as it pertains to pre-filled needle-free syringes, mini-needle devices, single-shot disposable devices and reusable needle-free devices. The Company's valuation of IPR&D identified development costs and overhead expenses only by technology area, and not by project. The IPR&D projects were approximately 10%-40% complete at the time of acquisition.

The nature of the efforts to develop the acquired in-process research and development into commercially viable products consists principally of planning, designing and testing activities necessary to determine that the product can

meet market expectations, including functionality, technical and performance requirements and specifications. The Company expects that the products incorporating the acquired technology will generally be completed and begin to generate cash flows over the 24 to 48 month period after the acquisition. Management estimates that it will cost approximately \$27 million to complete IPR&D over the next nine years. The risks of not completing development within a reasonable period of time and the impact from development delays are discussed more fully in the Company's risk factors, beginning on page 11 of this annual report. The Company's funding for all IPR&D expenses will come from the receipt of licensing fees, milestone payments and possible divestment of some of its non-core technology. If these receipts are insufficient to cover funding needs, the Company will consider raising additional amounts through equity investments from existing business partners and/or funding opportunities in the private or capital markets. All IPR&D efforts existing as of the beginning of 2001 are currently continuing. The projections the Company used in evaluating IPR&D are still applicable, and the Company does not expect to begin realizing the benefits from IPR&D until 2003. The efforts pertaining to the IPR&D projects will be completed over the next several years, in conjunction with management's judgment of market conditions and availability of investment funds, with benefits estimated to accrue through 2009.

#### Sales and Marketing

Sales and marketing expenses increased 443% from \$213,110 in 1999 to \$1,157,066 in 2000 and increased \$186,562 or 16% to \$1,343,628 in 2001. The majority of the increase from 1999 to 2000 was attributable to additional consulting expenses of approximately \$493,204 related to market evaluation and analysis. A commission fee of \$40,000 was incurred in 2000 while increased travel and relocation expenses related to the business combination accounted for the remainder of the increase. The 2001 increase is due primarily to the addition of Antares/Minnesota expenses since January 31, 2001, partially offset by a decrease of approximately \$1,000,000 in outside marketing travel and consulting expenses in Antares/Switzerland resulting from a management decision to reduce utilization of outside consulting services.

### General and Administrative

General and administrative expenses decreased 35% from \$3,220,514 in 1999 to \$2,101,749 in 2000 due to the closure of operations in France and Argentina, and increased to \$5,358,606 in 2001, an increase of \$3,256,857 or 155%. The decrease in 2000 is primarily due to the closing of operations in France and Argentina. The 2001 increase is primarily due to the addition of Antares/Minnesota general and administrative costs since January 31, 2001, partially offset by a \$266,790 decrease in Antares/Switzerland restructuring costs.

The Company recorded \$454,428 and \$266,790 of restructuring expenses during 1999 and 2000, respectively. Such expenses were in connection with the dissolution of Permatec Laboratorios (Permatec Argentina), and the related closure of the Company's research and development facility in Argentina and the dissolution of Permatec France and the related termination of employees associated with the Company's business development, patent administration, project management and administrative functions in France. The Company has recorded all restructuring charges incurred during the years ended December 31, 1999 and 2000, as general and administrative expenses.

The restructuring charges incurred during the year ended December 31, 2000 included involuntary severance benefits of \$178,257\$ for two employees of the Company's French operations resulting from an arbitration settlement finalized in March 2000. During 1999, at the time the original restructuring plan was formulated, management was

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unable to estimate the severance benefit for these two employees. In connection with the restructuring activities which commenced in 1999 approximately 25 employees were terminated, 13 of which received involuntary severance benefits.

As a result of management's ongoing review of the restructuring activities related to the dissolution of Permatec France and Permatec Argentina, which commenced in 1999, the Company recorded charges of approximately \$17,000 related to the write-off of certain equipment which was to be disposed of via scrap at its French subsidiary in the year ended December 31, 2000. Accordingly, the Company adjusted the carrying value of the equipment to zero, resulting in an impairment charge of \$17,000. The Company also incurred restructuring related expenses of \$71,533 in the year ended December 31, 2000 related to certain other incremental costs of exiting its facilities including legal and consulting fees, and lease termination costs.

The Company undertook these restructuring actions as part of an effort to reduce costs and to centralize developmental and administrative functions in Switzerland. These restructuring programs are now complete. The following table provides a summary of the Company's restructuring provision activity:

|                           | Asset Severance & Impairment Benefits (non-cash) |                      | Facilities,<br>Legal &<br>Other |
|---------------------------|--|----------------------|---------------------------------|
| Balance December 31, 1998 | \$<br>249,50<br>(70,21                           |                      | \$ _<br>101,528                 |
| Balance December 31, 1999 | 179,28<br>178,25<br>(357,54                      | 7 17,000             | 101,528<br>71,533<br>(173,061   |
| Balance December 31, 2000 | \$<br>======                                     | - \$ -<br>= ======== | \$ -<br>=======                 |

Other Income (Expense)

Other income (expense), net, increased 253% from (\$159,120) in 1999 to (\$562,200) in 2000 and changed to net income of \$73,464 in 2001. Interest expense increased 37% from \$294,318 in 1999 to \$402,217 in 2000 due to higher average borrowings during the period. Foreign exchange losses increased by \$198,257 in 2000 compared to 1999 due primarily to foreign exchange differences in shareholders' loans. Other income, net, in 2001 was primarily due to increased interest income of \$221,524 resulting from interest earned on funds received in the private placement of equity, decreased interest expense of \$301,380 due to the conversion of shareholder loans to equity on January 31, 2001 in connection with the Share Transaction, and a reduction of \$112,760 in foreign exchange losses and other expenses.

Liquidity and Capital Resources

Operating Activities

Cash used in operating activities was \$2,654,480, \$3,362,568 and \$7,999,042

for the years ended December 31, 1999, 2000 and 2001, respectively. This was the result of net losses of \$3,967,366, \$5,260,387 and \$9,499,101 in 1999, 2000 and 2001, respectively, adjusted by noncash expenses and changes in operating assets and liabilities.

Net noncash expenses of \$510,205 in 1999 were mainly due to depreciation and amortization. In 2000 noncash expenses totaled \$448,430 and resulted primarily from depreciation and amortization of \$392,847 and stock-based compensation expense of \$64,583. Noncash expenses totaled \$2,854,628 in 2001, consisting primarily of depreciation and amortization of \$1,324,539 and the write-off of in-process research and development and tooling-in-process costs of \$948,000 and \$404,811, respectively. The increases over 2000 result primarily from the addition of Antares/Minnesota.

The change in operating assets and liabilities in 1999 resulted in a net increase to cash of \$802,681, comprised mainly of a reduction in other receivables of \$322,008 and increases in accrued expenses and restructuring provisions of \$126,614 and \$299,537, respectively. In 2000, the change in operating assets and liabilities caused an increase in cash of \$1,449,389, primarily due to the increase in deferred revenue of \$1,659,612 resulting from the adoption of the cumulative deferral method of accounting. The change in operating assets and liabilities in 2001 utilized cash of \$1,354,569. This resulted primarily from the increase in Antares/Minnesota inventory of \$243,510 since January 31,

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2001, and from the reduction in current liabilities of \$1,194,029 after receiving the proceeds from the private placement of common stock in February and March of 2001.

#### Investing Activities

Net cash used in investing activities totaled \$480,033, \$1,218,333 and \$940,929 for the years ended December 31, 1999, 2000 and 2001, respectively. Purchases of equipment, furniture and fixtures utilized cash of \$424,053, \$133,641 and \$424,691 in 1999, 2000 and 2001, respectively. Spending for patent development and acquisitions in 1999, 2000 and 2001 were \$145,449, \$51,396 and \$360,759, respectively. Amounts incurred on behalf of or advanced to Medi-Ject totaled \$1,033,296 in 2000, and \$602,756 in January 2001 prior to closing of the Share Transaction. Cash used in investing activities was net of proceeds from equipment and furniture sales of \$89,469 and \$91,699 in 1999 and 2001, respectively, and cash of \$355,578 in 2001 acquired in the Share Transaction.

# Financing Activities

Net cash provided by financing activities totaled \$3,424,959 for the year ended December 31, 1999, compared to \$4,120,159 in 2000 and \$11,056,887 in 2001. The 1999 and 2000 net cash provided by financing activities was due to proceeds from subordinated loans from shareholders of \$3,560,640 and \$4,235,765, respectively, offset by principal payments on capital lease obligations of \$135,681 and \$115,606, respectively. In 2001, net cash provided by financing activities resulted primarily from net proceeds of \$9,991,391 from the private placement of common stock. Also in 2001, proceeds from stock option exercises totaled \$56,861 and proceeds from subordinated loans from shareholders received prior to January 31, 2001 totaled \$1,188,199, which were partially offset by principal payments on capital lease obligations of \$179,564

The Company's contractual cash obligations at December 31, 2001, as adjusted for the March 12, 2002 advance from Jacques Gonella noted below, are

summarized in the following table:

|  |   | 1                                     | Payment | Due by Period      |
|--|---|---------------------------------------|---------|--------------------|
|  | <br>Total                               | <br>Less than<br>1 year               |         | 1-3<br>years       |
| Capital leases Operating leases Jacques Gonella loan | \$<br>219,818<br>1,702,081<br>1,000,000 | \$<br>106,728<br>397,640<br>1,000,000 |         | 113,090<br>689,187 |
| Total contractual cash obligations                   | \$<br>2,921,899                         | \$<br>1,504,368                       | •       | 802 <b>,</b> 277   |

On March 12, 2002 the Company received an advance of \$1,000,000 from the Company's majority shareholder, Dr. Jacques Gonella, under a Term Note agreement dated February 20, 2002. The Company can receive a total of \$2,000,000 under the Term Note in increments of \$1,000,000. The note bears interest at the three month Euribor Rate as of the date of each advance, plus 5%. The principal and accrued interest is due on the earlier of (i) August 20, 2002, or (ii) the closing of a private placement of equity by the Company that results in net proceeds of \$5,000,000.

The report of the Company's independent accountants contains an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern as a result of recurring losses and negative cash flows from operations. The Company had negative working capital of \$2,439,577 and \$11,712 at December 31, 2000 and 2001, respectively, and has incurred net losses of \$3,967,366, \$5,260,387 and \$9,499,101 in 1999, 2000 and 2001, respectively. In addition, the Company has had net losses and has had negative cash flows from operating activities since inception. The Company expects to report a net loss for the year ending December 31, 2002, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products.

The Company has sufficient cash through April 2002 and will be required to raise additional working capital to continue to exist. Management intends to raise this additional capital through alliances with strategic corporate partners, equity offerings, and/or borrowing from the Company's majority shareholder. There can be no assurance that the Company will ever become profitable or that adequate funds will be available when needed or on acceptable terms.

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If for any reason we are unable to obtain additional financing we may not be able to continue as a going concern, which may result in material asset impairments, other material adverse changes in our business, results of operations or financial condition, or the loss by shareholders of all or a part of their investment in the Company.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable

to continue as a going concern.

New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued SFAS 141, "Business Combinations," and SFAS 142, "Goodwill and Other Tangible Assets." SFAS 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. SFAS 141 also specifies criteria that identify intangible assets acquired in a purchase method business combination that must be recognized and reported apart from goodwill. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually. SFAS 142 also requires that intangible assets with definite useful lives be amortized over their respective estimated useful lives. At December 31, 2001, the Company's goodwill and amortizable intangible assets aggregate \$1,159,767 and \$1,935,588, respectively.

The Company adopted SFAS 141 during 2001. SFAS 142 adoption will be effective January 1, 2002. The Company is evaluating whether any write-down of goodwill may be required as a result of implementing this new standard. The Company had goodwill amortization of \$177,963, \$177,963 and \$205,237 in each of the years ended December 31, 1999, 2000 and 2001, respectively. Adoption of SFAS 142 is expected to decrease expenses in 2002 by approximately \$253,000 as a result of ceasing amortization of goodwill and other intangible amounts allocated to workforce.

SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," was issued in October 2001. SFAS 144 provides new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued operation and how the results of a discontinued operation are to be measured and presented. The provisions of SFAS 144 are effective for fiscal years beginning after December 15, 2001. The Company will adopt the provisions of this statement on January 1, 2002, and does not expect adoption will have a material impact on its consolidated results of operations or financial position.

#### Item 7(a). MARKET RISK ASSESSMENT

The Company's primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of the Company's subsidiaries in Switzerland are translated into U.S. dollars for consolidation. The Company's exposure to foreign exchange rate fluctuations also arises from transferring funds to its Swiss subsidiaries in Swiss Francs. Most of the Company's sales and licensing fees are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. The effect of foreign exchange rate fluctuations on the Company's financial results for the years ended December 31, 1999, 2000 and 2001 was not material. The Company does not currently use derivative financial instruments to hedge against exchange rate risk. Because exposure increases as intercompany balances grow, the Company will continue to evaluate the need to initiate hedging programs to mitigate the impact of foreign exchange rate fluctuations on intercompany balances. The Company's exposure to interest rate risk is limited to \$1,000,000 borrowed on March 12, 2002 under a \$2,000,000 Term Note agreement with its majority shareholder dated February 20, 2002. The note bears interest at the three month Euribor Rate as of the date of each advance, plus 5%. The principal and accrued interest is due on the earlier of (i) August 20, 2002, or (ii) the closing of a private placement of equity by the Company that results in net proceeds of \$5,000,000. Due to the short-term nature of the note, the Company's exposure to interest rate risk is not believed to be material. The Company does not use derivative financial instruments to manage interest rate risk. All other existing debt agreements of the Company bear interest at fixed rates, and are therefore not subject to exposure from

fluctuating interest rates.

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Item 8. FINANCIAL STATEMENTS.

# ANTARES PHARMA, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

| Independent Auditors' Report  | 31 |
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| Consolidated Balance Sheets as of December 31, 2000 and 2001  | 32 |
| Consolidated Statements of Operations for the Years Ended December 31, 1999, 2000 and 2001  | 33 |
| Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Loss for the Years Ended December 31, 1999, 2000 and 2001 | 34 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 1999, 2000 and 2001  | 35 |
| Notes to Consolidated Financial Statements  | 36 |

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#### INDEPENDENT AUDITORS' REPORT

The Board of Directors and Shareholders Antares Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2000 and 2001, and the related consolidated statements of operations, shareholders' equity (deficit) and comprehensive loss, and cash flows for each of the years in the three-year 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 of America. 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Antares Pharma, Inc. and subsidiaries as of December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2001, in conformity with accounting principles

generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has negative working capital and has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 1 to the consolidated financial statements, the Company adopted the cumulative deferral method of revenue recognition for licensing arrangements in 2000.

KPMG LLP

Minneapolis, Minnesota March 12, 2002

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# ANTARES PHARMA, INC. CONSOLIDATED BALANCE SHEETS

|  |                | 200           |
|--|----------------|---------------|
| Assets Current Assets: Cash  | \$             | 2             |
| Accounts receivable, less allowance for doubtful accounts of \$18,000  VAT, capital taxes and other receivables  |                | 4             |
| Total current assets   |                | 6             |
| Equipment, furniture and fixtures, net.  Patent rights, net.  Goodwill, net.  Other intangibles, net.  Other assets.  Notes receivable and due from Medi-Ject Corporation. |                | 8<br>2<br>5,1 |
| Total Assets   | <br>\$<br>==== | 6 <b>,</b> 9  |
| Liabilities and Shareholders' Equity (Deficit) Current Liabilities:  |                |               |
| Accounts payable   | \$             | 3             |

| Accrued expenses and other liabilities  Deferred revenue  Capital lease obligations - current maturities  Liabilities to related parties  | 6<br>1,6<br>1<br>3                    |
|---|---------------------------------------|
| Total current liabilities   | 3,1                                   |
| Subordinated loans from shareholders  Capital lease obligations, less current maturities  | 17,6                                  |
| Total liabilities   | <br>20 <b>,</b> 8                     |
| Shareholders' Equity (Deficit):  Series A Convertible Preferred Stock: \$0.01 par; authorized 10,000 shares; 1,250 issued and outstanding at December 31, 2001  Common Stock: \$0.01 par; authorized 15,000,000 shares; 10,000 and 9,161,188 issued and outstanding at December 31, 2000 and 2001, respectively | <br>6<br>1,1<br>(17,2<br>1,5<br>(13,8 |
| Total Liabilities and Shareholders' Equity (Deficit)  | \$<br>6,9                             |

See accompanying notes to consolidated financial statements.

