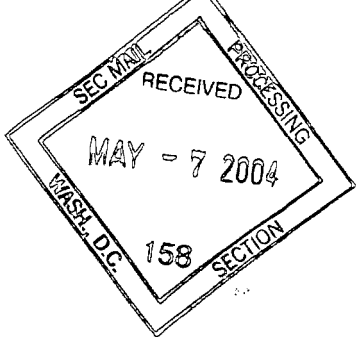
P.E. 12/31/03

CELLEGY
PHARMACEUTICALS INC



2003 Annual Report to Shareholders

Dear Shareholder:

In 2003, your Company made good progress on many fronts in advancing our product portfolio, including the achievement of key clinical milestones that bring our lead product candidates closer to commercialization. By year's end, we established the foundation for significant gains in 2004 and beyond.

Cellegesic™ (nitroglycerin ointment)

A Multi-Indication Product Candidate

Anal Fissures

In January 2004, we announced positive results from our confirmatory Phase 3 trial with Cellegesic™ (nitroglycerin ointment) for the treatment of pain associated with chronic anal fissures. We are now on track to submit a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) by mid-year 2004. Currently there is no FDA-approved drug therapy for this debilitating condition, which, according to Verispan data, afflicts over 700,000 Americans and results in more than one million physician visits each year. Surgery (Lateral Internal Sphincterotomy), which is expensive and can result in incontinence, is the most frequently performed procedure to treat anal fissures.

While uncertainty exists regarding the FDA's review of Cellegesic, we believe our agreement with the FDA on a Special Protocol Assessment (SPA) was an important step toward our goal of marketing approval and commercialization of Cellegesic. An SPA is designed to provide pharmaceutical companies, like Cellegy, a greater level of assurance that, if pre-specified clinical endpoints are achieved, the FDA will approve the product for commercial sale. Our Cellegesic trial results showed a statistically significant reduction in anal fissure pain compared with placebo during the first three weeks of therapy, which was the primary endpoint of the study under the SPA.

We market a product, similar in formulation to Cellegesic, through pharmacists in Australia, New Zealand and South Korea under the brand name Rectogesic® (nitroglycerin ointment). Rectogesic sales increased by 60% over the last two years in Australia, where it is approved for the treatment of anal fissures. Rectogesic is currently under regulatory review in the United Kingdom. If approved, the U.K. will be our representative country for approvals throughout Europe.

Dyspareunia

Dyspareunia is a condition characterized by intense vaginal pain, often recurrent and frequently causing significant impairment to normal sexual functioning in women. There are multiple possible causes of dyspareunia but often the condition is present without any obvious evidence of underlying disease. It has been reported that between 7% and 15% of American women of sexually active age are affected by the condition. There are no approved treatments for dyspareunia and while many different approaches are used none are completely satisfactory. We believe dyspareunia and other urogenital disorders, including vulvodynia, may be treatable by nitroglycerin.

A pilot study conducted by Dr. Jennifer Berman at the UCLA Medical Center demonstrated the utility of nitroglycerin ointment in the reduction of vaginal pain in over 90% of the women in the study. Cellegy's intellectual property covering these female sexual disorders includes five issued domestic patents with more than 20 worldwide patents pending. We have recently begun a vulvodynia dose ranging study in Australia with plans to progress toward more advanced clinical programs.

More than seven hundred thousand domestic patients are afflicted each year with anal fissures. Three million patient visits occur for hemorrhoids and another six million patients are in the so-called "silent market," not currently seeking treatment. Dyspareunia and related conditions afflict five million women. No FDA-approved drugs are available to treat these conditions.

Hemorrhoids

As is the case with anal fissures, hemorrhoid sufferers exhibit an abnormal contraction of the internal anal sphincter (IAS). Nitroglycerin relaxes the smooth muscle tissues of the IAS. This is the basis for Cellegy's Phase 2 clinical trial to determine Cellegesic's effectiveness in treating various symptoms of hemorrhoids. There are no products that have yet been proven effective and the number of hemorrhoid sufferers is significant – in excess of nine million people in the United States alone.

