NOVEN PHARMACEUTICALS INC
Form 10-K
March 16, 2005

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004 **Commission File Number 0-17254**

NOVEN PHARMACEUTICALS, INC.

Incorporated under the laws of the State of Delaware	**I.R.S. Employer Identification Number 59-2767632**

11960 S.W. 144th Street, Miami, Florida 33186
305-253-5099

Securities registered pursuant to Section 12(b) of the Act:	None
Securities registered pursuant to Section 12(g) of the Act:	Common Stock, Par Value $.0001

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

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 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. þ

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes þ No o

As of March 1, 2005, there were 23,505,846 shares of Common Stock outstanding.

The aggregate market value of such voting stock held by non-affiliates of the registrant was approximately $514 million (computed by reference to the price at which the voting stock was last sold on June 30, 2004, the last business day of the registrant s most recently completed second fiscal quarter).

DOCUMENTS INCORPORATED BY REFERENCE:

Part III: Portions of registrant s Proxy Statement for its 2005 Annual Meeting of Shareholders.

NOVEN PHARMACEUTICALS, INC.

Annual Report on Form 10-K
for the year ended December 31, 2004

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FORWARD-LOOKING INFORMATION

Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. These statements are made to enable a better understanding of our business, but because these forward-looking statements are subject to many risks, uncertainties, future developments and changes over time, actual results may differ materially from those expressed or implied by such forward-looking statements. Examples of forward-looking statements are statements about anticipated financial or operating results, financial projections, business prospects, future product performance, future research and development results, anticipated regulatory filings and approvals, and other matters that are not historical facts. Such statements often include words such as anticipates, believes, estimates, expects, intends, may, plans, could, should, seeks, will, would or similar expressions.

These forward-looking statements are based on the information that was currently available to us, and the expectations and assumptions that were deemed reasonable by us, at the time the statements were made. We do not undertake any obligation to update any forward-looking statements in this report or in any of our other communications, except as required by law, and all such forward-looking statements should be read as of the time the statements were made, and with the recognition that these forward-looking statements may not be complete or accurate at a later date.

Many factors may cause or contribute to actual results or events being materially different from those expressed or implied by forward-looking statements. Although it is not possible to predict or identify all such factors, they include those set forth under Factors Affecting Our Business and Prospects beginning on page 52 of this report.

PART I

Item 1. Business.

General

We develop and manufacture advanced transdermal patches utilizing our proprietary drug delivery technologies. Our principal commercialized products are prescription transdermal patches for use in menopausal hormone therapy (HT). These products consist of:

Vivelle-Dot (estradiol transdermal system), the most dispensed transdermal estrogen therapy product in the United States and the smallest estrogen patch approved by the United States Food and Drug Administration (FDA). This product is marketed under the brand name Estradot outside the United States and Japan.

Vivelle® (estradiol transdermal system), an estrogen patch utilizing an older generation of our transdermal delivery technology. This product is marketed under the brand name Femiest® in Japan and Menorest in most countries outside the United States and Canada.

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CombiPatch® (estradiol/norethindrone acetate transdermal system), was the first combination estrogen/progestin transdermal patch approved by the FDA for the treatment of menopausal symptoms. This product is marketed under the brand name Estalis® outside the United States.

Our business strategy is focused on diversifying our product offerings beyond HT through strategic collaborations and new product development. The new product applications that we are exploring consist of both new and proprietary formulations as well as generic versions of existing products where we believe our proprietary technology may be beneficially applied.

We submitted an Abbreviated New Drug Application (ANDA) to the FDA in July 2003 seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch for the management of chronic pain that contains fentanyl, an opioid analgesic and a Schedule II controlled substance. Our ANDA for this product was accepted for filing in October 2003 and is under review at the FDA. The patent and exclusivity period for Duragesic® expired in January 2005 and the market for this product presently consists of the branded product, an authorized generic and a generic version of Duragesic®. We have licensed our fentanyl patch to Endo Pharmaceuticals Inc. (Endo). Endo and Noven are working together to develop additional prescription patches.

We have a New Drug Application (NDA) pending with the FDA for a once-daily methylphenidate patch for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). We believe that this product, if approved by the FDA, may address several issues associated with existing therapies and compete in the United States market for ADHD therapies. We have licensed the exclusive global rights to market our methylphenidate patch to Shire Pharmaceuticals Group plc (Shire). Noven and Shire are working to address issues raised in a not approvable letter received from the FDA in April 2003 relating to the NDA for our methylphenidate patch.

We are working with Procter & Gamble Pharmaceuticals, Inc. (P&G Pharmaceuticals) to develop prescription transdermal delivery systems for Hypoactive Sexual Desire Disorder (HSDD). The products under development explore follow-on product opportunities for Intrinsa®, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women diagnosed with HSDD. P&G Pharmaceuticals withdrew its NDA for Intrinsa® in December 2004 based on feedback from an FDA Advisory Committee and has stated its intention to file a new NDA with additional clinical data.

We have an active research and development program investigating a broad range of products and therapeutic categories where we believe our technology may be successfully applied. Significant pre-clinical research is ongoing as we select new candidates for development. See Research and Development below for a more complete description of our product development program.

We were incorporated in Delaware in 1987, and our principal executive offices are located at 11960 S.W. 144th Street, Miami, Florida 33186; our telephone number is (305) 253-5099.

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Novogyne Pharmaceuticals

Our menopausal hormone therapy products are marketed and sold through Novogyne Pharmaceuticals (Novogyne), a joint venture that we formed with Novartis Pharmaceuticals Corporation (Novartis) in 1998 to market and sell women s prescription healthcare products. We own a 49% equity interest in the joint venture company and Novartis owns the remaining 51% equity interest. The joint venture company is a Delaware limited liability company organized under the name Vivelle Ventures LLC and doing business under the Novogyne name. In 2004, our equity in earnings of Novogyne, a non-cash item, represented substantially all of our income before income taxes.

Novogyne presently markets our Vivelle-Dot, Vivelle®, and CombiPatch® products in the United States. Novogyne s sales and marketing efforts have caused the Vivelle® product line to become the most dispensed product family in the transdermal estrogen therapy (ET) category, with a greater than 40% share of monthly total prescriptions dispensed in the United States as of December 2004.

Under the terms of the joint venture agreements, we manufacture and supply Novogyne with Vivelle®, Vivelle-Dot and CombiPatch®, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of the ET products. Novartis distributes Vivelle®, Vivelle-Dot and CombiPatch® and provides certain other services to Novogyne, including contracting with the managed care sector, and all regulatory, accounting and legal services.

Novogyne is managed by a committee (the Management Committee) of five members, three appointed by Novartis and two appointed by Noven. The President of Novogyne is Robert C. Strauss, who also serves as President, Chief Executive Officer and Chairman of the Board of Noven. Pursuant to the joint venture agreements, certain significant actions require a supermajority vote of the committee members, including approving or amending the annual operating and capital budgets of Novogyne, incurring debt or guaranties in excess of $1.0 million, entering into new supply or licensing arrangements, marketing new products and acquiring or disposing of material amounts of Novogyne assets. Novogyne s Management Committee has the authority to distribute cash to Novartis and Noven based upon a contractual formula. The joint venture agreements provide for an annual preferred return of $6.1 million to Novartis and then an allocation of income between Novartis and Noven depending upon sales levels attained. Our share of income increases as product sales increase, subject to a maximum of 49%.

Novartis has the right to dissolve the joint venture in the event of a change in control of Noven if the acquirer is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot under the terms of the license agreement in effect prior to the formation of the Novogyne joint venture, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement.

The joint venture operating agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If Noven is the

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purchaser, then Noven must pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. Novartis is a larger company with greater financial resources, and therefore may be in a better position to be the purchaser if the provision is triggered. In addition, this buy/sell provision may have an anti-takeover effect on Noven since a potential acquirer of Noven will face the possibility that Novartis could trigger this provision at any time and thereby require any acquirer to either purchase Novartis interest in Novogyne or to sell its interest in Novogyne to Novartis.

Growth Strategy

Our strategy for growth and continued profitability is to broaden the commercialized applications for our proprietary transdermal drug delivery technology to further our leadership position in the transdermal drug delivery field. This strategy includes:

- identifying and initiating development of new product opportunities that utilize our existing delivery technology;
- licensing these products at various stages of development to industry partners for completion of development and commercialization;
- developing and/or acquiring new technologies that will permit us to continue the cycle of development and partnering;
- remaining attentive to opportunities where it would be advantageous to market our own products through a specialty sales organization; and
- seeking to enhance the opportunity presented by our collaboration with Novartis through Novogyne by licensing certain of our developmental women s health products to Novogyne and by expanding Novogyne s product range beyond transdermal HT products.

In pursuing our strategy, we intend to focus on developing products in a range of therapeutic areas, including hormone therapy and central nervous system conditions, such as ADHD, HSDD and pain management.

Target areas for new product development may include proprietary prescription products, generic prescription products, or select over-the-counter product opportunities that offer desirable financial return. We generally seek to develop and commercialize these products through agreements with strategic industry partners. We believe that the introduction of our products in diverse therapeutic categories with multiple partners will work to reduce our reliance on any particular product or partner.

We regularly review our corporate strategies to evaluate the suitability and effectiveness of such strategies in light of evolving business, industry, market and other conditions. No assurance can be given that we will implement all or part of our long-term strategy, that our strategies may not change from time to time or that any strategy we adopt will be successful.

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Transdermal Drug Delivery

Transdermal patches utilize an adhesive patch containing medication that is administered through the skin and into the bloodstream over an extended period of time. Patches avoid first pass liver metabolism and may offer significant advantages over conventional oral and parenteral dosage forms, including non-invasive administration, controlled delivery, improved patient compliance, flexible dose duration and avoidance of certain adverse side-effects.

Our most advanced patches utilize our patented DOT Matrix® patch technology. DOT Matrix® is a highly efficient class of diffusion-based drug-in-adhesive patch technology that can often deliver more drug through a smaller patch area than competitive patches, without using irritating skin permeation enhancers and without compromising adhesion. We believe that reduced patch size can have a beneficial effect on patient preference and provide a competitive advantage over patches that deliver similar compounds through a larger patch. DOT Matrix® technology may also permit us to develop patient-friendly patches in cases where, due to the nature of the compound, competitors products could not deliver a therapeutic dose without making the patch objectionably large.

Patches incorporating our DOT Matrix® technology, such as Vivelle-Dot, CombiPatch® and our developmental methylphenidate patch, use a patented blend of silicone, acrylic and drug. This blend causes microscopic pockets of concentrated drug to be formed and uniformly dispersed throughout the patch s drug/adhesive layer. The resulting high concentration gradient between each drug pocket and the skin works to enhance the diffusion of drug from the patch, through the skin and into the bloodstream. This inherent delivery efficiency reduces the need for skin permeation enhancers. Precise ratios of silicone, acrylic and drug regulate the rate of drug delivery and help assure therapeutic blood levels over the intended course of therapy.

We believe that our technology enables us to develop patient-friendly transdermal systems that can reduce skin irritation sometimes associated with patches, improve adhesion, minimize patch size and improve patch appearance. Our patches are capable of being modified to deliver a wide variety of chemical entities.

Hormone Therapy Products

Overview

Our menopausal HT products consist of:

Vivelle®/Menorest/Femiest® our first generation estrogen patch,

Vivelle-Dot/Estradot our second generation estrogen patch, and

CombiPatch®/Estalis® our combination estrogen/progestin patch.

We currently derive a significant portion of our revenues from our HT products. Our total HT-related revenues were $39.8 million, $41.2 million and $54.5 million for 2004, 2003 and 2002, respectively, which represented 87%, 96% and 98% of our revenues in these years, respectively.

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Our HT products are indicated for menopausal symptoms. Menopause begins when the ovaries cease to produce estrogen, or when both ovaries are removed surgically prior to natural menopause. The most common acute physical symptoms of natural or surgical menopause are hot flashes and night sweats, which can occur in up to 85% of menopausal women. Another common problem is vaginal dryness. This condition, which affects an estimated 25% of women, usually begins within five years after menopause. Moderate-to-severe menopausal symptoms can be treated by replacing the estrogen that the body can no longer produce. Estrogen therapy relieves hot flashes and night sweats effectively, and prevents drying and shrinking of the reproductive system. Our ET products are also indicated for the prevention of osteoporosis, a progressive deterioration of the skeletal system through the loss of bone mass. There are, however, other approved therapies for the prevention of osteoporosis, and our labeling advises that ET should be used for this condition only in women who have a significant risk of osteoporosis and for whom non-estrogen therapies are inappropriate.

HT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with use of oral combination HT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin after an average follow-up period of 5.2 years because the oral combination HT product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, the National Cancer Institute (NCI) published the results of an observational study in which it found that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. Since 2002, several other published studies have identified increased risks from the use of HT. As a result of the findings from the WHI and other studies, the FDA has required that black box labeling be included on all HT products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention. Since the July 2002 publication of the WHI and NCI study data, total United States prescriptions have declined for substantially all HT products, including our products in the aggregate. For a discussion of the effects of these studies on our prescription rates and certain risks that we may face as a result of these studies, see Management s Discussion and Analysis of Financial Condition and Results of Operations Overview.

Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage. In particular, a private foundation has announced a new five-year study aimed at determining whether ET use by women aged 40 to 55 reduces the risk of heart disease. This study also seeks to determine if transdermal estrogen patches (as well as alternative dosage forms such as a gel and a cream) are more or less beneficial than a conjugated oral product. The foundation s website indicates that Vivelle-Dotwill be used as the estrogen patch in the study. Noven is not a sponsor of this study and has not reviewed the protocol. Among other risks related to this study, the market for Vivelle-Dot would likely be adversely affected if this study finds our transdermal estrogen patch is less beneficial than other dosage forms, and we could be subject to product liability claims if our products are found to increase the risk of adverse health consequences. To date we have been named as a defendant in one

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product liability lawsuit involving our HT products and we may have liability with respect to other actions in which we have not, to date, been made a party. See Item 3 Legal Proceedings.