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# ANTARES PHARMA, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

|   | Υe            | ears En | ded D   |
|---|---------------|---------|---------|
|   | <br>1999<br>  |         | 200     |
| Revenues:                                       |               | Ć       |         |
| Product sales Licensing and product development | 1,351,607     | Ş<br>   | 56      |
| Cost of product sales                           | 1,351,607<br> |         | 56      |
| Gross margin                                    | <br>1,351,607 |         | 5<br>56 |
| Operating Expenses:                             |               |         |         |
| Research and development                        | 1,647,059<br> |         | 93      |
| Sales and marketing                             | 213,110       |         | 1,15    |
| General and administrative                      | 3,220,514     |         | 2,10    |

|  | 5,080,683                              | 4,19              |
|--|--|-------------------|
| Net operating loss   |  |                   |
| Other income (expense):  Interest income   | 6,967<br>(294,318)<br>30,984<br>97,247 | (40<br>(16<br>(56 |
| Loss before income taxes and cumulative effect of change in accounting principle                       | (3,888,196)                            |                   |
| Income taxes   | (79,170)                               | (                 |
| Loss before cumulative effect of change in accounting principle  |  |                   |
| Cumulative effect of change in accounting principle  |  | (1,05             |
| Net loss   |  |                   |
| In-the-money conversion feature-preferred stock dividend (Note 8) Preferred stock dividends            |  |                   |
| Net loss applicable to common shares   | \$ (3,967,366)<br>============         | •                 |
| Basic and diluted net loss per common share before cumulative effect of change in accounting principle |  |                   |
| Cumulative effect of change in accounting principle  |  |                   |
| Basic and diluted net loss per common share  | \$ (.92)                               |                   |
| Basic and diluted weighted average common shares outstanding   |  |                   |
|  |  |                   |

See accompanying notes to consolidated financial statements

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# ANTARES PHARMA, INC. CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS

|                   | Conve        | rtible Pre | ferred St        | ock    |              |      |
|-------------------|--------------|------------|------------------|--------|--------------|------|
|                   | Series A     |            | eries A Series C |        |              | atec |
|                   | Number<br>of |            | Number<br>of     |        | Number<br>of |      |
|                   | Shares       | Amount     | Shares           | Amount | Shares       | Am   |
| December 31, 1998 |              | \$         |                  | \$     | 10,000       | 68   |

| Net loss   |        |        |                 |        |          |     |
|--|--------|--------|-----------------|--------|----------|-----|
| Translation adjustments                            |        |        |                 |        |          |     |
|  |        |        |                 |        |          |     |
| Comprehensive loss                                 |        |        |                 |        |          |     |
| December 31, 1999                                  |        |        |                 |        | 10,000   | 68  |
| Share issuance to employees                        |        |        |                 |        | 10,000   | 00  |
| Net loss   |        |        |                 |        |          |     |
| Translation adjustments                            |        |        |                 |        |          |     |
| Comprehensive loss                                 |        |        |                 |        |          |     |
|  |        |        |                 |        |          |     |
| Dagarban 21 2000                                   |        |        |                 |        | 10.000   |     |
| December 31, 2000  Net liabilities of subsidiaries |        |        |                 |        | 10,000   | 68  |
| assumed by shareholders                            |        |        |                 |        |          |     |
| Medi-Ject stock outstanding                        |        |        |                 |        |          |     |
| at date of share                                   |        |        |                 |        |          |     |
| transaction  | 1,150  | 12     |                 |        |          |     |
| Exchange of Permatec                               |        |        |                 |        |          |     |
| shares for Medi-Ject stock                         |        |        |                 |        | (10,000) | (68 |
| Conversion of shareholder                          |        |        |                 |        |          |     |
| loans to equity                                    |        |        |                 |        |          |     |
| Conversion of notes to                             |        |        |                 |        |          |     |
| preferred Series C                                 |        |        | 27 <b>,</b> 500 | 275    |          |     |
| Conversion of preferred  Series C to common stock  |        |        | (27,500)        | (275)  |          |     |
| Exercise of stock options                          |        |        | (27,300)        | (273)  |          |     |
| Stock issued in lieu of                            |        |        |                 |        |          |     |
| dividends  | 100    | 1      |                 |        |          |     |
| Stock-based compensation                           |        |        |                 |        |          |     |
| expense  |        |        |                 |        |          |     |
| Issuance of common stock                           |        |        |                 |        |          |     |
| in private placement                               |        |        |                 |        |          |     |
| Conversion of preferred Series                     |        |        |                 |        |          |     |
| B to common stock                                  |        |        |                 |        |          |     |
| Stock issued in technology                         |        |        |                 |        |          |     |
| acquisition agreement                              |        |        |                 |        |          |     |
| Translation adjustments                            |        |        |                 |        |          |     |
| Comprehensive loss                                 |        |        |                 |        |          |     |
| COMPTENDING TODS                                   |        |        |                 |        |          |     |
|  |        |        |                 |        |          |     |
| December 31, 2001                                  | 1,250  | \$ 13  |                 | \$     |          |     |
|  | ====== | ====== | ======          | ====== | =======  | === |
|  |        |        |                 |        |          |     |

|  | <br>Additional<br>Paid-In<br>Capital | <i>P</i> . | accumulated<br>Deficit     | Compe | erred<br>nsation |
|--|--------------------------------------|------------|----------------------------|-------|------------------|
| December 31, 1998  Net loss  Translation adjustments | \$<br>1,110,097<br><br>              | \$         | (8,036,710)<br>(3,967,366) | \$    | <br>             |
| Comprehensive loss                                   | <br>                                 |            |                            |       |                  |
| December 31, 1999                                    | 1,110,097                            |            | (12,004,076)               |       |                  |

| Share issuance to employees   | 64,583           |                 |              |
|---|------------------|-----------------|--------------|
| Net loss  |                  | (5,260,387)     |              |
| Translation adjustments   |                  |                 |              |
| Comprehensive loss  |                  |                 |              |
| December 31, 2000  Net liabilities of subsidiaries                    | 1,174,680        | (17,264,463)    |              |
| assumed by shareholders  Medi-Ject stock outstanding at date of share | (644,725)        | 2,720,931       |              |
| transaction  Exchange of Permatec                                     | 6,625,659        |                 |              |
| shares for Medi-Ject stock Conversion of shareholder                  | 660,655          |                 |              |
| loans to equity  Conversion of notes to                               | 13,069,870       |                 |              |
| preferred Series C  Conversion of preferred                           |                  | (275)           |              |
| Series C to common stock  | 5,286,900        | (5,314,125)     |              |
| Exercise of stock options   | 56,478           |                 |              |
| Stock issued in lieu of   |                  | 41.00.000       |              |
| dividendsStock-based compensation                                     | 99 <b>,</b> 999  | (100,000)       |              |
| expense  Issuance of common stock                                     | 396 <b>,</b> 397 |                 | (251,016)    |
| in private placement  Conversion of preferred Series                  | 9,974,326        |                 |              |
| B to common stock Stock issued in technology                          | 249,000          |                 |              |
| acquisition agreement   | 515,292          |                 |              |
| Net loss  |                  | (9,499,101)     |              |
| Translation adjustments   |                  |                 |              |
| Comprehensive loss  |                  |                 |              |
| December 31, 2001   | \$ 37,464,531    | \$ (29,457,033) | \$ (251,016) |
|   | ========         | ==========      |              |

See accompanying notes to consolidated financial statements.

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# ANTARES PHARMA, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

|   | Yea                 | rs En |
|---|---------------------|-------|
|   | <br>1999<br>        |       |
| Cash flows from operating activities:  Net loss                   | \$<br>(3,967,366)   | \$    |
| cash used in operating activities:  Depreciation and amortization | 560,628<br>(50,423) |       |

| Write-off of tooling in process  | <br><br>                    |
|--|-----------------------------|
| Accounts receivable  VAT, capital taxes and other receivables  | <br>322,008                 |
| Inventories  Prepaid expenses and other assets  Accounts payable  Accrued expenses and other             | 28,100<br>59,517<br>126,614 |
| Liabilities to related parties   | 299 <b>,</b> 537            |
| Other  | (33,095)                    |
| Net cash used in operating activities  |                             |
| Cash flows from investing activities:  |                             |
| Purchases of equipment, furniture and fixtures   | (424,053)                   |
| Proceeds from sale of equipment, furniture & fixtures  | 89,469                      |
| Additions to patent rights   |                             |
| Acquisition costs invoiced to Medi-Ject Corporation  Increase in notes receivable and due from Medi-Ject |                             |
| Acquisition of Medi-Ject, including cash acquired  |                             |
| Net cash used in investing activities  | (480,033)                   |
| Cash flows from financing activities:  |                             |
| Proceeds from subordinated loans from shareholders   |                             |
| Principal payments on capital lease obligations  |                             |
| Proceeds from issuance of common stock, net  |                             |
| Net cash provided by financing activities  |                             |
| Effect of exchange rate changes on cash and cash equivalents   |                             |
| Net increase (decrease) in cash and cash equivalents   |                             |
| Beginning of year  | 492,376                     |
| End of year  |                             |

Schedule of non-cash investing and financing activities: See information regarding non-cash investing and financing activities related to the Share Transaction in Notes 3 and 10.

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 1999, 2000 and 2001

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1. Description of Business and Summary of Significant Accounting Policies

#### Business

The Company develops, produces and markets pharmaceutical delivery solutions, including needle-free and mini-needle injector systems, gel technologies and transdermal products. The Company currently distributes its needle-free injector systems for the delivery of insulin and growth hormone in more than 20 countries and an estradiol transdermal patch for hormone replacement therapy. In addition, the Company has several products and compound formulations under development and is conducting ongoing research to create new products and formulations that combine various elements of the Company's technology portfolio. The corporate headquarters are located in Exton, Pennsylvania, with research and production facilities in Minneapolis, Minnesota, and research facilities in Basel, Switzerland.

#### Basis of Presentation

In July 2000, Medi-Ject Corporation, now known as Antares Pharma, Inc. ("Antares" or "the Company"), entered into a Purchase Agreement with Permatec Holding AG ("Permatec"), Permatec Pharma AG, Permatec Technology AG, and Permatec NV. Pursuant to the Purchase Agreement, on January 31, 2001, Antares purchased all of the outstanding shares of the three Permatec Subsidiaries (the "Share Transaction"). In exchange, Antares issued 2,900,000 shares of Antares common stock to Permatec. Upon the issuance, Permatec owned approximately 67% of the outstanding shares of Antares common stock. For accounting purposes, Permatec is deemed to have acquired Antares. The acquisition has been accounted for by the purchase method of accounting. The financial statements and related disclosures that were previously reported for Medi-Ject have been replaced with the Permatec financial statements and disclosures. The operating financial history of Antares has become that of Permatec.

Prior to the business combination, Permatec consisted of six entities: a holding company with no activity and five integrated operating subsidiaries. Two of the subsidiaries were not sold pursuant to the Purchase Agreement. The activities of these two subsidiaries were primarily research and development activities for other Permatec entities and to a lesser extent for third parties. The substantive operations of these two entities were moved into the remaining three subsidiaries as a result of restructuring activities undertaken by Permatec prior to the business combination. As these activities were integral to the historical financial statements of Permatec, they were included in the historical financial statements of Permatec until the date of the business combination, at which time their net liabilities of \$537,683 were reflected as a deemed contribution of capital. Because the substance of the transaction was the contribution of additional equity by the majority shareholder to the post-merger entity, this transaction was recognized by the Company as an equity transaction similar to the sale of stock by a subsidiary without recognition of a gain, as prescribed by Staff Accounting Bulletin 84. These two entities have been fully liquidated and are in the process of being legally dissolved. The consolidation of the operations of the five entities into three entities was for purposes of gaining efficiencies in Permatec's operations and did not substantively change the consolidated group's operations.

# Principles of Consolidation

As discussed in Note 3, on January 31, 2001 the Company completed a business combination to acquire the three operating subsidiaries of Permatec Holding AG ("Permatec"), headquartered in Basel, Switzerland. The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its three wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency Translation

Revenues of the subsidiaries are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. However, nearly all operating expenses, including labor, materials, leasing arrangements and other operating costs, are denominated in Swiss Francs. Additionally, bank accounts are denominated in Swiss Francs, there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent company. As such, under Financial Accounting Standards Board Statement No. 52, "Foreign Currency Translation," the Company has determined that the Swiss Franc is the functional currency for its three subsidiaries. The reporting currency for the Company is the United States Dollar ("USD"). The financial statements of the Company's three subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a separate component of shareholders' equity. Foreign currency transaction gains and losses are included in the statements of operations.

Cash Equivalents

The Company considers highly liquid debt instruments with original maturities of  $90~{\rm days}$  or less to be cash equivalents.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1999, 2000 and 2001

 Description of Business and Summary of Significant Accounting Policies (Continued)

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out basis. Certain components of the Company's products are provided by a limited number of vendors. Disruption of supply from key vendors may have a material adverse impact on the Company's operations.

Inventory Reserves

The Company records reserves for inventory shrinkage and for potentially excess, obsolete and slow moving inventory. The amounts of these reserves are based upon inventory levels, expected product lives and forecasted sales demand. Although management believes the likelihood to be relatively low, results could be materially different if demand for the Company's products decreased because of economic or competitive conditions, or if products became obsolete because of technical advancements in the industry or by the Company. The Company has recorded inventory reserves of approximately \$105,000 at December 31, 2001.

Equipment, Furniture, and Fixtures

Equipment, furniture, and fixtures are stated at cost and are depreciated using the straight-line method over their estimated useful lives ranging from three to ten years. Certain equipment and furniture held under capital leases is classified in equipment, furniture and fixtures and is amortized using the straight-line method over the lesser of the lease term or estimated useful life,

and the related obligations are recorded as liabilities. Lease amortization is included in depreciation expense.

#### Patent Rights

The Company capitalizes the cost of obtaining patent rights. These capitalized costs are being amortized on a straight-line basis over periods ranging from six to ten years beginning on the earlier of the date the patent is issued or the first commercial sale of product utilizing such patent rights. Recoverability of such patent assets is evaluated on a quarterly basis.

#### Goodwill

Goodwill arising from the purchase of minority ownership interests in 1996 was amortized on a straight-line basis over a period of five years. Goodwill arising from the Share Transaction described in Note 3 is being amortized on a straight-line basis over a period of ten years. Prior to the adoption of SFAS No. 142, the Company periodically estimated the future undiscounted cash flows to which goodwill relates to ensure that the carrying value of goodwill has not been impaired. To the extent the Company's undiscounted cash flows are less than the carrying amount of goodwill, the Company will recognize an impairment charge.