Testosterone Replacement Products

Tostrelle™ (testosterone gel) for Women

In June 2003, Cellegy announced favorable results from an interim analysis of a Phase 2 study using Tostrelle for treatment of female sexual dysfunction. Tostrelle uses a proprietary pump for metered dosing to deliver a specific amount of drug to postmenopausal women with testosterone deficiency. It is a transparent, non-staining and convenient once-a-day gel that is applied to a small area of the skin.

The interim Phase 2 data indicated that 71% of women who were administered Tostrelle reported an improvement in sexually satisfying events versus 13% for placebo. These favorable responses continue to be observed in additional women and we plan to continue gathering data on our Phase 2 study during the next several months. We believe Tostrelle will provide significant advantages to postmenopausal women suffering from diminished libido and other symptoms resulting from reduced testosterone levels.

Fortigel™ (testosterone gel) for Men

Since receiving a "Not Approvable" letter in July 2003 from the FDA for Fortigel, Cellegy's drug candidate for the treatment of male hypogonadism, we have been working diligently to clarify the Agency's requirements for marketing approval. However, it is highly likely that an additional Phase 3 trial will be required.

Male hypogonadism is caused by a testosterone deficiency that frequently results in lethargy, lack of concentration and a significant decrease in libido. Based on our market research and competitive attributes, we believe Fortigel has the potential to capture a meaningful share of this large and growing market, if approved. In 2002, we granted exclusive North American marketing rights for Fortigel to PDI, Inc., and subsequent to the FDA's Not Approvable letter, PDI proceeded with legal actions that ultimately became the subject of litigation between the two companies late last year. We believe PDI's claims are without merit and we will continue to aggressively pursue commercialization of Fortigel during this year.

Other Pipeline Products

Our product pipeline, which reflects Cellegy's expertise using nitroglycerin ointment and nitric oxide (NO) donors, addresses a number of serious medical conditions. Early stage pipeline products target prostate cancer, Raynaud's Disease, and Restless Leg Syndrome. Our prostate cancer program is testing the effectiveness of low doses of nitric oxide to prevent or slow down the rate of metastasis following prostate surgery. If successful, this program could save the lives of millions of men with prostate cancer.

Corporate Developments

To enhance our drug-development expertise, during 2003, we made important changes to our clinical/regulatory program. We also substantially strengthened our regulatory support with the addition of Washington D.C.-based regulatory affairs counsel, Hyman, Phelps & McNamara. They have a track record of regulatory success and have been advising Cellegy in our various interactions with the FDA.

We were very pleased in 2003 to augment our management team with strong leadership at the Board level. In November 2003, we appointed Richard C. Williams to the position of Chairman of the Board of Directors. Dick Williams has extensive financial and strategic experience in healthcare and other industries. He served as Vice Chairman, Strategic Planning for King Pharmaceuticals following its acquisition of Medco Research where he was Chairman, and he is currently a director of EP Med Systems and ISTA Pharmaceuticals. His contributions to Cellegy have already been significant and we look forward to his continued support and counsel.

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

FORM 10-K

(Mark one)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 000-26372

CELLEGY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

California	82-0429727
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
349 Oyster Point Boulevard, Suite 200, South San Francisco, California	94080
(Address of Principal Executive Offices)	**(zip code)**

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

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

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

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

(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. YES X NO

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 under the Securities Act of 1934). YES ___ NO X

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 30, 2003, the last business day of the Registrant's most recently completed second fiscal quarter, was $51,755,662, 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 29, 2004, there were 20,117,211 of shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information called for by Part III of this Report, and certain information called for by Part II, Item 5 of this Report, to the extent not set forth herein, is incorporated by reference to the definitive Proxy Statement relating to the Annual Meeting of Shareholders of the Company which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year to which this Report relates.

CELLEGY PHARMACEUTICALS, INC.
10-K Annual Report

For the Fiscal Year Ended December 31, 2003

Table of Contents

Unless the context otherwise requires, the terms "we", "our", and "Cellegy" refer to Cellegy Pharmaceuticals, Inc., a California corporation, and its subsidiaries. Cellegesic, Fortigel, 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 is a development stage specialty biopharmaceutical company, incorporated in California in 1989, that develops and intends to commercialize prescription drugs targeting primarily gastrointestinal conditions and sexual dysfunction using proprietary topical formulations and nitric oxide ("NO") donor technologies. In January 2004, Cellegy reported positive results from a confirmatory Phase 3 study using Cellegesic™ (nitroglycerin ointment) for the treatment of chronic anal fissure pain. We plan to submit a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") in the second quarter of 2004.