First Generation Transdermal Estrogen Patch

Our first generation transdermal estrogen patch (marketed as Vivelle®, Menorest, and Femiest®) is available by prescription and utilizes our adhesive matrix technology. This product delivers estradiol, the primary estrogen produced by the ovaries, through a patch that is applied twice weekly.

This product has been approved for marketing by the FDA, as well as by regulatory authorities in many foreign countries, for the treatment of menopausal symptoms and the prevention of osteoporosis. Marketing rights to this product are held by Novogyne in the United States, by Aventis Pharma AG (Aventis) in Japan, and by Novartis Pharma AG (Novartis Pharma) in all other territories. Novartis Pharma, an affiliate of Novartis, is selling this product under the brand name Menorest in a number of foreign countries. Novogyne and Novartis Pharma s Canadian affiliate market this product under the brand name Vivelle® in the United States and Canada, respectively, and Aventis markets this product under the brand name Femiest® in Japan. This product is in the process of being phased out in several jurisdictions (including certain dosage strengths in the U.S.) where Vivelle-Dot, our second generation ET patch, has gained acceptance.

Pursuant to license and supply agreements with Novartis Pharma, Novogyne and Aventis, we manufacture Vivelle®, Menorest and Femiest® for these parties and receive fees based on their sales of the products. The supply agreements for Menorest and Femiest® are long-term agreements. The supply agreement for Vivelle® (and Vivelle-Dot) expired in January 2003. Since the expiration of the Vivelle® product supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms. We cannot assure that we will enter into a new supply agreement on satisfactory terms or at all. A decision to discontinue operating in accordance with the supply agreement s commercial terms could have a material adverse effect on our business, results of operations and financial position. Novogyne s designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier. Due to our dependence on Novogyne and Novartis greater financial and business resources, we may be unable to negotiate favorable business terms with Novartis or resolve any dispute that we may be involved in with them in a favorable manner.

Second Generation Transdermal Estrogen Patch

Utilizing our proprietary DOT Matrix® technology, our second generation transdermal estrogen patch (marketed as Vivelle-Dot and Estradot) is one-third the area of our first generation estrogen patch at any given dosage level, yet provides the same delivery of drug over the same period. This system is more flexible and comfortable to wear than the first generation product, with a lower potential for skin irritation. Vivelle-Dot is the most dispensed transdermal estrogen therapy product in the United States. This product is bioequivalent to our first generation product and is available in the United States in five dosage strengths. The lowest dosage strength is approved only for osteoporosis, and in light of the HT studies described above and the label changes, many physicians may consider alternative treatments for the prevention of osteoporosis which would adversely affect the market for that dosage strength.

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Novogyne markets Vivelle-Dot in the United States and Aventis has marketing rights for Vivelle-Dot in Japan. Novartis Pharma holds the rights to market Vivelle-Dot under the name Estradot in all countries other than the United States, Canada and Japan. The agreement also grants Novartis Pharma marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by us.

Under the terms of the agreement, Novartis Pharma is responsible for seeking approval to market Estradot in its territories. The product has been approved for marketing in over 30 foreign countries and the regulatory authorities of other countries are reviewing Novartis Pharma s registration applications. Novartis Pharma has launched the product in Germany, in Spain (without the benefit of government reimbursement) and in a number of smaller European countries. We have been advised that Novartis Pharma is in the process of launching the product through a marketing partner in the United Kingdom and France and is in negotiations with regulatory authorities in Italy with respect to the reimbursement for Estradot in Italy. We cannot assure that Novartis Pharma will be successful in launching Estradot in these or other countries. The profitability of Estradot and our other products sold in the European Union may also be negatively affected by parallel trade practices whereby a licensed importer may take advantage of price disparity between markets by purchasing our products in a market with a relatively lower price and then importing them into a country with a relatively higher price. Novartis Pharma markets several other estrogen patches in addition to our products and Novartis Pharma may derive higher gross margins on the sale of its other products compared to ours. If pricing, government reimbursement and labeling issues are resolved, we expect that the growth of Estradot sales will depend, in part, on Novartis Pharma s willingness and ability to convert sales of its existing patches to Estradot. We cannot assure that Novartis Pharma will choose to actively convert sales of its existing patches to Estradot.

Pursuant to license and supply agreements with Novartis Pharma and Novogyne, we manufacture the product for these parties and receive fees based on their sales of the product. The supply agreement for Estradot product is a long-term agreement. Vivelle-Dot is supplied under the same agreement as Vivelle®. As discussed above, we cannot assure that the United States supply agreement will be extended on satisfactory terms or at all.

Transdermal Combination Estrogen/Progestin Patch

We developed the first combination transdermal therapy system approved for marketing by the FDA, a combination patch containing estradiol and norethindrone acetate, a progestin. Although benefits of ET include menopausal symptom control and osteoporosis prevention, estrogen-only therapy has been associated with an increased risk of endometrial cancer for women who have an intact uterus (non-hysterectomized). To address this situation, a combination therapy of estrogen and progestin may be prescribed. Using both hormones together has been shown to reduce the risk of endometrial cancer while continuing to produce the menopausal symptom control benefits of ET. Further, studies have shown that continuous use of both estrogen and low dose progestin may be effective for many women in eliminating the monthly menstrual cycle or irregular bleeding.

Novogyne acquired marketing rights to the product in March 2001 from Aventis (which was then our exclusive worldwide licensee for the product) and markets the product under the brand name CombiPatch® in two dosage strengths in the United States. Novartis Pharma holds the right to market this product outside of the United States and Japan and is marketing this product under the brand name Estalis® in a number of foreign countries. In 2001, we entered into a development

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agreement with Novartis Pharma relating to future generations of combination estrogen/progestin patch products.

Estalis® is presently approved in one dosage strength in most European countries. Novartis Pharma has advised us that they plan to seek marketing approval and commercialization of a lower dosage strength when and if a next generation combination product is developed. No assurance can be given that we will complete development of a next generation combination estrogen/progestin patch or that approval will be obtained, and the timing of any launch of a next generation combination estrogen/progestin patch product cannot be predicted. We expect that growth in this market will be limited unless and until a next generation combination estrogen/progestin patch product is developed, approved and launched.

Pursuant to license and long-term supply agreements with Novartis Pharma and Novogyne, we manufacture the combination product for these parties and receive fees based on their sales of the product.

Transmucosal Product

Our first transmucosal delivery system, DentiPatch®, utilizes a patented, proprietary technology consisting of a thin, solid state multi-laminate construction with a drug-bearing bio-adhesive that delivers lidocaine through the buccal mucosa over time. DentiPatch® was approved for marketing by the FDA in 1996 and was the first FDA-approved oral transmucosal patch. We launched the product in the United States in 1997. The product is indicated for the reduction of pain from oral injections and for the production of mild topical anesthesia prior to superficial dental procedures. It is the first topical anesthetic clinically proven to reduce pain when large needles are inserted to the bone. DentiPatch® is currently marketed in the United States through a network of independent distributors. Sales of DentiPatch® are not material to our results of operations.

Development Collaborations

Endo

In July 2003, we submitted an ANDA to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch containing fentanyl, an opioid analgesic and a Schedule II controlled substance, and is indicated for the management of chronic pain in patients who require continuous opioid analgesia and whose pain cannot be controlled by lesser means. Our ANDA for this product was accepted for filing as of October 1, 2003 and is under review at FDA. Johnson & Johnson s patent and exclusivity status for Duragesic® expired in January 2005, after which the FDA approved the fentanyl transdermal system ANDA filed by Mylan Laboratories. Also in January 2005, the FDA denied several citizen petitions intended to prevent or delay the approval of certain generic versions of Duragesic®.

In February 2005, the FDA approved a Supplemental New Drug Application filed by Johnson & Johnson for new labeling for its Duragesic® product. We have been advised by the FDA that all pending ANDAs relating to the Duragesic® product, including our ANDA, will be required to be amended prior to approval to reflect recent changes in the Duragesic® label. We are currently working with the FDA with respect to a revised label for our fentanyl patch. Once finalized, we will repackage existing inventory to reflect the revised labeling. We understand that there are other pending Duragesic® ANDAs, and we are unable to predict the timing or the impact of the required

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labeling changes on any pending ANDA, nor are we able to predict the timing of approval of any pending ANDA.

We have granted the exclusive right to market our fentanyl patch in the United States and Canada to Endo under a license agreement signed in the first quarter of 2004. We retained all rights to the fentanyl patch outside of the U.S. and Canada, and we are exploring strategies to commercialize the product in other territories. We received an up-front payment of $8.0 million from Endo upon signing the agreement. The agreement provides that, upon Endo s first commercial sale of the fentanyl patch, we are entitled to receive an additional milestone payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors in the market. Under a long-term supply agreement entered into between the parties, we will manufacture and supply the product at our cost and will share in Endo s profit generated from U.S. product sales.

Under the terms of the transaction, we remain responsible for securing final regulatory approval for our fentanyl transdermal system. The agreement provides that Endo may terminate the agreement, and its obligation to launch the product, if launch is delayed either (i) because of a delayed FDA approval or (ii) we fail to supply Endo with its launch requirements after approval, and in either case if as a result of the delay there is additional generic competition beyond that expected by the parties at the time of execution of the agreement. The earliest that this right could be triggered under the agreement is July 2005. In the event of such a termination, rights to the fentanyl patch would return to us.

As of December 31, 2004, we have incurred $10.8 million for the cost of pre-launch inventories for our fentanyl patch. If approval is not ultimately received or is delayed, our agreement with Endo provides that the parties will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed upon formula and we may be unable to recover our share of such costs, which could be up to approximately $6.0 million.

The agreement provides that Endo is responsible for seeking regulatory approval to market the product in Canada. If such efforts are successful, we will supply product for sale in Canada on a cost-plus basis, with no royalty or profit sharing arrangement.

In addition to the fentanyl license, we have established a collaboration with Endo to seek to identify and develop new transdermal therapies. Of the $8.0 million received at signing, $1.5 million has been allocated to fund feasibility studies that seek to determine whether certain compounds identified by the parties can be delivered through our transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

Shire

We have developed a once-daily transdermal methylphenidate patch for the treatment of ADHD. ADHD is the most commonly diagnosed and the most widely studied behavioral disorder in children in the United States. ADHD is characterized by developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity symptoms. The disorder typically causes functional impairment that can limit success and create hardship in school, and in social and familial relationships. As children age, the symptoms can lead to serious conduct disorders, criminal

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behavior, substance abuse and accidental injuries. Methylphenidate is a stimulant and designated as a Schedule II controlled substance by the United States Drug Enforcement Administration (DEA).

While prevalence rates can vary dramatically from study to study, it is widely reported that ADHD affects about 3% to 7% of school-aged children in the United States, over 2 million children nationwide. Stimulant therapies, including methylphenidate, are the most prescribed drug type for the treatment of ADHD. Presently, all ADHD medications approved in the United States are delivered orally. We believe that our patch will provide physicians with broad dosing flexibility, because dosing can be discontinued at any time during a day by simply removing the patch, and may offer other advantages as compared to certain oral ADHD medications.

In June 2002, we filed with the FDA an NDA for a methylphenidate transdermal system. In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market our methylphenidate patch to Shire for payments of up to $150.0 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25.0 million was paid upon closing of the transaction in April 2003; (ii) $50.0 million is payable upon receipt of final marketing approval for our methylphenidate patch by the FDA; and (iii) three installments of $25.0 million each are payable upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual net sales of our methylphenidate patch, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, we entered into a long-term supply agreement under which we expect to manufacture and supply our methylphenidate patch to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, our revenues and profits from sales of our methylphenidate patch would be adversely affected.

In April 2003, Noven received a not approvable letter from the FDA relating to our methylphenidate patch NDA. In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire are proceeding with the development of the methylphenidate patch. Development efforts include additional clinical studies, including another Phase 3 study. Pursuant to the agreements between the parties, Shire is managing these studies and Noven has committed to fund them. Noven s direct costs incurred in pursuit of approval are expected to be deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven s research and development expenses in 2004 and are not expected to impact research and development expenses in 2005, although the direct expenses incurred in pursuit of FDA approval will reduce Noven s cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of December 31, 2004, the amount of deferred revenues was $5.7 million (which excludes the $5.0 million of deferred revenues related to the repurchase right described below) and Noven does not expect the prospective cost in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for our methylphenidate patch.

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Under Noven s agreements with Shire, Shire has certain rights to terminate the license to our methylphenidate patch, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable product. If Shire were to terminate on this basis, all product rights would revert to Noven, and Noven would retain the $25.0 million previously paid by Shire. Shire also has the right to require Noven to repurchase the product rights to our methylphenidate patch for $5.0 million under certain circumstances.

In June 2004, we entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD. The agreement provides for the payment to Noven of up to $5.0 million if certain development milestones are achieved. The product is in pre-clinical development.

P&G Pharmaceuticals

In April 2003, we established a collaboration with P&G Pharmaceuticals for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa®, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women diagnosed with HSDD. P&G Pharmaceuticals withdrew its NDA for Intrinsa® in December 2004 based on feedback from an FDA Advisory Committee and has stated its intention to file a new NDA with additional clinical data.

