

AR/S

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



FORM 10-K

MAY 05 2003

(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  
(State or other jurisdiction of  
incorporation or organization)

82-0429727  
(I.R.S. Employer  
Identification No.)

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

94080  
(zip code)

PROCESSED  
MAY 07 2003  
THOMSON  
FINANCIAL

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

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

None  
(Title of each class)

Nasdaq National Market  
(Name of each exchange on  
which registered)

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

(Title of class)

Common Stock, no par value

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 X NO     

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

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 X

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.

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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<sup>™</sup> 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 utilizing its existing sales and marketing infrastructure. Cellegy received a payment of \$15.0 million upon 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<sup>™</sup> 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<sup>™</sup> 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 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:

- *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.

- *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 utilizing 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.
- *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.
- *Acquisition of Complementary Products and Companies.* As was done with the acquisitions of Vaxis in Canada in November 2001, of Rectogesic<sup>™</sup> (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.
- *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.
- *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<sup>®</sup> (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 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 their 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 been 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 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 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 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 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 sub-leased 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 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.

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

##### MANAGEMENT

The executive officers of Cellegy are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
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 private 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 STOCK-HOLDER 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.

<u>2001</u>	<u>High</u>	<u>Low</u>
First Quarter .....	\$8.80	\$5.15
Second Quarter .....	6.90	2.02
Third Quarter .....	2.44	1.66
Fourth Quarter .....	4.35	1.50
<u>2000</u>		
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.

**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,

(\$000's)	Years ended December 31,				
	2002	2001	2000	1999	1998
<b>Statement of Operations Data:</b>					
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 .....	<u>\$(15,936)</u>	<u>\$(19,465)</u>	<u>\$(11,418)</u>	<u>\$(9,301)</u>	<u>\$(7,366)</u>
Basic and diluted net loss per common share .....	<u>\$ (0.90)</u>	<u>\$ (1.26)</u>	<u>\$ (0.91)</u>	<u>\$ (0.85)</u>	<u>\$ (0.73)</u>
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
<b>Balance Sheet Data:</b> .....					
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.

## 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 utilizing its existing sales and marketing infrastructure and skills contained within the PDI Pharmaceutical Products Group. Cellegy received a payment of \$15.0 million upon signing of the agreement on December 31, 2002 and will

receive a milestone payment of \$10.0 million upon 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. 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 sub-lease 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):

<u>Contractual Obligations</u>	<u>Total</u>	<u>2003</u>	<u>2004-2005</u>	<u>2006-2007</u>	<u>Thereafter</u>
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 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 PDUFA 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 PDUFA 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 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 PDUFA 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:

- 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;
- the timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- analysis of data obtained from preclinical and clinical activities which could delay, limit or prevent regulatory approval;
- changes in policies or staff personnel at regulatory agencies during the lengthy drug application review; and
- 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.

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

- publicity or announcements regarding regulatory developments relating to our products under review, particularly relating to Tostrex or Cellegesic;
- clinical trial results, such as results of the Tostrelle trial;
- period-to-period fluctuations in our financial results, including our cash and investment balance, operating expenses, cash burn rate or revenues; or
- 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-23 of this report.

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

None.



### 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:

<u>Exhibit Number</u>	<u>Exhibit Title</u>
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 Therapeutics Corporation and certain stockholders of Vaxis. (Incorporated by reference to Exhibit 10.14 to the Company's Form 10-K for fiscal year ended December 31, 2001.)

<u>Exhibit Number</u>	<u>Exhibit Title</u>
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.

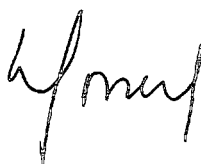
(c) Financial Statement Schedules

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.

**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.

A handwritten signature in black ink, appearing to read "K. Michael Forrest". The signature is written in a cursive style with a large initial "K" and a long horizontal stroke.

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.


