

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K

(Mark one)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2002

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number 000-26372

CELLEGY PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

California 82-0429727  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

349 Oyster Point Boulevard, Suite 200, South San Francisco, California 94080  
(Address of Principal Executive Offices) (zip code)

Registrant's telephone number, including area code: (650) 616-2200

Securities registered pursuant to Section 12(b) of the Act:

None Nasdaq National Market  
(Title of each class) (Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, no par value  
(Title of class)

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  NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 under the Securities Exchange Act of 1934).

YES  NO

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 28, 2002, the last business day of the Registrant's most recently completed second fiscal quarter, was \$27,767,037 based on the closing price for the common stock on The Nasdaq Stock Market on such date. This calculation does not include a determination that persons are affiliates or non-affiliates for any other purpose.

As of March 11, 2003, there were 19,889,946 of shares of common stock outstanding.

Documents Incorporated By Reference

The information called for by Part III, other than Item 14, and certain information called for by Part II, Item 5, is incorporated by reference to the definitive Proxy Statement for the Annual Meeting of Shareholders of the Company which will be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2002.

CELLEGY PHARMACEUTICALS, INC. 10-K ANNUAL REPORT

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002

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Unless the context otherwise requires, the terms "we", "our", and "Cellegy" refer to Cellegy Pharmaceuticals, Inc., a California corporation, and

its subsidiaries.

Cellegesic, Tostrex, Tostrelle, and Rectogesic are our trademarks. We also refer to trademarks of other corporations and organizations in this document.

## PART I

### ITEM 1: BUSINESS

Cellegy Pharmaceuticals, Inc. ("Cellegy" or the "Company"), incorporated in California in 1989, is a specialty biopharmaceutical company engaged in the development of prescription drugs and skin care products. Our prescription products are directed towards the treatment of gastrointestinal disorders, sexual dysfunction of both men and women, and selected conditions affecting women's health.

Cellegy's lead product candidate, Tostrex(TM) gel, is for the treatment of male hypogonadism, which usually results in diminished sexual function, lethargy and, in severe cases, reduced bone and muscle mass in men. Cellegy completed a pivotal Phase III clinical trial for Tostrex in November 2001 and filed a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") in June 2002. In December 2002, Cellegy entered into an exclusive license agreement with PDI, Inc. ("PDI") to commercialize Tostrex in North American markets. Under the terms of the agreement, PDI will be responsible for the marketing and sales of Tostrex and will utilize its existing sales and marketing infrastructure. Cellegy received a payment of \$15.0 million on signing of the agreement on December 31, 2002 and will receive a milestone payment of \$10.0 million upon approval of the product for marketing in the United States by the FDA. PDI will also make royalty payments on net sales ranging from 20% to 30%.

In addition to Tostrex, Cellegy is developing a second transdermal testosterone product, Tostrelle(TM) gel, for the treatment of female sexual dysfunction in postmenopausal women. Testosterone deficiency in women frequently leads to diminished libido, decreased bone and muscle mass and reduced energy levels. Tostrelle has successfully completed two Phase I/II clinical studies, and Cellegy is currently conducting an advanced Phase II/III clinical study.

Our Cellegesic(TM) ointment product candidate is being developed for the treatment of chronic anal fissures, a painful condition which, in the absence of an approved drug therapy, often requires surgery. In April 2002, we announced the withdrawal of our Cellegesic New Drug Application ("NDA") after it became clear that the FDA was not going to approve the NDA. We had several subsequent discussions and meetings with the FDA to supply additional information and to attempt to clarify and respond to the FDA's concerns and questions. We now intend to begin a confirmatory Phase III trial after the final protocol discussions with the FDA are completed, which we believe will be in the second quarter of 2003. Cellegy's proposed trial design is for a smaller trial of shorter duration than the prior Phase III trials, with a planned patient enrollment of about 150 subjects. If results are satisfactory, we plan to re-submit the NDA, and we expect that the FDA review of the re-submitted NDA could occur in approximately six months, although there can be no assurances regarding the duration of the FDA review. Cellegy is also conducting a Phase II clinical trial using Cellegesic to determine its effect on the symptoms of hemorrhoids. Hemorrhoids afflict an estimated 22 million people annually in the United States, Europe and Japan, according to published data.

In November 2001, Cellegy acquired Vaxis Therapeutics Corporation ("Vaxis" or "Cellegy Canada"), a private Canadian company based in Kingston, Ontario. This acquisition expanded our pipeline of products for the treatment of sexual dysfunction in males and females and complements our current products. In addition to product candidates for the treatment of sexual dysfunction, the Cellegy Canada product pipeline consists of nitric oxide donors for the treatment of various disorders including: Raynaud's Disease, Restless Leg Syndrome, prostate cancer, breast cancer and other potential indications.

#### Marketing and Commercialization Strategy

Cellegy intends to become a leader in the development and marketing of selected specialty biopharmaceutical products that are directed towards the treatment of gastrointestinal disorders, sexual dysfunction in both men and women, and conditions affecting women's health. Key elements of our business and commercialization strategy include the following:

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- o Self-Marketing to Specialty Physician Markets in United States. Whenever possible, we plan to self market our products to a targeted audience of key physician specialists, including Gastroenterologists and Obstetrician-Gynecologists, through the establishment of our own

sales force. We plan to seek pharmaceutical partners to assist in the promotion of products prescribed by larger physician groups. Cellegy intends to commercialize Cellegesic, if approved, on our own and potentially through co-promotion agreements with partners in the United States. We plan to outlicense the overseas rights for products we develop in exchange for upfront and milestone payments, as well as royalties on sales.

- o Tostrex License Agreement with PDI. Under the terms of the license agreement, PDI will be responsible for the marketing and sales of Tostrex in North American markets and will utilize its existing sales and marketing infrastructure contained within their PDI Pharmaceutical Products Group. Cellegy will be responsible for supplying finished product to PDI through Cellegy's contract manufacturer. Cellegy is seeking marketing partners for Tostrex overseas, particularly in Europe.
- o Marketing and Sales Agreements. We entered into a comprehensive license and commercialization agreement with Ventiv Health, Inc. ("Ventiv"), a contract sales organization, in August 2001. Ventiv was to provide certain sales and marketing services relating to the anticipated launch of Cellegesic. In September 2002, Cellegy and Ventiv terminated the agreement based on the delay in commercialization of Cellegesic due to the withdrawal of the NDA and our subsequent decision to conduct another Phase III clinical trial. We may, in the future, decide to enter into other such marketing agreements with contract sales or other organizations.
- o Acquisition of Complementary Products and Companies. As was done with the acquisitions of Vaxis in Canada in November 2001, of Rectogesic(TM) (nitroglycerin ointment) from Quay Pharmaceuticals Pty Ltd ("Quay") in Australia in June 2000, and of Cellegesic from Neptune Pharmaceuticals ("Neptune") in the United States in December 1997, we intend to acquire other products, technologies or companies with products and distribution capabilities consistent with our commercial objectives.
- o Manufacturing. Cellegy has manufacturing arrangements with PanGeo Pharma Inc., ("PanGeo") an FDA approved contract manufacturing company based in Canada. PanGeo has successfully manufactured Cellegesic, Tostrex and Tostrelle for our clinical trials and will be the commercial manufacturer for these products, when approved.
- o Distribution. Cellegy has entered into a distribution agreement for Rectogesic in South Korea and intends to contract additional distributors in Asia, Latin America and other overseas markets.

#### Marketed Skin Care Products

Cellegy has completed development of certain consumer skin care and cosmeceutical products, including skin barrier repairing/fortifying moisturizers and anti-aging lotions and creams. We are currently marketing our C79 Intensive Moisturizer formulation to a major specialty retailer which incorporates C79 into hand cream products. Our revenues from sales of these products totaled \$1,081,000 in 2002 and have totaled approximately \$4,481,000 since product introduction late in 1998.

#### Products Under Development

Tostrex (testosterone gel for male hormone replacement therapy)

Cellegy's lead product, Tostrex, is a transdermal testosterone gel to treat male hypogonadism, a condition involving clinically deficient levels of the sex hormone testosterone. Low levels of testosterone can result in lethargy, depression and a decline in libido. In severely deficient cases, loss of muscle mass and bone density can occur. Approximately 5 million men in the United States, primarily in the aging (over 40) male population group, have deficient levels of testosterone. Male hypogonadism is the first indication for which we will seek regulatory approval

in the United States. Subsequently, testosterone replacement may be used for "male andropause," a potentially greater market consisting of several million additional men with below normal levels of testosterone.

There are a number of companies currently marketing testosterone in several different product forms in domestic and international markets. Cellegy believes that a market opportunity exists for an improved product, as the side effects and patient inconveniences associated with many of the currently marketed products have limited their use to less than 5% of potential patients, according to published prescription data. Current product forms include orals, injectables, transdermal patches and two testosterone gel products launched in 2000 and 2003, respectively. The leading patch products are sold at prices

averaging approximately \$1,000 per year per patient with the gel products currently priced at approximately \$3,500 per year.

Cellegy's proprietary testosterone gel product candidate is transparent, rapid-drying and non-staining. It is designed as a once-a-day application from a unique metered dose dispenser to relatively small areas of the skin. Based on successful completion of a Phase III trial, including 201 patients at several study centers in the United States, positive trial results were announced in November 2001. Cellegy filed an NDA in the second quarter of 2002 and is awaiting a decision from the FDA on marketing approval in the United States.

Cellegesic (nitroglycerin ointment for treatment of anal fissures and hemorrhoids)

Our Cellegesic is a topical, nitroglycerin-based prescription product for the treatment of anal fissures and hemorrhoids. Anal fissures are painful tears in the lining of the anal mucosa, a condition afflicting men and women of all age groups. Of the over 600,000 new cases of anal fissures occurring each year in the United States, Europe and Japan, many of these chronic cases require painful and expensive surgery, a procedure that sometimes leaves patients incontinent. Hemorrhoids are dilated, swollen veins and tissue located either in the anal canal or at the margin of the anus. In the United States alone, there are approximately 9 million people who suffer from hemorrhoids each year. Both conditions are characterized by an increase in intra-anal pressure, which has been shown to be effectively reduced by the application of Cellegesic. Current drug therapies include anesthetics and anti-inflammatory agents that only partially relieve the symptoms of these conditions.

Cellegesic is a proprietary formulation that includes nitroglycerin, a drug that has been used for many years in the treatment of angina pectoris and certain other heart diseases. Several previous third party studies reported that nitroglycerin, once administered to the anal canal, causes relaxation of the sphincter muscle and helps to relieve pain and promote healing of the anal fissure in most patients.

We completed an initial Phase III clinical trial using Cellegesic for the treatment of anal fissures and announced the results in November 1999. The trial, which included 304 patients, did not demonstrate a statistically significant rate of healing in comparison to placebo, but did show rapid and significant pain reduction. Based on this outcome, we initiated a second Phase III trial in 2000 to confirm the drug's ability to reduce fissure pain, the primary trial endpoint, with healing of chronic anal fissures as a secondary endpoint.

The second Phase III clinical trial, which included 229 patients in several study centers in the United States and overseas, was completed in September 2001. Patients received either of two strengths of Cellegesic or placebo administered twice on a daily basis over an eight-week treatment period. The patient's pain scores were tabulated and the patients were examined to determine whether the fissure had healed. Positive results were achieved in the primary endpoint, which was pain reduction of chronic anal fissures. Statistical significance was not achieved in healing, the secondary endpoint.

In June 2001, we completed patient enrollment and filed an NDA with the FDA requesting marketing approval of Cellegesic for the treatment of pain associated with chronic anal fissures. We amended the NDA upon completion of the second Phase III anal fissure pain study in November 2001. In April 2002, we announced the withdrawal of our Cellegesic NDA after it became clear that the FDA was not going to approve the NDA. We had several subsequent discussions and meetings with the FDA to supply additional information and to attempt to clarify and respond to the FDA's concerns and questions. In September 2002, we announced that we believed most of the agency's previously stated concerns had been satisfactorily addressed with the exception that the FDA believed that

some aspects of the statistical analysis methodology used by Cellegy were not pre-specified in the statistical analysis plan submitted prior to unblinding the trial. Cellegy believes that it had adequately demonstrated that the statistical analysis methodology was properly set forth in the original analysis plan and was correctly utilized. However, the FDA concluded that the method was not pre-specified to its satisfaction and indicated that it would require another Phase III trial before considering approval of the product. We intend to begin the confirmatory Phase III trial after the final protocol discussions with the FDA are completed, which we believe will be in the second quarter of 2003. Based on our current protocol design, we expect that the trial will be smaller and of shorter duration than the prior Phase III trials, with a planned patient enrollment of about 150 subjects. If results are satisfactory, we plan to re-submit the NDA, and we expect that the FDA review of the re-submitted NDA could occur in approximately six months, although there can be no assurances regarding the duration of the FDA's review. In addition to this fissure trial, Cellegy is also conducting a Phase II clinical trial using Cellegesic to

determine its effect on the various symptoms of hemorrhoids.

Cellegesic is protected by two domestic patents, both of which have been issued, the most recent in December 1997. Similar Canadian and European patents have been issued and numerous patent applications have been filed in most major overseas markets. Rectogesic(TM) (nitroglycerin ointment), a product similar in formulation to Cellegesic, was approved by the Australian Therapeutic Goods Administration and has been successfully marketed in Australia since early 1999.

Tostrelle (testosterone gel for female hormone replacement therapy)

Normal blood concentrations of testosterone in women range from 10 to 20 times less than those of men. Nevertheless, in both sexes, testosterone plays a key role in building muscle tissue or bone and in maintaining sexual drive. In women, the ovaries and adrenal glands continue to synthesize testosterone after menopause, although the rate of production may diminish by as much as 50%. Approximately 15 million women in the United States suffer from symptoms of testosterone deficiency. At the present time, there are no approved products for the treatment of this condition.

Based on the results of pharmacokinetic studies in men receiving Tostrex, Cellegy's scientists were able to estimate the proper dosage of testosterone required to achieve normal pre-menopausal hormone levels in postmenopausal women. The result is Cellegy's Tostrelle, a product designed to restore normal testosterone levels in hormone deficient women.

Cellegy has successfully completed two Phase I/II pharmacokinetic studies in which we determined the proper dose necessary to restore normal testosterone levels to normally menopausal and surgically-induced menopausal women. Based on these results and a trial protocol meeting with the FDA, we initiated a Phase II/III clinical study in 2002 and intend to begin additional advanced trials in 2003.

#### Current Research Programs

Cellegy's research and development programs focus on nitric oxide pharmacology, inflammation and nitric oxide treatments for anorectal and gastrointestinal diseases, sexual dysfunction, peripheral vascular disorders and cancer. The November 2001 acquisition of Vaxis, now Cellegy Canada, significantly broadened our research and development efforts for the treatment of female sexual dysfunction and male erectile dysfunction, and has also expanded our research into potential oncology treatments. Cellegy has rights to future discoveries, technologies and products developed by Cellegy Canada. Most of the current research programs are being conducted at Queen's University in Kingston, Ontario or in our leased laboratories located at the University.

The Vaxis acquisition also expanded our overall expertise efforts in nitric oxide pharmacology. Based on research efforts at Cellegy Canada and at Queen's University by our consultants, we better understand the role of nitric oxide as a signaling molecule in modulating vascular smooth muscle relaxation, perhaps by down-regulating endothelin expression. The significance of this finding is that nitric oxide is capable of reducing vascular tone at a concentration much lower than needed for a direct vaso-dilatation effect, especially in tissues under an abnormally vaso-spasm or vaso-constrictive state. This discovery presents various potential approaches to treat conditions

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caused by vaso-constriction, such as peripheral vascular insufficiency found in Raynaud's disease, male erectile dysfunction, and selected aspects of female sexual dysfunction. We plan to verify and validate selected potential therapeutic indications via in vivo animal testing and in pilot human studies.

We are also investigating the role of nitric oxide in modulating cancer cell metastasis induced by hypoxia (low oxygen) and in attenuating pain due to nociceptor activation. Results published in the Journal of National Cancer Institute in December 2001 showed that the administration of nitric oxide to hypoxic cancer cells led to reversal of metastatic cells. Furthermore, nitric oxide can also reverse the development of certain hypoxia-induced drug resistant cancer cells to chemotherapeutic agents. Follow-up experiments since the publication further support the original findings. We will continue to expand upon these original findings with relevant in vitro and in vivo models through our research efforts at Cellegy Canada and Queen's University and to further explore the ability of nitric oxide to interfere with other nociceptive signaling pathway.

Cellegy continues to explore the role of nitric oxide in modulating cancer cell development, as well as, resistance to chemotherapeutic agents such as doxorubicin and 5-fluorouracil, and metastasis induced by hypoxia (low oxygen). In addition to the results published in the Journal of National Cancer Institute, recent progress shows that nitric oxide induces reversal of chemo-resistance in human breast cancer cells and prostate cancer cells, and in

3-dimensional human breast cancer spheroid culture. While the mechanism of action of reversal of chemo-resistance is largely unknown, the prevention of tumor cell metastasis in vitro by nitric oxide appears to be mediated via the cGMP protein kinase G pathway. These results continue to support our original scientific hypothesis and have taken us to the next step of verifying the nitric oxide effect in human xenograph models in vivo. Cellegy consultants and collaborators at Queens University have recently been awarded a research grant from the United States Army for its innovation in prostate cancer research.

Early observations by Cellegy Canada scientists showed that the co-administration of nitric oxide releasing agents blocks nociceptive pain response triggered by PGE1 injection. This concept is further supported by the July 2002 publication of a pilot study in Journal of Gender Specific Medicine reporting the efficacy of treating vulvar pain and pain with sexual activity in women with vulvodynia using 0.2% topical nitroglycerin ointment. Cellegy plans to conduct a placebo-controlled dose ranging study using topical nitroglycerin in treating vulvar pain associated with vulvodynia and dyspareunia in 2003.

#### Patents and Trade Secrets

Cellegy has 22 issued United States patents, more than 60 issued foreign patents, and over 80 pending patent applications worldwide. Two issued United States patents and 15 pending patent applications relate to our testosterone gel products for males and females. Two issued United States patents, over 20 issued foreign patents, and more than 10 pending patent applications relate to Cellegy's Cellegesic product for the treatment of anal fissure and other anal diseases. Two issued United States patents and over 25 pending patent applications relate to possible backup compounds for our Cellegesic product. As part of Cellegy's acquisition of Cellegy Canada, Cellegy gained rights to 5 issued United States patents, 3 issued foreign patents, and more than 40 pending patent applications. These patents and applications disclose methods of treatment of peripheral vascular conditions including male erectile dysfunction, female sexual dysfunction, and Raynaud's disease, as well as other conditions. United States and foreign patent applications disclosing novel store-operated calcium influx (SOC) inhibitors and their use in the treatment of various disorders are pending or have recently published. Additional patent applications are being prepared for filing that will cover methods or products currently under development. Corresponding patent applications for most of Cellegy's issued United States patents have been filed in countries of importance to us located in major world markets, including certain countries in Europe, Australia, South Korea, Japan, Mexico and Canada.

Our policy is to protect our technology by, among other things, filing patent applications for technology that we consider important to the development of our business. We intend to file additional patent applications, when appropriate, relating to our technology, improvements to our technology and to specific products that we develop. It is impossible to anticipate the breadth or degree of protection that any such patents will afford, or whether we can meaningfully protect our rights to our unpatented trade secrets. Cellegy also relies upon unpatented trade secrets and know-how, and no assurance can be given that competitors will not independently develop substantially equivalent

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proprietary information and techniques, or otherwise gain access to our trade secrets or disclose such technology. It is our policy to require our employees to execute an invention assignment and confidentiality agreement upon employment. Our consultants are required to execute a confidentiality agreement upon the commencement of their consultancy. Each agreement provides that all confidential information developed or made known to the employee or consultant during the course of employment or consultancy will be kept confidential and not disclosed to third parties except in specific circumstances. The invention assignment generally provides that all inventions conceived by the employee shall be the exclusive property of Cellegy. In addition, it is our policy to require collaborators and potential collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection of our trade secrets. For additional risks and uncertainties relating to our patents and intellectual property, see the discussion of our patents and intellectual property under the heading, "Management's Discussion and Analysis of Financial Condition and Results of Operation - Factors That May Affect Future Operating Results."

#### Product Acquisitions

On November 27, 2001, Cellegy acquired Vaxis Therapeutics Corporation, a private Canadian company for \$4.1 million primarily in Cellegy stock. Vaxis, subsequently renamed Cellegy Canada, is a wholly-owned research and development subsidiary with prominent scientists focusing in the areas of sexual dysfunction, peripheral vascular disorders, cancer and nitric oxide pharmacology. This research is in line with our goal of expanding our pipeline of products and protecting our patents.

In June 2000, Cellegy acquired Quay Pharmaceuticals, an Australian

company marketing Rectogesic, a nitroglycerin ointment product similar to Cellegesic. The acquisition cost totaled \$1,835,000, consisting primarily of Cellegy stock and warrants. Cellegy continues to self-market Rectogesic in Australia through its wholly-owned Cellegy Australia subsidiary and plans to sell Rectogesic through distributors in the Pacific Rim countries and potentially other countries around the world.

In December 1997, Cellegy acquired patent and related intellectual property rights relating to Cellegesic from Neptune Pharmaceuticals. Pursuant to the purchase agreement, we issued 462,809 shares of common stock to Neptune in 1997 with a value of \$3,750,000. The agreement calls for a series of additional payments, payable in shares of common stock, upon successful completion of various milestones tied to clinical trial results and commercialization of Cellegesic in domestic and foreign markets. During 2001, we issued 104,000 shares of common stock with a value of \$750,000 for two clinical and regulatory milestones achieved. Future potential milestones, payable in Cellegy common stock, could result in the issuance of up to an additional 1,285,000 shares of Cellegy common stock based on the closing price of Cellegy stock at the time of issuance. The agreement does not provide for the payment by Cellegy of any future product royalties to Neptune in connection with Cellegesic revenues.

#### Government Regulation

FDA Requirements for Human Drugs. The research, development, testing, manufacturing, storage, labeling, record keeping, distribution, advertising, promotion and marketing of drug products are extensively regulated by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous FDA regulation pursuant to, among other laws, the Food, Drug and Cosmetic Act or FD&C Act.

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include: (i) preclinical tests, (ii) the submission to the FDA of an Investigational New Drug Application, or IND, which must be approved before human clinical trials commence; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its proposed indication; (iv) the submission of a New Drug Application, or NDA, for a new drug or a Product License Application for a new biologic to the FDA; and (v) FDA review and approval of the NDA or Product License Application before any commercial sale or shipment of the product. Preclinical tests include laboratory evaluation of product formulation and animal studies (if an appropriate animal model is available) to assess the potential safety and efficacy of the product. Formulations must be

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manufactured according to the FDA's current Good Manufacturing Practice, or GMP, requirements, and preclinical safety tests must be conducted by laboratories that comply with FDA's Good Laboratory Practice regulations.

The results of preclinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA before commencement of human clinical trials. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. In some instances, the IND application process can result in substantial delay and expense. Clinical trials to support NDAs are typically conducted in three sequential phases, which may overlap and which usually require several years to complete. A clinical trial may combine the elements of more than one phase, and often two or more Phase III studies are required.

After successful completion of the required clinical testing, generally an NDA is submitted. FDA approval of the NDA (as described below) is required before marketing may begin in the United States. The FDA reviews all NDAs submitted and may request more information before it accepts the filing. The review process is often extended significantly by FDA requests for additional information or clarification. The FDA may refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. During the review process, the FDA generally will conduct an inspection of the relevant drug manufacturing facilities and clinical sites to ensure that the facilities are in compliance with applicable Good Manufacturing Practices requirements. If FDA evaluations of the NDA application, manufacturing facilities, and clinical sites are favorable, the FDA may issue either an approvable letter or a not approvable letter, which contains a number of conditions that must be met in order to secure approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approvable letter, authorizing commercial marketing of the drug for certain specific indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter, outlining the deficiencies in the submission and often requiring additional testing or information. Notwithstanding the submission of any requested additional data or information in response to an approvable or not approvable letter, the FDA ultimately may decide that the



application does not satisfy the regulatory criteria for approval. Even if FDA approval is obtained, a marketed drug product and its manufacturer are subject to continual review and inspection, and later discovery of previously unknown problems with the product or manufacturer may result in restrictions or sanctions on such product or manufacturer, including withdrawal of the product from the market.

The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and the expenditure of substantial resources. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all. Delays in obtaining regulatory approvals could have a material adverse effect on us. If we fail to comply with applicable regulatory requirements for marketing drugs, or if our cosmeceutical products are deemed to be drugs by the FDA, we could be subject to administrative or judicially imposed sanctions such as warning letters, fines, product recalls or seizures, injunctions against production, distribution, sales, or marketing, delays in obtaining marketing authorizations or the refusal of the government to grant such approvals, suspensions and withdrawals of previously granted approvals, civil penalties and criminal prosecution of Cellegy, our officers or our employees.