Research and Development

Our research and development strategy is to identify drugs that can be delivered transdermally and which we believe have substantial market potential, as well as those that we believe can be improved by using our patented technologies. We typically seek to develop products that use approved drugs that currently are being delivered to patients through means other than transdermal delivery, but we may also explore new formulations or proprietary products where we believe our technology may be beneficially applied. As part of our strategy, we seek to supplement our research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies.

In addition to the pre-clinical studies being conducted in connection with our Endo and Shire collaborations, we have entered into a number of other early stage development agreements with other pharmaceutical companies to determine the feasibility of transdermal delivery of various compounds, including our partners proprietary compounds.

For the years ended December 31, 2004, 2003 and 2002, we spent $9.9 million, $8.1 million and $11.6 million, respectively, for research and development activities, which does not include amounts we expended on additional clinical studies for our methylphenidate patch since those amounts were offset against the deferred revenue we received from Shire under our agreement with Shire. Our research and development expense may vary significantly from quarter to quarter depending on product development cycles, the timing of clinical studies and whether we or a third party are funding development. We intend to focus on long-term growth prospects, and, therefore, may incur higher than expected research and development expenses in a given period rather than delay clinical activities. These variations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations.

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The time necessary to complete clinical trials and the regulatory process to obtain marketing approval varies significantly. We cannot assure that we will have the financial resources necessary to complete products under development, that those projects to which we dedicate resources will be successfully completed, that we will be able to obtain regulatory approval for any such product, or that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, either by us or by a licensing partner. Similarly, we cannot assure that our competitors (which may include our development partners), many of whom have greater resources than we do, will not develop and introduce products that will adversely affect our business and results of operations.

Competition

The markets for our products are highly competitive. All drug delivery products that we are developing may face competition from conventional forms of drug delivery (i.e., oral and parenteral), from alternate forms of drug delivery, such as controlled release oral delivery, liposomes, implants, gels and creams and possibly from alternate non-drug therapies. Some or all of the products being marketed or developed by us face, or will face, competition from other transdermal products that deliver the same drugs to treat the same indications. In addition, medical science is constantly evolving. As developments in medicine are made, products may become obsolete or fall out of favor with physicians.

Competition in drug delivery systems is generally based on a company s marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. As a general matter, transdermal drug delivery systems are more expensive to manufacture than oral formulations. Acceptance by physicians and other health care providers, including managed care groups, is also critical to the success of a product. The first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share for a period of time. In a highly competitive marketplace and with evolving technology and medical science, there can be no assurance that additional product introductions or medical developments by others will not render our products or technologies noncompetitive or obsolete. We also compete with other drug delivery companies in the establishment of business arrangements with large pharmaceutical companies to assist in the development or marketing of products. It is also possible that Vivelle-Dot or other Noven products could, prior to the expiration of the applicable patent periods, face competition from a generic product if approved through the ANDA process or from a functionally-equivalent product that avoids our patents.

In the market for HT products, Novogyne competes against Wyeth Pharmaceuticals, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Berlex Laboratories, Women First HealthCare, Inc., Novavax, Inc., Solvay Pharmaceuticals, Inc., Barr Laboratories and others, including Novartis, Novartis Pharma and their affiliates. We expect increased competition in the HT market as a result of the recent launches of a vaginal estrogen delivery system, a combination estrogen/progestin patch, an estrogen cream, an estrogen gel product, and an ultra-low dose estrogen patch. Most of our competitors are substantially larger and have greater resources than we do, as well as greater experience in developing and commercializing pharmaceutical products.

The market for ADHD drugs is also highly competitive, with a product mix that includes generic methylphenidate, long-acting formulations, other stimulant medications, medications not containing Schedule II controlled substances, and a variety of other drug types. Other products which may have improved safety and efficacy profiles are also in development. Shire currently

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markets non-methylphenidate products for the treatment of ADHD, and we cannot assure that Shire will market our methylphenidate patch aggressively or effectively if it is approved, or that our methylphenidate patch will compete effectively against extended release oral formulations of methylphenidate and/or other ADHD medications, especially those not involving controlled substances. Some of the companies marketing competitive ADHD products are substantially larger and have greater financial resources than Shire does, including Johnson & Johnson, Novartis and Eli Lilly. Strattera®, a non-stimulant, non-controlled substance therapy marketed by Eli Lilly, has gained significant market share since its launch in 2003. If Strattera® or other therapies in development become recognized as therapeutically superior to stimulants, or are preferred by physicians, parents and/or patients, the market for stimulants, including our developmental methylphenidate patch product, would be adversely affected.

If approved by the FDA, our fentanyl transdermal system will face a highly competitive market. Currently, the market consists of: (i) Duragesic®, the branded product, (ii) a product supplied by the branded manufacturer and sold as a generic by a third party, and (iii) a generic version of Duragesic®. In addition to our ANDA, we understand that several additional companies have submitted ANDA s for a transdermal fentanyl system. In the market for generics, the first products to be commercialized typically achieve significant market share. As competing generic manufacturers receive regulatory approvals, market share, revenues and gross profit of those companies already on the market typically decline, in some cases dramatically. Companies seeking to enter the market with newly approved products will generally seek to gain market share through price reductions and other customer incentives, which can have the effect of reducing pricing and market share for all competitors in the market. Accordingly, we expect the level of market share, revenues and gross profit derived from our fentanyl patch will depend upon the timing of any FDA approval for our product, the number of competitors then in the market, and the timing of our launch in relation to competing approvals and launches.

Dependence on Licensees and Joint Venture

During 2004, 52% and 31% of our revenues were generated from sales to, and contract revenues, fees and royalties received from, Novogyne and Novartis Pharma and its affiliates, respectively, and substantially all of our income before income taxes was attributable to our equity in Novogyne s earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novartis Pharma, Novogyne and possibly Endo, Shire, P&G Pharmaceuticals and other collaboration partners, as well as fees, milestone payments, profit sharing and royalties generated from their sales of our transdermal delivery systems, for a significant portion of our expected revenues. No assurance can be given regarding the amount and timing of such revenues. Failure of these parties to successfully market our products would cause the quantity of products purchased from us and the amount of fees, milestone payments and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and results of operations. We expect to be able to influence the marketing of Vivelle®, Vivelle-Dot and CombiPatch® in the United States through our participation in the management of Novogyne, but the Management Committee of Novogyne is comprised of a majority of Novartis representatives, and we will not be able to control those matters. Our agreements with our marketing partners impose certain obligations on them, but there can be no assurance that such agreements will provide us with any meaningful level of protection or cause these companies to perform at a level that we deem satisfactory. Further, these companies and their affiliates sell competing products, both in the United States and abroad, and it is possible that they will promote their other competitive products at our expense. Any reduction in the level of support and promotion that these companies provide to our products, whether as a result of

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their focus on other products or otherwise, could have a material adverse effect on our business, results of operations, financial condition and prospects. Because of the legal complexities inherent in attempting to establish damages in litigation arising under agreements such as our agreements with Novartis, Shire and Endo, those agreements may not, as a practical matter, provide us with an adequate remedy for our partner s breach.

We expect that a significant portion of our earnings for at least the next several years will be generated through our interest in Novogyne, and no assurance can be given regarding Novogyne s future profitability. Novogyne s sales force is significantly smaller than the sales forces promoting several competitive products, and there can be no assurance that Novogyne s sales force will be successful. Prior to the publication of the HT study data described above, our CombiPatch® product prescription trends had not improved significantly since Novogyne acquired marketing rights in March 2001. Since the HT study data was published, CombiPatch® prescriptions have, like most HT products, declined, and we do not expect Novogyne to be able to grow CombiPatch® product sales and sales may continue to decline. Failure of Novogyne to successfully market Vivelle®, Vivelle-Dot or CombiPatch® would have a material adverse effect on our business and results of operations.

Manufacturing

We conduct our manufacturing operations in a single facility comprised of two approximately 40,000 square foot buildings located on approximately 10 acres in Miami-Dade County, Florida. This facility has been inspected by the FDA and by the Medicines and Healthcare Products Regulatory Agency of the United Kingdom and found to be in compliance with applicable regulatory requirements. This facility has also been certified by the DEA to manufacture products containing controlled substances. To bring new products to market as quickly as possible, we will seek to have the manufacturing capacity to produce the new product prior to obtaining FDA approval and, in certain circumstances, to begin manufacturing the new product prior to obtaining FDA approval. We are currently expanding our manufacturing area to facilitate the manufacture and storage of our methylphenidate patch and our transdermal fentanyl patch. In addition, we have supplemented our manufacturing facilities on our existing site with leased space located in close proximity to our existing site for the storage, and, if necessary, manufacture of new products. If FDA approval for our methylphenidate patch, our fentanyl transdermal patch or other products under development is not obtained, we may not be able to recover our upfront costs to expand our manufacturing facilities as well as raw material and other costs associated with manufacturing pre-launch supplies.

Some raw materials essential to our business are readily available from multiple sources. Certain raw materials and components used in the manufacture of our products (including essential polymer adhesives and other critical components) are, however, available from limited sources, and in some cases, a single source. The NDA for our methylphenidate patch includes only one supplier of the active pharmaceutical compound. This same supplier is also the only source of the active pharmaceutical compound for which we have sought approval under the ANDA for our transdermal fentanyl system. In addition, the DEA controls access to controlled substances (including methylphenidate, amphetamine and fentanyl), and we must receive authorization from the DEA to obtain these substances. Any curtailment in the availability of such raw materials could result in production or other delays, and, in the case of products for which only one raw material supplier exists, could result in a material loss of sales, with consequent adverse effects on our business and results of operations. In addition, because most raw material sources for transdermal patches must generally be approved by regulatory authorities, changes in raw material suppliers may result in

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production delays, higher raw material costs and loss of sales, customers and market share. Some raw materials used in our products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, there can be no assurance that such companies will not expand their restrictions to include our applications.

For information with respect to recent production issues, see Management s Discussion and Analysis Certain Items that Affect Historic or Future Comparability.

Marketing & Sales

Our business strategy generally is to seek to establish a collaboration for a new product with a third party who we believe has the clinical and regulatory resources and expertise necessary to develop the product and the marketing and sales resources necessary to broadly commercialize the product. We seek to retain manufacturing rights for ourselves, in part to help safeguard our proprietary technology. Except for DentiPatch®, we have historically granted product marketing rights to our Novogyne joint venture and to other pharmaceutical companies.

Our strategy, however, does not preclude the possibility that we may retain the rights to a particular new product and develop, market and sell it ourselves. A decision to retain rights to any product would be based upon an analysis of, among other things, our financial resources and capabilities at the time; the characteristics of the particular product and market; complementary products in our pipeline or available to us; and the estimated costs associated with clinical studies, sales, marketing and distribution.

Under the Novogyne joint venture agreements, Novartis has responsibility for Novogyne s distribution function (including managing the relationship and agreements with wholesale drug distributors and managed care organizations), while Noven has responsibility for the day-to-day management of Novogyne s marketing efforts and sales force. In fulfilling the marketing and sales function, we believe that we have established significant expertise in this area. We believe this expertise has helped lead the Vivelle® product line to become the most dispensed product family in the U.S. transdermal ET category. We also seek to use this expertise more broadly to help us identify and evaluate the commercial potential of new product development projects that may help advance our growth strategy.

Patents and Proprietary Rights

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained 31 United States patents and approximately 200 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have approximately 140 pending patent applications worldwide.

As a result of changes in United States patent law under the General Agreement on Tariffs and Trade and the accompanying agreement on Trade-Related Aspects of Intellectual Property Law, which took effect in their entirety on January 1, 1996, the terms of some of our existing patents have been extended beyond the original term of seventeen years from the date of grant. Our patents filed after June 7, 1995 will have a term of twenty years computed from the effective filing date.

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We are unaware of any challenge to the validity of our patents or of any third party claim of patent infringement with respect to any of our products, in either case that could have a material adverse effect on our business or prospects.

Although there is a statutory presumption as to a patent s validity, the issuance of a patent is not conclusive as to such validity, or as to the enforceable scope of the claims of the patent. We cannot assure that our patents or any future patents will prevent other companies from developing similar or functionally equivalent products. We cannot assure that we would have the resources to prosecute an action to enforce our patent rights against an alleged infringer or that we would be successful in any infringement action that we elect to bring. Likewise, we cannot assure that we would have the resources to defend an infringement action or that we would be successful in any such defense. Furthermore, we cannot assure that any of our future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that our processes or products will not infringe upon the patents of third parties. In addition, since our patents typically cover our product formulation rather than the compound being delivered, competitors may seek to create functionally equivalent products (i.e., patches delivering the same compound over the same time period to treat the same indication) that avoid our patents. In those cases, we may face competition from functionally equivalent products even before our patents expire.

We also attempt to protect our proprietary information under trade secret and confidentiality agreements. Generally, our agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent contain provisions designed to protect the confidentiality of our proprietary information. There can be no assurance that these agreements will not be breached, that we will have adequate legal remedies as a result thereof, or that our trade secrets will not otherwise become known or be independently developed by others.

Trademarks

The trademarks for the products that we manufacture as well as for other products referred to in this Form 10-K are registered as follows:

DOT Matrix® and DentiPatch® are registered trademarks of Noven Pharmaceuticals, Inc.;

Vivelle® is a registered trademark of Novartis Corporation;

Estradot (foreign) is a registered trademark of Novartis AG;

CombiPatch® and Estalis® (U.S.) are registered trademarks of Vivelle Ventures LLC;

Vivelle-Dot and Menorest are trademarks of Novartis AG;

Femiest® is a registered trademark of Aventis Pharma S.A. in Japan;

Duragesic® is a registered trademark of Johnson & Johnson;

Concerta® is a registered trademark of Alza Corporation;

Strattera® is a registered trademark of Eli Lilly and Company;

Intrinsa is a trademark of Procter & Gamble Pharmaceuticals, Inc.;

Vioxx® is a registered trademark of Merck & Co., Inc.;

Zoloft® is a registered trademark of Pfizer, Inc.; and

Adderall XR® is a registered trademark of Shire.