<u>Name</u>	<u>Title</u>	<u>Date</u>
<b>Principal Executive Officer:</b>		
/s/ K. Michael Forrest K. Michael Forrest	Chairman, President, and Chief Executive Officer	March 21, 2003
<b>Principal Financial Officer and Principal Accounting Officer:</b>		
/s/ A. Richard Juelis A. Richard Juelis	Vice President, Finance, Chief Financial Officer and Secretary	March 21, 2003
<b>Directors:</b>		
/s/ Jack L. Bowman Jack L. Bowman	Director	March 21, 2003
/s/ Tobi B. Klar Tobi B. Klar, M.D.	Director	March 21, 2003
/s/ Ronald J. Saldarini Ronald J. Saldarini, Ph.D.	Director	March 21, 2003
/s/ Alan A. Steigrod Alan A. Steigrod	Director	March 21, 2003
/s/ Larry J. Wells Larry J. Wells	Director	March 21, 2003

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



K. Michael Forrest  
President, Chief Executive Officer

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



A. Richard Juelis  
President, 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

Cellegy Pharmaceuticals, Inc.  
(a development stage company)  
Consolidated Balance Sheets

	December 31,	
	2002	2001
<b>Assets</b>		
Current assets		
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>		
Current liabilities		
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	—
Commitments:		
Shareholders' equity		
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.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Consolidated Statements of Operations

	Years ended December 31,			Period from June 26, 1989 through December 31, 2002
	2002	2001	2000	
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 .....	<u>1,355,828</u>	<u>876,925</u>	<u>1,513,830</u>	<u>5,102,412</u>
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 .....	—	<u>3,507,134</u>	—	<u>7,350,102</u>
Total costs and expenses .....	<u>17,858,351</u>	<u>21,846,860</u>	<u>13,573,022</u>	<u>97,934,254</u>
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 .....	<u>547,961</u>	<u>1,531,929</u>	<u>769,875</u>	<u>6,226,714</u>
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 .....	<u>\$(15,935,900)</u>	<u>\$ (19,464,72)</u>	<u>\$(11,418,213)</u>	<u>\$(86,312,448)</u>
Basic and diluted net loss per common share .....	<u>\$ (0.90)</u>	<u>\$ (1.26)</u>	<u>\$ (0.91)</u>	
Weighted average common shares used in computing basic and diluted net loss per common share.....				
	<u>17,642,640</u>	<u>15,502,918</u>	<u>12,542,232</u>	

See accompanying notes.

**Cellegy Pharmaceuticals, Inc.**  
(a development stage company)

**Consolidated Statements of Shareholders' Equity**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	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	—	\$ —	\$ —	—	\$11,780,000
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	—	—	—	—	—	—	—	—	1,199,536
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 1999 . . . . .	50,110	173,198	—	—	—	—	—	—	—	—	173,198
Issuance of Series B convertible preferred stock in exchange for convertible promissory notes . . .	—	—	12,750	114,000	—	—	—	—	—	—	114,000
Non-cash preferred dividends . . .	—	1,448,505	—	—	—	—	—	—	—	(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)	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.

**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		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	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	—	—	6,383,785
Issuance of common stock for cash through December 31, 1999	—	—	—	—	—	—	953,400	126,499	—	—	126,499
Issuance of common stock for services rendered through December 31, 1999	—	—	—	—	—	—	269,116	24,261	—	—	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	—	—	10,037,662
Repurchase of common shares in 1992	—	—	—	—	—	—	(3,586)	(324)	—	—	(324)
Issuance of common stock in exchange for notes payable	—	—	—	—	—	—	42,960	268,500	—	—	268,500
Exercise of warrants to purchase common stock	—	—	—	—	—	—	496,253	602,679	—	—	602,679
Exercise of options to purchase common stock	—	—	—	—	—	—	275,820	961,775	—	—	961,775
Compensation expense related to the extension of option exercise periods	—	—	—	—	—	—	—	338,481	—	—	338,481
Unrealized loss in investments	—	—	—	—	—	—	—	—	(35,471)	—	(35,471)
Net loss for the period	—	—	—	—	—	—	—	—	—	—	—
June 26, 1989 (inception) to December 31, 1999	—	—	—	—	—	—	12,010,242	55,367,903	—	(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	—	—	—	—	—	—	1,500,000	11,602,473	—	—	11,602,473
Exercise of warrants to purchase common stock	—	—	—	—	—	—	62,833	315,800	—	—	315,800
Exercise of options to purchase common stock	—	—	—	—	—	—	95,754	380,516	—	—	380,516

See accompanying notes.