Manufacturing. Each domestic drug manufacturing facility must be registered with the FDA. Domestic drug manufacturing establishments are subject to routine inspection by the FDA and other regulatory authorities and must comply with GMP requirements and any applicable state or local regulatory requirements. We intend to use contract manufacturers that operate in conformance with these requirements to produce our compounds and finished products in commercial quantities. We cannot assure you that manufacturing or quality control problems will not arise at the manufacturing plants of our contract manufacturers or that such manufacturers will have the financial capabilities or management expertise to be able to adequately supply product or maintain compliance with the regulatory requirements necessary to continue manufacturing our products.

Foreign Regulation of Drugs. Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities may be necessary in foreign countries before the commencement of marketing of the product in such countries. The approval procedures vary among countries, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of

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which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. We expect to rely principally on corporate partners, licensees and contract research organizations, along with our expertise, to obtain governmental approval in foreign countries of drug formulations utilizing our compounds.

Other Government Regulation. In addition to regulations enforced by the FDA, Cellegy is also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other similar federal and state laws regarding, among other things, occupational safety, the use and handling of radioisotopes, environmental protection and hazardous substance control. Although we believe that we have complied with these laws and regulations in all material respects and have not been required to take any action to correct any noncompliance, there can be no assurance that Cellegy will not be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, Cellegy could be held liable for any damages that result and any such liability could exceed our resources.

Health Care Reform. In the United States, there have been, and Cellegy expects there will continue to be, a number of federal and state proposals to implement cost controls and other health care regulatory measures. Future legislation could result in a substantial restructuring of the health care delivery system. While we cannot predict whether any legislative or regulatory proposals will be adopted or the effect such proposals may have on our business, the uncertainty of such proposals could have a negative effect on our ability to raise capital and to identify and reach agreements with potential partners, and the adoption of such proposals could have an adverse effect on Cellegy. In both domestic and foreign markets, sales of our therapeutic products, if any, will depend in part on the availability of reimbursement from third-party payors. There can be no assurance that our products will be considered cost effective or

that reimbursement will be available. We cannot predict the outcome of any government or industry reform initiatives or the impact thereof on our financial position or results of operations.

#### Competition

The pharmaceutical industry is characterized by extensive research efforts and rapid and significant technological changes. In the development and marketing of topical prescription drugs, Cellegy faces intense competition. Cellegy is much smaller in terms of size and resources than many of its competitors in the United States and abroad, which include, among others, major pharmaceutical, chemical, consumer product, and biotechnology companies, specialized firms, universities and other research institutions. Cellegy's competitors may succeed in developing technologies and products that are safer, more effective or less costly than any which are being developed by us that would render our technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience than we have. In addition, Cellegy's products are subject to competition from existing products. For example, Cellegy's Tostrex product, if commercialized, is expected to compete with a currently marketed transdermal patch product sold by Watson Pharmaceuticals and two transdermal testosterone gel products marketed by Unimed/Solvay and Auxilium Pharmaceuticals. Cellegy's Cellegesic product, if commercialized, is expected to compete with over-the-counter products, such as Preparation H marketed by American Home Products, and various other prescription products. As a result, we cannot assure you that Cellegy's products under development will be able to compete successfully with existing products or innovative products under development by other organizations.

Therapies for sexual dysfunction and women's health products represent a large market opportunity, especially as the overall population continues to age. As the size of the market continues to grow, competition will expand. The approval and marketing of competitive products and other products that treat the indications targeted by Cellegy could adversely affect the market acceptance of Cellegy's products. The presence of directly competitive products could also result in more intense price competition than might otherwise exist, which could have a material adverse effect on Cellegy. Cellegy is aware of other companies that are developing testosterone replacement products for

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women and two testosterone replacement products for men. We believe that competition will be intense for all of its female and male sexual dysfunction product candidates.

#### Employees

As of March 11, 2003, we had twenty full-time and three part-time employees. Thirteen of these employees, of whom 2 are M.D.'s and another 5 are Ph.D.'s, are engaged in clinical research and development. In addition, we utilize the services of several professional consultants, as well as contract manufacturing and research organizations to supplement our internal staff's activities. None of our employees are represented by a labor union. We have experienced no work stoppages and we believe that our employee relations are good.

#### ITEM 2: PROPERTIES

Cellegy currently leases 65,340 square feet of space located in South San Francisco, California with an estimated 2003 rental cost of \$106,000 per month or \$1,270,000 for 2003. Approximately 48,613 square feet of this space is currently subleased to one tenant with an estimated 2003 rental income of approximately \$91,000 per month or \$1,100,000 for 2003. We believe our current facilities will be adequate for our needs for expansion for the foreseeable future.

#### ITEM 3: LEGAL PROCEEDINGS

Cellegy is not a party to any material legal proceedings.

#### ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our shareholders during the fourth quarter of the year ended December 31, 2002.

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#### ITEM 4A: EXECUTIVE OFFICERS OF THE REGISTRANT

MANAGEMENT

The executive officers of Cellegy are as follows:

Name	Age	Position
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K. Michael Forrest	59	Chairman, President, Chief Executive Officer and Director
Daniel L. Azarnoff, M.D.	76	Senior Vice President, Medical and Regulatory Affairs
John J. Chandler	61	Vice President, Corporate Development
A. Richard Juelis	54	Vice President, Finance and Chief Financial Officer
David A. Karlin, M.D.	60	Vice President, Clinical Research

K. Michael Forrest. Mr. Forrest became Chairman in May 2000 and has been President, CEO, and a director since December 1996. From January 1996 to November 1996, he served as a biotechnology consultant. From November 1994 to December 1995, he served as President and CEO of Mercator Genetics, a public biotechnology company. From March 1991 to June 1994, he served as President and CEO of Transkaryotic Therapies, Inc., a public biotechnology company. From 1968 to 1991, Mr. Forrest held a series of positions with Pfizer, Inc. and senior management positions with American Cyanamid, including Vice President of Lederle U.S. and Lederle International. He is a director of INEX Pharmaceuticals, a public company developing anti-cancer products.

Daniel L. Azarnoff, M.D. Dr. Azarnoff joined Cellegy as Vice President, Clinical and Regulatory Affairs in October 1997. He became Senior Vice President in July 1999, and in February of 2001 was given the additional responsibility of Medical Director. Since January 1986, Dr. Azarnoff has been President of D.L. Azarnoff Associates and continues consulting to the industry on a part-time basis. From August 1978 to December 1985, he served as President of Research and Development at G.D. Searle and Co. From July 1967 to August 1978, he was KUMC Distinguished Professor of Medicine and Pharmacology, as well as the Director of the Clinical Pharmacology-Toxicology Center at the University of Kansas Medical Center. Dr. Azarnoff has also served as a member of advisory and expert committees within the Food and Drug Administration, World Health Organization, American Medical Association, National Academy of Sciences and National Institutes of Health. Dr. Azarnoff is a member of The Institute of Medicine of the National Academy of Sciences. He received his M.D. from the University of Kansas Medical School. Dr. Azarnoff is currently director of Western Center Clinical Trials.

John J. Chandler. Mr. Chandler became Vice President, Corporate Development in May 1998. From January 1995 to March 1998, he served as Vice President, Europe for the Medical Device Division of American Home Products. During 1994, he was Area Director, Europe/Latin America for American Home Products. From 1968 to 1993, he held a series of management and senior management positions with American Cyanamid Company. Mr. Chandler holds an M.B.A. in Marketing from Seton Hall University and a B.S. in Biology from the Queens College of the City University of New York.

A. Richard Juelis. Mr. Juelis became Vice President, Finance and Chief Financial Officer in November 1994. From January 1993 to September 1994 he served as Vice President, Finance and Chief Financial Officer for VIVUS, Inc., a publicly traded drug delivery company. From October 1990 to December 1992, he served as Vice President, Finance and Chief Financial Officer at XOMA Corporation, a public biotechnology company. Mr. Juelis has also held domestic and international financial and general management positions for seven years each with Hoffmann-LaRoche and Schering-Plough. He holds a B.S. in Chemistry from Fordham University and an M.B.A. from Columbia University.

David A. Karlin, M.D. Dr. Karlin joined Cellegy as Vice President, Clinical Research in October 2002. From February 2002 to July 2002, he served as Vice President, Clinical Development for Genteric, Inc., a privately held company specializing in gene therapy. From August 1999 to October 2001, Dr. Karlin was Senior Medical Director at Matrix Pharmaceuticals, a cancer and drug delivery company. He was Vice President, Clinical Research at

SciClone Pharmaceuticals from 1995 to 1999. Prior to SciClone, Dr. Karlin held various positions at Syntex Corporation over a nine-year period. Before joining the pharmaceutical industry, Dr. Karlin was an Associate Professor at Temple University School of Medicine and an Assistant Professor at University of Texas M.D. Anderson Hospital and Tumor Institute. He was an instructor at the University of Chicago, where he received his medical degree, and had Gastroenterology and Gastrointestinal Oncology training at that University.

## PART II

## ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

## Price Range of Common Stock

Cellegy's common stock currently trades on The Nasdaq Stock Market under the symbol "CLGY." The following table sets forth the range of high and low sales prices for the common stock as reported on The Nasdaq Stock Market for the periods indicated below.

2002 ----	High ----	Low ---
First Quarter.....	\$ 8.80	\$ 5.15
Second Quarter.....	6.90	2.02
Third Quarter.....	2.44	1.66
Fourth Quarter.....	4.35	1.50
2001 ----		
First Quarter.....	\$ 7.37	\$ 4.31
Second Quarter.....	7.75	4.20
Third Quarter.....	7.08	5.01
Fourth Quarter.....	9.15	6.36

## Holders

As of March 11, 2003, there were approximately 200 shareholders of record excluding beneficial holders of stock held in street name.

## Dividend Policy

We have never paid cash or declared dividends on our common stock. We do not anticipate that we will declare or pay cash dividends on our common stock in the foreseeable future.

Information with respect to equity compensation plans that is required by this Item will be included in our proxy statement for the 2003 annual meeting of shareholders under the heading "Equity Compensation Plans", and is hereby incorporated by reference.

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## ITEM 6: SELECTED FINANCIAL DATA

The following selected historical information has been derived from audited financial statements of Cellegy. The financial information as of December 31, 2002 and 2001 and for each of the three earlier years in the period ended December 31 are derived from audited financial statements. The financial statements, related notes thereto, and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K should be read carefully. The selected data is not intended to replace the financial statements.

(\$000's)	Years ended December 31,				
	2002	2001	2000	1999	1998
Statement of Operations Data:					
Revenues .....	\$ 1,402	\$ 877	\$ 1,586	\$ 1,045	\$ 832
Costs and expenses (1) .....	17,859	21,847	13,573	10,847	9,266
Loss from operations .....	(16,457)	(20,970)	(11,987)	(9,802)	(8,434)
Interest income and other net and interest expense .....	521	1,505	569	501	1,068
Net loss .....	\$ (15,936)	\$ (19,465)	\$ (11,418)	\$ (9,301)	\$ (7,366)
Basic and diluted net loss per common shareholder .....	\$ (0.90)	\$ (1.26)	\$ (0.91)	\$ (0.85)	\$ (0.73)
Weighted average common shares outstanding .....	17,643	15,503	12,542	10,914	10,160

(1) For the year ended December 31, 2002, Cellegy recorded non-cash compensation expense totaling \$1,017,000, with approximately \$961,000 occurring in the fourth quarter. The largest portion of these non-cash charges was approximately \$695,000 relating to the modification of certain previously granted stock options. The modification reduced the number of shares subject to the options and was implemented in connection with the restoration of salaries and fees for certain employees and board members whose compensation had been reduced earlier in 2002. Even though the modification reduced the number of outstanding options,

under generally accepted accounting principles, the modification resulted in a variable option accounting charge with respect to the vested portion of the modified options. The amount of the charge reflected in the financial statements is based on the number of options vested multiplied by the difference between the closing price of our common stock and the original exercise price of the options at year end. During the year ended December 31, 2001, we recorded non-cash charges of \$3,507,134 for in-process research and development associated with the Vaxis acquisition and \$750,000 in non-cash charges for research and development expenses associated with milestone payments to Neptune Pharmaceuticals.

	December 31,				
	2002	2001	2000	1999	1998
Balance Sheet Data:					
Cash, cash equivalents and investments (2) .....	\$ 23,858	\$ 17,190	\$ 15,923	\$ 16,737	\$ 15,220
Total assets .....	28,379	22,367	21,259	20,913	19,484
Deficit accumulated during the					
development stage .....	(86,312)	(70,377)	(50,912)	(39,494)	(30,192)
Total shareholders' equity .....	\$ 10,534	19,845	\$ 18,794	\$ 15,839	\$ 14,218

(2) Includes restricted cash of \$227,500 in 2002 and \$614,000 in 2001.

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#### ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Annual Report includes forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are not historical facts, but rather are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. Words such as "believes," "anticipates," "expects," "intends" and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. Our "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains many such forward-looking statements. These forward-looking statements are not guarantees of future performance and concern matters that involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements. These risks and uncertainties include those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Operating Results" and elsewhere in this Annual Report. Except as required by law, we undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that may arise after the date of this Annual Report. Actual events or results may differ materially from those discussed in this Annual Report.

Cellegy Pharmaceuticals, Inc., a specialty biopharmaceutical company incorporated in California in 1989, is engaged in the development of prescription drugs and skin care products. We are developing several prescription drugs, including two transdermal testosterone gel products, Tostrex, for the treatment of male hypogonadism, a condition that afflicts certain men, generally above the age of forty, and Tostrelle, for the treatment of sexual dysfunction in menopausal women. Cellegesic is our nitroglycerin-based product for the treatment of anal fissures and hemorrhoids.

#### General

In November 2001, we acquired a private Canadian based company, Vaxis Therapeutics, valued at \$4.1 million. The purchase was payable primarily in shares of Cellegy stock. The purchase price was allocated to net tangible assets of \$250,000, intangible assets of \$350,000 and \$3,507,000 million of in-process research and development. The intangibles of \$350,000 are being amortized over five years and the in-process research and development has been expensed in the fourth quarter of 2001. The acquired technology was in an early stage of development such that, as of the acquisition date, technological feasibility had not been reached and no alternative use existed. The assumptions used in determining the purchase price allocation were based on an appropriate discount rate applied to expected cash flows. The purchase agreement provides for future earn-out payments over a period of seven years that are based on commercial sales of any products developed by Cellegy based on technologies acquired from Vaxis. Any contingent consideration paid in the future will be accounted for as a cost of earning the related revenues. The results of operations of the acquired company have been included in our consolidated financial statements since the acquisition date.

In September 2002, Cellegy and Ventiv Health, Inc. terminated the Cellegesic License Agreement based on the delay in commercialization of

Cellegesic due to the withdrawal of the NDA and the subsequent decision to conduct another Phase III trial. Cellegy and Ventiv originally signed a six year agreement to commercialize Cellegesic, in the United States in August 2001. Ventiv was to have delivered integrated marketing and sales solutions providing pre-launch support, recruiting and training a sales force which would have been jointly managed by both companies.

In November 2002, we completed a private placement of 2.2 million shares of our common stock resulting in approximately \$5.5 million of gross proceeds to Cellegy. The financing was with a single investor, John M. Gregory, founder and former CEO of King Pharmaceuticals and currently managing partner of SJ Strategic Investments LLC.

In December 2002, Cellegy entered into an exclusive license agreement with PDI, Inc. to commercialize Tostrex in North American markets. Under the terms of the agreement, PDI's Pharmaceutical Products Group will be responsible for the marketing and sale of Tostrex and will utilize its existing sales and marketing infrastructure and skills contained within the PDI Pharmaceutical Products Group. Cellegy received a payment of \$15.0 million on signing of the agreement on December 31, 2002 and will receive a milestone payment of \$10.0 million upon

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approval of the product by the FDA in the United States. PDI will also make royalty payments on net sales ranging from 20% to 30%. Cellegy will be responsible for supplying finished product to PDI through Cellegy's contract manufacturer.

#### Critical Accounting Policies

**Use of Estimates.** The preparation of consolidated financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. We have identified below some of our more significant accounting policies. For further discussion of our accounting policies, see Note 1 in the Notes to Consolidated Financial Statements.

**Revenue Recognition.** Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects are incurred. Revenues related to milestones specified under development contracts are recognized as the milestones are achieved. Cellegy has received certain government grants that support our research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenues associated with these grants are recognized as costs under each grant are incurred. Revenues related to product sales are recognized upon shipment when title to the goods has been transferred to the customer. There is no right of return for our Rectogesic and skin care product sales.

Up-front payments, such as the \$15.0 million payment received from PDI for the Tostrex license, are recorded as deferred revenue at the time the cash is received. Amounts are recognized as revenue on a straight-line basis over the longer of the life of the contract or the service period. Royalties payable to Cellegy under the PDI License Agreement will be recognized as earned when the royalties are no longer refundable to PDI under certain minimum royalty terms defined in the agreement.

**Long-Lived and Intangible Assets and Goodwill.** Goodwill of \$814,000 and other intangible assets of \$382,000 are included in our December 31, 2002 balance sheet. Management reviews goodwill for impairment either on an annual basis or quarterly if an event occurs that might reduce the fair value of the long-lived asset below its carrying value. All other long-lived and intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount of the asset may not be recoverable. An impairment loss would be recognized based on the difference between the carrying value of the asset and its estimated fair value, which would be determined based on either discounted future cash flows or other appropriate fair value methods. The evaluation of goodwill and other intangibles for impairment requires management to use significant judgments and estimates including, but not limited to, projected future revenue, operating results, and cash flows.

Although management currently believes that the estimates used in the evaluation of goodwill and other intangibles are reasonable, differences between actual and expected revenue, operating results, and cash flow could cause these assets to be deemed impaired. If an impairment were to occur, Cellegy would be required to charge to earnings the write-down in value of such assets, which could have a material adverse effect on our results of operations and financial position.

**Clinical Trial Expenses.** Clinical trial expenses are payable to clinical sites and clinical research organizations. Expenses for both of these

groups are accrued on a straight-line basis over the contracted period subject to adjustment for actual activity based on such factors as the number of subjects enrolled and number of subjects that have completed treatment for each trial. A monthly reconciliation of costs accrued to cost incurred is performed by Cellegy's clinical project managers and the finance department. However, if activity levels associated with trials at a given point in time are underestimated, we would have to record additional research and development expenses in future periods that could be significant.

**Investment Policy.** Cellegy is subject to certain credit risk from our investment in marketable securities. By policy, we restrict amounts invested by investment type and by issuer, except for securities issued by the United States government. Cellegy has an investment policy that is approved and periodically reviewed by our Audit Committee. The policy states that investments must be highly liquid with maturities of less than three years.

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Cellegy's policy limits investments to the following: direct obligations of the United States Government or fully guaranteed by a government agency or by any of the states. Investments must have a rating of A1/P1 or A by Standard and Poors (or an equivalent rating); money market instruments must be a member of the Federal Reserve System with a net worth of at least \$100 million and a rating of A1/AA by Standard and Poors (or equivalent rating). Any exception to the above requires approval of the Chief Financial Officer and the Chief Executive Officer.

#### Results of Operations

Years Ended December 31, 2002, 2001 and 2000

**Revenues.** Cellegy had revenues of \$1,402,000, \$877,000, and \$1,586,000 in 2002, 2001 and 2000, respectively. Revenues in 2002 consisted of \$1,081,000, relating to product sales primarily to Gryphon Development ("Gryphon"), the product development arm of a major specialty retailer, \$275,000 in Rectogesic ointment sales in Australia and \$46,000 in Canadian government grants. Revenues in 2001 consisted of \$660,000 in product sales to Gryphon and \$217,000 in Rectogesic sales in Australia. Revenues in 2000 consisted of \$1,389,000 in product sales to Gryphon, \$125,000 in Rectogesic sales and \$72,000 in SBIR grant funding. The increase of \$525,000 in total revenues in 2002 compared with 2001 was primarily due to a \$421,000 or 64% increase in Gryphon sales relating to additional unit sales, a \$58,000 or 27% increase in Rectogesic sales and a \$46,000 increase in Canadian grants. The decrease of \$709,000 in total revenue in 2001 compared with 2000 was primarily due to a \$729,000 or 52% decrease in Gryphon sales, a \$72,000 grant funding completed in 2000, offset by a \$92,000 or 74% increase in Rectogesic sales.

**Research and Development Expenses.** Research and development expenses were \$10,672,000 in 2002 compared with \$14,098,000 in 2001 and \$9,574,000 in 2000. Total research and development expenses represented 61%, 65%, and 36% of our total operating expenses in 2002, 2001 and 2000, respectively. Total research and development expenses in 2002 compared with 2001 decreased by \$3,426,000 or by 24%. The decrease was due to completion of the Cellegesic Phase III clinical trial and the completion of smaller Tostrex trials in 2001 and non-cash charges of \$750,000 relating to milestone payments made to Neptune Pharmaceuticals in 2001. The increase of \$1,098,000 or 11% in 2002 compared with 2000 was primarily due to spending associated with the Tostrex Phase III NDA filing costs and non-cash compensation charges relating to stock options. Research and development expenses include salaries and benefits, laboratory supplies, external research programs, clinical studies and allocated overhead costs such as rent, supplies and utilities. In addition to clinical site payments, clinical costs include the manufacturing of clinical supplies and related costs associated with product testing stability studies.

We expect our research and development expenses in 2003 to be approximately equal to 2002 levels. Major expenses are planned for our Phase II/III Tostrelle clinical study, the pending Cellegesic Phase III trial, and for support of ongoing research in Cellegy Canada. Unexpected increases in research and development expenses may occur if the FDA requires further trials to support our NDA for Tostrex.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses were \$6,816,000 in 2002 compared with \$4,042,000 in 2001 and \$3,631,000 in 2000. The increases in 2002 compared with both 2001 and 2000 consisted primarily of sales and marketing expenses totaling \$2,094,000 primarily related to Cellegesic pre-launch activities in the first half of 2002. In addition, we incurred non-cash compensation expenses and investment banking fees, slightly offset by decreases in general office expenses. Our selling, general and administrative expenses are expected to increase in the second half of 2003 in support of our business development programs and product commercialization efforts.

Acquired-In-Process Research and Development. Acquired-in-process

research and development expenses of \$3,507,000 were incurred during 2001 as a result of the Vaxis acquisition. There were no acquired-in-process research and development expenses incurred during 2002 and 2000. The acquired technology was at an early state of development such that, at the acquisition date, technological feasibility had not been reached and no alternative use existed.

Interest Income and Other Net and Interest Expense. Cellegy recognized \$548,000 in interest income and other net, for 2002, compared with \$1,532,000 in 2001, and \$770,000 for 2000. Reductions in interest income were tied primarily to lower average investment balances, interest rates and rental income during 2002. Interest expenses were approximately \$27,000 in both, 2002 and 2001 and \$201,000 in 2000. Interest expenses for 2002 and 2001 were related to the Ventiv loan and a separate commercial bank loan, respectively. Interest expense decreased by \$174,000 in 2001 compared with 2000 due to the full repayment of commercial bank loan in 2001. Other income includes net rental income from our sub-lessees of \$119,000 in 2002, \$897,000 in 2001, and \$80,000 in 2000. One of Cellegy's earlier sub-lease agreements expired in December 2001 and was replaced by a new sublease agreement which became effective in August 2002.

Net Loss. The net loss in 2002 was \$15,936,000 or \$0.90 per share based on 17,643,000 weighted average shares outstanding compared with the net loss in 2001 of \$19,465,000 or \$1.26 per share based on 15,503,000 weighted average shares outstanding. In 2000, our net loss was \$11,418,000 or \$0.91 per share based on 12,542,000 weighted average shares outstanding.

Liquidity and Capital Resources

We have experienced net losses from operations each year since our inception. Through December 31, 2002, we had incurred an accumulated deficit of \$86.3 million and had consumed cash from operations of \$53.1 million. Cash from equity financing transactions have included \$6.4 million in net proceeds from our initial public offering in August 1995, \$6.8 million in net proceeds from a preferred stock financing in April 1996, \$3.8 million in net proceeds from a private placement of common stock in July 1997, \$13.8 million in net proceeds from a follow-on public offering in November 1997, \$10.0 million in net proceeds from a private placement in July 1999, \$11.6 million in net proceeds from a private placement in October 2000, \$15.2 million in net proceeds from a private placement in June 2001 and \$5.2 million in net proceeds from a private placement in November 2002.

Our cash and investments were \$23.9 million at December 31, 2002 compared with \$17.2 million at December 31, 2001, including \$227,000 and \$614,000 of restricted cash, respectively. The increase in cash and investments of \$6.6 million in 2002 was principally due to the net proceeds from the \$5.2 million financing completed in November and \$15.0 million in upfront payments from the licensing agreement with PDI in December, partially offset by other net cash used in operating activities of approximately \$13.4 million. During the fourth quarter of 2002, we had an operating burn rate of approximately \$800,000 per month; we expect the burn rate for the first quarter of 2003 to be at approximately the same level as the prior quarter. However, our operations have used and will continue to use increased amounts of cash in future quarters. Future expenditures and capital requirements depend on numerous factors including, without limitation, the progress and focus of our research and development programs, the progress and results of pre-clinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, our ability to establish new collaborative arrangement and the initiation of commercialization activities and the purchase of capital equipment and working capital increases associated with the scale up and manufacture of Tostrex.