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Government Regulation

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products and the possession and use of controlled substances. We devote significant time, effort and expense to address the extensive government regulations applicable to our business.

The marketing of pharmaceutical products requires the approval of the FDA in the United States. The FDA has established regulations, guidelines and safety standards, which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of pharmaceutical products. The process of obtaining FDA approval for a new product may take several years or more and is likely to involve the expenditure of substantial resources. The steps required before a product can be produced and marketed for human use typically include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Exemption (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials; (iv) submission to the FDA of a New Drug Application (NDA); and (v) review and approval of the NDA by the FDA. Approval of a product by the FDA does not serve as a guaranty of the product s safety or efficacy. In light of widely publicized events surrounding HT products and such other products as Vioxx® and Zoloft®, both citizen s groups and interests in the United States Congress have called for investigation and possible reform of the FDA s product approval and safety monitoring process to help better ensure the safety and efficacy of products approved by the FDA.

An NDA generally is required for products with new active ingredients, new indications, new routes of administration, new dosage forms or new strengths. An NDA requires that complete clinical studies of a product s safety and efficacy be submitted to the FDA, the cost of which is substantial. These costs can be reduced, however, for delivery systems that utilize approved drugs. In these cases, the company seeking approval may refer to safety and toxicity data reviewed by the FDA in its approval process for the innovator product. In addition, a supplemental NDA may be filed to add an indication to an already approved product.

An abbreviated approval process may be available for products that have, among other requirements, the same active ingredient(s), indication, route of administration, dosage form and dosage strength as an existing FDA-approved product covered by an NDA, if clinical studies have demonstrated bio-equivalence of the new product to the FDA-approved product covered by an NDA. For this abbreviated process, an Abbreviated New Drug Application (ANDA) is submitted to the FDA instead of an NDA. Under FDA ANDA regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on any approved product s patent listed with the FDA or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product s patent or that such patent is invalid, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), the FDA may not finally approve the ANDA until the later of thirty months from the date of the legal action or a final determination by a court that the applicable patent is invalid or would not be infringed by the applicant s product. We have filed an ANDA for our transdermal fentanyl system and we are developing other products for which we or a licensee intend to file an ANDA. There can be no assurance we will not be sued for patent infringement, that we would prevail in any litigation or that the costs of any such litigation would not be prohibitive.

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The Hatch-Waxman Act further provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, the FDA cannot grant final approval to any other Paragraph IV filer. If an ANDA containing a Paragraph IV certification is successful, it generally results in higher initial market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for generic drug products, we may lose significant advantages to a competitor who was first to file an ANDA containing a Paragraph IV certification. Disputes have arisen as to which of several ANDA applicants is first to file, and thus potentially entitled to exclusivity. FDA administration of its first to file policies has been the subject of unresolved litigation, and administrative and legislative activity. Thus, Noven cannot assure that even if it is otherwise entitled to such exclusivity, it will ultimately be awarded.

Pre-clinical studies are conducted to obtain preliminary information on a product s safety. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials begin. Human clinical trials may commence 30 days after receipt of the IND by the FDA, unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. Phase I trials consist of testing the product primarily for safety in healthy volunteers or a small number of patients at one or more doses. In Phase II trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase I trials. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population at different clinical test sites. A clinical plan, or protocol, accompanied by information on the investigator(s) conducting the trials, must be submitted to the FDA prior to commencement of each phase of the clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, including, for example, if it finds unacceptable risks to the study subject.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or ANDA in a timely manner. The FDA may deny an NDA or ANDA if applicable regulatory criteria are not satisfied or it may require additional clinical testing. Even if such data is submitted, the FDA may ultimately deny approval of the product. Further, if there are modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in manufacturing facility, an NDA or ANDA notification may be required to be submitted to the FDA and FDA approval required prior to implementation of the change. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing and surveillance programs to monitor the effect of products that have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. For example, many countries require additional governmental approval for price reimbursement under national health insurance systems. Additional studies may be required

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to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

Manufacturing facilities are subject to periodic inspections for compliance with the FDA s good manufacturing practices regulations and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may have similar regulations. In complying with standards set forth in these regulations, we must expend significant time, money and effort in the area of quality assurance to ensure full technical compliance. Facilities handling controlled substances, such as ours, also must be licensed by the DEA, and are subject to more extensive regulatory requirements than those facilities not licensed to handle controlled substances. We also require approval of the DEA to obtain and possess controlled substances, including methylphenidate, amphetamine and fentanyl. We produce transdermal drug delivery products in accordance with United States and international regulations for clinical trials, manufacturing process validation studies and commercial sale. FDA approval to manufacture a drug product is site specific. In the event our approved manufacturing facility becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations.

Failure to comply with governmental regulations may result in fines, warning letters, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales, withdrawal of previously approved marketing applications and criminal prosecution.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical industry or on our business or operating results.

Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, sales practices, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state, federal and foreign regulations. Under certain of these laws, we could be liable for substantial costs and penalties in the event that waste is disposed of improperly. While it is impossible to accurately predict the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not presently expected to have, a material adverse effect on our earnings or competitive position.

Employees

As of December 31, 2004, we had approximately 340 employees; approximately 223 of which are engaged in manufacturing, process development, quality assurance and quality control, 22 in research and development, 12 in clinical research and regulatory affairs, and 83 in marketing and administration. No employee is represented by a union and we have never experienced a labor-related work stoppage. We believe our employee relations are good. In addition to the employees employed directly by us, Novogyne has a contract sales force of approximately 120 individuals that we manage under the terms of the Novogyne joint venture agreements.

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Seasonality

Although our business is affected by the purchasing patterns of wholesale drug distributors, there are no significant seasonal aspects to our existing HT business. We may face increased seasonality if our ADHD product is approved by the FDA and successfully commercialized since ADHD products are generally prescribed and dispensed more frequently during the school year than in the summer months.

Available Information

Our Internet website address is www.noven.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports are available free of charge through its website, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our website the beneficial ownership reports (Form 3, Form 4 and Form 5) filed by Noven officers, directors and other reporting persons under Section 16 of the Securities Exchange Act of 1934. Our Internet website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

Item 2. Properties.

Our headquarters and manufacturing facility is located on a 10 acre site in Miami, Florida. On this site, we own an approximately 20,000 square foot building, which is used for laboratory, office and administrative purposes. We also lease from Aventis, for $1.00 per year, two approximately 40,000 square foot buildings on this site, which we use for manufacturing, engineering, administrative and warehousing purposes. The facility has been certified by the DEA to manufacture products containing controlled substances. The lease expires upon the earlier of 2024 or the termination of our license agreement with Aventis. We have an option to purchase the leased facilities at any time during the term of the lease. Aventis may terminate the lease prior to the expiration of its term upon termination or expiration of our 1992 license agreement with Aventis. We expect that we will have sufficient cash to purchase the facility in this event. Nonetheless, if we are unable to purchase the facility, termination of the lease by Aventis could have a material adverse effect on our business and results of operations.

We lease approximately 15,700 square feet of office space in a neighboring facility for certain administrative functions and an additional 78,600 square feet of industrial space for warehousing which, depending on need, may also be used for manufacturing new products. In addition, we own five acres of vacant land on a contiguous site that we believe could accommodate new buildings for a variety of manufacturing, warehousing and developmental purposes. We believe that our facilities are in satisfactory condition, and are suitable for their intended use and have adequate capacity for the manufacture of our HT products. We are currently expanding our manufacturing area to facilitate the manufacture and storage of our methylphenidate patch and our transdermal fentanyl patch. In addition, as noted above, we have supplemented our manufacturing facilities on our existing site with leased space located in close proximity to our existing site for the storage, and, if necessary, manufacture of new products.

Our sole manufacturing facility, our research and development activities, as well as our corporate headquarters and other critical business functions, are located in an area subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business,

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earnings and competitive position could be materially adversely affected in the event of a major windstorm or other casualty.

Item 3. Legal Proceedings.

Miller Donovan v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Juan A. Mantelle, United States District Court, Southern District of Florida; August 7, 2003.

Plaintiff filed the above referenced action on behalf of a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. The complaint alleges that, during the subject period, Noven and its officers named as defendants violated the Securities Exchange Act of 1934 by making false and misleading statements in its public disclosures regarding our methylphenidate patch. Following the filing of Plaintiff s complaint, five other substantially similar complaints were filed against Noven and its officers named as defendants in the above referenced action. In December 2004, the court entered an order appointing Equitec-Cole Investor Group as the lead plaintiff and, on or about February 11, 2005, the Plaintiffs filed an Agreed Motion and Proposed Order of Voluntary Dismissal seeking that the complaint be dismissed without prejudice. Noven believes the lawsuit is without merit. If the lawsuit is not ultimately dismissed or if the Plaintiffs decide to refile this lawsuit, Noven intends to vigorously defend the lawsuit. The lawsuit, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability, if any, with respect to the lawsuit is presently not determinable.

HT Litigation

In July 2004, an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including our CombiPatch® product, which is manufactured by Noven and sold by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount. In January 2005, the plaintiffs agreed to substitute Aventis for Noven and Novartis in this case. The parties are in the process of drafting the necessary documents to effect the substitution of Aventis and dismissal without prejudice of Noven and Novartis.

Novartis has advised Noven that Novartis has been named as a defendant in at least 11 additional lawsuits that include approximately 22 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches (Vivelle®, Vivelle-Dot and CombiPatch®) sold by Novogyne. To date neither Noven nor Novogyne has, to Noven s knowledge, been named as a party to these additional lawsuits. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. The outcome of these product liability lawsuits cannot ultimately be predicted.

We are a party to other pending legal proceedings arising in the normal course of business, none of which we believe is material to our financial position or results of operations.

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Item 4. Submission of Matters to a Vote of Security Holders.

We did not submit any matters to a vote of stockholders during the quarter ended December 31, 2004.

Executive Officers of the Registrant

Set forth below is a list of the names, ages, positions held and business experience of the persons serving as our executive officers as of March 1, 2005. Officers serve at the discretion of the Board of Directors. There is no family relationship between any of the executive officers or between any of the executive officers and any of our directors, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Eduardo G. Abrao, M.D. Dr. Abrao, age 62, has been Vice President Clinical Development & Chief Medical Officer of Noven since September 2003. Prior to joining Noven, Dr. Abrao served as the Vice President, Regulatory Affairs and Drug Safety of Berlex Laboratories, Inc. from March 2002 to October 2002. From 1996 to 2002, Dr. Abrao served Otsuka America Pharmaceutical, Inc. in a variety of regulatory and operational positions, most recently as its President and Chief Operating Officer. From 1989 to 1996, Dr. Abrao was Vice President, International Medical Department with Marion Merrell Dow/Hoechst Marion Roussel.

Diane M. Barrett. Ms. Barrett, age 44, has been with Noven since August 2000 and, since May 2003, has served as Vice President & Chief Financial Officer. From 1997 to 2000, Ms. Barrett served as Vice President and Chief Financial Officer of BioNumerik Pharmaceuticals, Inc. and, from 1990 to 1997, served Cordis Corporation in a variety of finance positions, most recently as Treasurer. Prior to joining Cordis, Ms. Barrett was a manager with Arthur Andersen & Co.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 39, has been with Noven since November 1998 and, since November 2000, has served as Vice President Strategic Alliances, General Counsel & Corporate Secretary. From 1995 through 1998, Mr. Eisenberg served as Associate General Counsel ode could have on existing arrangements with our executive officers. We entered into amendments to the agreements governing the restricted unit grants made in 2000 and 2004 to Mr. Essig in an attempt to be in good-faith compliance with the requirements of Section 409A of the Code, pending issuance of the final regulations.

Compensation Committee Report

We have reviewed and discussed with management the Compensation Discussion and Analysis prepared by management. Based on this review and discussion, we have recommended to the Board of Directors that the Compensation Discussion and Analysis prepared by management be included in this Proxy Statement.

The Compensation Committee of the Board of Directors

KEITH BRADLEY (CHAIR)

NEAL MOSZKOWSKI

CHRISTIAN S. SCHADE

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Summary Compensation Table

The following table set forth information regarding compensation paid to our Chief Executive Officer, the two people who served as principal financial officer in 2006 and each of our three other most highly compensated executive officers based on total compensation earned during 2006.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards[1] ($)	Option Awards[1] ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings[2] ($)	All Other Compensation[3] ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Stuart M. Essig President and Chief Executive Officer	2006	500,000	500,000		2,531,090			3,750	3,534,840
Maureen B. Bellantoni Executive Vice President and Chief Financial Officer	2006	293,077	120,000	117,091				118,411[4]	648,579
David B. Holtz Senior Vice President, Finance[5]	2006	250,000		233,275	181,772			350,777[6]	1,015,824
John B. Henneman, III Executive Vice President and Chief Administrative Officer	2006	420,000	168,000	1,169,462	785,907			3,750	2,547,119
Gerard S. Carlozzi Executive Vice President and Chief Operating Officer	2006	400,000	160,000	1,169,462	973,568				2,703,030
Judith E. O Grady Senior Vice President, Regulatory, Quality Assurance and Clinical Affairs	2006	227,577	3,000	37,411	167,828	41,112		3,750	480,678

(1) The amounts in Columns (e) and (f) reflect the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31,

2006 in accordance with FAS 123(R) of awards pursuant to the Company s equity incentive plans and therefore may include amounts from awards granted in 2006 and prior. Assumptions used in the calculation of these amounts for awards granted in fiscal years ended December 31, 2006, 2005, and 2004 are included in Note 2 *Summary of Significant Accounting Policies* to the Company s audited financial statements for the fiscal year ended December 31, 2006, included in the Company s Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission on March 2, 2007. Assumptions used in the calculation of

these amounts for the fiscal years ended December 31, 2003 and 2002 are included in Note 2 *Summary of Significant Accounting Policies* to the

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Company s audited financial statements for the fiscal year ended December 31, 2003, included in the Company s Annual Report on Form 10-K for the year ended December 31, 2003 as filed with the Securities and Exchange Commission on March 12, 2004. However, as required, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions.