**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		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	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.

**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		Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of common stock in connection with the achievement of Neptune milestones . . . . .	—	—	—	—	—	—	104,113	750,000	—	—	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 . . . . .	—	—	—	—	—	—	17,295,724	90,137,811	83,458	(70,376,548)	19,844,721
Exercise of options to purchase common stock . . . . .	—	—	—	—	—	—	156,632	454,983	—	—	454,983
Issuance of common stock in connection with the private placement of common stock in November 2002, net of issuance 2,200,000 costs of \$275,000 . . . . .	—	—	—	—	—	—	2,200,000	5,225,000	—	—	5,225,000
Compensation expense for options related to non-employees . . . . .	—	—	—	—	—	—	—	72,224	—	—	72,224
Compensation expense related to stock option modifications . . . . .	—	—	—	—	—	—	—	945,044	—	—	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 . . . . .	—	\$ —	—	\$ —	—	\$ —	19,652,356	\$96,835,062	\$ 11,831	\$(86,312,448)	\$ 10,534,445

See accompanying notes.



**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
<b>Operating activities</b>				
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)
<b>Investing activities</b>				
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)
<b>Financing activities</b>				
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.

**Cellegy Pharmaceuticals, Inc.**  
**(a development stage company)**

**Consolidated Statements of Cash Flows (Continued)**

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

See accompanying notes.

**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)

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements — (Continued)

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.

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 \$983,000.

*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.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Consolidated Financial Statements — (Continued)

*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 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.

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Notes to Consolidated Financial Statements — (Continued)

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
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

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:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
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 .....	<u>(2,923,231)</u>	<u>(2,687,751)</u>	<u>(1,686,989)</u>
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.

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Notes to Consolidated Financial Statements — (Continued)

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
	\$2,001,580	\$543	\$2,002,123	\$10,678,378	\$102,142	\$10,780,520

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
	4,321,002	4,081,116
Less accumulated depreciation and amortization .....	(1,704,809)	(1,613,209)
	\$ 2,616,193	\$ 2,467,907

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
	\$8,323,968	\$(7,347,959)	\$976,009

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.

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Notes to Consolidated Financial Statements — (Continued)

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.

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. 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.



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Notes to Consolidated Financial Statements — (Continued)

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.

*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 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

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Notes to Consolidated Financial Statements — (Continued)

\$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.

8. 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.

*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.

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

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 .....	<u>(95,754)</u>	\$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 .....	<u>(60,803)</u>	\$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 .....	<u>(156,632)</u>	\$0.50 - \$ 3.87	\$2.90
Balance at December 31, 2002 .....	<u>3,962,492</u>	\$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	<u>3,962,492</u>	5.6 years	\$4.83	<u>2,362,446</u>	\$4.72

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

*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.

Activity under the Directors' Plan is summarized as follows:

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

<u>Range of Exercise Price</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Outstanding at December 31, 2002</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Weighted Average Exercise Price</u>	<u>Exercisable at December 31, 2002</u>	<u>Weighted Average Exercise Price</u>
\$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	<u>18,000</u>	7.9 years	\$6.72	<u>7,334</u>	\$7.04
Total	<u>292,500</u>	6.7 years	\$4.61	<u>179,330</u>	\$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 .....	<u>1,864,551</u>

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

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.

**9. 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 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.

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Notes to Consolidated Financial Statements — (Continued)

**10. 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:

	Years ended December 31,		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Revenues:			
Pharmaceuticals .....	\$ 320,339	\$ 217,439	\$ 196,434
Cosmeceuticals .....	1,081,287	660,052	\$ 1,389,189
	<u>\$ 1,401,626</u>	<u>\$ 1,585,623</u>	<u>\$ 877,491</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>

Total assets were minimal for the cosmeceutical segment.

*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.

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**Notes to Consolidated Financial Statements — (Continued)**

*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.

**11. 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 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.

**12. Quarterly Financial Data ( unaudited )**

(amounts in thousands except per share data)

	2002	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total</u>
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	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total</u>
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)