We have a ten-year operating lease commitment on our facility with our current landlord. Our operating lease commitments are \$1,288,000 for 2003 and \$7,036,000 thereafter in annual amounts of approximately \$1.3 to \$1.5 million. Information about this commitment as of December 31, 2002 is presented in the table below (in thousands):

Contractual Obligations	Total	2003	2004 - 2005	2006 - 2007	Thereafter
Operating lease	\$8,324	\$1,288	\$2,691	\$2,854	\$1,491

In order to complete the research and development and other activities necessary to commercialize our products, additional financing will be required. As a result, we will seek private or public equity investments and future collaborative arrangements or other transactions with third parties to meet such needs. There is no assurance that financing will be available for us to fund our



operations on acceptable terms, if at all. Insufficient funding may

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require us to delay, reduce or eliminate some or all of our research and development activities, planned clinical trials, marketing, sales, product promotion and administrative programs. We believe that available cash resources and the interest thereon will be adequate to satisfy our capital needs through at least December 31, 2004.

#### Recent Accounting Pronouncements

In December 2002, the Financial Accounting Standards Board issued Statement No. 148 ("FAS 148"), "Accounting for Stock-Based Compensation - Transition and Disclosure." FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options.

#### Factors That May Affect Future Operating Results

This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in this Annual Report. Factors that might cause such a difference include, but are not limited to, those discussed below.

We are subject to regulation by regulatory authorities including the FDA, which could delay or prevent marketing of our products. Unexpected regulatory outcomes could adversely affect our business and stock price.

Cellegy's prescription product candidates, and our ongoing research and clinical activities such as those relating to our product candidates Cellegesic, Tostrex and Tostrelle, are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. Before we obtain regulatory approval for the commercial sale of our potential drug products, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. The timing of NDA submissions, the outcome of reviews by the FDA and the initiation and completion of other clinical trials are subject to uncertainty, change and unforeseen delays. Under the Prescription Drug User Fee Act, the FDA establishes a target date to complete its review of an NDA. Although the FDA attempts to respond by the relevant PADUFA date to companies which file NDAs, there is no assurance or obligation on the FDA's part to do so. For example, because Cellegy has not received feedback from the FDA on certain parts of our Tostrex NDA submission, the FDA could extend the approvability decision for this NDA beyond the current PADUFA date of April 6, 2003. In addition, extensive current pre-clinical and clinical testing requirements and the current regulatory approval process of the FDA in the United States and of certain foreign regulatory authorities, or new government regulations, could prevent or delay regulatory approval of Cellegy's products.

The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and the expenditure of substantial resources. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all. Delays in obtaining regulatory approvals could have a material adverse effect on us. If we fail to comply with applicable regulatory requirements, we could be subject to a wide variety of serious administrative or judicially imposed sanctions and penalties, any of which would materially and adversely affect our business, results of operations and stock price.

Disagreements may occur in the future, and one or more of our ongoing or planned clinical trials could be delayed or be required to be repeated in order to satisfy regulatory requirements. The FDA could impose requirements on future trials that could delay or prevent the regulatory approval process for Tostrex, Cellegesic or Tostrelle. For example, in June 2002, Cellegy announced that it had submitted an NDA for Tostrex including data from a Phase III clinical study using Tostrex to treat male hypogonadism. There can be no assurance that the FDA will find the trial data, the statistical analysis methodology used by Cellegy, or other sections of the NDA sufficient to approve Tostrex for marketing in the United States. The FDA could require further trials, decide to have an

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Advisory Panel review the submission, with an uncertain outcome of such panel's recommendation, or take other actions having the effect of delaying or preventing commercial introduction of Tostrex. If the FDA delays its response beyond the current PADUFA date for our Tostrex NDA, our business plans and the market price of our common stock would be adversely affected.

Sales of Cellegy's products outside the United States are subject to different regulatory requirements governing clinical trials and marketing approval. These requirements vary widely from country to country and could delay introduction of Cellegy's products in those countries.

Our clinical trial results are very difficult to predict in advance, and the clinical trial process is subject to delays. Failure of one or more clinical trials or delays in trial completion could adversely affect our business and our stock price.

Results of pre-clinical studies and early clinical trials may not be good predictors of results that will be obtained in later-stage clinical trials. We cannot assure you that Cellegy's present or future clinical trials, including, for example, the current Phase II/III study for Tostrelle, will demonstrate the results required to continue advanced trial development and allow us to seek marketing approval for this or our other product candidates. Because of the independent and blind nature of certain human clinical testing, there will be extended periods during the testing process when we will have only limited, or no, access to information about the status or results of the tests. Other pharmaceutical companies have believed that their products performed satisfactorily in early tests, only to find their performance in later tests, including Phase III clinical trials, to be inadequate or unsatisfactory, or that FDA Advisory Committees have declined to recommend approval of the drugs, or that the FDA itself refused approval, with the result that such companies' stock prices have fallen precipitously.

Delays in the clinical trial process can be extremely costly in terms of lost sales opportunities and increased clinical trial costs. The speed with which we complete our clinical trials and our regulatory submissions, including NDAs, will depend on several factors, including the following:

- o the rate of patient enrollment, which is affected by the size of the patient population, the proximity of patients to clinical sites, the difficulty of the entry criteria for the study and the nature of the protocol;
- o the timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- o analysis of data obtained from preclinical and clinical activities which could delay, limit or prevent regulatory approval;
- o changes in policies or staff personnel at regulatory agencies during the lengthy drug application review; and
- o the availability of experienced staff to conduct and monitor clinical studies, internally or through contract research organizations.

We have a history of losses, and we expect losses to continue for at least several years.

Our accumulated deficit as of December 31, 2002 was approximately \$86.3 million. We have never operated profitably and, given our planned level of operating expenses, we expect to continue to incur losses for at least the next two years. We plan to increase our operating expenses as we continue to devote significant resources to pre-clinical studies, clinical trials, administrative, marketing, sales and patent activities. Accordingly, without substantial revenues from new corporate collaborations, royalties on product sales or other revenue sources, we expect to incur substantial operating losses in the foreseeable future as our potential products move into commercialization, and we continue to invest in research and clinical trials. Our losses may increase in the future, and even if we achieve our revenue targets, we may not be able to sustain or increase profitability on a quarterly or annual basis. The amount of future net losses, and the time required to reach profitability, are both highly uncertain. To achieve sustained

profitable operations, we must, among other things, successfully discover, develop, obtain regulatory approvals for and market pharmaceutical products. We cannot assure you that we will ever be able to achieve or sustain profitability.

Our prospects for obtaining additional financing, if required, are uncertain and failure to obtain needed financing could affect our ability to develop or market products.

Throughout our history, we have consumed substantial amounts of cash. Our cash needs are expected to continue to increase over, at least, the next two years in order to fund the additional expenses required to expand our current research and development programs and to commercialize our products once regulatory approvals have been obtained. Cellegy has no current source of significant ongoing revenues or capital beyond existing cash and investments, certain product sales of Rectogesic in Australia, sales to Gryphon, the development subsidiary of a major specialty retailer, and possible payments under our license agreement with PDI relating to Tostrex. In order to complete the research and development and other activities necessary to commercialize our products, additional financing will be required.

Cellegy will seek private or public equity investments and future collaborative arrangements with third parties to help fund future cash needs. Such funding may not be available on acceptable terms, if at all. Including proceeds from a private placement financing during 2002 and upfront payments received from the Tostrex license agreement in the fourth quarter of 2002, Cellegy believes that available cash resources and interest earned will be adequate to satisfy its capital needs through at least December 31, 2004.

The type and scope of patent coverage we have may limit the commercial success of our products.

Cellegy's success depends, in part, on our ability to obtain patent protection for our products and methods, both in the United States and in other countries. Several of Cellegy's products and product candidates, such as Cellegesic, Tostrex and Tostrelle, are based on existing molecules with a history of use in humans but which are being developed by us for new therapeutic uses or in novel delivery systems which enhance therapeutic utility. We cannot obtain composition patent claims on the compounds themselves, and will instead need to rely on patent claims, if any, directed to use of the compound to treat certain conditions or to specific formulations. This is the case, for example, with our United States patents relating to Cellegesic and Tostrex. Such method-of-use patents may provide less protection than a composition-of-matter patent, because of the possibility of "off-label" use of the composition. Cellegy may not be able to prevent a competitor from using a different formulation or compound for a different purpose. No assurance can be given that any additional patents will be issued to us, that the protection of any patents that may be issued in the future will be significant, or that current or future patents will be held valid if subsequently challenged.

The patent position of companies engaged in businesses such as Cellegy's business generally is uncertain and involves complex legal and factual questions. There is a substantial backlog of patent applications at the United States Patent and Trademark Office ("USPTO"). Patents in the United States are issued to the party that is first to invent the claimed invention. There can be no assurance that any patent applications relating to Cellegy's products or methods will issue as patents, or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us a competitive advantage. For example, we earlier reported that two oppositions had been filed with the European Patent Office regarding our European patent protecting the manufacture and use of nitroglycerin ointment and related compounds for the treatment of anal disorders, including fissures and various hemorrhoidal conditions. An adverse outcome in either opposition proceeding could have a negative effect on Cellegy, impacting the success of our marketing efforts in Europe.

In addition, many other organizations are engaged in research and product development efforts in drug delivery and topical formulations that may overlap with Cellegy's products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by Cellegy. These rights may prevent us from commercializing technology, or may require Cellegy to obtain a license from the organizations to use the technology. Cellegy may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the

patents underlying any such licenses will be valid or enforceable. Moreover, the laws of certain foreign countries do not protect intellectual property rights relating to United States patents as extensively as those rights are protected in the United States. The issuance of a patent in one country does not assure the issuance of a patent with similar claims in another country, and claim interpretation and infringement laws vary among countries, so the extent of any patent protection is uncertain and may vary in different countries. As with other companies in the pharmaceutical industry, we are subject to the risk that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our patent rights if such activities were in the United States.

Our product sales strategy involving corporate partners is highly uncertain.

Cellegy is seeking to enter into agreements with corporate partners regarding commercialization of our lead product candidates. Other than the recently completed Tostrex license agreement with PDI, Cellegy does not currently have any other agreements with third parties to commercialize our product candidates. Cellegy may not be able to establish any such collaborative arrangements and we may not have the resources or the experience to successfully commercialize any such products on our own. Failure to enter into any such arrangements could prevent, delay or otherwise have a material adverse effect on our ability to develop and market Tostrex in markets outside of North America or other products that we desire to commercialize through third party arrangements.

With the current and future planned corporate partner arrangements, we may rely on our partners to conduct clinical trials, obtain regulatory approvals and, if approved, manufacture, distribute, market or co-promote these products. However, reliance on third party partners can create risks to our product commercialization efforts. Once agreements are completed, particularly if they are completed at a relatively early stage of product development, Cellegy may have little or no control over the development or marketing of these potential products and little or no opportunity to review clinical data before or after public announcement of results. Further, any arrangements that may be established may not be successful.

In its annual report on Form 10-K for the year ended December 31, 2002, PDI disclosed that on January 6, 2003, it was named as a defendant in a state court action by Auxilium Pharmaceuticals, Inc.; that Auxilium was seeking monetary damages and injunctive relief, based on several claims related to PDI's alleged breaches of its contract sales force agreement with Auxilium and claims that PDI misappropriated and is misappropriating Auxilium's trade secrets in connection with PDI's exclusive license agreement with us; that a hearing in Auxilium's preliminary injunction motion was conducted on February 11 through 13, 2003 and the court did not reach a decision; that final arguments in the hearing were scheduled for March 2003; that PDI intended to continue contesting the case vigorously; and that PDI believed the likelihood of any order enjoining PDI from marketing and selling under its agreement with us for any significant time was unlikely, as was the likelihood of any material damage award against PDI. An adverse outcome in that litigation might adversely affect PDI's ability to perform its obligations under our agreement with PDI and could have an adverse effect on our ability to timely and successfully introduce and commercialize our Tostrex product.

We do not have any history of manufacturing products, and we have a limited number of critical suppliers.

Cellegy has no direct experience in manufacturing commercial quantities of products and currently does not have any capacity to manufacture products on a large commercial scale. We currently rely on a limited number of contract manufacturers, primarily PanGeo Pharma, and suppliers to manufacture our formulations. Although we believe that there will be adequate third party manufacturers, there can be no assurance that we will be able to enter into acceptable agreements with them. In the future, we may not be able to obtain contract manufacturing on commercially acceptable terms for compounds or product formulations in the quantities we need. Manufacturing or quality control problems, lack of financial resources or qualified personnel could occur with our contract manufacturers causing product shipment delays, inadequate supply, or causing the contractor not to be able to maintain compliance with the FDA's current good manufacturing practice requirements necessary to continue manufacturing.. Such problems could reduce product sales, result in substantial Cellegy liabilities under our Tostrex license agreement or otherwise adversely affect Cellegy's business and stock price.

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We face intense competition from larger companies, and in the future Cellegy may not have the resources required to develop innovative products. Cellegy's products are subject to competition from existing products.

The pharmaceutical industry is subject to rapid and significant technological change. In the development and marketing of prescription drugs, Cellegy faces intense competition. Cellegy is much smaller in terms of size and resources than many of its competitors in the United States and abroad, which include, among others, major pharmaceutical, chemical, consumer product, specialty pharmaceutical and biotechnology companies, universities and other research institutions. Cellegy's competitors may succeed in developing technologies and products that are more effective than any that we are developing and could render Cellegy's technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience. In addition, Cellegy's products are subject to competition from existing products. For example, Cellegy's Tostrex product, if commercialized in the United States, is expected to compete with two currently marketed testosterone gel products sold by Unimed/Solvay and Auxillian Pharmaceuticals, and a transdermal patch product sold by Watson Pharmaceuticals. Cellegy's Cellegesic product, if commercialized, is expected to compete with

over-the-counter products, such as Preparation H marketed by American Home Products, and various other prescription products. As a result, we cannot assure you that Cellegy's products under development will be able to compete successfully with existing products or innovative products under development by other organizations.

We currently have no drug products we sell on our own and have limited sales and marketing experience.

We may market certain of our products, if successfully developed and approved, through a direct sales force in the United States and through sales and marketing partnership or distribution arrangements outside the United States. Cellegy has very limited experience in sales, marketing or distribution. To market certain of our products directly, we may establish a direct sales force in the United States or obtain the assistance of our marketing partner. If we enter into marketing or licensing arrangements with established pharmaceutical companies, our revenues will be subject to the terms and conditions of such arrangements and will be dependent on the efforts of our partner. Cellegy may not be able to successfully establish a direct sales force, or our collaborators may not effectively market any of our products, and either circumstance could have a material adverse effect on our business and stock price.

We have very limited staffing and will continue to be dependent upon key employees

Our success is dependent upon the efforts of a small management team, including K. Michael Forrest, our chief executive officer. We have employment agreements with certain officers, but none of our officers is bound to remain employed for any specific term. We had a reduction in force of nine people in August 2002 and an additional five people in December 2002. If key individuals leave Cellegy, we could be adversely affected if suitable replacement personnel are not quickly recruited. Our future success depends upon our ability to continue to attract and retain qualified scientific, clinical, marketing and administrative personnel. There is competition for qualified personnel in all functional areas, and particularly intense competition in the San Francisco Bay Area where our principal facility is located, which make it difficult to attract and retain the qualified personnel necessary for the development and growth of our business.

We are subject to the risk of product liability lawsuits.

The testing, marketing and sale of human health care products entails an inherent risk of allegations of product liability. We are subject to the risk that substantial product liability claims could be asserted against us in the future. Cellegy has obtained \$5 million in insurance coverage relating to our clinical trials. There can be no assurance that Cellegy will be able to obtain or maintain insurance on acceptable terms, particularly in overseas locations, for clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities.

Our stock price could be volatile.

Our stock price has from time to time experienced significant price and volume fluctuations, particularly during 2002 and the first quarter of 2003. Sometimes our stock price has varied depending on fluctuations in the NASDAQ Stock Market generally, and sometimes fluctuations have resulted from matters more specific to Cellegy, such as an

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announcement of clinical trial or regulatory results or other corporate developments. Announcements that could significantly impact our stock price include:

- o publicity or announcements regarding regulatory developments relating to our products under review, particularly relating to Tostrex or Cellegesic;
- o clinical trial results, such as results of the Tostrelle trial;
- o period-to-period fluctuations in our financial results, including our cash and investment balance, operating expenses, cash burn rate or revenues; or
- o negative announcements or financial constraints by our key suppliers, service providers or our corporate partners, particularly PDI.

#### ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Cellegy invests its excess cash in short-term, investment grade, fixed income securities under an investment policy. All of our investments are

classified as available-for-sale (see Financial Statements - Note 2). All of our securities owned as of December 31, 2002 will mature in 2003, with the remainder in money market funds. We believe that potential near-term losses in future earnings, fair values or cash flows related to our investment portfolio are not significant.

At December 31, 2002, our investment portfolio consisted of \$2,000,000 in corporate notes. We currently do not hedge interest rate exposure. If market interest rates were to increase by 100 basis points or 1% from December 2002 levels, the fair value of our portfolio would decline by no more than \$20,000. The modeling technique used measures the change in fair value from a hypothetical shift in market interest rates.

#### ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by Item 8 are set forth below on pages F-1 through F-21 of this report.

#### ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES.

None.

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### PART III

#### ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information required by this Item with respect to directors and compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the sections captioned "Election of Cellegy Directors" and "Compliance under Section 16(a) of the Securities Exchange Act of 1934" appearing in the definitive Proxy Statement (the "2003 Proxy Statement") to be delivered to shareholders in connection with the Annual Meeting of Shareholders expected to be held on June 4, 2003. Such information is incorporated herein by reference. Information required by this Item with respect to executive officers may be found in Part I hereof in the section captioned "Executive Officers of the Registrant."

#### ITEM 11: EXECUTIVE COMPENSATION

Information with respect to this Item may be found in the section captioned "Executive Compensation" appearing in the 2003 Proxy Statement and is incorporated herein by reference.

#### ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Information with respect to this Item may be found in the section captioned "Security Ownership of Certain Beneficial Owners and Management" appearing in the 2003 Proxy Statement and is incorporated herein by reference.

#### ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information with respect to this Item may be found in the section captioned "Certain Relationships and Related Transactions" appearing in the 2003 Proxy Statement and is incorporated herein by reference.

#### ITEM 14: CONTROLS AND PROCEDURES

##### (a) Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-14 (c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), within 90 days of the filing date of this annual report. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures are effective.

##### (b) Changes in Internal Controls

There have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referenced in paragraph (a) above.

## PART IV

## ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

## Exhibits

- (a) The following exhibits are attached hereto or incorporated herein by reference:

Exhibit Number -----	Exhibit Title -----
2.1	Asset Purchase Agreement dated December 31, 1997 between the Company and Neptune Pharmaceutical Corporation. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-3 file no. 333-46087 on February 11, 1998, as amended.)
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Registration No. 33-93288 LA) declared effective on August 11, 1995 (the "SB-2").)
3.2	Certificate of Amendment of Amended and Restated Articles of Incorporation filed with the California Secretary of State on August 6, 2002.
3.3	Bylaws of the Company. (Incorporated by reference to Exhibit 3.3 to the SB-2.)
4.1	Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.1 to the SB-2.)
*10.1	1992 Stock Option Plan. (Incorporated by reference to Exhibit 10.12 to the SB-2.)
*10.2	1995 Equity Incentive Plan (Incorporated by reference to Exhibit 4.03 to the Company's Registration Statement on Form S-8 (Registration No. 333-91588 on June 28, 2002.)
*10.3	1995 Directors' Stock Option Plan (Incorporated by reference to Exhibit 10.8 to the Company's Form 10-Q for fiscal quarter ended June 30, 2002.)
10.4	Loan and Security Agreement between Silicon Valley Bank and the Company dated June 10, 1998 (Incorporated by reference to Exhibit 10.01 to the Company's Form 10-QSB for the fiscal quarter ended June 30, 1998.)
10.5	Lease Agreement between the Company and TCNorthern California Inc. dated April 8, 1998 (Incorporated by reference to Exhibit 10.01 to the Company's Form 10-QSB for fiscal quarter ended March 31, 1998.)
*10.6	Employment Agreement dated November 20, 1996, between the Company and K. Michael Forrest. (Incorporated by reference to Exhibit 10.19 to the Company's Form 10-KSB for fiscal year ended December 31, 1996 (the "1996 Form 10-KSB").)
10.7	Services Agreement dated as of August 10, 2001 by and among the Company, Ventiv Health Inc. and VIS Financial LLC. (Incorporated by reference to Exhibit 10.12 to the Company's Form 10-K for fiscal year ended December 31, 2001. Confidential treatment has been requested with respect to portions of this agreement.)
10.8	Funding Arrangement dated August 10, 2001 by and among the Company, Ventiv Health Inc. and VIS Financial LLC. ((Incorporated by reference to Exhibit 10.13 to the Company's Form 10-K for fiscal year ended December 31, 2001. Confidential treatment has been requested with respect to portions of this agreement.)
10.9	Share Purchase Agreement dated as of November 27, 2001, by and among the Company, Vaxis

(Incorporated by reference to Exhibit 10.14 to the Company's Form 10-K for fiscal year ended December 31, 2001.)

- 10.10 Exclusive License Agreement dated as of December 31, 2002, by and between the Company and PDI, Inc. (Confidential treatment has been requested with respect to portions of this agreement.)
- 21.1 Subsidiaries of the Registrant
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.
- 24.1 Power of Attorney (See signature page.)

\* Represents a management contract or compensatory plan or arrangement.

(b) Reports on Form 8-K

A report on Form 8-K was filed by Cellegy on January 2, 2003 announcing our exclusive agreement with PDI, Inc. to commercialize Tostrex in North American markets. On January 13, 2003, we filed a Form 8-K announcing that Mr. Julian Baker and his brother, Dr. Felix Baker resigned from the Company's Board of Directors. On February 27, 2003, we filed a Report on Form 8-K to report our fourth quarter and year-end financial results.

(c) Financial Statement Schedules

All schedules are omitted because they are not applicable or the information required to be set forth therein is included in the financial statements or notes thereto.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California, on the 21st of March, 2003.

CELLEGY PHARMACEUTICALS, INC.

By: /s/ K. Michael Forrest

-----  
K. Michael Forrest  
Chairman, President and Chief  
Executive Officer

Power of Attorney

Each person whose signature appears below constitutes and appoints each of K. Michael Forrest and A. Richard Juelis, true and lawful attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and conforming all that said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated.