(2) The amounts in column (g) reflect cash awards earned under the Company s Management Incentive Compensation Plan (the MICP).

(3) Unless otherwise indicated, (a) the amounts in this column

consist of Company matching contributions made to the Company s 401(k) plan and (b) the aggregate amount of perquisites and other personal benefits was less than $10,000.

(4) This consists of (a) $116,380 for moving and relocation expenses, (b) $1,731 of Company matching contributions made to the Company s 401(k) plan, and (c) $300 paid by the Company for the annual fee for a corporate credit card provided only to certain employees.

(5) Mr. Holtz was the Company s principal financial officer until January 10, 2006. Mr. Holtz s last day with the Company was December 31, 2006.

(6) This consists of (a) $325,000 of

severance payments provided for under Mr. Holtz s employment agreement, (b) $9,708 of COBRA payments to be made by the Company on Mr. Holtz s behalf for the 12 months following the end of his employment that was earned on December 31, 2006 as a result of Mr. Holtz leaving the Company, (c) $12,019 of accrued personal time payable to Mr. Holtz as a result of Mr. Holtz leaving the Company, (d) $3,750 of Company matching contributions made to the Company s 401(k) plan and (e) $300 paid by the Company for the annual fee for a corporate credit card provided only to certain employees.

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Grants Of Plan Based Awards

The following table presents information on annual incentive opportunities grated under the MICP and equity awards granted under the Company s 2003 Equity Incentive Plan.

Name	Grant Date	Date of Comp. Committee Action	Estimated Future Payouts Under Non-Equity Incentive Plan Awards[1] Threshold ($)	Target ($)	Maximum ($)	Estimated Future Payouts Under Equity Incentive Plan Awards[2] Threshold (#)	Target (#)	Maximum (#)	All Other Stock Awards: Number of Shares of Stock or Units[3] (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards[4] ($)
(a)	(b)		(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
Stuart M. Essig	12-19-06	12-19-06								200,000[5]	42.53	3,942,680
Maureen B. Bellantoni	01-10-06	01-10-06					10,000					358,200
David B. Holtz	09-18-06	09-18-06	0	40,625	60,938							
	10-02-06	09-18-06							269[6]			9,985
John B. Henneman, III	01-03-06	12-19-05					100,000					3,531,00
Gerard S. Carlozzi	01-03-06	12-19-05					100,000					3,531,00
Judith E. O Grady	01-03-06	12-19-05							2,500			88,275
	07-03-06	06-16-06							1,282			49,988
	09-18-06	09-18-06	0	37,325	56,063							

(1) The amounts shown in these columns represent the executives annual incentive opportunity under the MICP. See Compensation Discussion and Analysis Elements of Compensation Annual Cash Incentives/Bonuses for more information regarding this plan. The Target is calculated by multiplying the officer s base salary by the executive s target award

percentage provided for under the MICP. The Maximum is calculated by multiplying the Target by 150%. The Threshold is $0 because no amounts are payable if the performance goals under the MICP are not achieved at the 90% level.

(2) The amounts shown in these columns represent shares of performance stock granted under the Company s 2003 Equity Incentive Plan. See Compensation Discussion and Analysis Elements of Compensation Long-Term Equity-Based Incentives for a description of the material terms of these performance stock awards.

(3) The amounts shown in these columns represent shares of restricted stock granted under the Company s 2003 Equity Incentive Plan. See Compensation Discussion and Analysis Elements of Compensation Long-Term Equity-Based Incentives for a description of the

material terms of these restricted stock awards.

(4) This column reflects the full grant date fair value of the restricted stock, performance stock and stock options under SFAS 123R granted to the named executive officers in 2006. Generally, the full grant date fair value is the amount that the company would expense in its financial statements over the award s vesting schedule. For restricted stock and performance stock, fair value is calculated using the closing price of the Company s common stock on the grant date noted. For the stock options granted to Mr. Essig, fair value is calculated using the binomial distribution value on the grant date. The fair value shown for stock awards and option awards are accounted for in accordance with SFAS 123R. For additional information on the valuation assumptions, refer to Note 2 of the Company s financial statements in the

Form 10-K for the year ended December 31, 2006, as filed	

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with the Securities and Exchange Commission on March 2, 2007. These amounts reflect the company accounting expense and do not correspond to the actual value that will be recognized by the named executive officers.

(5) This amount represents the annual stock option grant to Mr. Essig. 25% of the award vests one year after the grant date and the remaining 75% vests monthly thereafter over 36 months. The option has a term of 10 years.

(6) This award was forfeited by Mr. Holtz as a result of his leaving the Company prior to the vesting date.

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Outstanding Equity Awards At Fiscal Year-End

The following table presents information with respect to outstanding equity awards as of December 31, 2006.

	Option Awards[1]				Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price[2] ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested[3] ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested[4] ($)
(a)	(b)	(c)	(e)	(f)	(g)	(h)	(i)	(j)
Stuart M. Essig	282,086		11.00	12/22/2010				
	31,565		26.34	12/21/2011				
	36,208		17.65	12/31/2012				
	18,229	6,771	28.78	01/02/2014				
	100,000	100,000	34.49	12/17/2014				
	151,041	98,959	31.38	07/27/2014				
	50,000	150,000	35.57	12/19/2015				
	0	200,000	42.53	12/19/2016				
					1,250,000[5]	63,885,000		
Maureen B. Bellantoni							10,000[6]	425,900
David B. Holtz	200		17.65	12/31/2008				
	4,248	500	22.78	04/07/2009				
		230	32.39	11/03/2009				
	15,312	5,688	28.78	01/02/2010				
	4,687	2,813	32.32	06/01/2010				
	10,415	9,585	35.52	11/15/2010				
					269[7]	11,457		
John B. Henneman, III	10,000		27.78	08/14/2007				
	2,500		25.99	12/14/2007				
	125,000		26.70	12/17/2007				
	14,500		26.34	12/31/2007				

10,000		14.87	08/02/2008
5,000		17.72	11/21/2008
1,000		17.60	12/16/2008
19,062		17.65	12/31/2008
19,166	834	18.63	02/24/2009
18,333	1,667	22.78	04/07/2009
3,854	1,146	32.39	11/03/2009
18,229	6,771	28.78	01/02/2010
12,500	7,500	32.32	06/01/2010
13,020	11,980	35.52	11/15/2010
3,437	4,063	38.72	02/01/2011
25,000	75,000	30.25	07/26/2011

100,000(8) 4,259,000

(Continued on next page)

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Outstanding Equity Awards At Fiscal Year-End (continued)

	Option Awards[1]				Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price[2] ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested[3] ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested[4] ($)
(a)	(b)	(c)	(e)	(f)	(g)	(h)	(i)	(j)
Gerard S. Carlozzi	4,167	18,750	27.32	09/26/2009				
	1,563		32.39	11/03/2009				
	521	6,771	28.78	01/02/2010				
	6,250	7,500	32.32	06/01/2010				
	13,020	11,980	35.52	11/15/2010				
	3,437	4,063	38.72	02/01/2011				
		75,000	30.25	07/26/2011				
							100,000[8]	4,259,000
Judith S. O Grady	7,500		26.34	12/31/2007				
	1,875		14.87	08/02/2008				
	500		17.60	12/16/2008				
	9,583		17.65	12/31/2008				
	458	42	22.78	04/07/2009				
	1,541	459	32.39	11/03/2009				
	10,937	4,063	28.78	01/02/2010				
	3,125	1,875	32.32	06/01/2010				
	1,169	1,081	32.02	11/01/2010				
	7,812	7,188	35.52	11/15/2010				
	1,875	5,625	33.48	11/01/2011				
					3,782[9]	164,908		

(1) For option awards made to Mr. Essig and

options awards made prior to July 26, 2005 to other officers, 25% of the award vests one year after the grant date and the remaining 75% vests monthly thereafter over 36 months. Option awards made on or after July 26, 2005 to employees other than Mr. Essig vest in four equal annual installments beginning on the first anniversary of the grant date. Options issued to Mr. Essig have a term of 10 years. Options issued to other officers have a term of six years.

(2) The option exercise price is equal to the closing price of our common stock as reported by the Nasdaq Global Select Market on the date of grant.

(3) Market value is calculated by multiplying the number of shares in

column (g) by $42.59, the closing price of the Company s common stock as reported by the Nasdaq Global Select Market on December 29, 2006.

(4) Market value is calculated by multiplying the number of shares in column (i) by $42.59, the closing price of the Company s common stock as reported by the Nasdaq Global Select Market on December 29, 2006.

(5) Consists of 500,000 shares of common stock underlying restricted units granted in 2000 and 750,000 shares of common stock underlying restricted units granted in 2004. These restricted units vested as of the grant date, but Mr. Essig does not have the right to receive the underlying shares of common stock.

The shares underlying the 2004 grant are deliverable on March 4, 2008, but Mr. Essig has the right to defer the delivery of these shares until June 30, 2025 if certain conditions are met. The shares underlying the 2000 grant are deliverable as soon

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as administratively practicable on or after the first business day that occurs immediately following the 6-month period after the date of Mr. Essig s separation from service from the Company. Mr. Essig has the right to defer the delivery of these shares until June 20, 2029 if certain conditions are met.

(6) Consists of 10,000 shares of common stock underlying a performance stock award. The terms of the award provide that these shares will be deliverable as soon as practicable after December 31, 2008 if the performance condition is met. The performance condition was met in 2006.

(7) Consists of shares of restricted stock that were

scheduled to vest on October 2, 2009. These shares were forfeited as a result of Mr. Holtz leaving the Company on December 31, 2006.

(8) Consists of 100,000 shares of common stock underlying a performance stock award. The terms of the award provide that these shares will be deliverable as soon as practicable after December 31, 2008 if the performance condition is met. The performance condition was met in 2006.

(9) Consists of 2,500 shares of restricted stock that will vest on January 3, 2009 and 1,282 shares of restricted stock that will vest on July 3, 2009.

Option Exercises And Stock Vested

The following table presents information on stock option exercises and stock award vesting during 2006.

	Option Awards		Stock Awards	
	Number of Shares	Value Realized on Exercise[1]	Number of Shares	Value Realized on Vesting[2]

Name	Acquired on Exercise (#)	($)	Acquired on Vesting (#)	($)
(a)	(b)	(c)	(d)	(e)
Stuart M. Essig	7,084	170,760	750,000	26,025,000
Maureen B. Bellantoni				
David B. Holtz	87,616	1,337,523	6,750(3)	287,483
John B. Henneman, III	25,000	679,087		
Gerard S. Carlozzi	128,332	1,542,390		
Judith E. O Grady	8,051	187,765		

(1) Value realized is calculated on the basis of the difference between the exercise price and the market price of the Company s common stock as reported by the Nasdaq Global Select Market on the date of exercise, multiplied by the number of shares of common stock underlying the options exercised.

(2) Value realized is calculated on the basis of the closing price of our common stock as reported by the Nasdaq Global Select Market on the date of vesting multiplied by the number of shares of common stock that vested or, in the case of

Mr. Essig, that were delivered. The 750,000 shares delivered to Mr. Essig had vested on the grant date of the restricted units relating to these shares, but the terms of the restricted unit grant provided that these shares would not be deliverable until January 3, 2006.

(3) In connection with the vesting of 6,750 shares of restricted stock issued to Mr. Holtz, the Company withheld 2,021 shares to satisfy tax withholding obligations.

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Director Compensation

The Board of Directors believes that providing competitive compensation is necessary to attract and retain qualified non-employee directors. The key components of non-employee director compensation include an annual equity grant and an annual retainer.

Compensation. The compensation of directors during 2006 included the compensation payable during the one year period beginning with the Company s 2005 Annual Meeting of Stockholders on May 17, 2005 and the one year period beginning with the Company s 2006 Annual Meeting of Stockholders on May 17, 2006.

As compensation for their service during the one year period beginning with the Company s 2005 Annual Meeting of Stockholders, non-employee directors received a grant of options to purchase 7,500 shares of common stock, with the Chairman of the Board of Directors receiving options to purchase 10,000 shares. Directors also received an annual retainer of $40,000, payable in one of four ways, at their election: (1) in cash, (2) in restricted stock, (3) one half in cash and one half in restricted stock, or (4) in options to purchase common stock (the number of options determined by valuing the options at 25% of the fair market value of our common stock underlying the option), with a maximum of 5,000 options.

Effective as of the 2006 Annual Meeting of Stockholders, non-employee directors were able to elect to receive an annual equity grant of 1,875 shares of restricted stock instead of options to purchase 7,500 shares of common stock (with the Chairman of the Board of Directors being able to elect to receive 2,500 shares of restricted stock instead of options to purchase 10,000 shares of common stock). In addition, the annual retainer was increased to $50,000, payable in the four ways described above.