In July 2001, the Financial Accounting Standards Board issued SFAS 142, "Goodwill and Other Intangible Assets." SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually. The Company will adopt the provision of SFAS 142 beginning January 1, 2002, at which time the Company will cease the amortization of existing goodwill. SFAS No. 142 also establishes a new method of testing goodwill for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying value.

#### Other Intangible Assets

Other intangible assets include values assigned to workforce, ISO certification and clinical studies and are being amortized over estimated useful lives which range from five to ten years.

Impairment of Long-Lived Assets and Long-Lived Assets to Be Disposed Of

Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1999, 2000 and 2001

 Description of Business and Summary of Significant Accounting Policies (Continued)

Fair Value of Financial Instruments

All financial instruments are carried at amounts that approximate estimated fair value. At December 31, 2000 it was not practicable to estimate the fair value of the subordinated loans from shareholders, because of the lack of quoted market prices for similar investments, and such loans can only be repaid after achievement of positive shareholders' equity as defined by Swiss statutory regulations.

Revenue Recognition

The Company sells its proprietary needle-free injectors and related disposable products through pharmaceutical and medical product distributors. The Company's injectors and disposable products are not interchangeable with any competitive products and must be used together. The Company recognizes revenue upon shipment. The Company offers no price protection or return rights other than for customary warranty claims. Sales terms and pricing are governed by sales and distribution agreements.

Licensing and Product Development Revenue Recognition

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 101 which provides the Staff's views in applying generally accepted accounting principles to selected revenue recognition issues. The SAB provides additional guidance on when revenue is realized, earned and properly recognized. The Company elected to adopt the cumulative deferral method for recognizing milestone revenues beginning with the fourth quarter of fiscal 2000. This method defers milestone payments with amortization to income over the contract term using the percentage of completion or straight-line basis commencing with the achievement of a contractual milestone. If the Company is required to refund any portion of a milestone payment, the milestone will not be amortized into revenue until the repayment obligation no longer exists.

Upon adoption of the cumulative deferral method, the Company recognized a cumulative effect adjustment that increased its losses by \$1,059,622 or \$0.25 per share as of January 1, 2000. For the years ended December 31, 2000 and 2001, the Company recognized \$277,200 and \$267,180, respectively, of license revenues that were deferred at January 1, 2000 as the result of the adoption of the cumulative deferral method.

Prior to the adoption of the cumulative deferral method, licensing and product development revenue was recognized when underlying performance criteria for payment had been met and the Company had an unconditional right to such payment. Depending on a license or product development agreement's terms, recognition criteria was satisfied upon achievement of milestones or passage of time. Milestone payments were typically triggered by the successful achievement of important events such as the completion of clinical studies, filings with the FDA, bioequivalence to other drugs, and approval by the FDA as defined by the underlying licensing and product development agreement. The Company classified amounts received related to the performance of a series of tasks, (e.g. testing the transdermal penetration of a drug, manufacture of a clinical batch, etc.) as product development revenues.

The Company recognizes royalty revenues upon the sale of licensed products

by the licensee, and recognizes such revenue as license revenue. The Company occasionally receives payment of up-front royalty advances from licensees. Upon adoption of the cumulative deferral method, if vendor specific objective evidence of fair value exists, revenues from up-front royalty payments are deferred until earned through the sale of licensed revenue from the licensee or the termination of the agreement based on the terms of the license. If vendor specific objective evidence of fair value does not exist, revenues from up-front royalty payments are recognized using the cumulative deferral method. The Company classifies amounts received related to royalties from sales of products licensed by the Company, which the Company developed or partially developed, as license revenues in accordance with the terms of the underlying agreement.

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
December 31, 1999, 2000 and 2001

 Description of Business and Summary of Significant Accounting Policies (Continued)

In certain cases the Company receives up-front payments upon signing licensing and development agreements. Prior to the adoption of the cumulative deferral method, if the up-front payment related to services already performed, and there was no additional performance obligation under the agreement, the amount was recognized as revenue in the period the payment was received. If the Company had subsequent obligations under the agreement, or the payment did not relate to services already provided, the amount was deferred in relation to the performance requirements under the related licensing and development agreement. Upon adoption of the cumulative deferral method, up-front license payments are deferred and amortized into revenues on a straight-line basis.

Stock-Based Compensation

Compensation expense for stock incentives granted to employees and directors is recognized in accordance with Accounting Principles Board, Opinion 25 ("APB 25"), "Accounting for Stock Issued to Employees." Pro forma effects on net loss and loss per share are provided as if the fair value based method defined in Statement of Financial Accounting Standards No. 123 ("SFAS 123"), "Accounting for Stock-Based Compensation," had been applied.

The Company accounts for stock-based instruments granted to nonemployees under the fair value method of SFAS 123 and Emerging Issues Task Force (EITF) 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services." Under SFAS 123, options are recorded at their fair value on the measurement date, which is typically the vesting date.

Product Warranty

The Company recognizes the estimated cost of warranty obligations to customers at the time the products are shipped.

Research and Development

Research and development costs are expensed as incurred.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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. The Company's significant accounting estimates relate to the revenue recognition periods for license revenues, product warranty accruals, obsolete inventory accruals, and determination of the fair value and recoverability of intangible assets. Actual results could differ from these estimates.

#### Advertising Expense

Advertising costs (including production and communication costs) for 1999 and 2000 were insignificant, and for 2001 were approximately \$45,000. Production costs related to advertising are expensed as incurred.

#### Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to historical net losses of the Company, a valuation allowance is established to offset the deferred tax asset.

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# ANTARES PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) December 31, 1999, 2000 and 2001

 Description of Business and Summary of Significant Accounting Policies (Continued)

#### Net Loss Per Share

Basic EPS is computed by dividing net income or loss available to Common Shareholders by the weighted-average number of Common Shares outstanding for the period. Diluted EPS reflects the potential dilution from the exercise or conversion of securities into Common Stock. For the years ended December 31, 1999, 2000 and 2001, the effects of potential Common Shares were excluded from the calculation of diluted EPS because their effect was antidilutive.

### Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications did not impact previously reported net loss or net loss per share.

# New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued SFAS 141, "Business Combinations," and SFAS 142, "Goodwill and Other Tangible Assets." SFAS 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. SFAS 141 also specifies criteria that identify intangible assets acquired in a purchase method business

combination that must be recognized and reported apart from goodwill. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually. SFAS 142 also requires that intangible assets with definite useful lives be amortized over their respective estimated useful lives. At December 31, 2001, the Company's goodwill and amortizable intangible assets aggregate \$1,159,767 and \$1,935,588, respectively.

The Company adopted SFAS 141 during 2001. SFAS 142 adoption will be effective January 1, 2002. The Company is evaluating whether any write-down of goodwill may be required as a result of implementing this new standard. The Company had goodwill amortization of \$177,963, \$177,963 and \$205,237 in each of the years ended December 31, 1999, 2000 and 2001, respectively. Adoption of SFAS 142 is expected to decrease expenses in 2002 by approximately \$253,000 as a result of ceasing amortization of goodwill and other intangible amounts allocated to workforce.

SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," was issued in October 2001. SFAS 144 provides new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued operation and how the results of a discontinued operation are to be measured and presented. The provisions of SFAS 144 are effective for fiscal years beginning after December 15, 2001. The Company will adopt the provisions of this statement on January 1, 2002, and does not expect adoption will have a material impact on its consolidated results of operations or financial position.

#### 2. Going Concern

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities and other commitments in the normal course of business. The Company had negative working capital of \$2,439,577 and \$11,712 at December 31, 2000 and 2001, respectively, and has had net losses and negative cash flows from operating activities since inception, and incurred net losses of \$3,967,366, \$5,260,387 and \$9,499,101 in 1999, 2000 and 2001, respectively.

The Company expects to report a net loss for the year ending December 31, 2002, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products.

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
December 31, 1999, 2000 and 2001

#### 2. Going Concern (Continued)

The Company has sufficient cash through April 2002 and will be required to raise additional working capital to continue to exist. Management's intentions are to raise this additional capital through alliances with strategic corporate partners, equity offerings, and/or borrowing from the Company's majority shareholder. On March 12, 2002 the Company received an advance of \$1,000,000 from the Company's majority shareholder, Dr. Jacques Gonella, under a Term Note agreement dated February 20, 2002. The Company can receive a total of \$2,000,000

under the Term Note in increments of \$1,000,000. There can be no assurance that the Company will ever become profitable or that additional adequate funds will be available when needed or on acceptable terms.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

#### 3. Acquisition of Medi-Ject Corporation

Upon closing of the Share Transaction on January 31, 2001, the full principal amount of Permatec's shareholders' loans to the three Permatec subsidiaries which were included in the Share Transaction, of \$13,069,870, was converted to equity. There were no shares issued pursuant to this conversion, and the amounts were converted to additional paid—in capital using historical values.

Also on January 31, 2001, promissory notes issued by Medi-Ject to Permatec between January 25, 2000 and January 15, 2001, in the aggregate principal amount of \$5,500,000, were converted into Series C Convertible Preferred Stock ("Series C"). Permatec, the holder of the Series C stock, immediately exercised its right to convert the Series C stock, and Antares issued 2,750,000 shares of common stock to Permatec upon such conversion. Also on that date, the name of the corporation was changed to Antares Pharma, Inc.

The total consideration paid, or purchase price, for Medi-Ject was approximately \$6,889,974, which represents the fair market value of Medi-Ject and related transaction costs of \$480,095. For accounting purposes, the fair value of Medi-Ject is based on the 1,424,729 shares of Medi-Ject common stock outstanding on January 25, 2000, at an average closing price three days before and after such date of \$2.509 per share plus the estimated fair value of the Series A convertible preferred stock and the Series B mandatorily redeemable convertible preferred stock plus the fair value of outstanding stock options and warrants representing shares of Medi-Ject common stock either vested on January 25, 2000, or that became vested at the close of the Share Transaction plus the capitalized acquisition cost of Permatec.

The purchase price allocation, based on an appraisal by an independent third-party appraisal firm, was as follows:

| Cash acquired                                  | \$ | 394 <b>,</b> 535 |
|--|----|------------------|
| Current assets                                 |    | 900,143          |
| Equipment, furniture and fixtures              |    | 1,784,813        |
| Patents  |    | 1,470,000        |
| Other intangible assets                        |    | 2,194,000        |
| Goodwill                                       |    | 1,276,806        |
| Other assets                                   |    | 3 <b>,</b> 775   |
| Current liabilities                            |    | (2,026,723)      |
| Debt   |    | (55, 375)        |
| <pre>In-process research and development</pre> |    | 948,000          |
|  |    |                  |
| Purchase price                                 | \$ | 6,889,974        |
|  | == |                  |

In connection with the Share Transaction on January 31, 2001, the Company acquired in-process research and development projects having an estimated fair value of \$948,000 that had not yet reached technological feasibility and had no alternative future use. Accordingly, this amount was immediately expensed in the Consolidated

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1999, 2000 and 2001

#### 3. Acquisition of Medi-Ject Corporation (Continued)

Statement of Operations. The fair value of in-process research and development was determined by using discounted forecasted cash flows directly related to the products expected to result from the research and development projects. The discount rates used in the valuation take into account the stage of completion and the risks surrounding the successful development and commercialization of each of the purchased in-process technology projects that were valued. The weighted-average discount rate used in calculating the present value of the in-process technology was 65%. Projects included in the valuation were approximately 10% to 40% complete and related to ongoing injection research, mini-needle technology, pre-filled syringes and single-shot disposable injection devices. The nature of the efforts to develop the acquired in-process research and development into commercially viable products consists principally of planning, designing and testing activities necessary to determine that the products can meet market expectations, including functionality, technical and performance requirements and specifications.

Unaudited pro forma results of operations for the years ended December 31, 2000 and 2001, assuming Permatec's acquisition of Medi-Ject, the conversion of the \$5,000,000 in promissory notes, and the Company's implementation of SFAS 141 all collectively occurred on January 1, 2000, are as follows:

|                                    | Pro forma      | Pro forma      |
|------------------------------------|----------------|----------------|
|                                    | Year Ended     | Year Ended     |
|                                    | December 31,   | December 31,   |
|                                    | 2000           | 2001           |
|                                    |                |                |
| Net revenues                       | \$ 2,553,284   | \$ 3,811,362   |
| Loss before cumulative effect of a |                |                |
| change in accounting principle     | \$(10,030,643) | \$(15,086,836) |
| Net loss                           | \$(11,145,026) | \$(15,086,836) |
| Net loss per share                 | \$ (1.63)      | \$ (1.78)      |

#### 4. Composition of Certain Financial Statement Captions

|  |        | December 31,     |               |                              |
|--|--------|------------------|---------------|------------------------------|
|  |        | 2000             |               | 2001                         |
| Inventories:  Raw material  Work-in-process  Finished goods    | \$     | -                | - \$<br>-     | 254,890<br>29,611<br>371,190 |
| rinished goods   | <br>\$ |                  | -<br><br>- \$ | 655,691                      |
| Equipment, furniture and fixtures:                             | ==:    |                  | = =           | =======                      |
| Furniture, fixtures and office equipment  Production equipment | \$     | 583,89<br>442,47 |               | 1,254,568<br>1,567,849       |

| Less accumulated depreciation               |     | (194,819)            |    | (194,819)                                    |  | (194,819) |  | (897,742) |
|---|-----|----------------------|----|--|--|-----------|--|-----------|
|   | \$  | 831,541              |    | 1,924,675                                    |  |           |  |           |
| Patent rights:                              | === | =======              | == | =======                                      |  |           |  |           |
| Patent rights Less accumulated amortization | \$  | 343,036<br>(89,602)  | \$ | 2,697,975<br>(233,639)                       |  |           |  |           |
|   | \$  | 253,434              |    | 2,464,336                                    |  |           |  |           |
| Goodwill:                                   |     |                      |    |  |  |           |  |           |
| Goodwill  Less accumulated amortization     | \$  | 889,816<br>(800,834) | \$ | 2,182,813<br>(1,023,046)                     |  |           |  |           |
|   | \$  | 88 <b>,</b> 982      | \$ | 1,159,767                                    |  |           |  |           |
| Other intangibles:                          |     |                      |    |  |  |           |  |           |
| Clinical studies                            | \$  | <br><br>             | \$ | 1,270,000<br>625,000<br>299,000<br>(258,412) |  |           |  |           |
|   | \$  |                      | \$ | 1,935,588                                    |  |           |  |           |
|   |     |                      | == |  |  |           |  |           |

Accrued expenses and other liabilities include accrued VAT (value added taxes) of \$386,511 and \$291,678 at December 31, 2000 and 2001, respectively.

#### 5. Restructuring Activities

The Company recorded \$454,428 and \$266,790 of restructuring expenses during the years ended December 31, 1999 and 2000, respectively. Such expenses were in connection with the closure of the Company's developmental facility in Argentina and termination of employees associated with the Company's business development, patent administration, project management and administrative functions in France. The Company recorded all restructuring charges incurred during the years ended December 31, 1999 and 2000, as general and administrative expense.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 1, 1999, 2000 and 2001

#### 5. Restructuring Activities (Continued)

The restructuring charge is primarily comprised of involuntary severance benefits and other incremental costs of exiting facilities, including lease termination costs, and write-off of certain assets. In connection with the closure of these facilities, the Company involuntarily terminated in 1999 approximately 25 employees, of which 13 were entitled to receive severance benefits. The restructuring charges incurred during 2000 included involuntary severance benefits of \$178,257 for two employees of the Company's French operations resulting from an out of court arbitration settlement finalized in March 2000.

The Company reported charges of approximately \$103,400 and \$17,000 related to the write-off of assets which were disposed of in connection with the closure

of the France and Argentina facilities for the years ended December 31, 1999 and 2000, respectively. The assets disposed of consisted of certain laboratory equipment and office equipment that the Company decided not to transfer to its central facilities in Basel, Switzerland.