Name ----	Title -----	Date ----
Principal Executive Officer: /s/ K. Michael Forrest ----- K. Michael Forrest	Chairman, President, and Chief Executive Officer	March 21, 2003
Principal Financial Officer and Principal Accounting Officer:  /s/ A. Richard Juelis ----- A. Richard Juelis	Vice President, Finance, Chief Financial Officer and Secretary	March 21, 2003
Directors:  /s/ Jack L. Bowman	Director	March 21, 2003



----- Jack L. Bowman -----		
/s/ Tobi B. Klar -----	Director	March 21, 2003
Tobi B. Klar, M.D. -----		
/s/ Ronald J. Saldarini -----	Director	March 21, 2003
Ronald J. Saldarini, Ph.D. -----		
/s/ Alan A. Steigrod -----	Director	March 21, 2003
Alan A. Steigrod -----		
/s/ Larry J. Wells -----	Director	March 21, 2003
Larry J. Wells -----		

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CERTIFICATION PURSUANT TO  
SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002

I, K. MICHAEL FORREST, certify that:

1. I have reviewed this annual report on Form 10-K of Cellegy Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

- a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
- b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
- c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 21, 2003

By: /s/ K. Michael Forrest  
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K. Michael Forrest  
President, Chief Executive Officer

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CERTIFICATION PURSUANT TO  
SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002

I, A. RICHARD JUELIS, certify that:

1. I have reviewed this annual report on Form 10-K of Cellegy Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

Date: March 21, 2003

By: /s/ A. Richard Juelis

-----  
A. Richard Juelis  
Chief Financial Officer

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Report of Ernst & Young LLP, Independent Auditors

The Board of Directors and Shareholders  
Cellegy Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Cellegy Pharmaceuticals, Inc. (a development stage company) as of December 31, 2002 and

2001, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2002, and for the period from June 26, 1989 (inception) through December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cellegy Pharmaceuticals, Inc. (a development stage company) at December 31, 2002 and 2001 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, and for the period from June 26, 1989 (inception) through December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Palo Alto, California  
February 13, 2003

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Balance Sheets

	December 31,	
	2002	2001
	-----	-----
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents .....	\$ 21,628,517	\$ 5,795,378
Short-term investments .....	2,002,123	4,053,280
Prepaid expenses and other current assets .....	608,313	837,344
	-----	-----
Total current assets .....	24,238,953	10,686,002
Property and equipment, net .....	2,616,193	2,467,907
Long-term investments .....	--	6,727,240
Restricted cash .....	227,500	613,999
Intangible assets, net .....	1,196,622	1,522,266
Other assets .....	100,000	350,000
	-----	-----
Total assets .....	\$ 28,379,268	\$ 22,367,414
	=====	=====
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities .....	\$ 2,005,279	\$ 1,893,253
Accrued compensation and related expenses .....	122,925	144,614
	-----	-----
Total current liabilities .....	2,128,204	2,037,867
Long term liabilities .....	716,619	484,826
Deferred Revenue .....	15,000,000	--
<b>Commitments:</b>		
<b>Shareholders' equity</b>		
Preferred stock, no par value; 5,000,000 shares authorized: Series A convertible preferred stock 1,100 shares designated; no shares issued or outstanding at December 31, 2002 and 2001 .....	--	--
Common stock, no par value; 35,000,000 shares authorized: 19,652,356 shares issued and outstanding at December 31, 2002 and 17,295,274 shares issued and outstanding at December 31, 2001 .....	96,835,062	90,137,811
Accumulated other comprehensive income (loss) .....	11,831	83,458
Deficit accumulated during the development stage .....	(86,312,448)	(70,376,548)
	-----	-----
Total shareholders' equity .....	10,534,445	19,844,721
	-----	-----
Total liabilities and shareholders' equity .....	\$ 28,379,268	\$ 22,367,414
	=====	=====

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statements of Operations

	Years ended December 31,			Period from
	2002	2001	2000	June 26, 1989 through December 31, 2002
Revenues:				
Licensing and contract revenue from affiliate	\$ --	\$ --	\$ --	\$ 1,145,373
Licensing, milestone, and development funding	--	--	--	1,551,408
Government grants	45,798	566	71,793	548,133
Product sales	1,355,828	876,925	1,513,830	5,102,412
Total revenues	1,401,626	877,491	1,585,623	8,347,326
Costs and expenses:				
Cost of products sold	369,992	200,338	368,113	1,320,874
Research and development	10,672,146	14,097,746	9,574,293	61,886,316
Selling, general and administrative	6,816,213	4,041,642	3,630,616	27,376,962
Acquired in-process research and development	--	3,507,134	--	7,350,102
Total costs and expenses	17,858,351	21,846,860	13,573,022	97,934,254
Operating loss	(16,456,725)	(20,969,369)	(11,987,399)	(89,586,928)
Other income (expense):				
Interest expense	(27,136)	(27,283)	(200,689)	(1,503,729)
Interest income and other, net	547,961	1,531,929	769,875	6,226,714
Net loss	(15,935,900)	(19,464,723)	(11,418,213)	(84,863,943)
Non-cash preferred dividends	--	--	--	1,448,505
Net loss applicable to common shareholders	\$(15,935,900)	\$(19,464,723)	\$(11,418,213)	\$(86,312,448)
Basic and diluted net loss per common share	\$ (0.90)	\$ (1.26)	\$ (0.91)	
Weighted average common shares used in computing basic and diluted net loss per common share	17,642,640	15,502,918	12,542,232	

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statement of Shareholders' Equity

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of convertible preferred stock, net of issuance cost through December 31, 1999	27,649	\$ 6,801,730	--	\$ --	477,081	\$ 4,978,505
Issuance of Series A convertible preferred stock and warrants to purchase 14,191 shares of Series A convertible preferred stock in exchange for convertible promissory notes and accrued interest through December 31, 1999	625,845	1,199,536	--	--	--	--
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 1999	50,110	173,198	--	--	--	--
Issuance of Series B convertible preferred stock in exchange for convertible promissory notes	--	--	12,750	114,000	--	--
Non-cash preferred dividends	--	1,448,505	--	--	--	--
Conversion of preferred stock, including dividends, to common stock through December 31, 1999	(703,604)	(9,622,969)	(12,750)	(114,000)	(477,081)	(4,978,505)
Issuance of warrants in connection with notes payable in financing	--	--	--	--	--	--
Issuance of common stock in connection with private placement of common stock in July 1997, net of issuance cost	--	--	--	--	--	--
Issuance of common stock in connection with the public offering of common stock in November 1997, net of issuance cost	--	--	--	--	--	--
Issuance of common stock in connection with the acquisition of Neptune Pharmaceutical	--	--	--	--	--	--

See accompanying notes

	Common Stock		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount			
Issuance of convertible preferred stock, net of issuance cost through December 31, 1999 .....	--	\$ --	\$--	\$ --	\$11,780,235
Issuance of Series A convertible preferred stock and warrants to purchase 14,191 shares of Series A convertible preferred stock in exchange for convertible promissory notes and accrued interest through December 31, 1999 ..	--	--	--	--	1,199,536
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 1999 .....	--	--	--	--	173,198
Issuance of Series B convertible preferred stock in exchange for convertible promissory notes .....	--	--	--	--	114,000
Non-cash preferred dividends .....	--	--	--	(1,448,505)	--
Conversion of preferred stock, including dividends, to common stock through December 31, 1999 .....	3,014,644	14,715,474	--	--	--
Issuance of warrants in connection with notes payable in financing .....	--	487,333	--	--	487,333
Issuance of common stock in connection with private placement of common stock in July 1997, net of issuance cost .....	1,547,827	3,814,741	--	--	3,814,741
Issuance of common stock in connection with the public offering of common stock in November 1997, net of issuance cost .	2,012,500	13,764,069	--	--	13,764,069
Issuance of common stock in connection with the acquisition of Neptune Pharmaceutical .....	462,809	3,842,968	--	--	3,842,968

See accompanying notes

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statement of Shareholders' Equity (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common stock in connection with IPO in August 1995 .....	--	--	--	--	--	--	1,322,500	6,383,785
Issuance of common stock for cash through December 31, 1999 .....	--	--	--	--	--	--	953,400	126,499
Issuance of common stock for services rendered through December 31, 1999 .....	--	--	--	--	--	--	269,116	24,261
Issuance of common stock in connection with the private placement of common stock in July 1999, net of issuance cost	--	--	--	--	--	--	1,616,000	10,037,662
Repurchase of common shares in 1992 .....	--	--	--	--	--	--	(3,586)	(324)
Issuance of common stock in exchange for notes payable .....	--	--	--	--	--	--	42,960	268,500
Exercise of warrants to purchase common stock .....	--	--	--	--	--	--	496,253	602,679
Exercise of options to purchase common stock .....	--	--	--	--	--	--	275,820	961,775
Compensation expense related to the extension of option exercise periods ...	--	--	--	--	--	--	--	338,481
Unrealized loss in investments .....	--	--	--	--	--	--	--	--
Net loss for the period June 26, 1989 (inception) to December 31, 1999 .....	--	--	--	--	--	--	--	--
Balances at December 31, 1999 .....	--	--	--	--	--	--	12,010,242	55,367,903

Issuance of common stock in connection with the private placement of common stock in October 2000, net of issuance cost of \$22,527 .....	--	--	--	--	--	1,500,000	11,602,473
Exercise of warrants to purchase common stock .....	--	--	--	--	--	62,833	315,800
Exercise of options to purchase common stock .....	--	--	--	--	--	95,754	380,516

See accompanying notes.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statement of Shareholders' Equity (Continued)

	Accumulated Other Comprehensive Income (Loss) -----	Deficit Accumulated During the Development Stage -----	Total Shareholders' Equity -----
Issuance of common stock in connection with IPO in August 1995 .....	--	--	6,383,785
Issuance of common stock for cash through December 31, 1999 .....	--	--	126,499
Issuance of common stock for services rendered through December 31, 1999 .....	--	--	24,261
Issuance of common stock in connection with the private placement of common stock in July 1999, net of issuance cost	--	--	10,037,662
Repurchase of common shares in 1992 .....	--	--	(324)
Issuance of common stock in exchange for notes payable .....	--	--	268,500
Exercise of warrants to purchase common stock .....	--	--	602,679
Exercise of options to purchase common stock .....	--	--	961,775
Compensation expense related to the extension of option exercise periods ...	--	--	338,481
Unrealized loss in investments .....	(35,471)	--	(35,471)
Net loss for the period June 26, 1989 (inception) to December 31, 1999 .....	--	(38,045,107)	(38,045,107)
Balances at December 31, 1999 .....	(35,471)	(39,493,612)	(15,838,820)
Issuance of common stock in connection with the private placement of common stock in October 2000, net of issuance cost of \$22,527 .....	--	--	11,602,473
Exercise of warrants to purchase common stock .....	--	--	315,800
Exercise of options to purchase common stock .....	--	--	380,516

See accompanying notes.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statement of Shareholders' Equity (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
	-----	-----	-----	-----	-----	-----
Fair value of warrants issued in Quay acquisition .....	--	--	--	--	--	--
Common stock issued in connection with Quay acquisition .....	--	--	--	--	--	--
Compensation expense related to warrants and options granted to non-employees .....	--	--	--	--	--	--
Unrealized gain on investments .....	--	--	--	--	--	--
Foreign currency translation .....	--	--	--	--	--	--
Net loss .....	--	--	--	--	--	--
Total Comprehensive Loss .....	-----	-----	-----	-----	-----	-----
Balances at December 31, 2000 .....	--	--	--	--	--	--
Issuance of common stock in connection with the private placement of common stock in June 2001, net of issuance costs of \$184,795 .....	--	--	--	--	--	--
Exercise of warrants to purchase common stock .....	--	--	--	--	--	--
Exercise of options to purchase common stock .....	--	--	--	--	--	--
Common stock issued in connection with Vaxis acquisition .....	--	--	--	--	--	--
Compensation expense related to warrants and options granted to non-employees .....	--	--	--	--	--	--

See accompanying notes.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statement of Shareholders' Equity (Continued)

	Common Stock		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount			
	-----	-----			
Fair value of warrants issued in Quay acquisition .....	--	489,477	--	--	489,477
Common stock issued in connection with Quay acquisition .....	169,224	977,105	--	--	977,105
Compensation expense related to warrants and options granted to non-employees .....	--	601,748	--	--	601,748
Unrealized gain on investments .....	--	--	8,201	--	8,201
Foreign currency translation .....	--	--	(1,537)	--	(1,537)
Net loss .....	--	--	--	(11,418,213)	(11,418,213)
Total Comprehensive Loss .....	--	--	--	--	(11,411,549)
Balances at December 31, 2000 .....	13,838,053	69,735,022	(28,807)	(50,911,825)	18,794,390
Issuance of common stock in connection with the private placement of common stock in June 2001, net of issuance costs of \$184,795 .....	2,747,143	15,199,206	--	--	15,199,206
Exercise of warrants to purchase common stock .....	12,000	48,000	--	--	48,000
Exercise of options to purchase common stock .....	60,803	203,437	--	--	203,437
Common stock issued in connection with Vaxis acquisition .....	533,612	3,852,631	--	--	3,852,631
Compensation expense related to warrants and options granted to non-employees .....	--	349,515	--	--	349,515

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statements of Shareholders' Equity (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common stock in connection with the achievement of Neptune milestones .....	--	--	--	--	--	--	104,113	750,000
Unrealized gain/(loss) on investments ..	--	--	--	--	--	--	--	--
Foreign currency translation .....	--	--	--	--	--	--	--	--
Net loss .....	--	--	--	--	--	--	--	--
Total Comprehensive Loss .....	--	--	--	--	--	--	--	--
Balances at December 31, 2001 .....	--	--	--	--	--	--	17,295,724	90,137,811
Exercise of options to purchase common stock .....	--	--	--	--	--	--	156,632	454,983
Issuance of common stock in connection with the private placement of common stock in November 2002, net of issuance costs of \$275,000 .....	--	--	--	--	--	--	2,200,000	5,225,000
Compensation expense for options related to non-employees .....	--	--	--	--	--	--	--	72,224
Compensation expense related to stock option modifications .....	--	--	--	--	--	--	--	945,044
Unrealized gain (loss) on investments ..	--	--	--	--	--	--	--	--
Foreign currency translation .....	--	--	--	--	--	--	--	--
Net loss .....	--	--	--	--	--	--	--	--
Total Comprehensive Loss .....	--	--	--	--	--	--	--	--
Balances at December 31, 2002 .....	--	\$ --	--	\$ --	--	\$ --	19,652,356	\$96,835,062

See accompanying notes.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statements of Shareholders' Equity (Continued)

	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	-----	-----	-----
Issuance of common stock in connection with the achievement of Neptune milestones .....	--	--	750,000
Unrealized gain/(loss) on investments ..	130,655	--	130,655
Foreign currency translation .....	(18,390)	--	(18,390)
Net loss .....	--	(19,464,723)	(19,464,723)
Total Comprehensive Loss .....	--	--	(19,352,458)
Balances at December 31, 2001 .....	83,458	(70,376,548)	19,844,721
Exercise of options to purchase common stock .....	--	--	454,983
Issuance of common stock in connection with the private placement of common stock in November 2002, net of issuance costs of \$275,000 .....	--	--	5,225,000



Compensation expense for options related to non-employees .....	--	--	72,224
Compensation expense related to stock option modifications .....	--	--	945,044
Unrealized gain (loss) on investments ..	(82,916)	--	(82,916)
Foreign currency translation .....	11,289	--	11,289
Net loss .....	--	(15,935,900)	(15,935,900)
Total Comprehensive Loss .....	--	--	(16,007,527)
Balances at December 31, 2002 .....	\$11,831	\$ (86,312,448)	\$10,534,445
	=====	=====	=====

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statements of Cash Flows

	Years ended December 31,			Period from
	2002	2001	2000	June 26, 1989 (inception) through December 31, 2002
Operating activities				
Net loss .....	\$(15,935,900)	\$(19,464,723)	\$(11,418,213)	\$(84,863,943)
Adjustment to reconcile net loss to net cash used in operating activities:				
Acquired in-process technology .....	--	3,507,134	--	7,350,102
Depreciation and amortization .....	484,028	530,643	502,470	2,229,116
Intangible assets amortization .....	325,644	359,673	298,351	983,668
(Gain)/Loss on sale of fixed assets .....	(86,476)	--	--	(86,476)
Non-cash compensation expense related to warrants and options granted .....	1,017,268	349,516	601,748	1,968,532
Compensation expense related to option grants ..	--	--	--	338,481
Amortization of discount on notes payable and deferred financing costs .....	--	--	--	24,261
Issuance of common shares for services .....	--	--	--	990,918
Issuance of common stock for services rendered, interest, and Neptune milestones ...	--	750,000	--	567,503
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets ....	229,032	18,732	70,250	(708,312)
Other assets .....	250,000	--	--	250,000
Accounts payable and accrued liabilities .....	112,026	450,023	729,227	2,005,279
Other long term liabilities .....	231,793	484,826	--	716,619
Deferred revenue .....	15,000,000	--	--	15,000,000
Accrued compensation and related expenses ....	(21,689)	5,541	32,850	122,925
Net cash used in operating activities .....	1,605,726	(13,008,635)	(9,183,317)	(53,111,327)
Investing activities				
Purchases of property and equipment .....	(733,175)	(150,530)	(201,106)	(4,837,420)
Purchases of investments .....	--	(16,789,905)	(10,575,000)	(87,890,354)
Sales of investments .....	6,706,769	7,500,000	9,549,557	38,175,646
Maturities of investments .....	2,000,000	4,980,239	10,500,000	45,617,759
Proceeds from sale of property and equipment .....	187,337	--	--	187,337
Acquisition of Vaxis and Quay .....	--	(142,556)	(369,000)	(511,556)
Net cash provided by (used in) investing activities	8,160,931	(4,602,752)	8,904,451	(7,258,588)
Financing activities				
Proceeds from notes payable .....	\$ --	\$ --	\$ --	\$ 8,047,424
Proceeds from restricted cash .....	386,499	--	--	386,499
Repayment of notes payable .....	--	(882,070)	(3,152,828)	(6,610,608)
Net proceeds from issuance of common stock .....	5,679,983	15,450,643	12,298,789	69,111,551
Other assets .....	--	--	(613,999)	(613,999)
Other long-term liabilities .....	--	--	(218,993)	--
Issuance of convertible preferred stock, net of issuance costs .....	--	--	--	11,757,735
Deferred financing costs .....	--	--	--	(80,170)
Net cash provided by financing activities .....	6,066,482	14,568,573	8,312,969	81,998,432
Net increase (decrease) in cash and cash equivalents	15,833,139	(3,042,814)	8,034,103	\$ 21,628,517
Cash and cash equivalents, beginning of period .....	5,795,378	8,838,192	804,089	--
Cash and cash equivalents, end of period .....	\$ 21,628,517	\$ 5,795,378	\$ 8,838,192	\$ 21,628,517
	=====	=====	=====	=====

See accompanying notes

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(a development stage company)

Consolidated Statements of Cash Flows (Continued)

	2002	2001	2000	Period from June 26, 1989 through December 31, 2002
	----	----	----	----
Supplemental cash flow information				
Interest Paid .....	\$ 27,136	\$ 27,281	\$ 200,689	\$ 639,987
Supplemental disclosure of non-cash transactions:				
Issuance of common stock in connection with acquired-in-process technology .....	\$ --	\$ 3,507,134	\$ --	\$ 7,350,102
Conversion of preferred stock to common stock .....	\$ --	\$ --	\$ --	\$14,715,474
Issuance of common stock for notes payable .....	\$ --	\$ --	\$ --	\$ 277,250
Issuance of warrants in connection with notes payable financing	\$ --	\$ --	\$ --	\$ 487,333
Issuance of convertible preferred stock for notes payable .....	\$ --	\$ --	\$ --	\$ 1,268,316
Issuance of common stock for milestone payments .....	\$ --	\$ 750,000	\$ --	\$ 750,000

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements

1. Accounting Policies

Description of Business and Principles of Consolidation

The consolidated financial statements include the accounts of Cellegy Pharmaceuticals, Inc. and its subsidiaries (the "Company"). All significant inter-company balances and transactions have been eliminated in consolidation.

The Company was incorporated in California in June 1989 and is a development stage company. Since its inception, the Company has engaged primarily in research and clinical development activities associated with its current and potential future products and its transdermal drug delivery and topical formulation expertise. The Company has conducted a number of clinical trials using its products, including the preparation of manufactured clinical materials. A number of sponsored, external research programs have been undertaken.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition and Research and Development Expenses

Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects are incurred. Revenues related to milestones specified under development contracts are recognized as the milestones are achieved. The Company receives certain United States government grants that support the Company's research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenues associated with these grants are recognized as costs under each grant are incurred. Revenues related to product sales are recognized upon shipment when title to goods has been transferred to the customer. There is no right of return for product sales.

Up-front payments, such as the \$15.0 million payment received from PDI for the Tostrex license, are recorded as deferred revenue at the time the cash is received. Amounts are recognized as revenue on a straight-line basis over the longer of the life of the contract or the service period. Royalties payable to Cellegy under the PDI License Agreement will be recognized as earned when the royalties are no longer refundable to PDI under certain minimum royalty

terms defined in the agreement.

Research and development costs are expensed as incurred. The type of costs included in research and development expenses include salaries and benefits, laboratory supplies, external research programs, clinical studies and allocated costs such as rent, supplies and utilities.

Clinical trial expenses are payable to clinical sites and clinical research organizations. Expenses for both of these groups are accrued on a straight-line basis over the contracted period subject to adjustment for actual activity based on such factors as the number of subjects enrolled and number of subjects that have completed treatment for each trial.

#### Cash, Cash Equivalents and Investments

Cash equivalents consist of highly liquid financial instruments with original maturities of three months or less. The carrying value of cash and cash equivalents approximates fair value at December 31, 2002 and 2001. The Company considers all its investments as available-for-sale and reports these investments at estimated fair market value using available market information. Unrealized gains or losses on available-for-sale securities are included in shareholders' equity as other comprehensive income (loss) until their disposition. The cost of securities sold is based on the specific identification method. Realized gains or losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest income and other, net.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

#### Notes to Consolidated Financial Statements - (Continued)

The Company is subject to credit risk from its portfolio of marketable securities. By policy, the Company restricts amounts invested in such securities by investment type and by issuer except for securities issued by the United States government.

#### Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Furniture and fixtures, and office and laboratory equipment are depreciated using the straight-line method over estimated useful lives ranging from three to five years. Amortization for leasehold improvements is taken over the shorter of the estimated useful life of the asset or the remaining lease term.

#### Goodwill and Other Intangible Assets

Goodwill that is related to the purchase of Quay Pharmaceuticals in June 2000, included in intangible assets, represents the excess purchase price over the fair value of net assets acquired which was being amortized over 10 years using the straight-line method. The carrying value of goodwill is based on management's current assessment of recoverability using objective and subjective factors. Effective January 1, 2002, the Company will no longer amortize the remaining balance of goodwill of \$814,400. We performed an impairment test of goodwill upon transition to FAS 142 on January 1, 2002, and no impairment was found for either period. We will continue to evaluate our goodwill for impairment on an annual basis each year and whenever events and changes in circumstances suggest that the carrying amount may not be recoverable. An impairment loss, if needed, would be recognized based on the difference between the carrying value of the asset and its estimated fair value, which would be determined based on either discounted cash flows or other appropriate fair value methods.

FAS 142 also requires that intangible assets with definite lives be amortized over their estimated useful lives and reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. We currently amortize our other intangible assets on a straight-line basis over their estimated useful lives ranging from three to five years. Amortization taken to date as of December 31, 2002 was approximately \$983000.

#### Stock-Based Compensation

The Company accounts for its stock option grants in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related Interpretations. The Company has elected to follow the disclosure-only alternative prescribed by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"). Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no

compensation expense is recognized. Compensation for options granted to non-employees has been determined in accordance with FAS 123 and EITF 96-18 at the fair value of the equity instruments issued. Stock based compensation is recognized on a straight-line basis.

#### Foreign Currency Translation

The foreign subsidiaries functional currencies are their local currencies. The gains and losses resulting from translating the foreign subsidiaries' financial statements into US dollars have been reported in other comprehensive income (loss).

#### Comprehensive Income (Loss)

Comprehensive income (loss) consists of net loss and other comprehensive income (loss). Accumulated other comprehensive income (loss) presented in the consolidated balance sheets consists of the accumulated net unrealized gain (loss) on available-for-sale investments and foreign currency translation adjustments.

#### Basic and Diluted Net Loss per Common Share

Basic net loss per common share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per common share incorporates the incremental shares issued upon the assumed exercise of stock options and warrants, when dilutive. There is no difference between basic and diluted net loss per common share, as presented in the statement of

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

#### Notes to Consolidated Financial Statements - (Continued)

operations, because all options and warrants are anti-dilutive. The total number of shares excluded was 1,864,551, 5,041,375 and 5,232,337 for the years ended December 31, 2002, 2001 and 2000, respectively.

#### Recent Accounting Pronouncements

In June 2002, the Financial Accounting Standards Board issued Financial Accounting Standard 146 ("FAS 146"), "Accounting for Costs Associated with Exit or Disposal Activities," which addresses accounting for restructuring, discontinued operation, plant closing, or other exit or disposal activity. FAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. FAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The adoption of FAS 146 is not expected to have a significant impact on our financial position and results of operations.

In November 2002, the Financial Accounting Standards Board issued Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. Our adoption of FIN 45 did not have a material impact on our results of operations and financial position.

In December 2002, the Financial Accounting Standards Board issued Statement No. 148 ("FAS 148"), "Accounting for Stock-Based Compensation - Transition and Disclosure." FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options. See below in the "Shareholders' Equity" note for the disclosures required by FAS 148.

The Company has elected to follow APB Opinion No. 25 and related interpretations in accounting for its stock options since, as discussed below, the alternative fair market value accounting provided for under FAS 123 requires use of option valuation models that were not developed for use in valuing stock options. Under APB Opinion No. 25, if the exercise price of the Company's stock options is equal to the market price of the underlying stock on the date of grant, no compensation expense is recognized related to employee or director grants.

Pro forma information regarding net loss and net loss per common share is required by FAS 123, which requires that the information be determined as if the Company has accounted for its common stock options granted under the fair market value method. The fair market value of options granted has been estimated at the date of the grant using a Black-Scholes option pricing model.

The Company valued its options using the following weighted average assumptions for the years ended December 31, 2002, 2001 and 2000:

	2002	2001	2000
	----	----	----
Risk-free interest rate.....	2.5%	3.5%	6.0%
Dividend yield.....	0%	0%	0%
Volatility.....	1.06	0.60	0.91
Expected life of options in years..	4.3	4.3	4.3

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

The Black-Scholes option pricing model was developed for use in estimating the fair market value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair market value estimate. In management's opinion, the existing models do not necessarily provide a reliable single measure of the fair market value of its stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information for the years ended December 31 are as follows:

	2002	2001	2000
	-----	-----	-----
Net loss as reported .....	\$ (15,935,900)	\$ (19,464,723)	\$ (11,418,213)
Add: Stock-based employee compensation costs included in the determination of net loss, as reported.....	945,000	--	--
Deduct: Stock-based employee compensation costs that would have been included in the determination of net loss if the fair value method had been applied to all awards.....	(2,923,231)	(2,687,751)	(1,686,989)
	-----	-----	-----
Net loss, proforma .....	\$ (17,914,131)	\$ (22,152,474)	\$ (13,105,202)
Basic and diluted net loss per share as reported .....	\$ (0.90)	\$ (1.26)	\$ (0.91)
Pro forma basic and diluted net loss per share.....	\$ (1.02)	\$ (1.43)	\$ (1.04)

The weighted average grant date fair value of options granted during the years ended December 31, 2002, 2001, and 2000 was \$3.80, \$5.33 and \$4.30, respectively. The weighted average remaining contractual life of those options is 9.01 years, 6.8 years and 7.2 years during the years ended December 31, 2002, 2001 and 2000, respectively.