The Company pays reasonable travel and out-of-pocket expenses incurred by non-employee directors in connection with attendance at meetings to transact business of the Company or attendance at meetings of the Board of Directors or any committee thereof.

The following table provides details the total compensation earned by non-employee directors in 2006.

Name	Fees Earned or Paid in Cash[1] ($)	Stock Awards[2] ($)	Option Awards[2][3] ($)	Total ($)
(a)	(b)	(c)	(d)	(h)
Keith Bradley	15,217	120,359		135,576
Richard E. Caruso	7,609	143,815		151,424
Neal Moszkowski[4]			119,490	119,490
Christian Schade[5]	15,489	24,995	97,360	137,844
James M. Sullivan	23,098	95,364		118,462
Anne M. VanLent	30,978		97,360	128,338
David Auth[6]	15,217			15,217

(1) Includes amounts earned for 2006, but not paid until 2007

(2) Reflects the dollar amount recognized for financial statement

reporting purposes for the fiscal year ended December 31, 2006 in accordance with FAS 123(R). Assumptions used in the calculation of these amounts are included in Note 2 *Summary of Significant Accounting Policies* to the Company s audited financial statements for the fiscal year ended December 31, 2006, included in the Company s Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission on March 2, 2007.

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However, as required, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. The grant date fair value of stock and option awards is equal to the amounts set forth in these columns, except that the grant date fair value of the option awards made to Mr. Moszkowski was $152,625

(3) The aggregate number of options held by each director as of December 31, 2006 was as follows: Keith Bradley 30,000; Richard E. Caruso 70,000; Neal Moszkowski 12,500; Christian Schade - 7,500; James M. Sullivan 50,000 and Anne M. VanLent 27,500. All of these options had vested as of such date, other than the options held by Mr. Moszkowski. No shares of restricted stock

were held by any director as of such date.

(4) Mr. Moszkowski re-joined the Board of Directors on August 1, 2006.

(5) Mr. Schade joined the Board of Directors on May 17, 2006.

(6) Mr. Auth s term as a director ended on May 17, 2006.

Stuart Essig, the Company s President and Chief Executive Officer, is not included in this table because he is an employee of the Company and does not receive compensation for his services as a director. The compensation received by Mr. Essig as an employee of the Company is shown above in the Summary Compensation Table.

Changes to Director Compensation. At the beginning of 2007, the Company approved the following changes to the compensation of our non-employee directors, effective as of the 2007 Annual Meeting of Stockholders:

the annual retainer was increased from $50,000 to $55,000; and

for directors who choose to receive the annual retainer in options to purchase common stock, the number of options will be determined by valuing the options at 25% of the fair market value of our common stock underlying the option, with a maximum of 7,500 options.

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Potential Payments Upon Termination or Change in Control

The Company has entered into agreements with each of its named executive officers which provide certain payments and benefits upon several events of termination of employment, including termination of employment in connection with a change in control. This section describes these payments and benefits, with amounts based on the assumption that a named executive officer s termination of employment with the Company occurred on December 31, 2006. On December 29, 2006, the last trading day prior to December 31, 2006, the Company s common stock had a closing sale price on the Nasdaq Global Select Market of $42.59. Actual amounts payable would vary based on the date of the named executive officer s termination of employment and can only be finally determined at that time.

Unless specified otherwise, the information in this section is based upon the terms of (i) the Second Amended and Restated Employment Agreement between the Company and Stuart M. Essig, dated as of July 27, 2004 and subsequently amended on December 19, 2006, (the Essig Agreement); (ii) the Amended and Restated Employment Agreement, dated December 19, 2005, between the Company and John B. Henneman, III (the Henneman Agreement), (iii) the Amended and Restated Employment Agreement, dated December 19, 2005, between the Company and Gerard S. Carlozzi (the Carlozzi Agreement); (iv) the Amended and Restated Employment Agreement, dated December 19, 2005, between the Company and David B. Holtz (the Holtz Agreement); (v) the Severance Agreement, dated January 1, 2007, between the Company and Judith O Grady (the O Grady Agreement); and (vi) the Employment Agreement, dated January 10, 2006, between the Company and Maureen B. Bellantoni (the Bellantoni Agreement) which together with the Essig Agreement, the Henneman Agreement, the Carlozzi Agreement, the Holtz Agreement and the O Grady Agreement are collectively referred to in this section as, the Agreements).

Mr. David B. Holtz, who terminated his employment on December 31, 2006, is discussed at the end of this section under Terminated Executive During 2006 Calendar Year.

Payments Upon Termination By The Company Without Cause Or By The Executive For Good Reason

The Agreements provide each of the named executive officers (except Ms. O Grady) severance payments and benefits upon termination of their employment by the Company without cause or by the executive for good reason. For Mr. Essig and Ms. Bellantoni, the Company will pay them a lump sum cash severance payment equal to their annual base salary as of their last day of active employment. For Messrs. Henneman and Carlozzi, the Company will pay them a lump sum cash severance payment equal to the sum of their annual base salary as of their last day of active employment and their target bonus for the year of termination.

In addition, the Company will continue to provide to each of the named executive officers (other than Ms. O Grady) continued participation in all of the Company s life insurance, health and accident, disability and other employee benefit plans for a specified period of time. Specifically, Mr. Essig will receive continued coverage until December 31, 2009, and the other executives will have continued coverage for one year following their date of termination.

The Agreements also provide the named executive officers (except Mses. Bellantoni and O Grady) with accelerated vesting of their equity awards upon such termination of employment. In addition, for Mr. Essig only, all of his stock options will remain exercisable through their original expiration dates and he will receive payment of the shares of common stock underlying the 750,000 restricted stock units granted to him on July 27, 2004 (the 2004 RSUs), unless he previously elected a different payment date.

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The O Grady Agreement provides that upon termination of her employment prior to a change in control, the Company s standard employment termination policies and practices that are applicable to her at the time of her termination would be applicable. The Company currently does not have a written severance plan for employees generally. Accordingly, Ms. O Grady will not be entitled to any payments or benefits upon termination of her employment without cause prior to a change in control.

Good reason under the Agreements generally exists if (i) the Company materially breaches the respective Agreements and does not cure the breach within a specified period of time after its receipt of written notice of such breach; (ii) the Company relocates the executive to a location more than forty miles from Princeton, New Jersey (or for Mr. Essig only, more than thirty miles from Princeton, New Jersey and sixty miles from New York, New York); (iii) without the executive s express written consent, the Company reduces the executive s base salary or bonus opportunity, or materially reduces the aggregate fringe benefits provided to the executive, or substantially alters the executive s authority and/or title in a manner reasonably construed to constitute a demotion, provided that, for all executives (except Mr. Essig), the executive resigns within ninety days after the change objected to; (iv) without the executive s express written consent, the executive fails at any point after a change in control to hold the title and authority with the parent corporation of the surviving corporation after the change in control (or, for all executives other than Mr. Essig, if there is no parent corporation, the surviving corporation) that executive held with the Company immediately prior to the change in control, provided that the executive resigns within one year after the change in control (or for Mr. Essig only, he resigns for good reason within eighteen months after the change in control (in which case, no notice or cure period would apply)); or (v) the Company fails to obtain the assumption of the executive s Agreement by any successor company.

The Essig Agreement provides for the following additional good reason terminations that are specific only to Mr. Essig: (i) if the Board of Directors fails to nominate him as a candidate for director; (ii) if he is not appointed as the President and Chief Executive Officer of the Company or as a member of the Board of Directors; (iii) if the Company materially breaches any equity compensation plan implemented after July 27, 2004 or any of the agreements evidencing his equity grant awards; (iv) if the Company materially fails to provide annual medical examinations and vacation benefits, or to substantially provide any material employee benefits due to him (other than any such failure which affects all senior executive officers); (v) if the Company fails to indemnify him in all material respects in accordance with the Company s by-laws and terms of any directors and officers liability insurance policy**;** or (vi) if the Company fails to initiate the procedures, as soon as practicable, to establish and maintain registration statements with respect to stock options and restricted stock units granted to him prior to July 27, 2004.

Payments Upon Termination For Cause Or By Executive Without Good Reason

The Agreements generally do not provide the named executive officers with any payments or other benefits in the event of their termination of employment by the Company for cause or by the executive without good reason other than amounts accrued and owing, but not yet paid, as of the date of the executive s termination of employment.

A termination for cause under the Agreements generally would result from an executive s: (i) continued failure to perform the executive s stated duties in all material respects for a specified period of time after receipt of written notice of such failure; (ii) intentional and material breach of any provision of the Agreements which is not cured (if curable) within a specified period of time after receipt of written notice of such breach; (iii) demonstrated personal dishonesty in connection with the executive s employment with the Company; (iv) breach of fiduciary duty in connection with the executive s employment with the Company; (v) willful misconduct that is materially and demonstrably injurious to the Company or any of its subsidiaries; or (vi) conviction or plea of guilty or *nolo contendere* to a felony

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or to any other crime involving moral turpitude which conviction or plea is materially and demonstrably injurious to the Company or any of its subsidiaries.

Payments Upon Non-Renewal Of Employment Agreement

Only the Essig, Henneman and Carlozzi Agreements provide payments and benefits upon non-renewal of the term of the respective Agreements. For Mr. Essig, all of his outstanding stock options granted after July 27, 2004 will immediately vest and remain exercisable through their original expiration dates. In addition, he will receive the shares underlying his 2004 RSUs, unless he previously elected a different payment date.

For Messrs. Henneman and Carlozzi, the Company will pay them the same payments and benefits as those payments and benefits described under Payments Upon Termination By The Company Without Cause Or By The Executive For Good Reason discussed above. However, while their stock options will accelerate and become fully exercisable, only a pro-rata portion of Messrs. Henneman s and Carlozzi s outstanding shares of restricted stock will be deemed to have vested as of the last day of their employment. Such pro-rata portion will be based on the number of days that they worked for the Company after the grant of their restricted stock awards and the total number of days of the restriction period set forth in their respective restricted stock grant agreements.

Payments Upon Death

Only the Essig, Henneman and Carlozzi Agreements provide severance payments and benefits upon death. Specifically, if Messrs. Essig, Henneman and Carlozzi die during the term of their employment, then the Company will pay to their estate a lump sum payment equal to one times their annual base salary. In addition, their eligible beneficiaries will continue to participate in all of the Company s life insurance, health and accident, disability and other employee benefit plans generally for a period of one year from the date of their death.

The Essig, Henneman and Carlozzi Agreements also provide for acceleration of their respective equity compensation awards. In addition, all of Mr. Essig s stock options will remain exercisable until one year following his death, but in no event beyond their respective original expiration dates. Moreover, as promptly as practicable following his death, Mr. Essig s estate will receive the shares underlying the 2004 RSUs, unless he previously elected a different payment date.

Payments Upon Disability

Only the Essig Agreement provides payments upon termination of Mr. Essig s employment on account of disability. Specifically, if his employment is terminated on account of his disability, then the Company will pay him an amount equal to (i) if such payments are taxable, his then-current base salary, or alternatively, (ii) if such payments are not taxable, the after-tax equivalent of his then-current base salary, in either case until December 31, 2009. The Company will also generally continue all of the Company s life insurance, health and accident, disability and other employee benefits to him for a period of one year from the date of his termination. Following December 31, 2009, Mr. Essig will continue to be entitled to receive long-term disability benefits under the Company s long-term disability program in effect at such time to the extent he is eligible to receive such benefits.

In addition to the foregoing payments upon his termination of employment on account of his disability, all of Mr. Essig s stock options will immediately vest and will remain exercisable until one year following his termination, but in no event beyond their respective original expiration dates. As

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promptly as practicable following such termination, all shares underlying the outstanding 2004 RSUs will be paid to him, unless he previously elected a different payment date.

Although no severance payments will be made to Messrs. Henneman and Carlozzi upon their termination of employment on account of their disability, all of their equity awards will accelerate and become fully vested on the date of their termination of employment for disability.

Under the Agreements, disability generally means the executive s inability to perform his duties by reason of any medically determinable physical or mental impairment which is expected to result in death or which has lasted or is expected to last for a continuous period of not fewer than six months.

Payments Upon Termination Related To A Change In Control

The Agreements provide each of the named executive officers severance payments and benefits upon termination of their employment in connection with or following a change in control. If (i) Mr. Essig s employment is terminated by the Company for a reason other than death, disability, or cause, (ii) Mr. Essig terminates his employment for good reason, or (iii) the Company fails to renew the Essig Agreement, in each case, within eighteen months following a change in control, he will be entitled to a severance payment equal to the sum of (a) 2.99 times the sum of his base salary and target bonus for the fiscal year of his termination and (b) a pro rata portion of his bonus in the year of termination. In addition, the Company will generally provide him with continued participation in all of the Company s life insurance, health and accident, disability and other employee benefit plans until the end of the later of December 31, 2009 or one year following his termination date. Moreover, the Company will reimburse him for all reasonable legal fees and expenses incurred by him as a result of such termination of employment. The Company will also pay him interest on any severance payments that are delayed for six months because of the application of section 409A of the Code.

The Agreements with the other named executive officers provide that, if within twelve months of a change in control, their employment with the Company is terminated by the Company for a reason other than death, disability or cause, or they terminate employment with the Company for good reason, (or for Messrs. Henneman and Carlozzi only, the Company fails to renew their respective Agreements), the Company will pay to them a lump sum cash payment equal to 2.99 times (for Ms. O Grady only, 1.99 times) the sum of their annual base salary and target bonus. In addition, the Company will continue to maintain and provide to these executives continued participation in all of the Company s life insurance, health and accident, disability and other employee benefit plans for a period generally ending on the earlier to occur of (i) the fifth anniversary of their Agreements (or for Mses. Bellantoni and O Grady only, the first anniversary of their date of termination of employment), or (ii) their date of death. All of the Agreements (except the O Grady Agreement) also provide that the Company will pay all reasonable fees and expenses incurred by the executives as a result of their termination of employment.