The Company undertook these restructuring actions as part of its efforts to reduce costs and to centralize its developmental and administrative functions in Switzerland. These restructuring programs were completed during the year ended December 31, 2000. The following table provides a summary of the Company's restructuring provision activity:

|                             |    | verance and<br>Benefits |     | Asset<br>airment      | L  | cilities<br>egal and<br>Other<br> |
|-----------------------------|----|-------------------------|-----|-----------------------|----|-----------------------------------|
| Balance December 31, 1998   | \$ | <br>249,500             |     | <br>103 <b>,</b> 400  | \$ | -<br>101 <b>,</b> 52              |
| Amount utilized in 1999     |    | (70,212)                | ( ) | 103 <b>,</b> 400)<br> |    | -<br>                             |
| Balance December 31, 1999   |    | 179,288                 |     |                       |    | 101,52                            |
| 2000 restructuring expenses |    | 178 <b>,</b> 257        |     | 17,000                |    | 71 <b>,</b> 53                    |
| Amount utilized in 2000     |    | (357,545)               |     | (17,000)              |    | (173,06                           |
| Balance December 31, 2000   | \$ |                         | \$  |                       | \$ |                                   |

#### Leases

The Company has non-cancelable operating leases for its office, research and manufacturing facility in Minneapolis, MN, for office space in Exton, PA, and for its office and research facility in Basel, Switzerland. The leases require payment of all executory costs such as maintenance and property taxes. The Company also leases certain equipment and furniture under various operating and capital leases. The cost of equipment and furniture under capital leases at December 31, 2000 and 2001 was \$282,385 and \$245,905, respectively, and accumulated amortization was \$92,143 and \$113,478, respectively.

Rent expense incurred for the years ended December 31, 1999, 2000 and 2001 was \$270,537 \$143,349, and \$421,942 respectively.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1999, 2000 and 2001

# 6. Leases (Continued)

Future minimum lease payments are as follows as of December 31, 2001:

| Leases  | Leases    |
|---------|-----------|
| Capital | Operating |

| 2002  | \$     | 104,943         | \$ | 397 <b>,</b> 640 |
|---|--------|-----------------|----|------------------|
| 2003  |        | 80 <b>,</b> 913 |    | 411,583          |
| 2004  |        | 30 <b>,</b> 837 |    | 277,604          |
| 2005  |        |                 |    | 160,501          |
| 2006  |        |                 |    | 160,501          |
| Thereafter                                    |        |                 |    | 294,252          |
|   |        |                 |    |                  |
| Total future minimum lease payments           |        | 216,693         | \$ | 1,702,081        |
|   |        |                 | == |                  |
| Amount representing interest at 6.5% to 18.3% |        | (20,010)        |    |                  |
|   |        |                 |    |                  |
| Obligations under capital leases              |        | 196,683         |    |                  |
| Obligations due within one year               |        | (91,054)        |    |                  |
|   |        |                 |    |                  |
| Long-term obligations under capital leases    | \$     | 105,629         |    |                  |
|   | ====== | =======         |    |                  |

#### 7. Income Taxes

The Company incurred losses for both book and tax purposes in each of the years in the three-year period ended December 31, 2001, and, accordingly, no income taxes were provided. In 1999 and 2000 the Company was subject to Swiss taxes and in 2001 is subject to taxes in both the U.S. and Switzerland. Effective tax rates differ from statutory income tax rates in the years ended December 31, 1999, 2000 and 2001 as follows:

|  | 1999      | 2000     |
|--|-----------|----------|
|  |           |          |
| Statutory income tax rate                  | (20.0)%   | (20.0)%  |
| State income taxes, net of federal benefit |           |          |
| Research and experimentation credit        |           |          |
| In-process research and development costs  |           |          |
| Valuation allowance increase               | 20.0      | 17.0     |
| Other                                      |           | 3.0      |
|  |           |          |
|  | 0.0%      | 0.0%     |
|  | ========= | ======== |

Deferred tax assets as of December 31, 2000 and 2001 consist of the following:

|   | 2000             | 2001         |
|---|------------------|--------------|
|   |                  |              |
| Inventory reserve                             | \$               | 42,000       |
| Net operating loss carryforward - U.S         | 999 <b>,</b> 326 | 6,013,000    |
| Net operating loss carryforward - Switzerland |                  | 7,800,000    |
| Research & development costs and credit       |                  |              |
| carryforward                                  | 925 <b>,</b> 274 | 1,619,274    |
| Deferred revenue                              | 302,000          | 302,000      |
| Other   |                  | 360,000      |
|   |                  |              |
|   | 2,226,600        | 16,136,274   |
| Less valuation allowance                      | (2,226,600)      | (16,136,274) |
|   |                  |              |

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
December 31, 1999, 2000 and 2001

#### 7. Income Taxes (Continued)

The valuation allowance for deferred tax assets as of December 31, 2000 and 2001 was \$2,226,600 and \$16,136,274, respectively. The net change in the total valuation allowance for the years ended December 31, 2000 and 2001 was an increase of \$726,600 and \$13,909,674, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Due to the uncertainty of realizing the deferred tax asset, management has placed a valuation allowance against the entire deferred tax asset.

The Company has a U.S. federal net operating loss carryforward at December 31, 2001, of approximately \$31,872,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2009 through 2021. Additionally, the Company has a research credit carryforward of approximately \$694,000. These credits begin to expire in 2009.

The Company also has a Swiss net operating loss carryforward at December 31, 2001, of approximately \$7,800,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2004 through 2008. The Company's subsidiaries have deferred tax assets related to research and development costs, which are eligible for capitalization and amortization for tax purposes in certain of the Company's taxable jurisdictions.

The net operating losses and tax credits of Antares Pharma, Inc. are subject to annual limitations under Internal Revenue Code Sections 382 and 383, respectively, as a result of significant changes in ownership, including the business combination with Permatec and private placements. Subsequent equity changes could further limit the utilization of the net operations losses and credits.

#### 8. Shareholders' Equity

As discussed in Note 3, on January 31, 2001 Medi-Ject Corporation purchased Permatec Pharma AG, Permatec Technology AG, and Permatec NV from Permatec Holding AG ("Permatec"). The acquisition was consummated under the purchase method of accounting and Medi-Ject Corporation changed its name to Antares Pharma, Inc. The transaction was accounted for as a reverse acquisition because upon completion of the transaction the shareholders of Permatec held approximately 67% of the outstanding common shares. Accordingly, Permatec is deemed to have acquired Medi-Ject Corporation. As a result, the historical financial statements are those of Permatec. However, the outstanding common shares, preferred shares, stock warrants and employee, consultant and director stock options of Antares Pharma, Inc. are those that existed under Medi-Ject Corporation, adjusted for shares issued in the purchase transaction. The

employee, consultant and director stock options outstanding on January 31, 2001 became fully vested as a result of the purchase transaction.

The Company raised \$9,991,391 of net proceeds through an issuance of common stock Units to accredited investors in a private placement transaction. Each Unit was sold for \$23.44 and consisted of (i) four shares of common stock, \$0.01 par value, and (ii) a warrant to purchase one share of common stock. These five-year warrants allow for the purchase of 426,620 shares of common stock, at an exercise price of \$7.03 per share.

In October 2001 the Company issued 188,063 shares of common stock valued at \$517,173 in connection with a technology acquisition agreement with Endoscoptic, Inc. ("Endoscoptic"), a French Company, to purchase certain patents, patent applications, trademarks, trade secrets, know-how and other related technology incorporating or relating to the Hiprin single-use, needle-free, pre-filled, disposable syringe.

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
December 31, 1999, 2000 and 2001

8. Shareholders' Equity (Continued)

Series A Convertible Preferred Stock

On November 10, 1998, the Company sold 1,000 shares of Series A Convertible Preferred Stock ("Series A") and warrants to purchase 56,000 shares of common stock to Elan International Services, Ltd., for total consideration of \$1,000,000. The Series A carries a 10% dividend which is payable semi-annually. The Series A is redeemable at the Company's option at any time and is convertible into common stock for sixty days following the 10th anniversary of the date of issuance at the lower of \$7.50 per share or 95% of the market price of the Common Stock. The warrants to purchase Common Stock may be exercised at any time prior to November 10, 2005, at a price of \$4.51 per share.

Conversion of Series B Convertible Preferred Stock to Common Stock

On December 22, 1999, the Company sold 250 shares of Series B Convertible Preferred Stock ("Series B") to Bio-Technology General Corporation for total consideration of \$250,000. The Series B did not carry a dividend rate. Series B was automatically converted on June 30, 2001, into 100,000 shares of common stock pursuant to the terms of the Series B stock agreement.

In-The-Money Conversion Feature-Preferred Stock Dividend

During 2000 and 2001, prior to the closing of the Share Transaction on January 31, 2001, Medi-Ject borrowed a total of \$5,500,000 in convertible promissory notes from Permatec. At the closing of the Share Transaction, the principal amount of convertible promissory notes converted to 27,500 shares of Series C preferred stock. At the option of the holder, these shares were immediately converted into 2,750,000 shares of Antares common stock. As the conversion feature to common stock was contingent upon the closing of the Share Transaction, the measurement of the stated conversion feature as compared to the Company's common stock price of \$4.56 at January 31, 2001, resulted in an in-the-money conversion feature of \$5,314,125, which is a deemed dividend to the Series C preferred shareholder. This dividend increases the net loss applicable to common shareholders in the Antares' net loss per share calculation.

Restricted Stock

Roger G. Harrison, Ph.D., was appointed Chief Executive Officer of Antares Pharma, Inc., effective March 12, 2001. The terms of the employment agreement with Dr. Harrison include up to 216,000 restricted shares of common stock that will be granted after the achievement of certain time-based and performance-based milestones. The Company anticipates the time-based milestones will be achieved and has recorded deferred compensation expense related to 48,000 shares issued to Dr. Harrison in April 2001 and 40,000 shares expected to be earned in April 2002. The shares vest over a three-year period and had an aggregate market value of \$341,000 at the measurement date. Compensation expense is being recognized ratably over the three-year vesting period. Through December 31, 2001 compensation expense of \$89,984 has been recognized in connection with these shares.

Stock Options and Warrants

The Company's stock option plans allow for the grants of options to officers, directors, consultants and employees to purchase shares of Common Stock at exercise prices not less than 100% of fair market value on the dates of grant. The term of the options is either ten or eleven years and they vest in varying periods. As of December 31, 2001, these plans had 483,821 shares available for grant.

Warrants were issued in connection with debt financing, financial consulting and technology procurement during 1996 through 2001. The terms of the warrants do not exceed ten years and vest in varying periods. During 2000, the Company granted 26,500 warrants to non-employees for services rendered during 2000. In 2001 the Company completed a private placement of common stock in which 426,620 warrants were issued.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31,1999, 2000 and 2001

#### 8. Shareholders' Equity (Continued)

Stock option and warrant activity is summarized as follows:

|                                   | Number<br>of      |
|-----------------------------------|-------------------|
|                                   | Shares            |
| O Later d'accord Province 21 1000 | 0.60 110          |
| Outstanding at December 31, 1998  | 860,118<br>74,215 |
| Exercised Canceled                | (85, 483)         |
| Outstanding at December 31, 1999  | 848,850           |
| Granted                           | 360 <b>,</b> 217  |
| Exercised                         | (5 <b>,</b> 607)  |
| Canceled                          | (290,580)         |
| Outstanding at December 31, 2000  | 912,880           |
| Granted                           | 822 <b>,</b> 620  |

|                                  | =======   | ==== |
|----------------------------------|-----------|------|
| Outstanding at December 31, 2001 | 1,612,360 | \$   |
|                                  |           |      |
| Canceled                         | (84,833)  |      |
| Exercised                        | (38,307)  |      |

The following table summarizes information concerning currently outstanding and exercisable options and warrants by price range:

|                           |                                 | Outstanding                        |                  |                  | Exe |
|---------------------------|---------------------------------|------------------------------------|------------------|------------------|-----|
| Price Range               | Number of Shares<br>Outstanding | Weighted Average<br>Remaining Life | Weighted Average | Number           |     |
| Durament to Ontion        |                                 |                                    |                  |                  |     |
| Pursuant to Option Plans: |                                 |                                    |                  |                  |     |
| \$ 1.56                   | 268,057                         | 5.9                                | \$ 1.56          | 268,057          |     |
| 4.56                      | 360,700                         | 9.3                                | 4.56             | 120,000          |     |
| 9.05 to 16.40             | 7,514                           | 5.9                                | 11.76            | 7,514            |     |
| 23.00                     | 76,162                          | 4.1                                | 23.00            | 76,162           |     |
|                           | 712,433                         | 7.4                                | \$ 5.48          | 471,733          |     |
| Warrants:                 |                                 |                                    |                  |                  |     |
| \$ 2.40 to 4.66           | 92,500                          | 3.7                                | \$ 4.32          | 92,500           |     |
| 7.03                      | 426,620                         | 4.1                                | 7.03             | 426,620          |     |
| 29.55                     | 380,807                         | 4.1                                | 29.55            | 380,807          |     |
|                           | 899 <b>,</b> 927                | <br>4.1                            | 16.28            | 899 <b>,</b> 927 |     |
|                           |                                 |                                    |                  |                  |     |
| Total Options &           |                                 |                                    |                  |                  |     |
| Warrants                  | 1,612,360                       | 5.5                                | \$ 11.51         | 1,371,660        |     |
|                           | =======                         | ===                                | ======           | =======          |     |

The Company applies APB No. 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for stock plans. Accordingly, no compensation expense has been recognized for stock-based compensation plans. Had compensation cost been determined based on the fair value at the grant date for stock options under SFAS No. 123, Accounting and Disclosure of Stock-Based Compensation, the net loss and loss per share would have increased to the pro-forma amounts shown below:

|   | 1999          | 2000           |       |
|---|---------------|----------------|-------|
| Net loss applicable to common shareholders: |               |                |       |
| As reported                                 | \$(3,967,366) | \$(5,260,387)  | \$(14 |
| Pro forma                                   | \$(4,707,150) | \$ (5,633,490) | \$(15 |
| Net loss per common share:                  |               |                |       |
| As reported                                 | \$(0.92)      | \$(1.22)       | \$(1. |
| Pro forma                                   | \$(1.09)      | \$(1.30)       | \$(1. |

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# ANTARES PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) December 31,1999, 2000 and 2001

#### Shareholders' Equity (Continued)

The per share weighted-average fair value of stock based awards granted during 1999, 2000 and 2001 is estimated as \$1.82, \$1.20 and \$2.68 respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

|  | 1999 | 2000 |
|--|------|------|
|  |      |      |
| Risk-free interest rate                  | 5.5% | 5.5% |
| Annualized volatility                    | 100% | 100% |
| Weighted average expected life, in years | 5.0  | 5.0  |
| Expected dividend vield                  | 0.0% | 0.0% |

#### 9. Employee Savings Plan

The Company has an employee savings plan that covers all U.S. employees who have met minimum age and service requirements. Under the plan, eligible employees may contribute up to 20% of their compensation into the plan. At the discretion of the Board of Directors, the Company may contribute elective amounts to the plan, allocated in proportion to employee contributions to the plan, employee's salary, or both. No elective contributions have been made for the year ended December 31, 2001.

#### 10. Supplemental Disclosures of Cash Flow Information

The Company did not make any cash payments for interest during the years ended December 31, 1999 and 2000. All interest expense incurred in those years related to its subordinated loans from shareholders and has been included in the outstanding loan balance at December 31, 1999 and 2000. Cash paid for interest during the year ended December 31, 2001 was \$100,837.