The effects of applying FAS 123 pro forma disclosures are not likely to be representative of the effects on reported net loss for future years.

Reclassification

Certain prior year balances have been reclassified for comparative purposes.

2. Investments

At December 31, 2002 and 2001, investments consist of the following:

	2002			2001		
	Cost	Gross Unrealized Gains	Estimated Fair Value	Cost	Gross Unrealized Gains	Estimated Fair Value
Corporate notes .....	\$ 2,001,580	\$ 543	\$ 2,002,123	\$ 6,678,378	\$ 79,642	\$ 6,758,020
U.S. government notes.	--	--	--	2,000,000	22,500	2,022,500
Commercial paper .....	--	--	--	2,000,000	--	2,000,000
	<u>\$ 2,001,580</u>	<u>\$ 543</u>	<u>\$ 2,002,123</u>	<u>\$10,678,378</u>	<u>\$ 102,142</u>	<u>\$10,780,520</u>

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

3. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2002	2001
Furniture and fixtures .....	\$ 184,305	\$ 178,926
Office equipment .....	238,822	242,233
Laboratory equipment .....	978,485	742,882
Leasehold improvements .....	2,919,390	2,917,075
	<u>4,321,002</u>	<u>4,081,116</u>
Less accumulated depreciation and amortization	<u>(1,704,809)</u>	<u>(1,613,209)</u>
	<u>\$ 2,616,193</u>	<u>\$ 2,467,907</u>

4. Lease Commitments

The Company leases its facilities and certain equipment under non-cancelable operating leases. Rent expense is recorded on a straight-line basis over the term of the lease. During the third quarter of 2002, the Company subleased a portion of its facility. Rental income is recorded as received. Future minimum lease payments, net of future minimum sublease income at December 31, 2002, are as follows:

Years ending December 31,	Lease Commitments	Sublease Income	Future Minimum Lease Commitments
2003.....	1,287,948	(1,111,123)	176,825
2004.....	1,326,144	(1,174,738)	151,406
2005.....	1,365,468	(1,209,979)	155,489
2006.....	1,405,992	(1,246,278)	159,714
2007.....	1,447,716	(1,283,666)	164,050
Thereafter.....	1,490,700	(1,322,175)	168,525
	<u>\$ 8,323,968</u>	<u>\$ (7,347,959)</u>	<u>\$ 976,009</u>

Rent expense, net of sublease income, was \$891,620, \$1,653,337 and \$1,817,427 for the years ended December 31, 2002, 2001, and 2000, respectively. The Company received \$405,000 in sublease income during the year ended December 31, 2002.

Restricted cash at December 31, 2002 and 2001 was approximately \$227,500 and 614,000, respectively, and represents amounts that secure a letter of credit related to our leases.

## 5. 401(k) Plan

The Company maintains a savings and retirement plan under Section 401(k) of the Internal Revenue Code. All employees are eligible to participate on their first day of employment with the Company. Under the plan, employees may contribute up to 15% of salaries per year subject to statutory limits. The Company provides a matching contribution equal to 25% of the employee's rate of contribution, up to a maximum contribution rate of 4% of the employee's annual salary. Expenses related to the plan for the years ended December 31, 2002, 2001 and 2000 were not significant.

## 6. Restructuring

On July 23, 2002 and December 13, 2002 the Board of Directors formally adopted reduction in force programs affecting primarily research and marketing functions. The reductions resulted in a decrease of nine and five employees, respectively. During the third and fourth quarters, we recorded severance and other related charges of \$210,000 and \$143,000, respectively. In the fourth quarter, we recorded a stock based compensation charge of \$250,000 related to the extension of the exercise period of certain options held by terminated employees.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

## 7. Acquisitions, Licenses and Other Agreements

### Acquisitions

In December 1997, the Company acquired patent and related intellectual property rights relating to Cellegesic (the "Agreement"), a topical product candidate for the treatment of anal fissures and hemorrhoids from Neptune Pharmaceuticals Corporation ("Neptune"). Under the terms of the Agreement, the Company issued 429,752 shares of common stock to Neptune on December 31, 1997. Upon the signing of a letter of intent on November 3, 1997, 33,057 shares of common stock were issued to Neptune. The Agreement calls for a series of additional payments, payable in shares of common stock, upon successful completion of various development milestones. Upon completion of milestones in 2001, the Company issued 104,113 shares of common stock valued at \$750,000 which has been recorded to research and development expenses. The remaining milestones, if achieved, would become payable over the next several years. Depending on several factors, including the market price of the common stock, such payments, which are fixed based on the Agreement, could result in the issuance of a significant number of shares of common stock or cash. Future potential milestones, if all paid in Cellegy common stock could result in the issuance of up to an additional 1,285,000 shares of Cellegy common stock based on the closing price of Cellegy stock at time of issuance. The Agreement does not provide for the payment by the Company of any future product royalties in connection with sales of Cellegesic.

In June 2000, Cellegy acquired all assets of Quay Pharmaceuticals Pty Ltd ("Quay"), an Australian pharmaceutical company producing Rectogesic, a drug similar to Cellegesic. The acquired assets consisted of Quay's inventory, purchased at Quay's cost at the time of acquisition, other tangible assets and purchased technology. The aggregate purchase price of \$1,835,000 included the aggregate value of the 169,224 shares of Cellegy common stock issued to Quay with a value of \$977,000, warrants to purchase 171,146 shares of common stock with a fair value of \$489,000, and cash payments of \$369,000. The purchase price was allocated to the net tangible assets of \$97,000, purchased technology of \$770,000, and goodwill of \$968,000, based on their estimated fair values on the acquisition date. Purchased technology and goodwill were being amortized over three and ten years, respectively. Following the adoption of FAS 142, the goodwill will no longer be amortized as of January 1, 2002. This transaction has been accounted for by the purchase method of accounting and accordingly, the approximated purchase price, shown above, has been allocated to the net assets acquired and the liabilities assumed based on the estimated fair values at the date of acquisition, with the excess of the purchase price over assigned asset values recorded as goodwill. The results of operating the acquired company have been included in the Company's consolidated financial statements since the acquisition date.

On November 27, 2001, Cellegy acquired Vaxis Therapeutics, a private Canadian company. Vaxis, renamed Cellegy Canada, is a small early stage research and development entity with access to scientists in the areas of sexual dysfunction, peripheral vascular disorders and nitric oxide pharmacology. The acquisition of this research is in line with the Company's goal of expanding its pipeline of products and protecting its patents. The purchase price of \$4.1 million consisted of 533,612 shares of our common stock and \$142,000 in cash. The purchase price was allocated as follows: \$350,000 to intangible assets,

\$250,000 to tangible assets and \$3,500,000 to acquired in-process research and development. The acquired technology was in an early stage of development that, as of the acquisition date, technological feasibility had not been reached and no alternative use existed. One of the assumptions used in determining the purchase price allocation was a discount rate of 37% on probability of expected cash flows. The intangible assets will be amortized over 5 years, the period of contractual obligation.

The Vaxis purchase agreement contains earn-out provisions for seven years that are based on commercial sales of any products developed by the Company or other revenues generated from the acquired research. Any contingent consideration paid in the future will be accounted for as a cost of earning the related revenues. The results of operations of the acquired company have been included in the Company's consolidated financial statements since the acquisition date.

Accumulated amortization of the Vaxis intangible assets at December 31, 2002 was \$75,000. The expected amortization expense for Vaxis for the next four years will be approximately \$68,800 per year. The expected amortization expense for Quay for the next year will be approximately \$107,000.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

#### Other Agreements

In October 1993, Cellegy entered into a license agreement with the University of California providing for an exclusive, worldwide, royalty bearing license, subject to customary government rights, for patent rights relating to barrier repair formulations jointly held by the University and Cellegy, in consideration of the issuance to the University of certain shares of preferred stock (which subsequently converted into shares of common stock) and the payment by Cellegy of a licensing fee. In March 1994, Cellegy entered into an exclusive, worldwide, royalty bearing license agreement with the University for patent rights, jointly held by the University of California and Cellegy, relating to certain drug delivery technologies, in consideration of the payment by Cellegy of a licensing fee, and an annual maintenance fee payable each year until Cellegy is commercially selling a licensed product. In April 2000, Cellegy terminated the Exclusive License Agreement relating to barrier repair formulations and assigned its rights in the invention to the University. We are now in the process of terminating our license patent right relating to drug delivery technologies and assigning the rights to the University. The termination of these licenses reflects, in part, a shift towards development of products from the Company's own research efforts in areas which we believe have the potential to be more commercially viable.

In August 2001, Cellegy announced a comprehensive agreement with Ventiv Health, Inc. ("Ventiv"), a contract sales organization. Ventiv was to provide certain sales and marketing services relating to the anticipated launch of Cellegesic. In September 2002, Cellegy and Ventiv terminated the Cellegesic License Agreement based on the delay in commercialization of Cellegesic due to the withdrawal of the NDA and the subsequent decision to conduct another Phase III clinical trial.

In December 31, 2002, Cellegy entered into a license agreement with PDI, Inc. granting PDI the exclusive right to store, promote, sell and distribute Tostrex, one of our products awaiting FDA approval, in North American markets. Cellegy received an upfront payment of \$15.0 million on the effective date (December 31, 2002) and a payment of \$10.0 million is due to us no later than thirty days after we certify to PDI that Tostrex has received all FDA approvals required to manufacture, sell and distribute the product in the United States. We have recorded financing costs of \$947,000 to selling, general and administrative expenses for the year ended December 31, 2002 related to this agreement. If we receive the \$10.0 million payment, we will incur additional financing costs of \$600,000. Under the PDI agreement, Cellegy will also receive royalties each year until the expiration of the last patent right related to Tostrex of 20% - 30% of net sales and we will be reimbursed for 110% of burdened costs for any product supplied to PDI. The \$15 million upfront payment has been included as deferred revenue as of December 31, 2002 and will be recognized as revenue over the 18 year term of the agreement.

#### 9. Shareholders' Equity

##### Common Stock Private Placements

In October 2000, Cellegy completed a private placement of 1,500,000 shares of common stock at a price of \$7.75 per share to a group of institutional investors. Net proceeds were \$11,602,473.



In June 2001, we completed a private placement of approximately 2,700,000 million shares of common stock at a price of \$5.60 per share. Participants included two current investors, as well as five new investors. Net proceeds were \$15,199,206.

In November 2002, we completed a private placement of approximately 2,200,000 million shares our common stock at a price of \$2.50 per share to a single investor, John M. Gregory, founder and former CEO of King Pharmaceuticals and currently managing partner of SJ Strategic Investments LLC. Net proceeds were \$5,225,000.

Preferred Stock

The Company's Articles of Incorporation provide that the Company may issue up to 5,000,000 shares of preferred stock in one or more series. The Board of Directors is authorized to establish from time to time the number of shares to be included in, and the designation of, any such series and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon any wholly unissued series of preferred stock and to increase or decrease the number of shares of any such series without any further vote or action by the shareholders.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

Stock Option Plans

In 1995, Cellegy adopted the Equity Incentive Plan (the "Plan") to provide for the issuance of incentive stock options and non-statutory stock options. When the Plan was established, Cellegy reserved 700,000 shares for issuance. From 1996 to 2002, a total of 4,150,000 shares were reserved for issuance under the Plan. Options issued under the Plan have a term of 10 years and are generally subject to vesting over 3 years.

Activity under the Plan is summarized as follows:

	Shares Under Option	Exercise Price Range Per Share	Weighted Average Exercise Price
	-----	-----	-----
Balance at January 1, 2000 .	2,187,763	\$0.50 - \$8.81	\$ 4.82
Granted .....	191,350	\$3.31 - \$9.00	\$ 6.21
Canceled .....	(132,718)	\$3.00 - \$9.00	\$ 5.35
Exercised .....	(95,754)	\$1.81 - \$6.25	\$ 3.97
	-----		
Balance at December 31, 2000	2,150,641	\$0.50 - \$9.00	\$ 5.00
Granted .....	476,000	\$4.56 - \$15.00	\$ 7.96
Canceled .....	(123,634)	\$3.69 - \$7.87	\$ 5.71
Exercised .....	(60,803)	\$1.81 - \$4.62	\$ 3.35
	-----		
Balance at December 31, 2001	2,442,204	\$0.50 - \$15.00	\$ 5.59
Granted .....	1,898,789	\$1.80 - \$8.59	\$ 3.84
Canceled .....	(221,869)	\$1.80 - \$9.00	\$ 5.97
Exercised .....	(156,632)	\$0.50 - \$3.87	\$ 2.90
	-----		
Balance at December 31, 2002	3,962,492	\$1.80 - \$15.00	\$ 4.83
	=====		

At December 31, 2002, options to purchase 2,362,446 shares of common stock were vested and exercisable at exercise prices ranging from \$1.80 to \$15.00 per share. At December 31, 2001 and 2000, options to purchase 1,576,834 and 1,283,744 shares of common stock were vested and exercisable, respectively. At December 31, 2002, options to purchase 242,718 shares of common stock were available for future option grants under the Plan.

The following table summarizes information about stock options outstanding and exercisable related to the Plan at December 31, 2002:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Outstanding at December 31, 2002	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at December 31, 2002	Weighted Average Exercise Price
-----	-----	-----	-----	-----	-----
\$1.80 - \$3.88.....	1,830,078	6.8 years	\$2.48	1,106,644	\$2.90
\$4.00 - \$6.99.....	1,295,114	3.5 years	\$5.78	789,636	\$5.37

\$7.00 - \$15.00.....	837,300	6.7 years	\$8.52	466,166	\$7.91
Total.....	3,962,492	5.6 years	\$4.83	2,362,446	\$4.72

Director's Stock Option Plan

In 1995, Cellegy adopted the 1995 Directors' Stock Option Plan (the "Directors' Plan") to provide for the issuance of non-qualified stock options to eligible outside Directors. When the plan was established, Cellegy reserved 150,000 shares for issuance. From 1996 to 2002, a total of 350,000 shares were reserved for issuance under the Directors' Plan. Options issued under the Plan have a term of 10 years and are generally subject to vesting over 3 years.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

Activity under the Directors' Plan is summarized as follows:

	Shares Under Option -----	Price Range Per Share -----	Weighted Average Exercise Price -----
Balance at January 1, 2000.....	112,500	\$3.25 - \$8.50	\$5.13
Granted.....	70,000	\$4.81	\$4.81
	-----		
Balance at December 31, 2000.....	182,500	\$3.25 - \$8.50	\$5.01
Granted.....	46,000	\$5.50 - \$6.50	\$5.85
	-----		
Balance at December 31, 2001.....	228,500	\$3.25 - \$8.50	\$7.26
Granted.....	64,000	\$2.56	\$2.56
	-----		
Balance at December 31, 2002.....	292,500	\$2.56 - \$8.50	\$4.61

At December 31, 2002, options to purchase 179,330 shares of common stock were vested and exercisable at exercise prices ranging from \$3.25 to \$8.50 per share. At December 31, 2002, options to purchase 36,833 shares of common stock were available for future option grants under the Directors' Plan.

The following table summarizes information about stock options outstanding and exercisable related to the Directors' Plan at December 31, 2002:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Outstanding at December 31, 2002	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at December 31, 2002	Weighted Average Exercise Price
\$2.56 - \$3.25.....	68,000	9.1 years	\$2.60	4,000	\$3.25
\$4.50 - \$5.50.....	206,500	6.2 years	\$5.08	167,996	\$5.09
\$6.50 - \$8.50.....	18,000	7.9 years	\$6.72	7,334	\$7.04
Total.....	292,500	6.7 years	\$4.61	179,330	\$5.13

Shares reserved

As of December 31, 2002, we have reserved shares of common stock for future issuance as follows:

Warrants.....	300,000
Stock Option Plans...	279,551
Neptune Agreement....	1,285,000
	-----
Total.....	1,864,551
	=====

Warrants to purchase 300,000 shares of our common stock at an average exercise price of \$11.75 per share are outstanding as of December 31, 2002. The warrants expire between March and September 2005.

Non-cash Compensation Expense related to Stock Options

For the year ended December 31, 2002, the Company recorded non-cash compensation expense of \$1,017,000. \$72,000 of this expense related to options

issued to non-employees under the Equity Incentive Plan. \$250,000 related to the extension of the exercise period of certain options issued to employees that were terminated in December, 2002 (see Note 6 Restructuring). \$695,000 related to the modification of certain previously granted stock options. The modification reduced the number of shares subject to the options and was implemented in connection with the restoration of salaries and fees for certain employees and board members whose compensation had been reduced earlier in 2002. The modification resulted in a variable option accounting charge with respect to the vested portion of the modified options. The expense reflected in the 2002 financial statements is based on the number of options vested multiplied by the difference between the closing price of our common stock as of year end of \$4.05 per share and the original exercise price of the options of \$1.80. The outstanding variable options to purchase 309,000 shares of our common stock as of December 31, 2002 will be subject to re-measurement until the options are exercised or cancelled.

10. Income Taxes

At December 31, 2002 the Company had net operating loss carryforwards of approximately \$55,000,000 and \$10,000,000 for federal and state purposes, respectively. The federal net operating loss carryforwards expire between the years 2004 and 2022. The state net operating loss carryforwards expire between the years 2004 and 2013. At December 31, 2002, the Company also had research and development credit carryforwards of approximately \$1,200,000 and \$700,000 for federal and state purposes, respectively. The federal credits expire between the years 2006 and 2022 and the state credits do not expire. Pursuant to the "change in ownership" provisions of

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements - (Continued)

the Tax Reform Act of 1986, utilization of the Company's net operating loss and research and development tax credit carryforwards may be limited if a cumulative change of ownership of more than 50% occurs within any three-year period. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax liabilities and assets are as follows (in thousands):

	December 31,	
	----- 2002 -----	2001 -----
Deferred tax assets:		
Net operating loss carryforwards	\$ 19,300	\$ 20,200
Deferred revenue .....	6,000	--
Credit carryforwards .....	1,600	1,900
Capitalized intangibles .....	1,900	1,800
Other, net .....	800	300
	-----	-----
Total deferred tax assets .....	29,600	24,200
Valuation allowance .....	(29,600)	(24,200)
	-----	-----
Net deferred tax assets .....	\$ --	\$ --
	=====	=====

The valuation allowance for deferred tax assets for 2002, 2001, and increased by approximately \$5,400,000, \$5,700,000 and \$3,500,000, respectively.

11. Segment Reporting

The Company has two business segments: pharmaceuticals and cosmeceuticals. Pharmaceuticals include primarily research and clinical development expenses for potential prescription products to be marketed directly by Cellegy or through corporate partners.

Current pharmaceutical revenues consist primarily of Rectogesic sales in Australia, in addition to the PDI License Agreement for Tostrex. The Company expects to complete other corporate collaborations in the future for a number of its potential pharmaceutical products, which may result in milestones, development funding and royalties on sales.

Cellegy expects to generate future revenues on potential products it intends to self-market. The cosmeceutical business segment includes development expenses for non-prescription anti-aging products. During 2001 and 2000, Cellegy incurred development expenses for its cosmeceutical products. No development expenses were incurred in 2002. Our product sales are from one customer, Gryphon Development, Inc., which is selling one of the Company's skin care products, exclusively in the United States, through a major specialty retailer.

Cellegy allocates its revenues and operating expenses to each business segment, but does not assess segment performance or allocate resources based on a segment's assets and, therefore, asset depreciation and amortization and capital expenditures are not reported by segment. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

The Company's segments are business units that will, in some cases, distribute products to different types of customers through different marketing programs. The potential future sales of cosmeceutical products require a significantly different marketing effort than sales of pharmaceutical products to physicians and other traditional pharmaceutical distribution channels. Pharmaceutical products require more extensive clinical testing and ultimately regulatory approval by the FDA and other worldwide health registration agencies, requiring a more extensive level of development, manufacturing and compliance than a cosmeceutical product.

The following table contains information regarding revenues and operating income (loss) of each business segment for the years ended December 31, 2002, 2001, and 2000:

Total assets were minimal for the cosmeceutical segment.

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Cellegy Pharmaceuticals, Inc.  
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Notes to Consolidated Financial Statements - (Continued)

	Years ended December 31,		
	2002	2001	2000
Revenues:			
Pharmaceuticals .....	\$ 320,339	\$ 217,439	\$ 196,434
Cosmeceuticals .....	1,081,287	660,052	1,389,189
	<u>\$ 1,401,626</u>	<u>\$ 877,491</u>	<u>\$ 1,585,623</u>
Operating Income (Loss):			
Pharmaceuticals .....	\$ (17,157,562)	\$ (21,021,796)	\$ (13,114,538)
Cosmeceuticals .....	700,837	52,427	1,127,139
	<u>\$ (16,456,725)</u>	<u>\$ (20,969,369)</u>	<u>\$ (11,987,399)</u>

Revenue from Major Customer

Revenues from product sales to one customer represented approximately 70%, 75% and 88% of consolidated revenue for 2002, 2001 and 2000, respectively.

Geographic data

Approximately 20% of our total revenues are from sales of Rectogesic in Australia. All other sales are in the United States. Primarily all our total assets are located in the United States.

12. Related Party Transactions

Cellegy has paid fees to the Company's board members for their services on the board, audit committee and compensation committee. The total fees paid to these directors during 2002, 2001 and 2000 were \$10,000, \$30,000 and \$46,500.

There were no consulting fees paid in cash to any board members in 2002. For 2001, consulting fees of \$ 80,000 were paid to two board members based on consulting agreements.

The Company also recognized \$33,000 in compensation expense during 2002 for a consulting agreement with a former board member. Cellegy issued stock options to this board member for his consulting services.

Cellegy has an interest bearing \$100,000 loan outstanding to a non-officer employee, which was issued in conjunction with the purchase of his home.

13. Quarterly Financial Data ( unaudited )

(amounts in thousands except per share data)

2002	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Total revenue.....	\$ 267	\$ 150	\$ 145	\$ 840	\$ 1,402
Operating loss.....	(4,642)	(5,753)	(1,756)	(4,306)	(16,457)
Net loss.....	(4,387)	(5,624)	(1,623)	(4,302)	(15,936)
Basic & diluted net loss per common share.....	\$ (0.25)	\$ (0.32)	\$ (0.09)	\$ (0.24)	\$ (0.90)

2001	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Total revenue.....	\$ 41	\$ 53	\$ 265	\$ 518	\$ 877
Operating loss.....	(4,206)	(4,352)	(4,182)	(8,229)	(20,969)
Net loss.....	(3,777)	(4,156)	(3,871)	(7,661)	(19,465)
Basic & diluted net loss per common share.....	\$ (0.27)	\$ (0.29)	\$ (0.23)	\$ (0.47)	\$ (1.26)

F-21

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

EXHIBITS

to

Form 10-K

Under

THE SECURITIES EXCHANGE ACT OF 1934

CELLEGY PHARMACEUTICALS, INC.

EXCLUSIVE LICENSE AGREEMENT FOR TOSTREX(TM)

BETWEEN

PDI, INC.

AND

CELLEGY PHARMACEUTICALS, INC.

[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

[\*] designated portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

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#### EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (this "Agreement") is made and entered into as of December 31st, 2002 (the "Effective Date"), by and between Cellegy Pharmaceuticals, Inc., a California corporation ("Cellegy"), and PDI, Inc., a Delaware corporation ("Licensee").

#### W I T N E S S E T H:

WHEREAS, Cellegy owns or possesses certain intellectual property rights current and pending with respect to the Licensed Product (as hereinafter defined) and certain rights pertaining to the Trademark (as hereinafter defined);

WHEREAS, Licensee desires to obtain an exclusive license to certain rights current and pending to the Licensed Product under such intellectual property rights, and to the Trademark within the Territory (as hereinafter defined);

WHEREAS, Cellegy is willing to grant an exclusive license to Licensee under such current and pending intellectual property rights, and is willing to grant an exclusive license to the Trademark to Licensee, each within the Territory, all as more particularly described in, and subject to the terms and conditions of, this Agreement.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties mutually agree as follows:

#### ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms, whether used in the singular or the plural, shall have the following meanings:

"Affiliates" shall mean, with respect to any party, any person, which, directly or indirectly, is controlled by, controls or is under common control with such party. For purposes of this definition, the term control (including with correlative meanings, the terms controlled by and under common control with) means having the power, whether held directly or indirectly and by whatever means (and whether or not enforceable at law or in equity) to:

(i) exercise or control the right to vote attached to 50% or more of the issued shares in the party;

(ii) dispose of or exercise a right of disposal in respect of 50% or more of the issued voting shares in the party;

(iii) appoint one half or more of the number of directors to the board of the party; or

(iv) determine substantially the conduct of the party's business activities.

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"Agreement" means this Exclusive License Agreement.

"Approvals" are registration approvals, registrations or authorizations provided by the Relevant Regulatory Authority in the Territory for the manufacturing, importation, storage, promotion, sale or distribution of the Licensed Product.

"Auditor" shall mean an independent public accountant and auditor that has not been employed or had been employed by Licensee, Cellegy or PanGeo and possesses no beneficial ownership of Cellegy, Licensee or PanGeo.