The Agreements (except the O Grady Agreement) provide that if any payment, coverage or benefit provided to them is subject to the excise tax under section 4999 of the Code, the executives will be grossed-up so that the executive would be in the same net after-tax position he or she would have been in had sections 280G and 4999 not been part of the Code. The O Grady Agreement provides that if any payment or benefit provided to her would be subject to the excise tax under section 4999 of the Code, she will have the amounts payable to her and benefits she will receive reduced so that no amounts she would receive would be subject to the excise tax under section 4999 of the Code if such reduction would result in her receiving a greater amount on an after-tax basis than if no reduction had occurred.

The Company s equity plans provide for the acceleration of the vesting and/or delivery of all equity compensation awards for all of the named executive officers upon a change in control, regardless

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of whether their employment has terminated. The Essig Agreement provides that all stock options granted to Mr. Essig will remain exercisable through their original expiration dates, and he will generally receive payment of all outstanding restricted stock units (including the shares underlying the 2004 RSUs and the 500,000 shares underlying the restricted stock units granted to Mr. Essig in 2000) on the date of the change in control.

Under the Agreements, a change in control would be deemed to have occurred: (i) if the beneficial ownership of securities representing more than fifty percent (or for Mr. Essig only, thirty-five percent) of the combined voting power of the voting securities of the Company is acquired by any individual, entity or group; (ii) if the individuals who, as of the date of the Agreement, constitute the Board of Directors cease for any reason during any period of at least twenty-four months to constitute at least a majority of the Board of Directors; (iii) upon consummation of a reorganization, merger or consolidation or sale or other disposition of all or substantially all of assets of the Company or the acquisition of assets or stock of another entity; or (iv) upon approval by the stockholders of a complete liquidation or dissolution of the Company.

Restrictive Covenants And Other Conditions

The foregoing severance benefits payable upon termination of employment prior to or after a change in control to the named executive officers (except Ms. O Grady) are conditioned on, for Messrs. Essig, Henneman and Carlozzi, their execution of a mutual release, and for Ms. Bellantoni, her execution of a general release.

In addition, for all of the named executive officers, such benefits are consideration for the restrictive covenants set forth in their respective Agreements; provided, however, that such restrictive covenants would not apply to Mr. Essig if he is terminated by the Company without cause or he terminates his employment for good reason prior to a change in control. Specifically, during the term of their employment with the Company and the one year period thereafter (or for Mr. Essig, the two year period thereafter), all of the named executive officers may not compete against the Company or solicit employees and customers of the Company.

Terminated Executive During 2006 Calendar Year

Effective as of December 31, 2006, Mr. David Holtz terminated his employment as the Senior Vice President, Finance of the Company for good reason. In connection therewith, Mr. Holtz received payments and benefits totaling $337,000, which consisted of cash severance in the amount of $325,000 and continued health benefits in the amount of $12,000. These amounts were paid to him pursuant to his Agreement.

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Summary of Potential Payments

The following table summarized the payments to be made by the Company to the named executive officer s upon the events discussed above:

Named Executive Officer	Termination Without Cause Or With Good Reason (Before A Change In Control)	Non-Renewal Of Agreement	Death	Disability	Upon A Change In Control (No Termination)	Termination Without Cause Or With Good Reason (After A Change In Control)
Stuart M. Essig						
Cash Severance	$ 500,000		$ 500,000	$ 1,500,000		$ 3,490,000
Continued Health & Other Benefits[1]	$ 24,000		$ 12,000	$ 12,000		$ 36,000
Acceleration of Stock Options	$ 3,537,347	$ 3,537,347	$ 3,537,347	$ 3,537,347	$ 3,537,347	$ 3,537,347
Acceleration of Other Grants	$ 31,942,500	$ 31,942,500	$ 31,942,500	$ 31,942,500	$ 53,237,500	$ 53,237,500
Fees/Interest[2]						$ 86,722
280G Gross-up Amount						
Total	$ 36,003,847	$ 35,479,847	$ 35,991,847	$ 36,991,847	$ 56,774,847	$ 60,387,569
John B. Henneman, III						
Cash Severance	$ 588,000	$ 588,000	$ 420,000			$ 1,758,120
Continued Health & Other Benefits[1]	$ 12,000	$ 12,000	$ 12,000			$ 48,000
Acceleration of Stock Options	$ 1,279,912	$ 1,279,912	$ 1,279,912	$ 1,279,912	$ 1,279,912	$ 1,279,912
Acceleration of Other Grants	$ 4,259,000	$ 1,411,901	$ 4,259,000	$ 4,259,000	$ 4,259,000	$ 4,259,000
Fees/Interest[2]						
280G Gross-up Amount						
Total	$ 6,138,912	$ 3,291,813	$ 5,970,912	$ 5,538,912	$ 5,538,912	$ 7,345,032
Gerard S. Carlozzi						
Cash Severance	$ 560,000	$ 560,000	$ 400,000			$ 1,674,400
Continued Health & Other Benefits[1]	$ 12,000	$ 12,000	$ 12,000			$ 48,000
Acceleration of Stock Options	$ 1,500,491	$ 1,500,491	$ 1,500,491	$ 1,500,491	$ 1,500,491	$ 1,500,491
Acceleration of Other Grants	$ 4,259,000	$ 1,411,901	$ 4,259,000	$ 4,259,000	$ 4,259,000	$ 4,259,000
Fees/Interest[2]						
280G Gross-up Amount						$ 962,189
Total	$ 6,331,491	$ 3,484,392	$ 6,171,491	$ 5,759,491	$ 5,759,491	$ 8,444,080
Maureen B. Bellantoni						

Cash Severance	$ 300,000			$ 1,255,800
Continued Health & Other Benefits[1]	$ 12,000			$ 12,000
Acceleration of Stock Options				
Acceleration of Other Grants			$ 425,900	$ 425,900
Fees/Interest[2]				
280G Gross-up Amount				$ 448,432
Total	$ 312,000		$ 425,900	$ 2,142,132
Judith O Grady				
Cash Severance				$ 640,780
Continued Health & Other Benefits[1]				$ 12,000
Acceleration of Stock Options			$ 194,315	$ 194,315
Acceleration of Other Grants			$ 161,075	$ 161,075
Fees/Interest				
280G Gross-up Amount				
Total			$ 355,390	$ 1,008,170

(Continued on next page)

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Named Executive Officer	Termination Without Cause Or With Good Reason (Before A Change In Control)	Non-Renewal Of Agreement	Death	Disability	Upon A Change In Control (No Termination)	Termination Without Cause Or With Good Reason (After A Change In Control)
David B. Holtz						
Cash Severance	$ 325,000					
Continued Health & Other Benefits[1]	$ 12,000					
Acceleration of Stock Options						
Acceleration of Other Grants						
Fees/Interest						
280G Gross-up Amount						
Total	$ 337,000					

(1) For these purposes, the cost of continued participation in the Company s health and other employee benefit plans for each executive is assumed to be $1,000 per month.

(2) The Essig, Henneman, Carlozzi and Bellantoni Agreements provide for reasonable legal fees and expenses that may be incurred by each executive as a result of their termination of

employment related to a change in control. However, the table does not include a value for these fees and expenses because they would be incurred only if there is a dispute under these Agreements. Thus, these amounts are undeterminable. For Mr. Essig only, the $86,722 value represents the interest on his cash severance payment if it is required to be delayed for six months because of the application of section 409A of the Code at the rate of 4.89% compounded monthly.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information as of December 31, 2006 regarding existing compensation plans (including individual compensation arrangements) under which equity securities of the Company are authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (1)
Equity compensation plans approved by stockholders	4,905,681(2)	$ 20.61(3)	2,456,195(4)
Equity compensation plans not approved by stockholders			

Total	4,905,681	$	20.61	2,456,195

(1) Excludes securities to be issued upon the exercise of outstanding options, warrants and rights.

(2) Consists of (a) 1,250,000 shares of common stock underlying Restricted Units, (b) 210,000 shares of common stock underlying outstanding performance stock, (c) 8,083 shares of common stock underlying outstanding contract stock and (d) 3,437,598 shares of common stock underlying outstanding options.

(3) Excluding the Restricted Units, performance stock and contract stock, the weighted average exercise price is $29.41.

(4) Consists of 1,101,303

shares of common stock which remain available for issuance under the Employee Stock Purchase Plan and 1,354,892 shares which remain subject to awards under the other Approved Plans.		

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COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Dr. Bradley, Mr. Moszkowski and Mr. Schade are the current members of the Compensation Committee. Dr. Bradley, Ms. VanLent and Dr. David Auth, a former director of the Company, served as members until May 17, 2006, and Dr. Bradley, Mr. Schade and Ms. VanLent served as members from May 17, 2006 through August 1, 2006. None of these persons was an officer, employee or former officer of the Company or had any relationship requiring disclosure herein pursuant to Securities and Exchange Commission regulations. No executive officer of the Company served as a member of a compensation committee or a director of another entity under circumstances requiring disclosure under Securities and Exchange Commission regulations.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Review and Approval of Related Person Transactions

Pursuant to a written policy, the Company reviews all transactions, arrangements or relationships (or any series of similar transactions, arrangements or relationships) in excess of $100,000 in which the Company (including any of its subsidiaries) was, is or will be a participant and the amount involved exceeds $100,000, and in which any Related Person had, has or will have a direct or indirect interest. For purposes of the policy, a Related Person means:

(a) any person who is, or at any time since the beginning of the Company s last fiscal year was, a director or executive officer of the Company or a nominee to become a director of the Company;

(b) any person who is known to be the beneficial owner of more than 5% of any class of the Company s voting securities;

(c) any immediate family member of any of the foregoing persons; and

(d) any firm, corporation or other entity in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest.

If the Company s legal department determines that a proposed transaction is a transaction for which approval is required under applicable rules and regulations of the Securities and Exchange Commission, the proposed transaction shall be submitted to the Audit Committee for consideration.

The Audit Committee, will consider all of the relevant facts and circumstances available to the Committee, including (if applicable) but not limited to: the benefits to the Company; the impact on a director s independence in the event the Related Person is a director, an immediately family member of a director or an entity in which a director is a partner, shareholder or executive officer; the availability of other sources for comparable products or services; the terms of the transaction; and the terms available to unrelated third parties or to employees generally. No member of the Audit Committee shall participate in any review, consideration or approval of any Related Person Transaction with respect to which such member or any of his or her immediate family members is the Related Person. The Audit Committee shall approve only those Related Person Transactions that are in, or are not inconsistent with, the best interests of the Company and its stockholders, as the Audit Committee determines in good faith.

The policy provides that the above determination should be made at the next Audit Committee meeting. In those instances in which the legal department, in consultation with the Chief Executive

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Officer or the Chief Financial Officer, determines that it is not practicable or desirable for the Company to wait until the next Audit Committee meeting, the transaction shall be presented to the Chair of the Audit Committee (who will possess delegated authority to act between Audit Committee meetings).

Related Person Transactions

The Company leases its manufacturing facility in Plainsboro, New Jersey from Plainsboro Associates, a New Jersey general partnership. Ocirne, Inc., a subsidiary of Provco Industries (Provco), owns a 50% interest in Plainsboro Associates. Provco s stockholders are trusts whose beneficiaries include the children of Dr. Caruso, the Chairman and a principal stockholder of the Company. Dr. Caruso is the President of Provco. The Company paid $231,000 in rent for this facility during 2006.

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AUDIT COMMITTEE REPORT

The following report of the Audit Committee is required by the rules of the Securities and Exchange Commission to be included in this Proxy Statement. This report shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, by virtue of any general statement in such filing incorporating this Proxy Statement by reference, except to the extent that the Company specifically incorporates the information contained in this section by reference, and shall not otherwise be deemed filed under either the Securities Act or the Exchange Act.

The purpose of the Audit Committee is to oversee the Company s accounting and financial reporting process and the audits of the Company s financial statements. The Audit Committee operates pursuant to a Charter that the Board amended and restated on March 2, 2004, a copy of which is available on the Company s website.

As set forth in the Audit Committee Charter, management of the Company is responsible for the preparation, presentation and integrity of the Company s financial statements, the Company s financial reporting process, accounting policies, internal audit function, internal controls and disclosure controls and procedures. The independent registered public accounting firm is responsible for auditing the Company s financial statements and expressing an opinion as to their conformity with generally accepted accounting principles and on management s assessment of the effectiveness of the Company s internal control over financial reporting. The Audit Committee s responsibility is to monitor and oversee this process.

In the performance of its oversight function, the Audit Committee has reviewed and discussed with management and the independent registered public accounting firm the audited financial statements and management s assessment of the effectiveness of the Company s internal control over financial reporting and the independent registered public accounting firm s evaluation of the Company s internal control over financial reporting. The Audit Committee has also discussed with the independent registered public accounting firm the matters required to be discussed by Statement on Auditing Standards No. 61, *Communication with Audit Committees*, as currently in effect. Finally, the Audit Committee has received the written disclosures and the letter from the independent registered public accounting firm required by Independence Standards Board Standard No. 1, *Independence Discussions with Audit Committees,* as currently in effect, has discussed with the independent registered public accounting firm its independence in relation to the Company and has considered the compatibility of non-audit services with such independence. Management has represented to the Audit Committee that the Company s consolidated financial statements were prepared in accordance with generally accepted accounting principles.