Cash paid for taxes during the years ended December 31, 1999, 2000 and 2001 was \$79,170, \$1,231 and \$2,026, respectively.

The Company incurred capital lease obligations of \$130,629,\$96,550 and \$142,729 in the years ended December 31, 1999, 2000 and 2001, respectively.

In connection with the purchase transaction discussed in Note 3, Permatec's primary shareholder, Dr. J. Gonella, advanced operating funds directly to Medi-Ject Corporation on behalf of Permatec. As a result of these transactions Permatec had recorded \$4,100,000 in notes receivable and a corresponding increase in subordinated loans from shareholders. In addition, Permatec incurred acquisition related costs of \$1,033,296, which were billed to Medi-Ject pursuant to the terms of the amended acquisition agreement. At December 31, 2000, an aggregate of \$900,000 of the acquisition cost obligation was converted to notes receivable, bringing the total to \$5,000,000 in notes receivable from Medi-Ject Corporation, and \$133,296 is reflected as due from Medi-Ject Corporation.

As a result of the purchase transaction described in Note 3, the appraised

value of the assets and liabilities of Medi-Ject as of January 31, 2001 were added to those of Permatec. In addition, subordinated loans from shareholders of \$13,069,870 were converted to equity.

The Company recorded \$341,000 of deferred compensation expense related to 48,000 shares of common stock issued in April 2001 to its Chief Executive Officer and 40,000 shares expected to be earned in April 2002. Through December 31, 2001 compensation expense of \$89,984 has been recognized in connection with these shares.

During 2001 the Company extended the expiration date of certain directors' stock options, resulting in recognition of compensation expense and an increase to additional paid in capital of \$45,284.

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# ANTARES PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) December 31, 1999, 2000 and 2001

#### 10. Supplemental Disclosures of Cash Flow Information (Continued)

In October 2001 the Company issued 188,063 shares of common stock in connection with a technology acquisition agreement with Endoscoptic, Inc. ("Endoscoptic"), a French Company, to purchase certain patents, patent applications, trademarks, trade secrets, know-how and other related technology incorporating or relating to the Hiprin single-use, needle-free, pre-filled, disposable syringe. As a result of the issuance of these shares both patents and equity were increased by \$517,173.

During 2001, the Company paid \$100,000 of dividends payable to the Series A shareholder through the issuance of additional shares of Series A preferred stock.

#### 11. License Agreements

#### Segix License Agreement

In May 1999, the Company entered into an exclusive agreement to license one application of its drug-delivery technology to Segix Italia S.p.a. ("Segix") in Italy, the Vatican and San Marino (collectively, "the Segix Territories"). The Company is required to transfer technology know-how, provide technical assistance, and to reimburse an estimated \$75,000 to Segix for one-half of the cost of a bio-equivalency study, if that study is required by the Italian regulatory authorities. Segix will use the licensed technology to seek marketing approval of a hormone replacement therapy product. The license agreement requires Segix to pay a \$25,000 exclusivity fee, \$125,000 upon signing of the license, \$100,000 upon the first submission by Segix to any one of the regulatory authorities in the Segix Territories, \$100,000 upon the first completed registration with any of the regulatory officials in the Segix Territories, and \$150,000 upon the earlier of receipt of reimbursement classification from regulatory authorities or the launch of product sales in the Segix Territories.

The Company recognized \$228,720 in 1999, which is net of filing and registration fees of \$21,280, related to milestone payments under this agreement. The Company must also provide Segix with licensed product under a

supply agreement that runs for two years from the date of first delivery of products ordered by Segix, which is automatically renewable for additional one-year periods unless terminated by either party. The supply agreement is a separately priced, independent agreement that is not tied to the license agreement. The Company will receive from Segix a 5% royalty from the sale of licensed products in the Segix Territories.

In 2000, the Company adopted the cumulative deferral method for recognizing revenue, which results in the ratable revenue recognition of milestone payments from the date of achievement of the milestone through the date that is the earlier of receipt of reimbursement classification from regulatory authorities or the launch of product sales in the Segix Territories. The Company expects the receipt of reimbursement classification from regulatory authorities to occur first, and estimates this date to be March 2003. The Company will recognize the first two milestone payments of \$125,000 and \$100,000 over estimated 47 and 46-month periods, respectively, the next milestone payment of \$100,000 over an estimated 7-month period, and the final \$150,000 payment in March 2003.

Solvay License Agreement

In June 1999, the Company entered into an exclusive agreement to license one application of its drug-delivery technology to Solvay Pharmaceuticals ("Solvay") in all countries except the United States, Canada, Japan and Korea (collectively, "the Solvay Territories"). The Company is required to transfer technology know-how and to provide developmental assistance to Solvay until the licensed product is approved by each country's applicable regulatory authorities. The Company will be reimbursed by Solvay for all technical assistance provided during Solvay's development. Solvay will use the licensed technology for the development of a hormone replacement therapy gel. The license agreement requires Solvay to pay the Company milestone payments of \$1,000,000 upon signing of the license, \$1,000,000 upon the start of Phase IIb/III clinical trials, as defined in the agreement, \$1,000,000 upon the first submission by Solvay to regulatory authorities in the Solvay Territories, and \$2,000,000

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
December 31, 1999, 2000 and 2001

#### 11. License Agreements (Continued)

upon the first completed registration in either Germany, France or the United Kingdom. The Company recognized \$1,000,000 in 1999 related to milestone payments under this agreement. The Company will receive from Solvay a 5% royalty from the sale of licensed products.

In 2000, the Company adopted the cumulative deferral method for recognizing revenue, which results in the ratable revenue recognition of milestone payments from the date of achievement of the milestone through the estimated date of the first completed registration in either Germany, France or the United Kingdom. The Company expects the first completed registration to occur in June 2005. The Company will recognize the first three \$1,000,000 milestone payments over estimated periods of 73, 37 and 13-months, respectively, and the final \$2,000,000 milestone payment in June 2005.

BioSante License Agreement

In June 2000, the Company entered into an exclusive agreement to license four applications of its drug-delivery technology to BioSante Pharmaceuticals,

Inc. ("BioSante") in the United States, Canada, China, Australia, New Zealand, South Africa, Israel, Mexico, Malaysia and Indonesia (collectively, "the BioSante Territories"). The Company is required to transfer technology know-how and to provide significant development assistance to BioSante until the licensed product is approved by each country's regulatory authorities. BioSante will use the licensed technology for the development of hormone replacement therapy products. At the signing of the contract, BioSante made an upfront payment to the Company, a portion of which will offset future royalties from BioSante's sale of licensed products and/or sublicense up front payments. This milestone payment was for the delivery of intellectual property to BioSante. BioSante is required to tender milestone payments upon commencement of manufacturing of each of the first two licensed products. In the event that the Company fails to produce or have produced the ordered clinical batches, then the Company is required to repay 25% of these two milestone payments to BioSante.

The Company will receive payments upon the achievement of certain milestones and will receive from BioSante a royalty from the sale of licensed products. The Company will also receive a portion of any sublicense fees received by BioSante. The Company is obligated to incur the first \$150,000 of production costs for each of the four products, for an aggregate of \$600,000. The Company is further obligated to provide BioSante licensed products under a twenty-year supply agreement. The supply agreement is a separately priced, independent agreement that is not tied to the license agreement.

In the agreement, the Company has granted BioSante the option for additional licensed territories and the licensed products. The Company will receive additional milestone payments if this option is exercised.

In 2000, the Company adopted the cumulative deferral method for recognizing revenue, which results in the ratable revenue recognition of milestone payments from the date of achievement of the milestone through the estimated date of receipt of final regulatory approval in the BioSante Territory. The Company is recognizing the initial milestone payment in revenue over a 74-month period. All other milestone payments will be recognized ratably on a product-by-product basis from the date the milestone payment is earned and all repayment obligations have been satisfied until the receipt of final regulatory approval in the BioSante Territory for each respective product. It is expected that these milestones will be earned at various dates from July 2002 to July 2006 and will be recognized as revenue over periods of up to 49 months.

In August 2001, BioSante entered into an exclusive agreement with Solvay in which Solvay has sublicensed from BioSante the U.S. and Canadian rights to an estrogen/progestogen combination transdermal hormone replacement gel product, one of the four drug-delivery products the Company has licensed to BioSante. Under the terms of the license agreement between the Company and BioSante, the Company received a portion of the up front payment made by Solvay to BioSante, net of the portion of the initial up front payment the Company received from BioSante intended to offset sublicense up front payments. The Company is also entitled to a portion of any

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1999, 2000 and 2001

#### 11. License Agreements (Continued)

milestone payments or royalties BioSante receives from Solvay under the sublicense agreement. The Company is recognizing the payment received from

BioSante in revenue over a 48-month period. All other milestone payments will be recognized ratably from the date the milestone payment is earned until the receipt of final regulatory approval in the U.S. and Canada. It is expected that these milestones will be earned at various dates from July 2002 to July 2005 and will be recognized as revenue over periods of up to 37 months.

SciTech Medical Products License Agreement

In April 2001, the Company entered into an exclusive agreement to license certain drug-delivery technology to SciTech Medical Product Pte Ltd ("SciTech") in various Asian countries ("the SciTech Territories") with options to other countries if certain conditions are met. The Company is required to transfer technology know-how necessary and/or useful to seek and apply for registration of the products in the SciTech Territories. SciTech will purchase the product needed for development purposes from the Company. The Company will formulate, produce and supply products in sufficient quantities for all purposes of development and registration as reasonably needed for SciTech to perform its development obligations under this agreement. The Company will receive an aggregate license fee of \$600,000 in milestone payments upon the occurrence of certain events. In addition to the license fees, the Company will receive a 5% royalty from the sale of licensed products. At June 30, 2001, the first milestone payment of \$200,000 had been recorded in accounts receivable and deferred revenue in connection with the SciTech agreement. In the third quarter the agreement was amended to change the due date of the initial \$200,000 payment from June 30, 2001 to December 31, 2001. The agreement was amended a second time to change the due date for this payment from December 31, 2001 to June 30, 2002. The Company has recorded no deferred license fee revenue at December 31, 2001 and has recognized no license fee revenue in 2001 in connection with this agreement.

#### 12. Segment Information and Significant Customers

Upon consummation of the Share Transaction, the Company has one operating segment, drug delivery, which includes the development of drug delivery transdermal and transmucosal pharmaceutical products and drug delivery injection devices and supplies.

The geographic distributions of the Company's identifiable assets and revenues are summarized in the following table:

The Company has operating assets located in two countries as follows:

|                                      | December 31, |                           |  |
|--------------------------------------|--------------|---------------------------|--|
|                                      | 2000         | 2001                      |  |
| Switzerland United States of America | \$ 6,974,548 | \$ 2,388,337<br>8,740,113 |  |
|                                      |              |                           |  |
|                                      | \$ 6,974,548 | \$ 11,128,450             |  |
|                                      | ========     | =========                 |  |

Revenues by customer location are summarized as follows:

|                          |    | For the | Years | Ended Dece | mber 31,     |
|--------------------------|----|---------|-------|------------|--------------|
|                          | 1  | 999     |       | 2000       | 2001         |
| United States of America | \$ |         | \$    | 122,808    | \$ 1,335,939 |

Dogombon 21

|        | \$ 1,351,607 | \$ 560,043 | \$ 3,498,524 |
|--------|--------------|------------|--------------|
|        |              |            |              |
| Other  |              |            | 314,494      |
| Europe | 1,351,607    | 437,235    | 1,848,091    |

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# ANTARES PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) December 31, 1999, 2000 and 2001

### 12. Segment Information and Significant Customers (Continued)

The following summarizes significant customers comprising 10% or more of total revenue for the years ended December 31:

|          | 1999      | 2000    | 2001             |  |
|----------|-----------|---------|------------------|--|
|          |           |         |                  |  |
| Ferring  | \$        | \$      | \$ 1,318,982     |  |
| Solvay   | 1,036,534 | 196,680 | 173,600          |  |
| Segix    | 228,720   | 80,451  | 67 <b>,</b> 790  |  |
| BioSante |           | 122,808 | 983 <b>,</b> 566 |  |

There were no customer receivables at December 31, 2000. The following summarizes significant customers comprising 10% or more of outstanding accounts receivable as of December 31:

|          | 2001                   |
|----------|------------------------|
|          | <br>                   |
| BioSante | \$<br>353 <b>,</b> 952 |
| Ferring  | 82 <b>,</b> 654        |

#### 13. Quarterly Financial Data (unaudited)

|  | First       | Second       | Third       |
|--|-------------|--------------|-------------|
| 2000: Total revenues Net loss Net loss applicable to common shares Weighted average shares (1) | \$ 69,301   | \$ 186,843   | \$ 133,981  |
|  | (2,315,683) | (1,041,830)  | (958,898)   |
|  | (.54)       | (.24)        | (.22)       |
|  | 4,324,729   | 4,324,832    | 4,326,733   |
| 2001: Total revenues   | \$ 587,169  | \$ 1,106,153 | \$ 596,757  |
|  | (7,968,072) | (1,728,723)  | (2,156,890) |
|  | (1.14)      | (.20)        | (.24)       |
|  | 7,012,134   | 8,840,448    | 8,955,347   |

<sup>(1)</sup> Loss per Common Share is computed based upon the weighted average number of

- shares outstanding during each period. Basic and diluted loss per share amounts are identical as the effect of potential Common Shares is anti-dilutive.
- (2) The net loss and net loss applicable to common shares include preferred stock dividends of \$5,314,125, \$50,000 and \$50,000 in the first, second and fourth quarters, respectively.

#### 14. Related Party Transactions

The Company received approximately \$3,334 in 1999 for patent registration and other administration and research and development services provided by the Company for other companies owned by shareholder Dr. Gonella.

Based on a memorandum of understanding and corresponding invoices, the Company paid approximately \$637,500 in 1999 related to certain costs incurred by other companies owned by Dr. Gonella. These costs primarily relate to management and administrative services provided by the related companies on behalf of the Company. This agreement was terminated effective January 1, 2000.

At December 31, 2000 the Company had \$321,640 payable to other companies ultimately owned by the Company's shareholder, Dr. Gonella, related to administrative and management services provided by related companies in the period. This amount was non-interest bearing and was classified as a current liability. As further discussed in Note 3 these related party loans were converted to equity on January 31, 2001.

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ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
December 31, 1999, 2000 and 2001

#### 14. Related Party Transactions (Continued)

At December 31, 2000 the Company had subordinated loans payable to its majority shareholder, Dr. Jacques Gonella of \$15,227,131 and to its minority shareholder, VECAP, of \$2,436,889. These parties have provided the loans, which bear an annual interest rate of 3%, in several installments throughout the Company's operating history. As further discussed in Note 3 the subordinated loans were converted to equity on January 31, 2001.

Effective February 1, 2001, the Company entered into a consulting agreement with JG Consulting AG, a company owned by the Company's majority shareholder, Dr. Jacques Gonella. In 2001 the Company recognized expense of \$245,532 in connection with this agreement, and had liabilities to JG Consulting AG at December 31, 2001 of \$90,532. In addition, in 2001 the Company sold equipment, furniture and fixtures to JG Consulting AG for \$91,699, which approximated the book value of the assets sold.

In October 2001, in connection with a technology acquisition agreement with Endoscoptic, Inc. ("Endoscoptic"), a French Company, the Company issued 85,749 and 52,314 shares of common stock to Dr. Jacques Gonella and New Medical Technologies ("NMT"), respectively. Jacques Rejeange, one of the Company's board members, is Chairman of the Board of NMT. The Company issued the shares to satisfy Endoscoptic debt assumed in the technology acquisition agreement.