"Cellegy Information" means the technical and clinical information concerning the Licensed Product that is developed by Cellegy or licensed in by Cellegy (with the right to grant sublicense rights to Licensee), and that is included in the new drug application filed with the FDA, and Cellegy's European common technical document format, and which may include, without limitation, data in support of registered indications, bioequivalency data and information, clinical data, pharmaco-toxicological data, analytical methods, stability and pharmaceutical data concerning the Licensed Product, Know How, and any other related supporting documentation in the possession of Cellegy from time to time relating to such package.

"Dollars" or "\$" means United States dollars.

"Defective Product" means any condition that violates the warranty defined in Section 7.9 or conditions to the Licensed Product in packaging or utility that prevents it from being sold to a Third Party up to and including any FDA concerns with compliance to regulatory and manufacturing guidelines.

"Exclusive License" means a license whereby Licensee's rights in the Licensed Product in the Territory shall be sole and exclusive and shall operate to exclude all others, including Cellegy.

"Effective Date" means the date set forth at the beginning of this Agreement.

"FDA" means the United States Food and Drug Administration, or any successor entity thereto.

"FD&C Act" means the Federal Food, Drug and Cosmetic Act, as amended.

"Good Manufacturing Practice" means manufacturing practices in conformity with the FDA's regulations and regulatory interpretations of such regulations covering good manufacturing practices set forth in the FD&C Act and any other applicable law or regulation, as such regulations may be amended and interpreted by the appropriate government authorities from time to time.

"Improved Product" means any and all new developments or versions of the Licensed Product delivered to Licensee under this Agreement.

"Intellectual Property Rights" means all rights and interests, current and pending, vested or arising out of any industrial or intellectual property, whether protected at common law or under statute, which includes (without limitation) the Proprietary Rights, Patent Rights and Know-How and any rights and interests in inventions (both patentable and unpatentable), patents, copyrights, moral rights, designs (whether registered or unregistered), trade marks (whether registered or unregistered), trade secrets, goodwill, samples, materials, data, know-how, results and Confidential Information.

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"Joint Manufacturing Committee" means a committee consisting of two designees of each of Cellegy and Licensee; such committee shall work jointly to manage the process of supplying the Licensed Product to the Licensee, as further set forth in Section 7.1(a).

"Launch Date" means the date upon which the first arms length commercial sale of the Licensed Product in finished product form, packaged and labeled for sale to a Third Party in the Territory occurs after securing regulatory Approval required to promote, manufacture, sell, and distribute the Licensed Product in the applicable country in the Territory.

"Loss" means any and all loss, liability, damage, fee, cost, (including without limitation actual reasonable court costs and reasonable attorneys' fees regardless of outcome) expense, suit, claim, demand, judgment and prosecution.

"Licensed Product" means the testosterone based transdermal gel product for the treatment of male hypogonadism and low levels of testosterone in men

developed by Cellegy and generally referred to as Tostrex(TM) testosterone gel.

"Know-How" means any technology or information developed by Cellegy or licensed in by Cellegy (with the right to grant sub-license rights to the Licensee) used for manufacturing or formulating the Licensed Product or in exercise of the rights granted to Licensee hereunder, including, but not limited to: manufacturing data; formulation or production technology; methods of synthesis, isolation and purification methods and other manufacturing information and any proprietary reagents and other materials required to manufacture the Licensed Product; and any data developed by Cellegy related to pharmacology, toxicology, pathology, clinical data, results of clinical efficacy studies, clinical effects and indications for use of the Licensed Product.

"Net Sales" means the gross sales of a Licensed Product that is due, or otherwise received by, Licensee, or its Affiliates or its Sublicensees from Third Party customers for such Licensed Product, less:

(i) reasonable credited allowances actually granted to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Licensed Product and for reasonable retroactive price reductions,

(ii) the amounts of reasonable trade, quantity and cash discounts actually allowed, to the extent such trade, quantity and cash discounts are specifically allowed on account of the purchase of such Licensed Product,

(iii) sales taxes, excise taxes, use taxes and import/export duties and any other government charges (other than taxes on income) actually due or incurred in connection with the manufacture, use or sales of the Licensed Product to any Third Party, and

(iv) reasonable allowances, adjustments, reimbursements, discounts, chargebacks and rebates actually granted to Third Parties, including, but not limited to, rebates given to health care organizations or other Third Parties, and any bona fide payment made in respect of any sales of Licensed Product to any governmental or quasi-governmental body or agency, whether during the actual royalty period or not.

"Patent Rights" means: (i) the patents and patent applications listed in Exhibit C hereto and any patents and patent applications existing as of the Effective Date but inadvertently omitted from Exhibit C; (ii) any patent or patent application hereafter which is acquired by Cellegy or under which Cellegy becomes licensed and with the right to sublicense to Licensee, during the term of this Agreement, in each

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case of (i) and (ii) above relating to the Licensed Product, its manufacture, use or sale, including methods of use and screening or processes that use the Licensed Product; (iii) any divisions, continuations and continuations-in-part defined in (i) or (ii); (iv) any extension, renewal or reissue or a patent identified in (i), (ii) or (iii); and (v) any continuation, continuation-in-part, or divisional or any patent application and any reissue or reexamination of any patent or patent application identified in (i) through (iv), in each case, to the extent that such items relate to the Licensed Product its manufacture, use or sale including methods of use and screening or processes that use the Licensed Product. Such items set forth in subitems (i) through (iv) will be identified and added by the parties to Exhibit C from time to time during the term of this Agreement.

"Proprietary Rights" means all of Cellegy's Intellectual Property Rights and interests in, to, or covering the Licensed Product, or the manufacture, use or sale, including methods of use and screening, or processes, that use the Licensed Product, to the extent that such Intellectual Property Rights are of such legal status and nature as to permit the same to be lawfully licensed and, without limiting the generality thereof, specifically include unpatented inventions, ideas, data, Know-How, technology, trade secrets and Confidential Information; but only to the extent that the foregoing relate to the Licensed Product within the scope of the License granted under this Agreement.

"Relevant Regulatory Authority", in relation to a country or region in the Territory, means the governmental authority, whether Federal, State or municipal, regulating the use, importation, manufacture, marketing, sale and/or distribution of therapeutic substances and the grant of Approvals in such country or region.

"Territory" means the United States, its territories, Puerto Rico, Mexico and Canada.

"Third Party" means any party other than Cellegy or Licensee, or Licensee's Affiliates or Sublicensees, or Cellegy's Affiliates or sublicensees.

"Trademark" means Tostrex (R) and any other trademark developed or acquired by Cellegy for use in connection with the sale of the Licensed Product in the Territory, as further set forth in Exhibit F.

"Sublicensee" means any person to whom Licensee sublicenses the rights, or any portion thereof, granted by Licensee pursuant to Section 3.1 hereof.

ARTICLE 2  
REPRESENTATIONS AND WARRANTIES

2.1 Representations and Warranties of Cellegy. cellegy hereby represents and warrants to Licensee that:

(a) Cellegy is a corporation duly incorporated, validly existing and in good standing under the laws of the State of California, with the corporate power and authority to enter into this Agreement and to perform its obligations hereunder. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all requisite corporate action on the part of Cellegy. This Agreement has been duly executed and delivered by Cellegy and constitutes the valid, binding and enforceable obligation of Cellegy, subject to applicable bankruptcy, reorganization, insolvency, moratorium and other laws affecting creditors' rights generally from time to time in effect and to general principles of equity.

(b) Cellegy is not subject to, or bound by, any provision of: (i) its articles of incorporation or by-laws, (ii) any mortgage, deed of trust, lease, note, shareholders' agreement, bond,

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indenture, license, permit, trust, custodianship, or other instrument, agreement or restriction, or (iii) any judgment, order, writ, injunction or decree of any court, governmental body, administrative agency or arbitrator, that would prevent, or be violated by, or under which there would be a default as a result of, nor is the consent of any person required for, the execution, delivery and performance by Cellegy of this Agreement and the obligations contained herein, including without limitation, the grant to Licensee of the license described in Article 3.1 hereof.

(c) Cellegy is the exclusive owner of all right, title and interest in the Patent Rights that have been granted in the applicable countries in the Territory, the claims in the patents included in the Patent Rights are valid and enforceable, and the patent applications included in the Patent Rights have been duly filed and contain no material errors. Attached hereto as Exhibit C is a complete and accurate list of all patents and patent applications included in the Patent Rights as of the Effective Date.

(d) Cellegy is the exclusive owner of all right, title and interest in the Trademark in the Territory, and has taken those measures reasonably necessary to secure its interest in the Trademark. Attached hereto as Exhibit F is a complete and accurate list of all trademarks and trademark applications included in the Trademark, and their status, as of the Effective Date.

(e) Cellegy has taken reasonable measures to protect the confidentiality of the Know-How. On occasions where Cellegy has granted access to Third Parties with respect to material elements of either the Know-How or the confidential information concerning the Licensed Product, to the best of Cellegy's knowledge, such access has been granted pursuant to an enforceable confidentiality agreement that has not been materially breached by the appropriate Third Party.

(f) To the best of Cellegy's knowledge, as of the Effective Date, neither the manufacture, use or sale of the Licensed Product or the practice of any of the inventions included in the Patent Rights nor the use of the Know-How by Licensee as contemplated by this Agreement infringes upon any Third Party's know-how, patent or other intellectual property rights in the Territory.

(g) To the best of Cellegy's knowledge, there is no Third Party using or infringing any or all of the Patent Rights or the Trademark in derogation of the rights granted to Licensee in this Agreement.

(h) Cellegy has obtained the assignment of all interests of all rights of Cellegy's employees, and to the best of its knowledge, Cellegy has obtained the assignment of all interests and all rights of any and all other Third Parties with respect to the Patent Rights and to the Trademark. To the best of Cellegy's knowledge, Cellegy has obtained all interests and all rights of any and all Third Parties (including, but not limited to Cellegy's employees) with respect to confidential or proprietary portions of the Know-How.

(i) To the best of Cellegy's knowledge, there is no interference or opposition actions or litigations pending or any communication, which threatens interference or opposition actions, or other litigation before any patent and trademark office, court or any other governmental entity in any jurisdiction in regard to the Patent Rights or the Trademark.

(j) Cellegy represents and warrants that, to the best of its knowledge, it has furnished or will furnish (in accordance with the terms of this Agreement) to Licensee all of the Know-How which Cellegy owns or possesses.

(k) Nothing has come to the attention of Cellegy which would indicate the existence of any material side effect, toxicity effect, carcinogenicity effect, adverse effect or any instances of

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deleterious physical effects or reactions resulting from, or alleged to result from, the Licensed Product, which are not identified in the Know-How delivered to the Licensee under this Agreement, or which has not been otherwise disclosed to the Licensee by Cellegy.

(l) Cellegy has or will maintain access to manufacturing facilities capable of producing a sufficient quantity of the Licensed Product, under Good Manufacturing Practices, to meet market demand.

(m) Cellegy, its Affiliates and sublicensees, and their respective employees, agents and contractors, will manufacture the Licensed Product under Good Manufacturing practices, in compliance with all applicable laws, statues, rules and regulations.

(n) Cellegy, its Affiliates and sublicensees will manufacture, transport, distribute and dispose, if applicable, of the Licensed Product in compliance with all applicable laws, statues, rules and regulations.

(o) Cellegy shall provide Licensee promptly in writing all adverse events and safety data that Cellegy or its Affiliates or sublicensees obtain concerning the Licensed Product and Improved Products.

2.2 Representations and Warranties of Licensee. Licensee hereby represents and warrants to Cellegy:

(a) that Licensee is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware, with the corporate power and authority to enter into this Agreement and to perform its obligations hereunder. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all requisite corporate action on the part of Licensee. This Agreement has been duly executed and delivered by Licensee and constitutes the valid, binding and enforceable obligation of Licensee, subject to applicable bankruptcy, reorganization, insolvency, moratorium and other laws affecting creditors' rights generally from time to time in effect and to general principles of equity.

(b) the compliance of its Affiliates, and Sublicensees with this Agreement and obligations such Affiliates and Sublicensees may have to Cellegy, including, but not limited to payment of any fees or royalties.

ARTICLE 3  
GRANT OF LICENSE

3.1 Grant. Cellegy hereby grants to Licensee an Exclusive License, with a right to sublicense as set forth herein, under all of Cellegy's Intellectual Property Rights to make or have made, manufacture, market, use, offer for sale, import and export Licensed Product within the Territory, and to use Cellegy's Intellectual Property Rights in connection with the storage, promotion, sale and distribution of Licensed Product and obtaining any Approvals under Section 13. Licensee's rights to the Licensed Product and the Intellectual Property Rights are limited to those expressly granted, and all others are reserved to Cellegy.

3.2 Addition to the Territory. The parties may mutually agree to add to the Territory other countries and their respective territories and principalities.

3.3 Restrictions on Territory. Licensee will use its commercially reasonable efforts not to knowingly directly distribute or otherwise make available Licensed Product outside the Territory or

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knowingly sell, distribute or otherwise make available Licensed Product to persons for the purpose of resale or distribution outside the Territory, exclusive of government, or military customers, and (inside the Territory) for charitable organizations. Without limiting the foregoing, Licensee agrees to use all reasonable commercial efforts to ensure compliance with the preceding sentence, including (i) placing appropriate notices on the labels on Licensed Products, and (ii) enforcing the foregoing restrictions against any Third Party to which Licensee, or any Affiliate of Licensee, sells Licensed Products that Licensee learns is violating such restriction and stop selling or distributing Licensed Products to such Third Party. Cellegy agrees that in any other licenses to Third Parties to distribute the Licensed Product outside the Territory, and in any manufacturing and distribution of the Licensed Product on its own account, Cellegy will institute materially similar restrictions to those set forth in this Section 3.3.

3.4 Right to sub-license in the Territory. Subject to Section 3.5 below, Licensee may sub-license any of its rights or obligations under this Agreement, directly or indirectly, in whole or in part:

(a) to third parties, provided the third party agreement does not impact on Sections 3.3, 3.7, Article 4 and Article 5 hereof, and that Licensee gives Cellegy reasonable prior notice of such an arrangement, and will consider Cellegy's advice about such third parties in good faith; and

(b) to any of its Affiliates that are engaged primarily in the business of distribution of pharmaceutical products, as Licensee sees fit; provided that any such Third Party or Affiliate must agree in writing with Cellegy, in form and substance reasonably satisfactory to Cellegy, to be bound by the provisions of this Agreement.

3.5 [\*]

3.6 Marketing Effort. Licensee agrees to exert its best reasonable efforts, consistent with the profit opportunity relative to other products in Licensee's pipeline and market conditions in the Territory to introduce and diligently promote, sell and service the Licensed Product within the Territory, including, without limitation, the full and complete attainment of the Minimum Sales Requirements as set forth below in Section 3.7.

3.7 Maintenance of Exclusivity.

(a) [\*]

(b) [\*]

3.8 Covenant Not To Compete. Cellegy hereby covenants and agrees that, for the term of this Agreement, Cellegy shall not, nor shall it permit any of its affiliates, nor any of their respective officers, employees, agents, or wholly owned subsidiaries, nor authorize any of its Affiliates, directors, or Sublicensees to, individually or jointly with other persons, manufacture, develop, test, sell, market or distribute any product within the Territory which contains testosterone for the treatment of male hypogonadism.

3.9 Notice Regarding other Testosterone Product Deals. Cellegy hereby covenants and agrees to provide Licensee with prompt written notice in the event that Cellegy executes a license agreement, development agreement or other collaboration agreement with respect to the development, marketing or distribution of any testosterone products within the Territory.

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ARTICLE 4  
LICENSE FEE AND RELATED PAYMENTS

4.1 License Fee. As consideration of the rights granted to Licensee by Cellegy under Article 3 and Section 8.4 hereof, Licensee shall pay Cellegy Fifteen Million Dollars (\$15,000,000) in cash on the Effective Date Cellegy hereby agrees to use its commercially reasonable efforts to take, or cause to be taken, all action, and to do, or cause to be done, all things necessary to expeditiously as possible seek all FDA Approvals for the Licensed Product required to manufacture, label, promote, sell and distribute the Licensed Product in the United States, and acknowledges that obtaining FDA Approval for the Licensed Product is a primary corporate priority.

4.2 Milestone Payment. Licensee shall pay Cellegy a milestone payment of ten million dollars (\$10,000,000) in cash no later than thirty (30) days after Cellegy certifies in writing to Licensee that the Licensed Product has all FDA Approvals required to promote, sell and distribute the Licensed Product in the United States.

4.3 Fee Conditions. Each and every payment made under this Article 4 shall be independent, non-refundable and shall not be considered an advance or credit on any royalties or other obligation received or owed.

ARTICLE 5  
ROYALTIES AND PAYMENTS FOR ORDERED GOODS

5.1 Royalties in General. In consideration of the exclusive license granted to Licensee hereunder, Licensee shall pay or cause to be paid to Cellegy the Royalty set forth in this Section 5.

5.2 Royalty Defined. The "Royalty" shall be equal to the following amounts:

- (a) [\*]
- (b) [\*]
- (c) [\*]
- (d) [\*]

5.3 Burdened Costs. In addition to the Royalty set forth above, for so long as Licensee purchases Licensed Product from Cellegy, Licensee will pay Cellegy the Burdened Cost, as set forth pursuant to Exhibit E hereof, which is subject to adjustment at the end of each calendar year to reflect actual costs incurred during such year, as reviewed by the Joint Manufacturing Committee. Such adjustment (if necessary) will be communicated by Cellegy to Licensee during the first calendar quarter of the subsequent year together with a payment representing a refund of an overpayment by Licensee, or an invoice for any shortfall in payments by Licensee. For each order of Licensed Product under Section 7, Licensee will pay Cellegy the Burdened Costs within thirty (30) days

of the receipt of the invoice for such order.

5.4 Minimum Royalty.

(a) [\*]

(b) [\*]

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[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

(c) [\*]

ARTICLE 6  
ROYALTY REPORTS AND ACCOUNTING

6.1 Quarterly Royalty Reports; Records. During the term of this Agreement after the Launch Date of the Licensed Product, Licensee shall furnish or cause to be furnished to Cellegy within a thirty (30) day period from the end of a calendar quarter a written report or reports (the "Royalty Report") covering the preceding calendar quarter (each such quarter being sometimes referred to herein as a "royalty period") showing:

(a) the Net Sales of the Licensed Product in each country of the Territory during the royalty period;

(b) the Royalties, payable in Dollars, which shall have accrued hereunder in respect to such Net Sales; and

(c) the exchange rate used in determining the amount of Dollars.

With respect to sales of Licensed Product invoiced in Dollars, the Net Sales and royalty payable shall be expressed in Dollars. With respect to sales of Licensed Product invoiced in a currency other than Dollars, the Net Sales and royalty payable shall be expressed in the domestic currency of the country where such sale was made together with the Dollar equivalent of the royalty payable, calculated using the exchange rates normally used by Licensee in its management and financial reporting, provided, however, that the exchange rates used by Licensee in preparation of the Royalty Report shall not be materially different from the exchange rates posted in the Wall Street Journal published on the last day of such royalty period. Royalty Reports shall be due on the thirtieth (30th) day following the close of each respective royalty period. Licensee, and its Affiliates and Sublicensees shall keep contemporaneous, legible, verifiable and accurate records in sufficient detail to enable the royalties payable hereunder to be determined and substantiated. A final Royalty Report shall be due upon the expiration or termination of this Agreement. Licensee agrees that it shall pay all Royalties otherwise owed during a particular royalty period hereunder, which are allowable by the law, provided that any restrictions that may be imposed by the government of any applicable country in the Territory regarding the payment of royalties to companies outside of said countries shall not eliminate Licensee's overall obligation to pay Royalties owed, either from Licensee's headquarters or elsewhere.

6.2 Payment Due Dates. Royalties shown to have accrued by each royalty report provided for under Article 6 of this Agreement shall be due and payable on the date such Royalty Report is due. Payment of royalties in whole or in part may be made in advance of such due date. All royalty and other payments due to Cellegy hereunder, shall be made in Dollars, delivered to the account(s) specified by Cellegy from time to time.

6.3 Right to Audit Licensee.

(a) Upon the written request of Cellegy, at Cellegy's expense and not more than twice in each year, Licensee and its Affiliates shall permit an Auditor selected by Cellegy to have access during normal business hours to those records of Licensee and its Affiliates as may be reasonably necessary to verify the accuracy of the Royalty Reports furnished by Licensee hereunder in respect of any year ending not more than one (1) year following the end of any Licensee fiscal year, the calculation of royalties payable in respect of such year shall be binding and conclusive upon Cellegy and Licensee and



[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

its Affiliates shall be released from any liability or accountability with respect to royalties for such fiscal year. Cellegy's Auditors will provide a copy of their audit to Licensee at the time it provides it to Cellegy.

(b) Licensee shall include in each written sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to keep and maintain records of sales made pursuant to such Sublicense and to grant access to such records by Cellegy's Auditor subject to the same terms and conditions as stated in Article 6.3(a) hereof.

(c) [\*]

6.4 Right to Audit Cellegy. Upon the written request of Licensee, at Licensee's expense and not more than twice in each year, Cellegy and its Affiliates shall permit an Auditor selected by Licensee to have access during normal business hours to those records of Cellegy as may be reasonably necessary to verify the accuracy of the Burdened Costs furnished by Cellegy hereunder in respect of any year ending not more than one (1) year following the end of Cellegy's fiscal year, the calculation of Burdened costs payable to respect of such year shall be binding and conclusive upon Licensee, its Affiliates and Cellegy shall be released from any liability or accountability with respect to royalties for such fiscal year. Licensee's auditors will provide a copy of their audit to Cellegy at the time it provides it to Licensee.

6.5 Overpayment or Underpayment of Burdened Costs. [\*]

6.6 Disagreement with Auditor Findings. If either party hereto disagrees with the determination made above by the Auditor and such disagreement over the amount in question is in excess of \$1,000,000, then the party who disagrees with such amount shall (i) provide written notice to the other party within thirty days, (ii) discuss such disagreement with the other party hereto; and (iii) reserve all rights under Section 16.17 (Dispute Resolution) and Article 12 (Term and Termination) hereof.

#### ARTICLE 7 SUPPLY OF LICENSED PRODUCT BY CELLEGY

7.1 Purchasing Commitment. [\*]

(a) [\*]

(b) [\*]

(c) [\*]

(d) [\*]

7.2 Forecasts and Ordering Procedure.

(a) Within sixty (60) days after the Effective Date, Licensee will provide to Cellegy an initial sales forecast for orders of the Licensed Product by Licensee for the following year ("Forecast"). Thereafter, commencing on the first day of the following calendar quarter, and each calendar quarter thereafter during the term of the Purchase Commitment, Licensee will provide a rolling three month update to the Forecast. The Forecasts will be deemed nonbinding estimates.

(b) Purchases and sales of the Licensed Product between Licensee and Cellegy under this Agreement shall be made by means of purchase orders (the "Orders") submitted from time to time by

[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

Licensee to Cellegy, specifying, among other things, the number of units of each Licensed Product ordered under each Order, and the desired date and place of delivery (the "Delivery Date"). The terms and provisions of this Agreement shall govern and control each Order submitted by Licensee to Cellegy, and any different terms or provisions contained in any such Order shall have no force and affect whatsoever.

7.3 Orders. In order to facilitate manufacturing planning requirements:

- (a) [\*]
- (b) [\*]
- (c) [\*]

7.4 Production and Supply of Licensed Product. During the term of this Agreement or thereafter, Cellegy reserves the right after Joint Manufacturing Committee approval, to manufacture, produce, assemble, warehouse or source the Licensed Product at any worldwide location, including locations outside of the United States of America and locations within or outside the Territory. Subject to the remainder of this Agreement, Cellegy will use reasonable commercial efforts to provide an adequate supply of raw materials to the manufacturer of Licensed Product in order to fulfill its obligations under this Agreement and supply the Licensed Product to Licensee in accordance with the Orders. Cellegy agrees to solicit and to allow Licensee's input and advice on manufacturing issues that may arise from time to time in relation to the Licensed Product and will not take any intentional action with regard to the manufacturing of the Licensed Product that will materially disadvantage Licensee's ability to use, promote or sell the Licensed Product.

7.5 Defective Product

(a) If Licensee notifies Cellegy within forty-five (45) days of the receipt of any shipment of the Licensed Product and Licensee believes any of the Licensed Product does not conform to the warranties for the Licensed Product set out in Section 7.9 (the "Defective Product") the parties agree to consult with each other in order to resolve the issue. If a recall is the basis of FDA directives, Cellegy will cooperate fully and expediently to assist Licensee in meeting the objections and concerns of the FDA.

(b) If such consultation does not resolve the discrepancy within a further forty-five (45) days from receipt of the notice, the parties agree to nominate promptly an independent analyst, reasonably acceptable to both parties (the "Independent Analyst"), that will carry out tests on representative samples taken from such shipment, and the results of such tests will be binding on the parties.

(c) If the Independent Analyst determines that the Defective Product does not conform to the warranties set out in Section 7, Cellegy will, at its expense, replace any such Defective Product and reimburse Licensee for the costs of the Independent Analyst.

(d) If the Independent Analyst determines that the Defective Product does conform to the warranties set out in Section 7, Licensee will reimburse Cellegy for the costs of the Independent Analyst.