Based upon the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the audited financial statements of the Company for the fiscal year ended December 31, 2006 be included in the Company s Annual Report on Form 10-K for such fiscal year, as filed with the Securities and Exchange Commission on March 2, 2007.

The Audit Committee of the Board of Directors

ANNE M. VANLENT (CHAIR)

CHRISTIAN S. SCHADE

JAMES M. SULLIVAN

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PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of common stock as of February 28, 2007 by: (a) each person or entity known to the Company to be the beneficial owner of more than five percent of the outstanding shares of common stock, based upon Company records or statements filed with the Securities and Exchange Commission; (b) each of the Company s directors and nominees for directors; (c) each of the Named Officers; and (d) all executive officers, directors and nominees as a group. Except as otherwise indicated, each person has sole voting power and sole investment power with respect to all shares beneficially owned by such person.

	AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP	
NAME AND ADDRESS OF BENEFICIAL OWNER	SHARES [1]	PERCENT OF CLASS
Thomas J. Baltimore, Jr.	0	*
Keith Bradley, Ph.D.	33,207[2]	*
Richard E. Caruso, Ph.D.	7,207,999[3]	26.3%
Stuart M. Essig	1,598,541[4]	5.7%
Neal Moszkowski	16,011[5]	
Christian S. Schade	8,166[6]	*
James M. Sullivan	74,806[7]	*
Anne M. VanLent	28,748[8]	*
Maureen B. Bellantoni	0	*
John B. Henneman, III	331,636[9]	1.2%
Gerard S. Carlozzi	46,654[10]	*
Judith E. O Grady	61,903[11]	*
David B. Holtz	8,347	*
All directors, nominees for director and executive officers as a group (13 persons)	9,417,472[12]	32.9%
Capital Research and Management Company 333 South Hope Street Los Angeles, CA 90071	2,740,000[13]	10.0%
Provco Leasing Corporation 209B Bayard Building 3411 Silverside Road Wilmington, DE 19810	7,114,543[14]	26.0%
TRU ST PARTNERSHIP, L.P. 795 E. Lancaster Avenue, Suite 200 Villanova, PA 19085	7,091,205[15]	25.9%
T. Rowe Price Associates, Inc. 100 E. Pratt Street Baltimore, MD 21202	2,346,450[16]	8.6%
William Blair & Company, L.L.C 222 W. Adams Street Chicago, IL 60606	3,335,590[17]	12.2%

* Represents beneficial ownership of less than 1%.

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(1) Shares not outstanding but deemed beneficially owned by virtue of the right of an individual to acquire them within 60 days of February 28, 2007 upon the exercise of an option or other convertible security are treated as outstanding for purposes of determining beneficial ownership and the percentage beneficially owned by such individual.

(2) Consists of 30,000 shares that Dr. Bradley has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him.

(3) Includes 7,091,205 shares held by TRU ST PARTNERSHIP, L.P., a Pennsylvania general partnership (TRU ST) (also see Note 15 below). Also includes

23,338 shares held by Provco Leasing Corporation (Provco), of which Dr. Caruso is President and sole director and 19,000 shares held by The Uncommon Individual Foundation, of which Dr. Caruso is the Chief Executive Officer. Provco is the corporate general partner of TRU ST. Dr. Caruso may be deemed to have shared voting and dispositive power over the shares held by TRU ST and Provco. Also includes 70,000 shares that Dr. Caruso has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him. Dr. Caruso disclaims beneficial ownership of the shares held by TRU ST, except to the extent of his pecuniary interest therein. Dr. Caruso s address is c/o TRU ST PARTNERSHIP,

L.P, 795 E. Lancaster Avenue, Suite 200, Villanova, PA 19085.

(4) Includes 725,378 shares that Mr. Essig has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him. Excludes outstanding Restricted Units awarded to Mr. Essig in 2000 and 2004, which entitle him to receive an aggregate of 1,250,000 shares of common stock. The Restricted Units held by Mr. Essig vested on the grant dates, but are not yet deliverable and do not give him the right to acquire any shares within 60 days of February 28, 2007. Pursuant to the terms of a forward sale contract entered into with Credit Suisse First Boston Capital LLC on December 14, 2004, Mr. Essig is obligated to deliver to Credit

Suisse First Boston Capital LLC on March 28, 2013 between 264,550 and 500,000 shares of common stock (or, at the election of Mr. Essig, the cash equivalent of such shares). Mr. Essig retains voting power over these shares pending the settlement of the forward sale contract. Mr. Essig s address is c/o Integra LifeSciences Holdings Corporation, 311 Enterprise Drive, Plainsboro, NJ 08536.

(5) Includes 12,500 shares that Mr. Moszkowski has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him.

(6) Includes 7,500 shares that Mr. Schade has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by

him.

(7) Includes 50,000 shares that Mr. Sullivan has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him.

(8) Includes 27,500 shares that Ms. VanLent has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by her.

(9) Includes 309,064 shares that Mr. Henneman has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him.

(10) Includes 44,165 shares that Mr. Carlozzi has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by him.

(11)

Includes 42,185 shares that Ms. O Grady has the right to acquire within 60 days of February 28, 2007 upon the exercise of options held by her.

(12) See Notes 2 through 11 above. Also includes 1,454 shares held by an executive officer of the Company and/or its subsidiaries who is not listed in the above table. This amount does not include shares held by Mr. Holtz, who is no longer an executive officer of the Company.

(13) Capital Research and Management Company (CRMC), an investment adviser registered under Section 203 of the Investment Advisers Act of 1940 is deemed to be the beneficial owner of 2,740,000 shares as a result of acting as investment adviser to various investment companies registered under

Section 8 of the Investment Company Act of 1940. CRMC has sole voting and dispositive power of these shares SMALLCAP World Fund, Inc. (SCWF), an investment company registered under the Investment Company Act of 1940, which is advised by CRMC, is the beneficial owner of 2,240,000 of these shares and has no voting or dispositive power of these share. The foregoing information has been included solely in reliance upon, and without independent

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investigation of, the disclosures contained in the Schedule 13G filed by CRMC and SCWF with the Securities and Exchange Commission on February 12, 2007.

(14) Includes 7,091,025 shares held by TRU ST (see note 15 below), of which Provco is the general corporate partner. Provco may be deemed to have shared voting and dispositive power over these shares.

(15) Pursuant to the terms of a forward sale contract entered into with Credit Suisse First Boston Capital LLC on November 23, 2004, TRU ST is obligated to deliver to Credit Suisse First Boston Capital LLC on January 15, 2013 between 322,581 and 600,000 shares of common stock (or, at the election of TRU

ST, the cash equivalent of such shares). TRU ST retains voting power over these shares pending the settlement of the forward sale contract.

(16) T. Rowe Price Associates, Inc. (T. Rowe Price) has sole dispositive power over all of these shares and has sole voting power over 331,750 of these shares. These securities are owned by various individual and institutional investors which T. Rowe Price Associates, Inc. (Price Associates) serves as investment adviser with power to direct investments and/or sole power to vote the securities. For purposes of the reporting requirements of the Exchange, Price Associates is deemed to be a beneficial owner of such securities; however, Price Associates

expressly disclaims that it is, in fact, the beneficial owner of such securities. The foregoing information has been included solely in reliance upon, and without independent investigation of, the disclosures contained in the Schedule 13G/A filed by T. Rowe Price with the Securities and Exchange Commission on February 14, 2007.

(17) William Blair & Company, L.L.C. (William Blair) has sole dispositive and voting power over all of these shares. The foregoing information has been included solely in reliance upon, and without independent investigation of, the disclosures contained in the Schedule 13G/A filed by William Blair with the Securities and Exchange Commission on January 17, 2007.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires the Company s directors and executive officers, as well as persons beneficially owning more than 10% of the Company s outstanding shares of common stock and certain other holders of such shares (collectively, Covered Persons), to file with the Securities and Exchange Commission, within specified time periods, initial reports of ownership and subsequent reports of changes in ownership of common stock and other equity securities of the Company.

Based solely upon the Company s review of copies of such reports furnished to it and upon representations of Covered Persons that no other reports were required, to the Company s knowledge all of the Section 16(a) filing requirements applicable to Covered Persons were complied with during 2006, except for the following, which resulted from an administrative error:

(a) a statement of changes in beneficial ownership of securities on Form 4 for the grant of restricted stock on July 3, 2006 was filed late by Judith O Grady, an executive officer of the Company; and

(b) a statement of changes in beneficial ownership of securities on Form 4 for the grant of restricted stock on October 2, 2006 was filed late by David Holtz, an executive officer of the Company.

STOCKHOLDER PROPOSALS

The deadline for stockholders to submit proposals pursuant to Rule 14a-8 of the Exchange Act for inclusion in the Company s proxy statement and form of proxy for the 2008 Annual Meeting of Stockholders is December 16, 2007. Such proposals must be sent to: Integra LifeSciences Holdings Corporation, 311 Enterprise Drive, Plainsboro, New Jersey 08536, Attention: Senior Vice President,

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General Counsel and Secretary. The date after which notice of a stockholder proposal submitted outside of the processes of Rule 14a-8 of the Exchange Act is considered untimely is March 2, 2008. If notice of a stockholder proposal submitted outside of the processes of Rule 14a-8 of the Exchange Act is received by the Company after March 2, 2008, then the Company s proxy for the 2008 Annual Meeting of Stockholders may confer discretionary authority to vote on such matter without any discussion of such matter in the proxy statement for such annual meeting of stockholders.

OTHER MATTERS

A copy of the Company s 2006 Annual Report to Stockholders is being mailed simultaneously herewith to stockholders but is not to be regarded as proxy solicitation material. In addition, our Code of Conduct, which applies to all of the Company s directors and officers, and the charters for each of our Audit, Compensation, and Nominating and Corporate Governance Committees are accessible via our website at www.integra-LS.com through the Investor Relations link under the heading Corporate Governance.

The Company, upon request, will furnish to record and beneficial holders of its common stock, free of charge, a copy of its Annual Report on Form 10-K (including financial statements and schedules, but without exhibits) for the fiscal year ended December 31, 2006. Copies of exhibits to the Form 10-K also will be furnished upon request and the payment of a reasonable fee. All requests should be directed to the investor relations department, at the offices of the Company set forth on page one of this Proxy Statement.

By order of the Board of Directors,

/s/ Richard D. Gorelick

Plainsboro, New Jersey
April 16, 2007

Richard D. Gorelick
Senior Vice President, General Counsel and Secretary

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ANNUAL MEETING OF STOCKHOLDERS OF
INTEGRA LIFESCIENCES HOLDINGS CORPORATION
May 17, 2007
Please date, sign and mail
your proxy card in the
envelope provided as soon
as possible.
↓ Please detach along perforated line and mail in the envelope provided ↓

THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE ELECTION OF DIRECTORS AND FOR PROPOSAL 2. PLEASE SIGN, DATE AND RETURN PROMPTLY IN THE ENCLOSED ENVELOPE. PLEASE MARK YOUR VOTE IN BLUE OR BLACK INK AS SHOWN HERE x

1. Election of Directors:

Nominees:	For	Against	Abstain
Thomas J. Baltimore, Jr.	o	o	o
Keith Bradley	o	o	o
Richard E. Caruso	o	o	o
Stuart M. Essig	o	o	o
Neal Moszkowski	o	o	o
Christian S. Schade	o	o	o
James M. Sullivan	o	o	o
Anne M. VanLent	o	o	o

	For	Against	Abstain
2. Proposal to ratify the appointment of PricewaterhouseCoopers LLP as the Company s independent registered public accounting firm for the current fiscal year.	**O**	**O**	**O**

In their discretion, the Proxies are authorized to the extent permitted by the rules of the Securities and Exchange Commission, to vote upon such other business as may properly come before the meeting or any adjournment or postponement thereof.

To change the address on your account, please check the box at right and indicate your new address in the space above. Please note that changes to the registered name(s) on the account may not be submitted via this method. **O**

Signature of Stockholder Date Signature of Stockholder Date

Note: Please sign exactly as your name or names appear on the Proxy. When shares are held jointly, each holder should sign. When signing as executor, administrator, attorney, trustee or guardian, please give full title as such. If the signer is a corporation, please sign full corporate name by duly authorized officer, giving full title as such. If signer is a partnership, sign in partnership name by authorized person.

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PROXY CARD

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

311 ENTERPRISE DRIVE

PLAINSBORO, NEW JERSEY 08536

PROXY Annual Meeting of Stockholders Thursday, May 17, 2007

THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS

The undersigned hereby appoints Stuart M. Essig and John B. Henneman, III as proxies, each with the power to appoint his substitute, and hereby authorizes them to represent and to vote, as designated on the reverse side hereof, all the shares of Common Stock of Integra LifeSciences Holdings Corporation (the Company) held of record by the undersigned on March 30, 2007 at the Annual Meeting of Stockholders to be held on Thursday, May 17, 2007 or at any adjournment or postponement thereof.

THIS PROXY WHEN PROPERLY EXECUTED WILL BE VOTED IN THE MANNER DIRECTED HEREIN BY THE UNDERSIGNED STOCKHOLDER. IF NO DIRECTION IS MADE, THIS PROXY WILL BE VOTED IN FAVOR OF PROPOSAL 2, FOR ALL NOMINEES LISTED FOR ELECTION OF DIRECTORS UNDER PROPOSAL 1; AND IN ACCORDANCE WITH THE PROXIES JUDGMENT UPON OTHER MATTERS PROPERLY COMING BEFORE THE MEETING AND ANY ADJOURNMENT OR POSTPONEMENT THEREOF.

(Continued and to be signed on the reverse side)