During 2001 the Company recognized expense of \$92,500 for feasibility study and market research services performed by a company in which Dr. Gonella has an ownership interest of approximately 25%. At December 31, 2001 the Company had a payable to this company of \$92,500.

During 2001 the Company recognized expense of \$49,845 for consulting services provided by John Gogol, one of the Company's board members. The Company had a payable to Mr. Gogol at December 31, 2001 of \$6,363.

During 2001 the Company recognized expense of \$97,292 for legal services provided by Rinderknecht Klein and Stadelhofer, and had a payable to this firm of \$54,297 at December 31, 2001. Dr. Thomas Rinderknecht, one of the Company's board members, is a partner in the firm of Rinderknecht Klein and Stadelhofer.

On March 12, 2002 the Company received an advance of \$1,000,000 from the Company's majority shareholder, Dr. Jacques Gonella, under a Term Note agreement dated February 20, 2002. The Company can receive a total of \$2,000,000 under the Term Note in increments of \$1,000,000. The note bears interest at the three month Euribor Rate as of the date of each advance, plus 5%. The principal and accrued interest is due on the earlier of (i) August 20, 2002, or (ii) the closing of a private placement of equity by the Company that results in net proceeds of \$5,000,000.

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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

DIRECTORS OF THE REGISTRANT

Directors Whose Terms Continue Until the 2002 Annual Meeting of Shareholders

Age

Franklin Pass, M.D.

- Dr. Pass has been a member of the Board of 65 Directors since January 1992 and currently serves as Vice Chairman of the Board. He joined the Company as a director and consultant in January 1992 and served as President, Chief Executive Officer and chairman of the Board of Directors from February 1993 until March 2001. From 1990 to 1992, Dr. Pass served as President of International Agricultural Investments, Ltd., an agricultural technology consulting and investment company. Dr. Pass, a physician and scientist, was Director of the Division of Dermatology at Albert Einstein College of Medicine from 1967 to 1973, the Secretary and Treasurer of the American Academy of Dermatology from 1978 to 1981 and the co-founder and Chief Executive Officer of Molecular Genetics, Inc., now named MGI Pharma, Inc., from 1979 to 1986. He is the author of more than 40 published medical and scientific articles
- Dr. Philippe Dro 39 Dr. Dro joined the Board of Directors in January 2001 and is a member of the Audit Committee. He is

currently the Chief Operating Officer for Axovan Limited, a Swiss drug discovery biotechnology company. Dr. Dro served as the President and Chief Operating Officer of Permatec from January 2000 through October 2000. From June 1997 to January 2000, Dr. Dro was the Executive Director of Permatec. From March 1995 to June 1997, Dr. Dro served as Executive Director of JAGO Pharma. From 1992 to 1995, Dr. Dro held various finance and controller positions at Sandoz Corporation in Basel, Switzerland. From 1989 to 1992, Dr. Dro held various positions in the production and development area at Ethypharm Corporation in France and India. He received a doctorate in Pharmacy from the School of Pharmacy of the University of Grenoble, France and holds an MBA from the Cranfield School of Management in the United Kingdom.

James L. Clark

Mr. Clark joined the Board of Directors in March 2001 and is Chairman of the Compensation Committee. Mr. Clark is the principal officer of Pharma Delivery Systems, which he founded in 1991, a drug delivery consultancy group that identifies and develops drug delivery technologies for use by multinational pharmaceutical companies. Holding degrees in chemistry and marketing from St. Joseph's University in Philadelphia, Mr. Clark has held senior management positions in the areas of medical devices, wound care and drug delivery.

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Directors Whose Terms Continue Until the 2003 Annual Meeting of Shareholders

Kenneth Evenstad

Mr. Evenstad joined the Board of Directors in May 1993 and is Chairman of the Audit Committee. Since 1969, Mr. Evenstad has been the Chairman and Chief Executive Officer of Upsher-Smith Laboratories, Inc., a private pharmaceutical company specializing in branded generic cardiovascular drugs. Mr. Evenstad holds a degree in pharmacy from the University of Minnesota College of Pharmacy.

Dr. Roger Harrison

54 Dr. Harrison joined the Company as Chief Executive Officer and a member of the Board of Directors in March 2001. Since 1984, Dr. Harrison held various positions at Eli Lilly and Company. His most recent role there was Director of Alliance Management from May 1999 until March 2001. Other positions at Eli Lilly and Company included Global Product Team Leader from March 1997 to May 1999 and Director, Development Projects Management and Technology Development and Planning from September 1993 to May 1997. He is the author of twelve publications, has contributed to four books and holds nine patents. Dr. Harrison earned a Ph.D. in organic chemistry and a B.Sc. in chemistry from Leeds University in the United Kingdom and conducted postdoctoral research work at Zurich University in Switzerland.

Professor Ubaldo Conte

60 Professor Conte has been a member of the Board of Directors since January 2001 and has been Permatec's Scientific Advisor since July 1997. Professor Conte is currently the head of the postgraduate school in Industrial Pharmacy at the University of Pavia in Italy, where he has held various professorships since 1965. From 1991 to 1997, he was the Dean of Faculty at the University of Pavia. Professor Conte is the author of 48 patents and has authored approximately 170 publications in scientific journals. Professor Conte is a member of a number of pharmacy and chemical societies.

Directors Whose Terms Continue Until the 2004 Annual Meeting of Shareholders

Dr. Jacques Gonella

60 Dr. Gonella joined the Board of Directors in January 2001 as its Chairman and is a member of the Compensation Committee. He is the founder of Permatec and has served as the Chairman of the Board of Directors of Permatec since its founding in June 1997. Prior to founding Permatec, Dr. Gonella founded JAGO Pharma AG in 1983 and served as the President and Chief Executive Officer from its founding until its acquisition in May 1996 by SkyePharma, a United Kingdom company listed on the London Stock Exchange. Dr. Gonella is currently a non-executive member of the Board of Directors of SkyePharma. Prior to founding JAGO, Dr. Gonella occupied various positions with Roche and Pfizer between 1968 and 1979. Dr. Gonella currently also sits on the board of directors of several private pharmaceutical companies and pharmaceutical investment funds. He holds a doctorate in analytical chemistry from the Polytechnic Institute of Lausanne, Switzerland.

Dr. Thomas Rinderknecht 47 Dr. Rinderknecht joined the Board of Directors in January 2001 and serves on its Compensation Committee. He also served on the Audit Committee until March 14, 2002. He has also been a director of Permatec since its founding in June 1997. Dr. Rinderknecht has been a partner in the firm of Rinderknecht Klein & Stadelhofer in Zurich, Switzerland since 1985, and has been practicing commercial law in Europe since 1982. He holds law degrees from the University of Zurich, Switzerland and the University of Munich, Germany.

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Jacques F. Rejeange

62 Mr. Rejeange joined the Board of Directors in August 2001 and serves on its Audit Committee. He is currently Chairman of the Board of NMT Management AG, a medical technology investment group located in Basel, Switzerland. He also works as an independent consultant to various pharmaceutical, healthcare and medical technology companies. Mr. Rejeange previously held various positions including CEO, President and COO at

Sterling Winthrop, Inc., a pharmaceutical company located in New York. Prior to that, he had managed a number of Sandoz pharmaceutical facilities, including the U.S., France, Belgium and United Kingdom operations. Mr. Rejeange serves on the Board of Directors for several healthcare companies in the United States and Europe. He also served on the Board of Directors of the Pharmaceutical Manufacturers Association in Washington, DC and as a member of the Board of Trustees of Drew University in New Jersey.

John S. Gogol

45 Mr. Gogol joined the Board of Directors in August 2001. An independent consultant since 1998, Mr. Gogol identifies business opportunities for investments, mergers and acquisitions and assists clients during the negotiation and decision-making processes. Previously, Mr. Gogol was with Stokors SA, an asset management firm in Geneva, Switzerland, where he was responsible for public relations, marketing and client acquisition. He also served as Area Manager for Business International (part of The Economist Group), where he was responsible for marketing and sales for Europe, Eastern Europe and Canada. Throughout his career, Mr. Gogol has created, sponsored and managed humanitarian aid and trading companies in Europe, the Middle East and Eastern Europe.

None of the above directors are related to one another or to any executive officer of the Company.

Pursuant to General Instruction G(3) to Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K, information as to executive officers is set forth in Part 1 of the Form 10-K under separate caption.

Information Concerning the Board of Directors

The Board of Directors met five times during 2001 and acted by written action two times during 2001. The Board of Directors has an Audit and a Compensation Committee.

The Audit Committee, consisting of Mr. Evenstad, Dr. Philippe Dro and Dr. Thomas Rinderknecht met three times during 2001. The Audit Committee reviews the results and scope of the audit and other services provided by the Company's independent auditors, as well as the Company's accounting principles and systems of internal controls, and reports the results of its review to or holds concurrent meetings with the full Board of Directors.

The Compensation Committee, consisting of Mr. Clark, Dr. Gonella and Dr. Rinderknecht, met informally during 2001 with compensation actions being considered by the full Board. The Compensation Committee makes recommendations concerning executive salaries and incentive compensation for employees and administers the 1993 Stock Option Plan (the "1993 Plan"). The Board of Directors as a whole administers the 1996 Incentive and Stock Option Plan (the "1996 Plan"), the 2001 Incentive Stock Option Plan for Employees (the "2001 Plan"), the 1998 Stock Option Plan for Non-Employee Directors (the "1998 Directors Plan") and the 2001 Stock Option Plan for Non-Employee Directors and Consultants (the "2001 Directors Plan").

During 2001, each of the directors attended at least 50% of the aggregate number of meetings of the Board of Directors and of the Committees on which he

serves with the exception of Prof. Ubaldo Conte who attended 20% of the Board of Directors meetings held during the year due to his commitments with other business interests.

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Compensation Committee Interlocks and Insider Participation

No member of the Compensation Committee was, during the 2001 fiscal year or previously, an officer or employee of the Company, nor did any member have any relationship or transaction with the Company which is required to be reported under Item 402(k) of Regulation S-K under the Securities Exchange Act of 1934, as amended, except for Dr. Rinderknecht. Dr. Rinderknecht served as a member of both the Audit Committee and the Compensation Committee and his law firm, Rinderknecht, Klein & Stadelhofer, of which he is a principle, also served as legal advisor on various matters. The Company recognized expenses of \$97,292 for services provided by Rinderknecht, Klein & Stadelhofer in 2001.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16 (a) of the Securities Exchange Act of 1934 requires the Company's directors, certain officers and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership on Form 3 and changes in ownership on Forms 4 or 5 with the SEC. Such officers, directors and ten percent shareholders are also required by the SEC's rules to furnish the Company with copies of all Section 16(a) reports they file.

Specific due dates for such reports have been established by the SEC and the Company is required to disclose any failure to file reports by such dates. Based solely on a review of the copies of such reports received by the Company or by written representations from certain reporting persons, the Company believes that during the year ended December 31, 2001, all Section 16(a) filing requirements applicable to officers, directors and ten percent shareholders were met.

Item 11. EXECUTIVE COMPENSATION

Compensation of Directors

The Company has not in the past paid directors' fees. All directors may be reimbursed for expenses actually incurred in attending meetings of the Board of Directors and its committees. In the past, the Board of Directors has made annual discretionary grants of options to purchase shares of Common Stock under the 1993 Plan, 1996 Plan and 2001 Plan to certain members of the Board of Directors. The size of these grants has varied from year to year. In accordance with the Directors' Plan, eligible non-employee directors will receive an automatic grant of an option to purchase 5,000 shares of Common Stock as of the first business day of each calendar year. The Directors' Plan also provides for an initial option grant of 15,000 shares of Common Stock on the day they are first elected to the Board of Directors.

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The following table provides certain summary information concerning compensation paid or accrued by the Company (or Medi-Ject prior to January 31, 2001) to or on behalf of the Chief Executive Officer and the four other most highly compensated executive officers (the "Named Executive Officers") as of the year ended December 31, 2001, for services in all capacities as well as compensation earned by such person for the previous two fiscal years (if the person was an executive officer during any part of such fiscal year):

#### SUMMARY COMPENSATION TABLE

|  |         | Annu                             | Long-Te<br>Compensa |   |                            |
|--|---------|----------------------------------|---------------------|---|----------------------------|
| -  |         | -                                |                     | Other Annual<br>Compensation<br>(\$)(1) | Options                    |
| Dr. Roger Harrison, Chief Executive Officer and President                            | 2001    | 221,939(2)                       |                     | 14,250                                  |                            |
| · · · · · · · · · · · · · · · · · · ·  |         | 228,000(3)<br>228,300<br>216,300 | •                   | 23,336<br>39,798<br>16,545              | 10,000                     |
| Lawrence Christian, Chief Financial Officer, Secretary, and Vice President, Finance  | 2000    | 140,655<br>114,833<br>68,538(4)  | 12,000              | <br><br>                                | 20,000<br>10,000<br>21,000 |
| Dr. Dario Carrara, Managing<br>Director-Formulations Group                           | 2001(5) | 123,456                          | 9,037               | 57,157                                  | 60,000                     |
| Dr. Peter Sadowski, Chief<br>Technology Officer and<br>Vice President, Devices Group | 2000    | 150,000<br>135,820<br>118,300    | •                   | 5,400<br><br>                           | 50,000<br>30,000<br>3,000  |
| Carlos Samayoa<br>Assistant Secretary, Manager<br>Finance and Administration -       | 2001(6) | 60,374                           | 9,037               |   | 30,000                     |

Formulations Group

<sup>(1)</sup> Represents auto allowance payments and premiums paid for disability and life insurance policies with coverage limits in excess of those provided under the Company's standard employee insurance policies.

<sup>(2)</sup> Represents salary paid from employment date of March 12, 2001.

<sup>(3)</sup> Franklin Pass served as chief executive officer until January 31, 2001 and has remained an employee of the Company in a different capacity. The compensation shown is for the full year.

<sup>(4)</sup> Represents salary paid from employment date of March 23, 1999.

<sup>(5)</sup> Represents compensation information from February 1, 2001, the date of the business combination.

<sup>(6)</sup> Represents compensation information from February 1, 2001, the date of the business combination until Mr. Samayoa resigned on August 31, 2001.

<sup>(7)</sup> Compensation for Dr. Carrara and Mr. Samayoa was in Swiss Francs converted to U.S. dollars at the December 31, 2001 exchange rate of 1.6598 Swiss

Francs per U.S. dollar.

Dr. Jacques Gonella, the Chairman of the Board of Directors of the Company and the Company's majority shareholder, receives 5,000 stock options annually, as do all of the Company's directors. Effective February 1, 2001, the Company entered into a consulting agreement with JG Consulting AG, a company solely owned by Dr. Gonella. Under this agreement, the Company pays a monthly fee of \$15,500 to JG Consulting AG.

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Employment Agreements with Executive Officers

The Company has written employment agreements with Dr. Roger Harrison, Franklin Pass, M.D., Lawrence Christian, Dr. Dario Carrara and Dr. Peter Sadowski.

Employment Agreement with Dr. Harrison. Roger G. Harrison, Ph.D., was appointed to the position of Chief Executive Officer of Antares Pharma, Inc., effective March 12, 2001. The terms of the employment agreement with Dr. Harrison include an annual salary of \$275,000 and up to 216,000 restricted shares of common stock which will be granted after the achievement of certain time-based and performance-based milestones. In addition, if within twelve months of the commencement of his employment the Company sells all or substantially all of its assets to an unaffiliated third party, or merges with or into an unaffiliated third party in which the Company is not the surviving entity, then the Company shall pay to Dr. Harrison either (i) two percent of the aggregate cash, securities or other consideration received from the sale, or (ii) an amount, in cash, equal to two percent of the value of the aggregate cash, securities or other consideration distributed to the shareholders in the merger; provided, however, that the Company shall have no obligation to make any payment to Dr. Harrison if he is employed as the chief executive or chief operating officer of the acquiring or surviving entity in the transaction.