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(e) Except with respect to Defective Product arising from gross negligence or willful misconduct of Cellegy or its suppliers, with respect to indemnification obligations hereunder, and except with respect to the remedy for failure to supply the Licensed Product as set forth in Section 7.10 hereof, replacement of Defective Product shall be Licensee's sole remedy under this Agreement with respect to Defective Products. For the avoidance of doubt, the parties acknowledge and agree that Defective Product issues contemplated in this Section 7.5 could trigger a Stockout period, subject to the terms set forth in Section 7.10.

7.6 Product Packaging. Licensee agrees to provide Cellegy with all artwork

desired for packaging and labeling of the Licensed Product, and Cellegy agrees to pack and label the Licensed Product in a manner approved by Licensee and pursuant to Licensee's standard export procedure.

7.7 Title and Risk of Loss. All Licensed Product shall be delivered F.O.B. Licensee at a location in the Territory set forth in writing by Licensee. Title to Licensed Products and all risk of loss shall pass from Cellegy to Licensee at the time and place of such delivery by Cellegy to a location in the Territory designated by Licensee. Licensee shall be solely responsible for insuring Licensed Product after such delivery.

7.8 Export Controls. Cellegy's obligation to sell and deliver Licensed Product to Licensee shall be subject in all respects to such laws and regulations of the United States of America and the Territory as shall from time to time govern, respectively, the sale and delivery of goods abroad by persons subject to the jurisdiction of the United States of America and the sale and delivery of goods in the Territory. Subject to the right of the Licensee to export, re-export or transship any of the Licensed Product to another country within the Territory, excluding the actions of any government or military purchaser, Licensee shall not directly or indirectly export, re-export or transship any of the Licensed Product, except as shall be permitted by the laws and regulations of the United States of America and the Territory in effect from time to time. Upon Cellegy's reasonable request, Licensee shall give written assurances against such export, re-export, or transshipment.

#### 7.9 Supply Warranty and Disclaimer.

(a) Cellegy represents and warrants to Licensee that Cellegy will use its best efforts to ensure that the Product supplied under this Agreement will upon delivery and for the duration of shelf life: (1) conform in all respects to the approved product specifications; (2) be manufactured, tested, and (subject to Licensee's contributions under Section 7.5 above) labeled and packaged in accordance with the Laws in the Territory relating to the manufacture, labeling, packaging and testing of the Licensed Product; and (3) will be manufactured in accordance with the Good Manufacturing Practice.

(b) Warranty Limitation; Disclaimer. Except as set forth in Section 7.9(a) above, the sole warranty given by Cellegy regarding any Licensed Product shall be that written limited warranty, if any, which shall accompany such Product or which shall otherwise be designated in writing by Cellegy as applicable to such Licensed Product, as the same may be revised by Cellegy from time to time. After the Launch Date of the Licensed Product, subsequent changes to the limited warranty must be approved by Licensee, which approval shall not be unreasonably withheld. Licensee agrees to provide to its customers within the Territory a written warranty for each Licensed Product on terms which are at least as favorable to such customers as that provided by the applicable limited warranty provided by Cellegy, if any, for such Licensed Product. EXCEPT AS EXPRESSLY SO WARRANTED AND REPRESENTED IN THIS AGREEMENT, CELLEGY HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS, STATUTORY AND IMPLIED, APPLICABLE TO THE LICENSED PRODUCT INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, DESIGN, AND/OR FITNESS FOR A PARTICULAR PURPOSE AND/OR AGAINST INFRINGEMENT OR THE

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LIKE. EXCEPT TO THE EXTENT ARISING FROM CELLEGY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR ANY BREACH OF THIS AGREEMENT, AND EXCEPT WITH RESPECT TO INDEMNIFICATION OBLIGATIONS HEREUNDER, THE WRITTEN LIMITED WARRANTY, IF ANY, APPLICABLE TO ANY PARTICULAR PRODUCT SHALL STATE THE FULL EXTENT OF CELLEGY'S LIABILITY, WHETHER DIRECT OR INDIRECT, SPECIAL OR CONSEQUENTIAL, RESULTING FROM ANY BREACH OF SUCH WARRANTY. EXCEPT AS EXPRESSLY SET FORTH IN ARTICLE 2, CELLEGY FURTHER DISCLAIMS ALL EXPRESS, STATUTORY AND IMPLIED WARRANTIES APPLICABLE TO THE LICENSED PRODUCT, WHICH ARE NOT MANUFACTURED BY CELLEGY, OR BY A LICENSEE OR SUBLICENSEE OF CELLEGY. EXCEPT AS EXPRESSLY SET FORTH IN ARTICLE 2, THE ONLY WARRANTIES APPLICABLE TO LICENSED PRODUCT NOT MANUFACTURED BY CELLEGY OR BY A LICENSEE OR SUBLICENSEE THEREOF SHALL BE THE WARRANTIES, IF ANY, OF THE MANUFACTURERS OF THOSE ITEMS.

(c) EXCEPT FOR SUCH WARRANTIES SET FORTH IN ARTICLE 2, LICENSEE

HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, STATUTORY AND IMPLIED, APPLICABLE TO THE LICENSED PRODUCT INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, DESIGN, FITNESS FOR A PARTICULAR PURPOSE AND/OR AGAINST INFRINGEMENT OR THE LIKE. EXCEPT TO THE EXTENT ARISING FROM LICENSEE'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR ANY BREACH OF THIS AGREEMENT, AND EXCEPT WITH RESPECT TO INDEMNIFICATION OBLIGATIONS HEREUNDER, THE WRITTEN LIMITED WARRANTY, IF ANY, APPLICABLE TO ANY PARTICULAR PRODUCT SHALL STATE THE FULL EXTENT OF LICENSEE'S LIABILITY, WHETHER DIRECT OR INDIRECT, SPECIAL OR CONSEQUENTIAL, RESULTING FROM ANY BREACH OF SUCH WARRANTY.

7.10 Remedy for Failure to Supply Licensed Product.

(a) In the event that Cellegy breaches its obligation to supply the Licensed Product in accordance with Section 7.1 through Section 7.5, and [\*]

(b) For the purposes of this Section 7.10, the following definitions shall apply:

- (i) [\*]
- (ii) [\*]
- (iii) [\*]
- (iv) [\*]
- (v) [\*]

ARTICLE 8  
PATENT RIGHTS

8.1 No Ownership By Licensee. Subject to Section 8.2 below, Licensee shall not be deemed by anything contained in this Agreement or done pursuant to it to acquire any right, title or interest in the Patent Rights or any patent owned by or licensed to Cellegy now or hereafter covering or applicable to any Product, nor in or to any invention or improvement, owned by Cellegy under Section 8.2, now or

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hereafter embodied in any Product, whether or not such invention or improvement is patentable under the laws of any country.

8.2 New Cellegy Inventions/Improvements. [\*]

8.3 Improvements by Licensee. [\*]

8.4 [\*]

ARTICLE 9  
INFRINGEMENT AND OTHER CLAIMS

9.1 Infringement by Third Person. In the event Cellegy or Licensee have reason to believe that a Third Person may be infringing Patent Rights or Proprietary Rights or misappropriating any of the Licensed Products, or infringing, misappropriating or diluting any Licensed Trademark, such party shall promptly notify the other party. Cellegy may, in its discretion, elect to enforce the Licensed Products, Proprietary Rights or Cellegy Trademarks, through legal action or otherwise, and Licensee agrees to reasonably cooperate with Cellegy in such enforcement. At all times in any such enforcement action, Cellegy shall be entitled to retain recovery which may be obtained in any lawsuit brought by Cellegy. In the event Cellegy elects not to enforce the Patent Rights relating to the Licensed Product within one (1) month after notice of the possible infringement is given between Cellegy and Licensee, and Licensee can demonstrate that the potential infringement may result in material lost sales of the Licensed Product within the applicable country, then Licensee may institute a lawsuit or other such actions at its expense to prevent continuation of such potential infringement, and then (1) Licensee may discontinue the payment in such country by 50% during the suit, until such time as the

infringement of the Patent Rights relating to the Licensed Patents ceases, (2) Licensee will retain all award, damages or compensation obtained by Licensee in such suit in full, and (3) Cellegy will provide reasonable cooperation with respect to any lawsuit which Licensee may bring pursuant to this Article.

## 9.2 Alleged Infringement of Third Person Patents.

(a) If a claim or lawsuit is brought against Licensee alleging infringement of any patent or infringement or dilution of any trademark owned by a Third Person arising from Licensee's use, sale, offer for sale, or importing of the Licensed Product or any improved Product or use of Proprietary Rights, Licensee shall provide to Cellegy all information in Licensee's possession regarding such claim or lawsuit. Within a reasonable time after receiving notice of such claim or lawsuit, but in any event within forty five (45) days after receiving such notice, Cellegy shall advise Licensee of Cellegy's decision as to what action it plans to take to dispose of such claim or defend such lawsuit.

(b) Cellegy shall defend, indemnify and hold Licensee harmless against any judgment, damage, liability, loss, cost or other, expense (including reasonable legal fees) resulting from any claim or lawsuit which relates to or arises out of the alleged infringement by Licensee of any patent owned by a Third Person to the extent that the alleged infringement relates to actions covered by the Exclusive License granted to Licensee.

(c) If Cellegy elects not to dispose of such claim or defend such lawsuit, Licensee may defend the claim or lawsuit. For purposes of Licensee's conduct of the disposition or defense, Cellegy shall furnish to Licensee such reasonable assistance as Licensee may need and from time to time reasonable request. If Licensee takes on the disposition of a claim or defense of a lawsuit for which Cellegy is obligated to indemnify Licensee pursuant to this Article, then the payments for such Licensed

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Product in such country, which would otherwise be payable to Cellegy hereunder, shall be reduced by 50% during the pendency of such lawsuit or any appeal taken from it, provided that such reduction shall not occur in the event that, in the opinion of Cellegy's counsel, the defense of such claim is unwarranted. Upon final resolution of the above-described claim, lawsuit and/or appeal, Licensee shall resume paying Cellegy any royalties or license payments payable hereunder, but in no event shall Licensee be liable for back royalties otherwise reduced hereunder during the suit.

(d) If Licensee becomes obligated to pay royalties to any Third Person, in order to make, have made, or sell the Licensed Product in the Territory, said royalties shall be creditable against royalties otherwise payable to Cellegy hereunder; provided, that no such credit shall be allowed with respect to any royalty paid for the use of any technology, method, process, device, or equipment in connection with manufacturing, packaging or any container or delivery system, or the use of any trademark, that was developed by Licensee, any Affiliate of Licensee or any sublicensee, or obtained from a Third Person.

9.3 By Cellegy. Cellegy shall defend, indemnify and hold Licensee harmless against any liability, damage, loss, cost or expense, including reasonable legal fees ("Liability") arising out of or resulting from any Third Person claims or lawsuits made or brought against Licensee, any Affiliate of Licensee or sublicensee, or any of their respective employees, agents, or contractors, to the extent such Liability arises out of or relates to (i) negligence or willful misconduct of Cellegy, or any of this employees, agents or contractors, with regard to clinical trials or testing of the Licensed Product or any Improved Product, the preparation and filing of FDA Applications, the maintenance of NDAs, product labeling, reporting required by the FDA, or any other negligent or wrongful act or omission of Cellegy; (ii) the manufacture, storage, promotion, sale or distribution or use of the Licensed Product, (iii) any claim that Licensee's use of the Licensed Product violated the patent rights of a Third Party in any country of the Territory in which Cellegy has a patent application filed or granted covering the Licensed Product; (iv) a Product Liability Claim based on action or inaction of Cellegy, (iv) Cellegy's breach of, or failure to comply with any representations, warranties, covenants or obligations or this Agreement and (v) any material failure of Cellegy or any of its employees, agents or contractors to comply with any applicable law, rule or regulation.

9.4 By Licensee. Licensee shall defend, indemnify and hold Cellegy harmless against any liability, damage, loss, cost or expense, including reasonable legal fees ("Liability"), arising out of or resulting from: (i) any Third Person claims or lawsuits made or brought against Cellegy, or any of its employees, agents or contractors, to the extent such Liability arises out of or relates to negligence or willful misconduct of Licensee, any Affiliate of Licensee or sublicensee, or any of their respective employees, agents or contractors, with regard to the promotion, labeling, distribution or sale of, the Licensed Product, and Improved Product, or the use of the Proprietary Rights; or (ii) breach of, or failure to perform or comply with, any of its representations, warranties, covenants and obligations under this Agreement, or (iii) any material failure of Licensee or any of its employees, agents or contractors to comply with any applicable law, rule or regulation.

9.5 Conditions to Indemnification. The indemnified party shall: (i) advise the indemnifying party of any claim or lawsuit, in writing promptly, after the indemnified party has received notice of said claim or lawsuit and (ii) assist the indemnifying party and its representatives in the investigation and defense of any claim and/or lawsuit for which indemnification is provided. The agreement of the parties to indemnify each other shall not be valid as to any settlement of a claim or lawsuit or offer of settlement or compromise without the prior written approval of the indemnifying party. Failure of the indemnified party to provide the notice described in (i) shall affect the indemnifying party's obligation to indemnify the indemnified party only to the extent the indemnifying party's rights are prejudiced by such failure.

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9.6 Control of Proceedings. In actions in which one or both of Licensee and Cellegy is named as a defendant, neither party shall assert a crossclaim or third-party claim against the other party for either contribution or indemnity in that action, but each agrees and reserves the right to fully litigate such claims for indemnity and contribution at a later time. Further, neither party will pursue a litigation strategy of affirmatively asserting the fault or liability of the other party as opposed to simply demonstrating the absence of their own fault. Each party will provide its own defense; provided, however, that Cellegy has the right, at any time, subject to the rights and obligations set forth below, to assume the defense of any action against Licensee.

9.7 Indemnification Claim. If, at the conclusion of an action, either party believes it is entitled to contribution or indemnification under the provisions above, such party shall give the other written notice of its claim for contribution or indemnification (the "Indemnification Claim"). The party who receives the Indemnification Claim shall have thirty (30) business days in which to respond. In the event the parties cannot agree on the validity or amount of the Indemnification Claim, then the parties shall submit their dispute to confidential mediation, in accordance with Section 16.17. Neither party may assert the statute of limitations as a defense to the claim for contribution or indemnification unless the limitations period had already expired and would have barred the underlying action against that party at the time the underlying action was filed.

9.8 Assumption of Defense by Cellegy. In the event Cellegy exercises its right to assume the defense of an action against Licensee, Cellegy shall have the exclusive right to control the defense (including all decisions relating to litigation, defense and appeal) of any Claim related to Licensee as described by Section 9.6. In such instances the Licensee shall have the right to retain its own counsel at its sole cost and expense and participate in such defense. With respect to settlement, Cellegy shall obtain Licensee's consent to any settlement of a Claim, related to Licensee as described in Section 9.6, prior to settlement of such claim, which consent shall not be unreasonably withheld. If Cellegy requests Licensee's cooperation, Licensee shall reasonably cooperate with Cellegy in its defense of the Claim, related to Licensee as described in Section 9.6 (including, without limitation, making documents and records available for review and copying and making persons within its control available for interview, trial preparation assistance and testimony) and Cellegy shall be responsible for all costs and expenses associated with Licensee's cooperation.

10.1 Treatment of Confidential Information. Except as otherwise provided in this Article 10, during the term of this Agreement and for a period of three (3) years thereafter, Licensee and its Affiliates will retain in confidence and use only for purposes of this Agreement any information, data, and materials supplied by Cellegy or on behalf of Cellegy to Licensee and its Affiliates under this Agreement, and Cellegy will retain in confidence and use only for purposes of this Agreement any information, data, and materials supplied by Licensee or on behalf of Licensee to Cellegy under this Agreement. For purposes of this Agreement, all such information and data which a party is obligated to retain in confidence shall be called "Confidential Information." For the avoidance of doubt, Cellegy Information shall constitute Confidential Information of Cellegy.

10.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, Licensee may disclose Confidential Information to its Affiliates, Sublicensees, consultants, outside contractors, clinical investigators or other Third Parties on condition that such entities or persons agree in writing (a) to keep the Confidential Information confidential for the same time periods and to the same extent as Licensee is required to keep the Confidential Information confidential and (b) to

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use the Confidential Information only for such purposes as Licensee is entitled to use the Confidential Information. Each party or its Affiliates or Sublicensees may disclose such Confidential Information to government or other regulatory authorities to the extent that such disclosure (i) is reasonably necessary to obtain Approvals; or (ii) is otherwise legally required.

10.3 Release From Restrictions. The foregoing obligations in respect of disclosure and use of Confidential Information shall not apply to any part of such Confidential Information that the non-disclosing party, or its Affiliates (all collectively referred to as the "Receiving Party") can demonstrate by contemporaneously prepared written evidence:

(a) is or becomes part of the public domain other than by acts of the Receiving Party in contravention of this Agreement;

(b) is disclosed to the Receiving Party or its Affiliates or Sublicensees by a Third Party, provided such Confidential Information was not obtained by such Third Party directly or indirectly from the other party under this Agreement;

(c) prior to disclosure under this Agreement, was already in the possession of the Receiving Party or its Affiliates or Sublicensees, provided such Confidential Information was not obtained, directly or indirectly, from the other party under this Agreement; or

(d) results from research and development by persons who have not had access to the disclosures made to Receiving Party under this Agreement, including any information obtained through the testing, manufacturing regulatory approval, or distribution of the Licensed Product, or other activities undertaken in connection with this Agreement by the Receiving Party.

10.4 Confidentiality of Agreement. Except as otherwise required by law or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat as confidential the terms, conditions and existence of this Agreement, except that Cellegy and Licensee may disclose such terms and conditions and the existence of this Agreement to its Affiliates and Sublicensees, and that Cellegy and Licensee may disclose the terms to its shareholders to the extent required by the federal securities laws, and provided, that Cellegy shall seek confidential treatment of the key business terms contained in this Agreement, including but not limited to all payments owed hereunder. Upon the execution of this Agreement, the parties shall draft a joint press release, the text of such shall be mutually agreeable to each party, announcing the execution of the Agreement.

10.5 Return of Confidential Information. Upon termination of this Agreement with respect to the entire Territory, the parties hereto shall return to the respective party all of such parties confidential information in their respective possession along with a certification that such party no longer

possesses any such Confidential Information of such other party.

ARTICLE 11  
TRADEMARKS

11.1 Cellegy's Marks. Cellegy owns or has the right to use certain Trademarks, and certain of the Trademarks may be registered in the jurisdiction(s) which comprise the Territory.

11.2 Use of Cellegy's Marks by Licensee. Licensee will have the exclusive right to use the Trademark in the Territory in connection with the promotion, marketing, sale and distribution of Licensed Product. Licensee shall

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not use The Trademark only in the form and manner prescribed by Cellegy and shall further have the right to use a different trademark on the Licensed Product, provided, that Licensee shall not use the Trademark in conjunction with a different trademark in accordance with Section 11.8 hereof. In no event shall Licensee use any of the Trademark or any similar mark or term as part of its business name. In the event that Licensee does not desire to use the Trademark, Licensee will notify Cellegy within twelve (12) months after the Effective Date, and Cellegy shall have the right to terminate the license to the Trademark in its entirety. A termination of the Licensee to the Trademark shall not be deemed to terminate the License to the Licensed Product granted in Section 3 hereof.

11.3 Acknowledgment of Ownership. Licensee acknowledges that

(a) Cellegy owns the Trademark and all goodwill associated with or symbolized by the Trademark;

(b) Licensee has no ownership right in or to any of the Trademark;  
and

(c) Licensee shall acquire no ownership interest in or to any of the Trademark by virtue of this Agreement. Licensee shall do nothing inconsistent with Cellegy's ownership of the Trademark and related goodwill and agrees that all use of the Trademark by Licensee shall inure to the benefit of Cellegy. Nothing in this Agreement shall be deemed to constitute or result in an assignment of any of the Trademark to Licensee or the creation of any equitable or other interests therein. Licensee shall not use any of the Trademark in any manner as a part of its business, corporate or trade name.

11.4 Marking. Licensee shall mark all advertising, promotional or other materials created by it and bearing any of the Trademark (the "Licensee Material") with such notices as Cellegy may require, including, but not limited to, notices that the Trademark are trademarks of Cellegy and are being used with the permission of Cellegy.

11.5 Registration. Cellegy shall have the sole right to take such action as it deems appropriate to obtain trademark registration in the Territory for the Trademark. If it shall be necessary for Licensee to be the applicant to effect any such registrations, Licensee shall cooperate with Cellegy to effect any such registrations, and hereby does assign all of its right, title and interest in and to each such application, and any resulting registration, to Cellegy, and shall execute all papers and documents necessary to effectuate or confirm any such assignment. Licensee shall perform all reasonable and necessary acts and execute all necessary documents to affect the registration of the Trademark as Cellegy may request, all at Cellegy's sole expense. Licensee shall not obtain or attempt to obtain in the Territory, or elsewhere, any right, title or interest, registration, or otherwise, in or to the Trademark, or any of them. In the event that any such right, title or interest should be obtained by Licensee in contravention hereof, Licensee shall hold the same on behalf of Cellegy and shall transfer the same to Cellegy upon request and without expense to Cellegy.

11.6 Infringement Information. Licensee shall notify Cellegy promptly of any unauthorized use of the Trademark or of any mark confusingly similar, thereto which comes to its attention. Cellegy shall have the sole right to determine whether or not any action shall be taken against any such infringement, and Licensee shall not institute any suit or take any action on account of any such infringement or imitation without first obtaining the



written consent of Cellegy to do so.

11.7 Termination of Use. Upon expiration or earlier termination of this Agreement, Licensee shall cease using the Trademark in any manner, either similar or dissimilar to the use enumerated above.

11.8 Trademarks. Licensee covenants and warrants that Licensee's use of the Trademark or other trademarks, trade names, logos and designations of Cellegy on any and all Licensed Product,

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Licensed Product packaging or labels, stationery, invoices, catalogs, brochures, packages, containers, and advertising or promotional materials which Licensee or its Agents prepare or use will be in accordance with Cellegy's intellectual property policies in effect from time to time, including but not limited to trademark usage and cooperative advertising policies. Cellegy agrees to provide copies of such policies to Licensee. Licensee agrees not to attach any additional trademarks, trade names, logos or designations to any Licensed Product except in compliance with such policies or otherwise with Cellegy's prior written consent which will not be unreasonably withheld or delayed.. Licensee further agrees not to use any Cellegy trademark, trade name, logo or designation in connection with any products other than the Licensed Product. Licensee will include on each Licensed Product that it distributes, and on all containers and storage media therefor, all trademark, copyright and other notices of proprietary rights included by Cellegy on such Licensed Product. Licensee agrees not to alter, erase, deface or overprint any such notice on anything provided by Cellegy. Licensee also will include the appropriate trademark notices when referring to any Licensed Product in advertising and promotional materials. Licensee shall submit to Cellegy for its prior written approval and before any use is made thereof, representative samples of the initial Licensed Product, stationery, invoices, catalogs, brochures, packages, containers, and advertising or promotional materials bearing any of the Trademark which Licensee or its Sublicensees prepare, but need not seek prior approval for subsequent uses of such materials that are in compliance with Cellegy's policies. Licensee shall also submit to Cellegy for its prior written approval any such materials that may not be consistent with Cellegy's intellectual property policies in effect from time to time, and Cellegy shall use all reasonable efforts to respond promptly to give its approval or indicate the respects in which changes are required in light of Cellegy's policies.

ARTICLE 12  
TERM; TERMINATION

12.1 Term. Unless terminated sooner pursuant to Articles 12.2, 12.3 or 12.4 below, this Agreement shall become effective as of the Effective Date and shall continue in full force and effect in each country until the later of (a) the date of expiration of the last to expire of the Patent Rights in such country, on a country-by-country basis, or (b) the end of the commercial life of the Licensed Product, as determined by Licensee, country by country, with one (1) year written notice from Licensee to Cellegy for each country. For countries in which none of the Patent Rights are filed, the date set forth in subitem (a) above shall be deemed to be the date of the last to expire of the Patent Rights in the last applicable country. Such termination may be made with respect to one or more regions of the Territory without effecting the rest of this Agreement or the Exclusive License granted hereunder in any other region of the Territory.

12.2 Bilateral Termination Rights. Either party may terminate this Agreement upon the occurrence of any of the following:

(a) The other party becomes the subject of a voluntary bankruptcy or insolvency case;

(b) The other party becomes the subject of an involuntary bankruptcy or insolvency case that is not dismissed within 60 days; or

(c) Upon or after the material breach of any provision of this Agreement by the other party (other than an actual or claimed breach of 3.7(a) by Licensee, which shall instead be governed by the provisions of Section 3.7(b) hereof) if such material breach is not cured within ninety (90) days after written notice thereof to the party in default.

### 12.3 Bankruptcy Rights.

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(a) If Licensee terminates this Agreement based on Article 12.2(a), the License rights will remain intact pursuant to Section 365(n) of the US Bankruptcy Code.

(b) If Cellegy plans to seek bankruptcy or reorganization relief, Cellegy will notify Licensee of such intent prior to filing, and Cellegy at its option may offer to Licensee all rights to the Licensed Product at the fair market value of the Licensed Product to Cellegy.

(c) If Licensee plans to seek bankruptcy or reorganization relief, Licensee will notify Cellegy of such intent prior to filing, and Licensee at its option may offer to Cellegy those assets and personnel relating to the performance of this Agreement at the fair market value of such assets to Licensee.

12.4 Rights Upon Termination or Expiration. Upon expiration or termination of this Agreement, the rights and obligations of the parties shall cease, including without limitation all licenses, except as follows:

(a) Upon expiration or termination for any reason, the obligations of confidentiality and use of Confidential Information under Article 10 shall survive for the period provided therein;

(b) Upon expiration or termination for any reason, Articles 9 and 12 of this Agreement shall survive for the maximum duration permitted by law;

(c) Articles 4, 5, 6.1 6.2 and 7.10 shall survive until all outstanding payment obligations and reporting obligations of Licensee and its Affiliates and Sublicensees have been fulfilled, and Article 6.3 shall survive for three years following the year in which such termination or expiration became effective; and

(d) Expiration or termination of this Agreement shall not relieve the parties of any other obligation accruing prior to such termination.

(e) To the extent that the then-current inventory was purchased by Licensee from Cellegy under Article 7 hereof, Cellegy shall have the right to repurchase all then-current inventory of the Licensed Product then in Licensee's possession, at the Burdened Cost originally paid by Licensee for such inventory.

### ARTICLE 13 REGULATORY MATTERS

13.1. Licensee's Obligations. Licensee shall be responsible to, and shall use all reasonable commercial efforts to do the following:

(a) Upon Approval of the Licensed Product, Licensee, at its own cost, will comply with any and all applicable statutory, administrative or regulatory requirements of the Territory or any governmental or political subdivisions thereof (collectively, "Laws") in relation to the importation, storage, resale, promotion or distribution of the Licensed Product in the Territory under this Agreement, including, without limitation, Licensed Product documentation such as Licensed Product tracking, samples, Licensed Product complaints, adverse event reporting requirements, post-marketing surveillance activities, and documentation of recalls, which documentation shall be maintained by the Licensee for the period required by the Relevant Regulatory Authorities in the Territory notwithstanding termination or

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expiration of this Agreement, any Licensed Product registrations with any government agency or health authority, or any registration, approvals, or filing of this Agreement.

(b) Upon Approval of the Product, Licensee shall inform Cellegy on

at least a semi-annual basis about the progress of such registration work, and will provide Cellegy with a copy of all presentations and documents submitted by Licensee to any regulatory authority with respect to the Licensed Product.

(c) As between the parties, Cellegy shall be responsible for regulatory costs relating to Approval in the United States, and for those mutually agreed clinical costs necessary for Approvals in the Territory, and Licensee will be responsible for regulatory costs relating to Approvals in Canada and Mexico, and for conducting and bearing the costs of all post-Approval regulatory monitoring and reporting in the Territory.

#### 13.2. Cellegy's Obligations. Cellegy shall:

(a) use its commercially reasonable efforts to expeditiously obtain FDA Approval necessary for the sale of the Licensed Product within the United States, including without limitation, any additional clinical trials, studies or data in addition to the Cellegy Information that may be required in order to obtain Approvals for Licensed Product in the United States at Cellegy's sole expense; Cellegy shall provide Licensee with all information regarding the obtainment of such Approval and shall seek Licensee's input prior to taking any actions for seeking the Approval with the Relevant Regulatory Authorities;

(b) provide to Licensee within one (1) month from the date of execution of this Agreement a then-current and complete copy of the Cellegy Information;

(c) not intentionally withhold any information in its possession regarding the Licensed Product;

(d) at its cost, promptly provide a sufficient quantity of the Licensed Product reasonably necessary for Cellegy to prepare and submit the application, and the grant, maintenance, variation or renewal of Approvals;

(e) use reasonable commercial endeavors to procure raw materials to meet the demands of the Relevant Regulatory Authority relating to any application and any grant, maintenance, variation or renewal of Approvals; and

(f) at the request of Licensee, at Cellegy's expense supply all customary documentation (e.g., free sale certification, certification of analysis, etc.) that is normally necessary to gain an import pharmaceutical product license in the Territory.

(g) assist Licensee in the preparation and execution of any post-Approval trials in the United States that Licensee reasonably deems appropriate for the Licensed Product. All costs associated with the post-Approval trials will be borne by Licensee.

#### 13.3. Adverse Drug Events and Recalls.

(a) The parties will comply with the adverse drug event reporting guidelines as set out in Exhibit A or modified from time to time in accordance with that Exhibit.

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(b) Subject to Licensee's right to initiate a Licensed Product recall pursuant to subparagraph (c) below, Licensee will notify Cellegy of any product recalls on any quantity of Licensed Product at any time, and Licensee will administer any such recall in the Territory.

(c) If the Relevant Regulatory Authority requires or otherwise initiates a recall of the Licensed Product for any reason whatsoever, Licensee will immediately administer the recall.

(d) The parties may submit a sample of the Licensed Product to an Independent Analyst for a report. The cost of the report of the Independent Analyst will be paid by the party against which the report is unfavorable.

If an Independent Analyst finds that the sole reason for the recall of the Licensed Product is the action or inaction of Cellegy, then Cellegy will be liable for the cost of the recall and will reimburse Licensee for all reasonable costs and expenses of such recall and will provide replacement quantities of

Licensed Product, free of charge. If an Independent Analyst finds that the sole reason for the recall of the Licensed Product is the action or inaction of Licensee, then Licensee will be liable for all such costs and expenses and will reimburse Cellegy for all reasonable costs and expenses (and the cost of any replacement quantities of Licensed Product) incurred by Cellegy in connection with such recall. If an Independent Analyst finds that the action or inaction of both Cellegy and Licensee were reasons for the recall, then Cellegy and Licensee will each be responsible for one-half of such costs of the recall unless the report of the Independent Analyst allocates responsibility in a different proportion.

#### 13.4 Approvals

(a) All Approvals by any governmental agency or health authority which are necessary to sell the Licensed Product within the Territory shall be issued to, and held in the name of Licensee for the benefit of Cellegy; provided, however, that all such Approvals shall constitute the sole property of Cellegy.

(b) Cellegy shall promptly provide to Licensee, upon Licensee's request, such evidence that Licensee shall require, confirming that all Approvals necessary to import and sell the Licensed Product in the Territory have been obtained. If such evidence is not received by Licensee within thirty (30) days of the request, Licensee shall be entitled to not take shipment of the Licensed Product until such evidence is received.

(c) Cellegy hereby acknowledges that, except as may otherwise be required by law, Licensee has no obligation to verify the Cellegy Information.

13.5. Cellegy Information Warranties. Cellegy represents and warrants to Licensee that:

(a) to its knowledge, the Cellegy Information supplied to Licensee under this Agreement in relation to the Licensed Product will be true and that it will be legally entitled to supply this information to Licensee;

(b) it will use all reasonable commercial efforts to ensure that Cellegy will not alter the Cellegy Information supplied to Licensee or the materials or processes described in that information in relation to the Licensed Product without the prior written notification to and approval of Licensee; and

(c) it will use all reasonable commercial efforts to ensure that in no event will Cellegy implement any alteration to the Cellegy Information or the materials or processes described in the Cellegy Information in relation to any of the Licensed Product supplied to Licensee under this

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[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

Agreement until the Relevant Regulatory Authority in the Territory has approved all requisite amendments to the applicable Approvals.

13.6 Insurance. To the extent commercially available, both parties shall maintain in full force and effect for the term of this Agreement and for five (5) years thereafter product liability insurance and property damage insurance on its operations naming the other party as an additional insured, with terms reasonably satisfactory to the other party, and shall make a copy of such policy available to the other party upon request. The amount and extent of coverage of the insurance required hereunder, if any, shall be not less than a single limit liability of not less than U.S. \$5 million in one claim and in the aggregate, and each party shall furnish to the other party copies of policies of insurance or certificates evidencing the existence and amounts of such insurance within thirty (30) days of the other party's request for such copies. Each party shall provide the other party with written notice of any cancellation of any insurance hereunder at least thirty (30) days prior to such cancellation.

#### ARTICLE 14 REGISTRATION OF LICENSE; LIMITATION OF LIABILITY

14.1 Licensee may, at its expense, register the exclusive license granted

under this Agreement in any country of the Territory where the government of such country would require one for use, sale or distribution of the Licensed Product in such country and Cellegy shall reasonably cooperate in such registration at Licensee's expense. Upon request by Licensee, Cellegy agrees promptly to execute any "short form" licenses developed in a form reasonably acceptable to Cellegy and submitted to it by Licensee from time to time in order to affect the foregoing registration in such country.

14.2 NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

ARTICLE 15  
[\*]

ARTICLE 16  
GENERAL PROVISIONS

16.1 Force Majeure. Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, other than an obligation to make payments hereunder, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, acts of God or any other cause beyond the reasonable control of the affected party to anticipate, prevent, avoid or mitigate (a "Force Majeure Event"); provided, however, that any failure or delay in fulfilling a term of this Agreement shall not be considered a result of a Force Majeure Event if it arises from a failure of Licensee or Cellegy to comply with applicable laws and regulations.

16.2 Further Assurances. Each party hereto agrees to perform such acts, execute such further instruments, documents or certificates, and provide such cooperation in proceedings and actions as may be reasonably requested by the other party in order to carry out the intent and purpose of this Agreement, including without limitation the registration or recordation of the rights granted hereunder.

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16.3 Severability. Both parties hereby expressly acknowledge and agree that it is the intention of neither party to violate any public policy, statutory or common law, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries and specifically agree that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the parties hereto in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, then in such event such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the parties hereto.

16.4 Notices. Any notice required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or if mailed by registered or certified mail (return receipt requested) postage prepaid, or by a nationally recognized overnight courier, or by facsimile (and promptly confirmed by registered, certified mail or overnight courier), to the addresses given below or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. Any notice sent by registered, certified mail or overnight courier as aforesaid shall be deemed to have been given when mailed.

In the case of Cellegy:  
Cellegy Pharmaceuticals, Inc.  
349 Oyster Point Boulevard  
San Francisco, California 94080  
Attention: John Chandler  
Telephone No.: (650) 616-2200  
Facsimile No.: (650) 616-2222

With a required copy to:  
Fenwick & West LLP  
815 Connecticut Avenue, Suite 200  
Washington, DC 20006  
Attention: Kevin Kelso, Esq.  
Telephone No.: (202) 261-0405  
Facsimile No.: (202) 463-6520

In the case of Licensee:

PDI, Inc.  
10 Mountainview Road, Suite C-200  
  
Upper Saddle River, NJ 07458  
Attention: Charles T. Saldarini  
  
Telephone No.: (201) 258-8456  
Facsimile No.: (201) 258-8445

With a required copy to:

PDI, Inc.  
10 Mountainview Road, Suite C-200  
Upper Saddle River, NJ 07458  
Attention: Beth R. Jacobson  
Telephone No.: (201) 574-8383  
Facsimile No.: (201) 258-8445

16.5 Assignment. This Agreement may not be assigned or otherwise transferred by either party without the written consent of the other party; provided, however, that either party may, without such consent, assign this Agreement in connection with the transfer or sale of all or substantially all of its business related to this Agreement or in the event of the merger or consolidation of such party with another corporation, or in the case of Licensee, in the event of a sale by Licensee of all or substantially all of its business; and further provided that Cellegy may assign, transfer or pledge its rights to receive any payments due Cellegy hereunder without Licensee's consent; provided, however, that Licensee's consent shall be required for any payments due to Cellegy under this Agreement that are to be divided among separate entities. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

16.6 Amendment. The parties hereto may amend, modify or alter any of the provisions of this Agreement, but only by a written instrument duly executed by both parties hereto.

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16.7 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement.

16.8 Waiver. The failure of a party to enforce at any time for any period any of the provisions hereof shall not be construed as a waiver of such provisions or of the rights of such party thereafter to enforce each such provisions.

16.9 No Implied Licenses. Except as expressly and specifically provided under this Agreement, the parties agree that neither party is granted any implied rights to or under any of the other party's current or future patents, trade secrets, copyrights, moral rights, trade or service marks, trade dress, or any other intellectual property rights.

16.10 Injunctions. The parties agree that any breach or threatened breach by one party of the confidentiality provisions contained in this Agreement will cause substantial harm to the other party that cannot be remedied by monetary damages, and therefore each party agrees that either party shall have the right to obtain equitable remedies, without bond, including injunctions and repossession of Confidential Information, to abate actual or threatened breaches of this Agreement.

16.11 Independent Contractors. The parties agree that the relationship of Cellegy and Licensee established by this Agreement is that of independent licensee and licensor. Furthermore, the parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other party, or otherwise act as an agent for the other party for any purpose.

16.12 No Third Party Beneficiaries. All rights, benefits and remedies under this Agreement are solely intended for the benefit of Cellegy and Licensee, and no Third Party shall have any rights whatsoever to (i) enforce any obligation contained in this Agreement (ii) seek a benefit or remedy for any breach of this Agreement, or (iii) take any other action relating to this

Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the parties.

16.13 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, exclusive of its choice-of-law rules, except that questions affecting the construction and effect of any patent shall be determined by the laws of the country in which such patent has been granted.

16.14 Headings. The Article and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

16.15 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same document.

16.16 Publicity. The parties agree that subsequent to the execution of this Agreement, a press release approved by both parties will be issued. Except for such press releases and for periodic disclosures required by law or regulation or in the ordinary course of its SEC filings, neither party shall (i) originate any publicity, news release or other public announcement, written or oral, whether to the public

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press, stockholders or otherwise, relating to this Agreement, any amendment hereto or performance hereunder, or (ii) use the name of the other in any publicity, news release or other public announcement, except (a) with the prior written consent of the other party, or (b) as required by law, in which case the originating party will give to the other party at least two (2) days prior notice of such proposed disclosure to complete a review in order to offer comments and modifications. Consistent with applicable law, the other party will have the right to request reasonable changes to the disclosure to protect its interests. In all other cases, the originating party shall give the consenting party at least two (2) days to complete a review in order to offer comments, modifications or to give such consent. The party required to give consent shall respond in less than two (2) days if practicable

#### 16.17 Dispute Resolution; Venue

(a) Mediation. If a controversy or claim arising out of or relating to this Agreement (hereinafter "Controversy") cannot be resolved through negotiations, Cellegy and Licensee agree to try in good faith to settle the Controversy through mediation before resorting to litigations.

(1) Either Party may invoke mediation at any time during negotiations by notifying the other party in writing (the "Mediation Notice") that it wishes to appoint a mediator. If the Parties cannot agree on a mediator within 30 days of the receipt of the Mediation Notice (or such longer time as may be mutually agreed), the Parties agree to submit the Controversy to the American Arbitration Association (hereinafter "AAA") for mediation under its Commercial Mediation Rules, to the extent that those rules are not inconsistent with this Section.

(2) Mediation shall be conducted within 30 days of the agreement of the mediator to conduct the mediation, or such longer time as may be agreed by the parties. It shall be conducted in Chicago, Illinois at such location as may be mutually agreeable to the Parties and shall continue for no longer than two consecutive business days, ending by 5 pm of the second day.

(3) The parties agree that each will be represented at each mediation session by a person with full authority to settle the Controversy.

(4) All fees and expenses of the mediation shall be borne by the parties equally. However, each party shall bear the expense of its own counsel, representatives, preparation and attendance.

(5) Neither party may commence litigation until the parties have conducted and ended mediation. In the event that the provisions of this

subsection (b) would result in an otherwise timely claim being barred by an applicable statute of limitations, then the parties agree to toll the application of the statute of limitations for a period equal to the delay caused by the mediation.

(6) In the event that a controversy cannot be resolved through mediation, each Party shall thereafter have the right to pursue any and all remedies available at law or in equity.

(b) Venue. Any court proceeding instituted by one party against the other with respect to this Agreement may be commenced in the federal courts residing in the Southern District of New York or in the Northern District of California.

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[Signature Page to Exclusive License Agreement]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

PDI, INC.

CELLEGY PHARMACEUTICALS, INC.

By: \_\_\_\_\_

By: \_\_\_\_\_

EXHIBIT A  
REPORTING OF ADVERSE DRUG EVENTS FOR THE PRODUCT

1. This Schedule describes the manner in which each of Cellegy and Licensee will meet their legal obligations of reporting adverse drug events connected with the product to each other.

2. DEFINITIONS

In this document the following terms have the meanings set out below:

"Adverse Drug Event" is any untoward medical occurrence in a patient or clinical investigation subject administered with a pharmaceutical product. This includes any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

"Minimum Criteria" means the minimum criteria for an Adverse Drug Event report and must include the following:

- (a) name of the drug;
- (b) a description of the adverse drug event;
- (c) patient identifiers (any one or more of name, initials or clinical investigation number, age, sex or weight); and
- (d) an identifiable source of the report;

"Non-serious Adverse Drug Event" is any Adverse Drug Event other than a Serious Adverse Drug Event;

"Serious Adverse Drug Event" is any Adverse Drug Event that satisfies one or more of the following criteria:

- (a) fatal; or
- (b) life-threatening; or
- (c) causing disability or incapacity; or
- (d) causing or prolonging hospitalization; or



(e) congenital anomaly or cancer; or

(f) requiring medical intervention to prevent permanent impairment or damage;

"Spontaneous reports" are reports from any non-clinical trial source, including regulatory agencies, consumers and literature;

"Unexpected Adverse Drug Event" is any Adverse Drug Event, the nature or severity of which is not consistent with the applicable product information.

### 3. COMMENCEMENT OF REPORTING TIME PERIOD

In this Schedule, where a time is specified within which any report is to be forwarded by either party to the other party, that period of time will commence when anyone representing the reporting party first learns of enough information to satisfy the Minimum Criteria.

### 4. REGULATORY REPORTING

#### 4.1 Licensee will:

(a) be responsible for all reporting under this Schedule to the relevant regulatory authority in the Territory including reporting, where applicable, of any international case reports forwarded by Cellegy;

(b) send to Cellegy a copy of all mail exchanges with the relevant regulatory authority in the Territory; and

(c) give Cellegy timely notice of any meetings or discussions with the relevant regulatory authority in the Territory concerning the safety of any of the Licensed Products.

#### 4.2 Cellegy will:

(a) be responsible for all reporting to other regulatory authorities and the other licensees/distributors outside the Territory;

(b) notify Licensee of any action taken by any regulatory authority concerning the safety of any of the Licensed Products within one (1) working day (references in this Schedule to working days refer to U.S. calendar days, other than a Saturday or Sunday, on which Citibank's San Francisco, California, offices are open for commercial banking business during normal banking hours) of that action being taken and will provide Licensee with complete information concerning that action;

(c) provide to Licensee an EU PSUR on an annual basis for three years following all relevant Approvals (four quarterly or two six-monthly reports are acceptable as an annual report). Thereafter provide to Licensee a half yearly summary of all spontaneous reports in relation to the Licensed Products; and

### 5. SPONTANEOUS SERIOUS or UNEXPECTED ADVERSE DRUG EVENTS

5.1 Licensee will forward to Cellegy any spontaneous Serious or Unexpected Adverse Drug Event report within 72 hours of receipt of these by Licensee on A CIOMS 1 form.

5.2 All reports from Licensee on Adverse Drug Events shall be addressed to Cellegy as follows:

Cellegy Pharmaceuticals, Inc.  
349 Oyster Point Boulevard  
San Francisco, California 94080  
Telephone No.: (650) 616-2200  
Facsimile No.: (650) 616-2222

5.3 Cellegy will acknowledge receipt of any such report within 5 working days of that receipt.

### 6. SPONTANEOUS NON-SERIOUS ADVERSE DRUG EVENT REPORT

6.1 Licensee will forward to Cellegy any spontaneous Non-serious Adverse

Drug Event reports on a CIOMS 1 form on a monthly basis.

6.2 All reports from Licensee on Adverse Drug Events shall be addressed to Cellegy as follows:

Cellegy Pharmaceuticals, Inc.  
349 Oyster Point Boulevard  
San Francisco, California 94080  
Telephone No.: (650) 616-2200  
Facsimile No.: (650) 616-2222

6.3 Cellegy will acknowledge receipt of any such report within 5 working days of that receipt.

#### 7. ARCHIVING OF REPORTS

7.1 Licensee will maintain all reports in accordance with any regulatory requirements in Territory.

7.2 Notwithstanding clause 7.1, Licensee will maintain a record of each report for at least 5 years from Licensee's receipt or creation of each report and such maintenance will include:

(a) a copy (hard copy or electronically available copy) of the report;

(b) the date of the initial receipt or creation of the report by Licensee; and

(c) for Serious or Unexpected Adverse Drug Event reports, the date the report was forwarded to and received by Cellegy.

#### 8. CLINICAL TRIAL REPORTS

8.1 Licensee will forward to Cellegy any Serious or Unexpected Adverse Drug Event report that is considered to be drug related and occurs during clinical trials within 72 hours of receipt of such report by Licensee.

8.2 Any Serious Adverse Drug Event report based upon clinical trials forwarded to Cellegy according to clause 8.1 will:

(a) be reported on the Serious Adverse Event form from the case report form;

(b) include an assessment of causality by the investigator with an indication on the case report form; and

(c) if blinded studies are carried out, a disclosure of the randomization code by a person not directly involved in the study if it is ongoing, in order to permit entry of that data into a central database.

8.3 Licensee will forward to Cellegy any Non-serious Adverse Drug Event report from clinical trials as part of the end of study reports, provided however, that at least the safety sections of the end of study reports will be forwarded to Cellegy within 30 days of completion of the end of study reports.

8.4 All reports from Licensee on Adverse Drug Events from clinical trials shall be addressed to Cellegy as follows:

Cellegy Pharmaceuticals, Inc.  
349 Oyster Point Boulevard  
San Francisco, California 94080  
Telephone No.: (650) 616-2200  
Facsimile No.: (650) 616-2222

8.5 Cellegy will acknowledge receipt of any such report within 5 days of that receipt.

#### 9. VARIATION OF THIS SCHEDULE

9.1 This Schedule may be amended by mutual consent of the parties as

evidenced in writing and the amended Schedule will then prevail as the Schedule to the Agreement.

[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

EXHIBIT B  
MINIMUM SALES REQUIREMENTS  
[\*]

EXHIBIT C  
PATENT RIGHTS FOR LICENSED PRODUCT

- A. U.S. Patent Number 6,319,913 B1 entitled "Penetration Enhancing and Irritation Reducing Systems" issued November 20, 2001
- B. U.S. Patent Application Number 09/963,287 (U.S. Publication Number US 2002/0058650 A1), a continuation of US 6,319,913 B1, entitled "Penetration Enhancing and Irritation Reducing Systems"
- C. Canadian Patent Application Number 2,309,688 entitled "Penetration Enhancing and Irritation Reducing System" (National Phase of PCT Application Number PCT/US98/23750, Publication Number WO 99/24041)
- D. Mexican Patent Application Number 4513 (National Phase of PCT Application Number PCT/US98/23750, Publication Number WO 99/24041)
- E. U.S. Patent Application (number not yet assigned) entitled "Semisolid Topical Hormonal Compositions and Methods for Treatment", filed October 4, 2002, claiming priority to U.S. Provisional Application Number 60/327,423, filed October 4, 2001
- F. PCT Application Number PCT/US02/31997 (not yet published) entitled "Semisolid Topical Hormonal Compositions and Methods for Treatment", designated states include Canada and Mexico
- G. U.S. Patent Application Number 10/197,627 entitled "Taper Well Meter Dose Pump"
- H. PCT Application yet to be filed corresponding to U.S. Application Number 10/197,627, filing deadline June 4, 2003

EXHIBIT D  
OTHER TESTOSTERONE PRODUCTS OWNED BY CELLEGY

Tostrelle(R) testosterone gel

[\*] designates portions of this document that have been omitted pursuant to a request for confidential treatment filed separately with the Commission.

EXHIBIT E  
BURDENED COST

"Burdened Cost" means [\*]

Cellegy's estimated Burdened Cost for 2003 is as follows: [\*]

EXHIBIT F  
TRADEMARKS

Tostrex(TM)

- A. US: Filed, second request; Application Number 75/866,691, class IN 5
- B. Canada: Filed, pending; Application Number 1128610, class IN

C. Mexico: Registered, Registration Number 737847 issued 2/28/02, class IN 5

Subsidiaries of Cellegy Pharmaceuticals, Inc.

Cellegy Australia Pty Ltd  
Australia

Cellegy Canada Inc.  
Canada

Cellegy International Holdings Pty Ltd  
Bermuda

Cellegy UK Limited  
Europe

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-06065, 333-32301, 333-60343, 333-42840 and 333-91588) pertaining to the 1992 Stock Option Plan, the 1995 Equity Incentive Plan, and the 1995 Directors' Stock Option Plan, and the Registration Statements (Form S-3 Nos. 333-11457, 333-36057, 333-46087, 333-86193, 333-49466, 333-64864 and 333-102485) of Cellegy Pharmaceuticals, Inc. and in the related Prospectuses, as applicable, of our report dated February 13, 2003, with respect to the consolidated financial statements of Cellegy Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2002.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 21, 2003