Employment Agreement with Dr. Pass. The employment agreement with Dr. Pass became effective as of January 31, 2001. The agreement provides (a) employment for three years, unless terminated in accordance with this agreement; (b) a salary of \$228,000 per year; (c) bonuses of (i) \$25,000 payable at the closing of the Share Transaction and (ii) \$25,000 payable at the closing of the Share Transaction if Dr. Pass is successful (as determined by Dr. Jacques Gonella) in negotiating revisions to a certain licensing agreement; and (d) an option to purchase 30,000 shares of common stock with vesting over a three-year period at 33.5% per year. Dr. Pass shall serve as a member of the Board of Directors until the annual meeting of 2002. In addition to the normal employee benefits, the Company will pay directly, or reimburse Dr. Pass, for premiums on \$2,000,000 additional personal life insurance, on the life of Dr. Pass, limited to a maximum of \$25,000 per year. The Company also agrees to provide employee benefits for a seven-year period following Dr. Pass' termination of employment.

Employment Agreements with Lawrence Christian and Dr. Peter Sadowski. Mr. Christian and Dr. Sadowski entered into employment agreements with the Company as of December 22, 1999, with updated agreements as of May 1, 2000, (each, an "Employment Agreement"). The Employment Agreements provided for 2000 base salaries of \$102,000 for Mr. Christian until May 1, 2000, and \$124,000 thereafter and \$135,820 for Dr. Sadowski. Salaries have subsequently been adjusted to \$145,600 for Mr. Christian and \$156,000 for Dr. Sadowski. Upon the closing of the Share Transaction, the Company paid Mr. Christian and Dr. Sadowski a bonus of \$17,000. Upon the closing of the Share Transaction, the Company granted an option to purchase 20,000 shares of Antares common stock to Mr. Christian and 50,000 shares of Antares common stock to Dr. Sadowski. The

Employment Agreements also contain provisions regarding participation in benefit plans, repayment of expenses, participation as a director or consultant to other companies (which is permitted provided that such participation does not materially detract from their respective obligations to the Company or otherwise violate the terms of their Employment Agreements), protection of confidential information and ownership of intellectual property. In addition, the Employment Agreements contain covenants not to compete and covenants with respect to nonsolicitation and noninterference with customers, suppliers or employees. Mr. Christian's Employment Agreement is for 365 days continuing each day on a rolling 365-day basis. Dr. Sadowski's Employment Agreement has a term through December 31, 2002.

Employment Agreement with Dr. Dario Carrara. Dr. Carrara entered into an employment agreement with Permatec on May 31, 2000. The Company assumed all employment obligations of Permatec upon consummation of the business combination as of January 31, 2001. Dr. Carrara is a citizen of Argentina and accordingly is considered a foreign service employee for Swiss employment purposes. The Employment Agreement provides for a 2000 base salary of \$102,415, bonuses at the discretion of the board of directors, participation in stock option programs as may be available, expense account allowance of \$482 per month, two family trips per year to his home country, private school cost for his children up to \$15,062 per year, family housing cost in Switzerland up to \$21,689 per year and family local language lessons up to \$6,025 during the first twelve months. The agreement is for an indeterminate period of time and either party may terminate the agreement with a three month written notice.

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Original Option Grants During 2001

The table below sets forth individual grants of stock options made to the Named Executive Officers during the year ended December 31, 2001.

|                       | Number of<br>Securities<br>Underlying<br>Options | Percent of Total Options Granted to Employees During | Exercise Price or Base Price/sh. | Expiration | Potential Re<br>Value at A<br>Annual R<br>of Stock<br>Apprecia<br>for Option |
|-----------------------|--|--|----------------------------------|------------|--|
| Name Granted(#)       |  | the Year(%)  | (\$)                             | Date       | 5%(\$)   |
|                       |  |  |                                  |            |  |
| Franklin Pass, M.D.   | (2) 30,000                                       | 12.5   | 4.56                             | 03/22/11   | 86,100   |
| Lawrence Christian(2  | 20,000   | 8.3  | 4.56                             | 03/22/11   | 57,355   |
| Dr. Dario Carrara(2)  | 60,000   | 25.0   | 4.56                             | 03/22/11   | 172,200  |
| Dr. Peter Sadowski (2 | 50,000   | 20.8   | 4.56                             | 03/22/11   | 143,500  |
| Carlos Samayoa(2)     | 30,000   | 12.5   | 4.56                             | 03/22/11   | 86,100   |

<sup>(1)</sup> The 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by rules of the Securities and Exchange Commission and do not represent the Company's estimate or projection of the Company's future

Common Stock prices.

(1) Incentive stock option granted pursuant to the Company's 2001 Stock Option Plan on March 22, 2001. These options vest in three equal installments on March 22 of each of 2002, 2003 and 2004, except for Franklin Pass whose options vest in three equal installments on January 31 of each of 2002, 2003 and 2004.

Aggregated Option Exercises in 2001 and Year End Option Values

The following table provides information concerning stock option exercises and the value of unexercised options at December 31, 2001 for the Named Executive Officers:

|                     | Shares Acquired on Value Exercise Realized |      | Num<br>Securitie<br>Unex<br>Options at | Val<br>Unex<br>In-The-Mo<br>at Yea |             |
|---------------------|--|------|--|------------------------------------|-------------|
| Name                | (#)  | (\$) | Exercisable                            | Unexercisable                      | Exercisable |
| Franklin Pass, M.D. | 0  | 0    | 131,517                                | 30,000                             | 281,118     |
| Lawrence Christian  | 0  | 0    | 31,000                                 | 20,000                             | 66,263      |
| Dr. Dario Carrara   | 0  | 0    |  | 60,000                             |             |
| Dr. Peter Sadowski  | 0  | 0    | 48,407                                 | 50,000                             | 103,470     |

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### REPORT OF THE COMPENSATION COMMITTEE ON EXECUTIVE COMPENSATION

### Overview

The Compensation Committee is responsible for establishing compensation policies for all executive officers of the Company, including the four most highly compensated executive officers named in the accompanying tables (the "Named Executives Officers"). The members of the Compensation Committee are James Clark, Dr. Jacques Gonella and Dr. Thomas Rinderknecht. The Compensation Committee establishes the total compensation for the executive officers in light of these policies.

The objectives of the Company's executive compensation program are:

- 1. to attract and retain superior talent and reward individual performance;
- to support the achievement of the Company's financial and strategic goals; and
- 3. through stock based compensation, align the executive officers' interests with those of the shareholders of the Company.

The following report addresses the Company's executive compensation policies and discusses factors considered by the Compensation Committee in

determining the compensation of the Company's Chief Executive Officer and President and other executive officers for the year ended December 31, 2001.

Compensation Policies for Executive Officers

The Compensation Committee's executive compensation policies are designed to provide competitive levels of compensation that integrate pay with the Company's annual and long term performance goals, reward above average corporate performance, recognize individual initiative and achievements, and assist the Company in attracting and retaining qualified executives. To that end, the Compensation Committee has established certain parameters of corporate performance that must be met before the discretionary features of its executive compensation plans apply. These discretionary features include stock option grants and performance bonuses based upon an executive officer's base salary. Absent the discretionary features, the Company's executive officers are paid base salaries that are subject to annual cost-of-living increases, along with periodic adjustments to make such salaries competitive with other similar sized companies in the drug delivery industry. The Company's executive officers are also given the opportunity to participate in certain other broad-based employee benefit plans. As a result of the Company's emphasis on tying executive compensation to corporate performance, in any particular year the Company's executives may be paid more or less than the executives of other companies in the drug delivery industry. The Company's use of stock option grants as a key component of its executive compensation plans reflects the Compensation Committee's position that stock ownership by management and stock based compensation arrangements are beneficial in aligning management's and shareholders' interests to enhance shareholder value.

#### Bonuses

Cash bonuses are used to reward executive officers for achievement of financial and technical milestones, as well as for individual performance. Bonuses of \$12,000 each were awarded to certain of the executive officers in December 2000 and bonuses ranging from \$9,037\$ to \$50,000 were awarded to certain executive officers in February 2001.

### Stock Options

Stock options awarded under the Company's 1993, 1996 and 2001 Plans are intended as incentive compensation and have historically been granted annually to officers, other key employees and consultants based on the Company's financial performance and achievement of technical and regulatory milestones. During 1999, stock options to purchase a total of 24,115 shares held by the five outside directors were canceled and reissued at an exercise price of \$3.50 per share. Also, on January 3, 2000, options to purchase a total of 31,829 shares held by the five outside

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directors, options to purchase a total of 160,924 shares held by three executive officers and options to purchase a total of 86,200 shares held by 37 employees were canceled and reissued at an exercise price of \$1.5625 per share (see report on repricing of options below). The 1999 annual stock option grant totaling 50,000 and 26,200 shares, with a grant date of January 3, 2000, were granted to three executive officers and 37 employees, respectively. The 2000 annual stock option grant totaling 160,000 and 90,000 shares with a grant date of March 22, 2001, were granted to 5 executive officers and 40 employees, respectively and the 2001 annual stock option grant totaling 35,625 and 52,052 shares with a grant date of February 1, 2002, were granted to 4 executive officers and 52 employees, respectively. All grants are made to provide ongoing incentives to

the Company's consultants, outside directors and employees.

Chief Executive Officer's Compensation

Compensation for Dr. Roger Harrison during 2001, as reflected in the Summary Compensation Table in "Item 11. Executive Compensation" herein, consisted of base compensation and certain employee benefits. Dr. Harrison's base compensation for 2001 was \$221,939 from March 12, 2001, date of employment.

At this time the Committee has no formal long-range written plan for CEO compensation separate and apart from the employment agreement (see above).

SUBMITTED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS:

James Clark Dr. Jacques Gonella Dr. Thomas Rinderknecht

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### Performance Graph

The graph below provides an indication of cumulative total shareholder returns ("Total Return") for the Company as compared with the Nasdaq Composite Index and the Nasdaq Biotechnology Stocks weighted by market value at each measurement point.

This graph covers the period beginning December 31, 1996, through December 31, 2001. The graph assumes \$100 was invested in each of the Company's Common Stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Stock Index on December 31, 1996 (based upon the closing price of each). Total Return assumes reinvestment of dividends.

### [PERFORMANCE GRAPH APPEARS HERE]

|                           | December 31,<br>1996 | December 31,<br>1997 | December 31,<br>1998 | December 31<br>1999<br> | December 31<br>2000 |
|---------------------------|----------------------|----------------------|----------------------|-------------------------|---------------------|
| Antares Pharma            | \$ 100.00            | \$ 55.10             | \$ 10.47             | \$ 41.32 \$             | 119.56              |
| Nasdaq Composite<br>Index | 100.00               | 121.64               | 169.84               | 315.20                  | 191.36              |
| Biotechnology<br>Stocks   | 100.00               | 99.93                | 144.18               | 290.72                  | 357.56              |

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Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information concerning beneficial ownership of the Company's Common Stock as of March 31, 2002, with respect to (i) all persons known to be the beneficial owners of more than 5% of the outstanding Common Stock, (ii) each of the directors, (iii) each Named Executive Officer, and (iv) all directors and executive officers as a group.

| Name of Beneficial Owner                                     | Shares<br>Beneficially<br>Owned(1) | Percentage<br>of Outstanding<br>Shares |
|--|------------------------------------|--|
| Permatec Holding AG (3) (4)                                  | 5,650,000                          | 61.7%                                  |
| NMT Management AG (5)  | 692,245                            | 7.5%                                   |
| Lombard Odier & Co. (6)                                      | 639 <b>,</b> 931                   | 6.9%                                   |
| Becton Dickinson and Company (7)                             | 609 <b>,</b> 292                   | 6.3%                                   |
| Dr. Jacques Gonella (3) (8)                                  | 100,749                            | 1.1%                                   |
| Franklin Pass, M. D. (8)                                     | 161,542                            | 1.7%                                   |
| Dr. Roger Harrison (8)                                       | 91,000                             | 1.0%                                   |
| James Clark (8)  | 15,000                             | *                                      |
| Prof. Ubaldo Conte (8)                                       | 15,000                             | *                                      |
| Dr. Philippe Dro (8)   | 15,000                             | *                                      |
| Kenneth Evenstad (8)   | 22 <b>,</b> 999                    | *                                      |
| John Gogol (8)   | 15,000                             | *                                      |
| Jacques Rejeange (8)   | 15,000                             | *                                      |
| Dr. Thomas Rinderknecht (8)                                  | 15,000                             | *                                      |
| Lawrence Christian (8)                                       | 49,600                             | 1.0%                                   |
| Dr. Dario Carrara (8)  | 19,800                             | *                                      |
| Dr. Peter Sadowski (8)                                       | 64,907                             | 1.0%                                   |
| All directors and executive officers as a group (13 persons) | (3) 6,250,597                      | 65.4%                                  |

<sup>\*</sup> Less than 1%.

- (1) Beneficial ownership is determined in accordance with rules of the Securities and Exchange Commission, and includes generally voting power and/or investment power with respect to securities. Shares of Common Stock subject to options or warrants currently exercisable or exercisable within 60 days of March 31, 2002, are deemed outstanding for computing the percentage of the person holding such options but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, the Company believes that the persons named in this table, based on information provided by such persons, have sole voting and investment power with respect to the shares of Common Stock indicated.
- (2) Shares of Antares Common Stock issuable upon the exercise of outstanding options and warrants.
- (3) Dr. Jacques Gonella owns controlling interest in Permatec Holding AG and, therefore, exercises voting and investment control for the entity.
- (4) The address of Permatec Holding AG is Hauptstrasse 16, 4132 Muttenz, Switzerland.
- (5) Axel Bolte is the Investment Manager of NMT Management AG and exercises voting and investment control for the entity. The address of NMT Management AG is Elisabethenstrasse 23, 4051 Basel, Switzerland
- (6) Anne-Sophie Borgeaud is the Vice President and Senior Investment Officer of Lombard Odier & Co. and exercises voting and investment control for the entity. The address of Lombard Odier & Co. is 11 Rue de La Corraterie, 1204 Geneva, Switzerland.
- (7) Bridget M. Healy is the Vice President, General Counsel and Secretary of Becton Dickinson and Company and exercises voting and investment control for the entity. The address of Becton Dickinson is 1 Becton Drive, Franklin Lakes, NJ 07417.

(8) The director's or officer's address is 707 Eagleview Boulevard, Suite 414, Exton, PA 19341.

#### Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

At December 31, 2000 the Company had \$321,640 payable to other companies ultimately owned by the Company's majority shareholder, Dr. Jacques Gonella, related to administration and management services provided by related companies in the period. This amount was non-interest bearing and was classified as a current liability. These related party loans were converted to equity on January 31, 2001.

At December 31, 2000, the Company had subordinated loans payable to its majority shareholder, Dr. Jacques Gonella of \$15,227,131 and to one of its minority shareholders, VECAP, of \$2,436,889. These parties have provided the loans, which bear an annual interest rate of 3%, in several installments throughout the Company's operating history. The subordinated loans were converted to equity on January 31, 2001.

Effective February 1, 2001, the Company entered into a consulting agreement with JG Consulting AG, a company owned by the Company's majority shareholder, Dr. Jacques Gonella. In 2001 the Company recognized expense of \$245,532 in connection with this agreement, and had liabilities to JG Consulting AG at December 31, 2001 of \$90,532. In addition, in 2001 the Company sold equipment, furniture and fixtures to JG Consulting AG for \$91,699, which approximated the book value of the assets sold.

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During 2001 the Company recognized expense of \$92,500 for a feasibility study and market research services performed by a company in which Dr. Gonella has an ownership interest of approximately 25%. At December 31, 2001 the Company had a payable to this company of \$92,500.

During 2001 the Company recognized expense of \$49,845 for consulting services provided by John Gogol, one of the Company's board members. The Company had a payable to Mr. Gogol at December 31, 2001 of \$6,363.

During 2001 the Company recognized expense of \$97,292 for legal services provided by Rinderknecht Klein and Stadelhofer, and had a payable to this firm of \$54,297 at December 31, 2001. Dr. Thomas Rinderknecht, one of the Company's board members, is a partner in the firm of Rinderknecht Klein and Stadelhofer.

In October 2001 in connection with a technology acquisition agreement with Endoscoptic, Inc. ("Endoscoptic"), a French Company, the Company issued 85,749 and 52,314 shares of common stock to Dr. Jacques Gonella and New Medical Technologies ("NMT"), respectively. Jacques Rejeange, one of the Company's board members, is Chairman of the Board of NMT. The Company issued the shares to satisfy Endoscoptic debt assumed in the technology acquisition agreement.

On March 12, 2002 the Company received an advance of \$1,000,000 from the Company's majority shareholder, Dr. Jacques Gonella, under a Term Note agreement dated February 20, 2002. The Company can receive a total of \$2,000,000 under the term note in increments of \$1,000,000. The note bears interest at the three month Euribor Rate as of the date of each advance, plus 5%. The principal and accrued interest is due on the earlier of (i) August 20, 2002, or (ii) the closing of a private placement of equity by the Company that results in net proceeds of \$5,000,000.

### Item 14. Controls and Procedures

Item 14 has been omitted pursuant to the transition provisions of Exchange Act Release No. 34--46427.

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### PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

- (a) The following documents are filed as part of this report:
  - (1) Financial Statements see Part II
  - (2) Financial Statement Schedules

Independent Auditors Report on Financial Statement Schedule - see page 68 Schedule II - Valuation and Qualifying Accounts - see page 69

All other schedules have been omitted because they are not applicable, are immaterial or are not required because the information is included in the financial statements or the notes thereto.

- (3) Item 601 Exhibits see list of Exhibits below
- (b) Reports on Form 8-K

There were no reports filed on Form 8-K for the fourth quarter of 2001.

(c) Exhibits

The following is filed as an exhibit to Part I of this Form 10-K/A:

| Exhibit No. | Description  |  |  |  |  |  |  |  |
|-------------|--|--|--|--|--|--|--|--|
| 3.1         | Second Amended and Restated Articles of Incorporation as amended to date (a) |  |  |  |  |  |  |  |
| 3.2         | Articles of Amendment Restating Articles of Incorporation (g)                |  |  |  |  |  |  |  |
| 3.3         | Second Amended and Restated Bylaws (a)                                       |  |  |  |  |  |  |  |
| 3.4         | Certificate of Designations for Series A Convertible Preferred Stock (d)     |  |  |  |  |  |  |  |
| 3.5         | Certificate of Designations for Series B Convertible Preferred Stock (i)     |  |  |  |  |  |  |  |
| 3.6         | Certificate of Designations for Series C Convertible Preferred Stock (g)     |  |  |  |  |  |  |  |
| 4.1         | Form of Certificate for Common Stock (a)                                     |  |  |  |  |  |  |  |

| 4.2    | Stock Warrant, dated January 25, 1996, issued to Becton Dickinson and Company (a)  |
|--------|--|
| 4.3    | Stock Option, dated January 25, 1996, issued to Becton Dickinson and Company (a)   |
| 4.6    | Preferred Stock, Option and Warrant Purchase Agreement, dated January 25, 1996, with Becton Dickinson and Company (filed herewith as Exhibit 10.7) (a)   |
| 4.7    | Warrant issued to Elan International Services, Ltd. on November 10, 1998 (d)   |
| 4.8    | Warrant issued to Grayson & Associates, Inc. on September 23, 1999 (e)   |
| 4.9    | Warrant issued to Plexus Ventures, Ltd. on September 12, 2000 (g)  |
| 4.10   | Form of warrant issued to: Aventic Partners AG on February 5, 2001 for 85,324 shares Basellandschaftliche Kantonalbank on February 5, 2001 for 85,324 shares HCI Healthcare Investments Limited on February 5, 2001 for 127,986 shares Lombard Odier & Cie on March 5, 2001 for 127,986 shares (g) |
| 10.0   | Stock Purchase Agreement with Permatec Holding AG, Permatec Pharma AG, Permatec Technologie AG and Permatec NV with First and Second Amendments dated July 14, 2000 (f)  |
| 10.1   | Third Amendment to Stock Purchase Agreement, date January 31, 2001 (g)   |
| 10.2   | Registration Rights Agreement with Permatec Holding AG dated January 31, 2001 (g)  |
| 10.3   | Registration Rights Agreement with Aventic Partners AG,<br>Basellandschaftliche Kantonalbank and HCI Healthcare<br>Investments Limited dated February 5, 2001, and Lombard<br>Odier & Cie dated March 5, 2001 (g)  |
| 10.4   | Office/Warehouse/Showroom Lease, dated January 2, 1995, including amendments thereto (a)   |
| 10.5   | Exclusive License & Supply Agreement with Bio-Technology General Corporation, dated December 22, 1999 (e)  |
| 10.6   | Preferred Stock Purchase Agreement with Bio-Technology<br>General Corporation, dated December 22, 1999 (e)   |
| 10.7   | Preferred Stock, Option and Warrant Purchase Agreement, dated January 25, 1996, with Becton Dickinson and Company (a)  |
| 10.8*  | Employment Agreement, dated January 31, 2001, with Franklin Pass, M.D. (g)   |
| 10.9*  | Employment Agreement, dated March 12, 2001, with Roger Harrison, Ph.D. (g)   |
| 10.10* | Employment Agreement and Term and Compensation Addendum for 2000, dated May 1, 2000, with Lawrence Christian (g)   |

10.11\* Employment Agreement and Term and Compensation Addendum for 2000, dated May 1, 2000, with Peter Sadowski (g) 10.12\* Employment Agreement, dated May 31, 2000 with Dr. Dario Carrara (i) 10.13\* 1993 Stock Option Plan (a) 10.14\* Form of incentive stock option agreement for use with 1993 Stock Option Plan (a) 10.15\* Form of non-qualified stock option agreement for use with 1993 Stock Option Plan (a) 10.16\* 1996 Stock Option Plan, with form of stock option agreement 10.17+ Development and License Agreement with Becton Dickinson and Company, effective January 1, 1996 (terminated January 1, 1999). See Exhibit 10.21 (a) 10.18 Office - Warehouse lease with Carlson Real Estate Company, dated February 11, 1997 (b) 10.19\* 1998 Stock Option Plan for Non-Employee Directors (c) 10.20\* Letter consulting agreement dated February 20, 1998 with Geoffrey W. Guy (c) 10.21# Agreement with Becton Dickinson dated January 1, 1999 (d) 10.22 Securities Purchase Agreement with Elan International Services, Ltd. dated November 10, 1998 (d) License & Development Agreement with Elan Corporation, plc, 10.23# dated November 10, 1998 (d) 10.24 2001 Stock Option Plan for Non-Employee Directors and Consultants (h) 10.25 2001 Incentive Stock Option Plan for Employees (h) 10.26\* Consulting Agreement with JG Consulting AG dated February 1, 2001 (i) 10.27 Office lease agreement with 707 Eagleview Boulevard Associates, a Pennsylvania Partnership, dated June 18, 2001 10.28\*\* \$2,000,000 Term Note with Dr. Jacques Gonella dated February 20, 2002 10.29\*\*\* Securities Purchase Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund, L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership. 10.30\*\*\* Registration Rights Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New

Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC;

- XMark Fund, L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership.
- 10.31\*\*\* Security Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund, L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership.
- 10.32\*\*\* Form of Secured Convertible Debenture, dated July 12, 2002.
- 10.33\*\*\*\* License Agreement with Solvay Pharmaceuticals BV, dated June 9, 1999.
- 10.35\*\*\*\* Amendment No. 1 to License Agreement with BioSante Pharmaceuticals, Inc., dated May 20, 2001.
- 10.36\*\*\*\* Amendment No. 2 to License Agreement with BioSante Pharmaceuticals, Inc., dated July 5, 2001.
- 10.37\*\*\*\* Amendment No. 3 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 28, 2001.
- 10.38\*\*\* Amendment No. 4 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 8, 2002.
- 23.1 Consent of KPMG LLP
- 24.1 Form of Confirming Statement, together with form of Power of Attorney
- 99.1 Section 906 CEO and CFO Certification
- \* Indicates management contract or compensatory plan or arrangement.
- \*\* Previously filed as an Exhibit to our Form 10-Q for the period ended March 31, 2002, filed with the SEC on May 13, 2002.
- \*\*\* Previously filed as the same numbered exhibit to our Current Report on Form 8-K filed with the SEC on July 17, 2002.
- \*\*\*\* Confidential portions of this document have been redacted and have been separately filed with the Securities and Exchange Commission.
- + Pursuant to Rule 406 of the Securities Act of 1933, as amended, confidential portions of Exhibit 10.17 were deleted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment, which was subsequently granted by the Securities and Exchange Commission.
- # Pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, confidential portions of Exhibits 10.21 and 10.23 were deleted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.
- (a) Incorporated by reference to the Registration Statement on Form

 $S\!-\!1$  (File No. 333-6661), filed with the Securities and Exchange Commission on October 1, 1996.

- (b) Incorporated by reference to Form 10-K for the year ended December 31, 1996.
- (c) Incorporated by reference to Form 10-K for the year ended December 31, 1997.
- (d) Incorporated by reference to Form 10-K for the year ended December 31, 1998.
- (e) Incorporated by reference to Form 10-K for the year ended December 31, 1999.
- (f) Incorporated by reference to the Proxy Statement filed December 28, 2000.
- (g) Incorporated by reference to Form 10-K for the year ended December 31, 2000.
- (h) Incorporated by reference to the Registration Statement on Form S-8 (File No. 333-64480), filed with the Securities and Exchange Commission on July 3, 2001.

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### 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, in the City of Minneapolis, State of Minnesota, on September 19, 2002.

ANTARES PHARMA, INC.

/s/ Roger G. Harrison, Ph.D.

Roger G. Harrison, Ph.D. Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this Report has been signed by the following persons on behalf of the registrant in the capacities indicated on September 19, 2002.

| Signature                    | Title   |
|------------------------------|---|
|                              |   |
| /s/ Roger G. Harrison, Ph.D. | Chief Executive Officer and Director                                |
| Roger G. Harrison, Ph.D.     | (principal executive officer)                                       |
| /s/ Lawrence M. Christian    | Vice President of Finance,<br>Chief Financial Officer and Secretary |
| Lawrence M. Christian        | (principal financial and accounting officer)                        |
|                              | Director, Chairman of the Board                                     |

| Dr. Jacques Gonella            |           |      |          |    |     |       |
|--------------------------------|-----------|------|----------|----|-----|-------|
| *                              | Director, | Vice | Chairman | of | the | Board |
| Franklin Pass, M.D.            |           |      |          |    |     |       |
| *                              | Director  |      |          |    |     |       |
| Jim Clark                      |           |      |          |    |     |       |
| *                              | Director  |      |          |    |     |       |
| Prof. Ubaldo Conte             |           |      |          |    |     |       |
|                                | Director  |      |          |    |     |       |
| Dr. Philippe Dro               |           |      |          |    |     |       |
|                                | Director  |      |          |    |     |       |
| John S. Gogol                  |           |      |          |    |     |       |
|                                | Director  |      |          |    |     |       |
| Jacques F. Rejeange            |           |      |          |    |     |       |
| *                              | Director  |      |          |    |     |       |
| Dr. Thomas Rinderknecht        |           |      |          |    |     |       |
|                                |           |      |          |    |     |       |
| * By /s/ Lawrence M. Christian |           |      |          |    |     |       |

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# Certifications

I, Roger G. Harrison, Ph. D., certify that:

Lawrence M. Christian, Attorney in fact

- I have reviewed this amended annual report on Form 10-K/A of Antares Pharma, Inc.;
- 2. Based on my knowledge, this amended annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this amended annual report; and
- 3. Based on my knowledge, the financial statements, and other financial

information included in this amended annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this amended annual report.

[Items 4, 5 and 6 omitted pursuant to the transition provisions of Release No. 34-46427.]

Date: September 19, 2002

/s/ Roger G. Harrison, Ph. D.

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Roger G. Harrison, Ph. D.

Chief Executive Officer and President

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- I, Lawrence M. Christian, certifiy that:
- I have reviewed this amended annual report on Form 10-K/A of Antares Pharma, Inc.;
- 2. Based on my knowledge, this amended annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this amended annual report; and
- 3. Based on my knowledge, the financial statements, and other financial information included in this amended annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this amended annual report.

[Items 4, 5 and 6 omitted pursuant to the transition provisions of Release No. 34-46427.]

Date: September 19, 2002

/s/ Lawrence M. Christian

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Lawrence M. Christian

Chief Financial Officer, Vice President - Finance and Secretary

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Independent Auditors' Report

The Board of Directors and Shareholders Antares Pharma, Inc.:

Under date of March 12, 2002, we reported on the consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2000 and 2001, and the related consolidated statements of operations,

shareholders' equity (deficit) and comprehensive loss and cash flows for each of the years in the three-year period ended December 31, 2001, as included in Antares Pharma, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2001. In connection with our audits of the aforementioned consolidated financial statements, we also audited the related consolidated financial statement schedule as listed in the accompanying index. This financial statement schedule is the responsibility of Antares Pharma, Inc.'s management. Our responsibility is to express an opinion on this financial statement schedule based on our audits.

In our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

The audit report on the consolidated financial statements of Antares Pharma, Inc. and subsidiaries referred to above contains an explanatory paragraph that states that the Company's negative working capital, recurring losses and negative cash flows from operations raise substantial doubt about the entity's ability to continue as a going concern. The financial statement schedule included in the annual report on Form 10-K does not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 1 to the consolidated financial statements, the Company adopted the cumulative deferral method of revenue recognition for licensing arrangements in 2000.

KPMG LLP

Minneapolis, Minnesota March 12, 2002

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Antares Pharma, Inc.

### Schedule II

Valuation and Qualifying Accounts For the Years Ended December 31, 1999, 2000 and 2001

| Description  |    | Balance at<br>Beginning of<br>Year |    | Charged to<br>Costs and<br>Expenses |    | Charged to<br>Other<br>Accounts |    | Deducti |  |
|--|----|------------------------------------|----|-------------------------------------|----|---------------------------------|----|---------|--|
|  |    |                                    |    |                                     |    |                                 |    |         |  |
| Year Ended December 31, 1999<br>Restructuring reserve  | \$ |                                    | \$ | 454,428                             | \$ |                                 | \$ | 17      |  |
| Year Ended December 31, 2000<br>Restructuring reserve  | \$ | 280,816                            | \$ | 266,790                             | \$ |                                 | \$ | 54      |  |
| Year Ended December 31, 2001 Allowance for doubtful accounts (Deducted from accounts receivable) | \$ |                                    | \$ | 18,913/(1)/                         | \$ |                                 | \$ |         |  |
| Inventory reserves<br>(Deducted from inventory)  | \$ |                                    | \$ | 151,259/(1)/                        | \$ |                                 | \$ | 4       |  |

<sup>(1)</sup> Includes reserves acquired from Medi-Ject Corporation at the time of acquisition.