In addition to the anal fissure indication, we are developing Cellegesic for the treatment of hemorrhoids and a painful condition called dyspareunia, which prevents or inhibits sexual intercourse in more than five million women in the United States. Other early stage NO donor product candidates in our pipeline address a number of conditions including prostate cancer, Raynaud's Disease and Restless Leg Syndrome.

Cellegy is also developing two transdermal testosterone gel products. Tostrelle™ (testosterone gel) 0.5% is for the treatment of female sexual dysfunction in postmenopausal women. We have previously announced results of an interim analysis of a Phase 2 study using Tostrelle for the treatment of female sexual dysfunction showing a favorable response rate of 71% versus a placebo response of 13%. Fortigel™ (testosterone gel) 2.0%, a replacement therapy for male hypogonadism, was the subject of a Not Approvable letter by the FDA in July 2003. Cellegy has had discussions and exchanges with the FDA which we believe may lead to agreement on any remaining work required for approval of the product. There can, however, be no assurances regarding the timing and outcome of these interactions and the FDA's decisions regarding Fortigel or our other products.

Products Under Development

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

Cellegesic is a topical, nitroglycerin-based prescription product being developed for the treatment of anal fissures, hemorrhoids and dyspareunia. Nitroglycerin is a drug that has safely and effectively been used for many years to treat cardiac conditions, primarily angina pectoris.

Anal fissures are painful tears in the lining of the anal canal, a condition afflicting men and women of all age groups and nationalities. The condition is associated with increased pressure in the anal canal and a decrease in blood supply to the region. Many chronic cases require a painful and expensive surgical procedure (Lateral Internal Sphincterotomy), that is designed to reduce anal pressure by severing the muscles of the inner anal sphincter. This procedure, while highly effective, frequently leaves patients incontinent. Cellegesic, which is applied intra-anally, works to reduce anal pressure by gently relaxing the inner anal sphincter muscles. If approved, Cellegesic, will likely reduce the number of surgeries and the associated incontinence risk.

There are currently no FDA approved drug therapies for anal fissures, although anesthetics and anti-inflammatory agents which only partially relieve the symptoms of the condition are currently prescribed. According to Verispan audits, anal fissures afflict an estimated 750,000 Americans, resulting in over one million physician visits each year. The most recent audit data for 2003 show about 100,000 annual uses of pharmacy-compounded nitroglycerin for the treatment of anal fissures. We believe that, if Cellegesic is approved, the extensive compounding of nitroglycerin by pharmacies will decline as physicians begin to prescribe Cellegesic, a stable, homogeneous formulation that will be to FDA standards and will be consistent from batch to batch. We plan to enforce our issued United States patents if compounding continues after FDA approval of Cellegesic.

Hemorrhoids are dilated, swollen veins and tissue located either in or near the anal canal. In the United States alone, there are approximately nine million people who suffer from hemorrhoids each year, according to published data. Hemorrhoids are also characterized by an increase in intra-anal pressure,

which has been shown to be effectively reduced by the application of Cellegesic. Cellegy is currently conducting a Phase 2 clinical trial to test the efficacy of Cellegesic ointment in the treatment of various symptoms of hemorrhoids.

Dyspareunia is a condition that is characterized by intense vaginal pain. The condition can be recurrent and frequently causes significant impairment to normal sexual functioning in woman. There are multiple possible causes of dyspareunia but often the condition is present without any obvious evidence of underlying disease. It has been reported that between 7% to 15% of American women of sexually active age are affected by the condition. There are no approved treatments for dyspareunia and while many different approaches are used none are completely satisfactory. In a recent, non placebo controlled clinical study of nitroglycerin ointment conducted by Dr. Jennifer Berman of the University of California Los Angeles Medical Center, the product was reported to reduce the pain of women suffering from vulvodynia, a condition that is a major contributor to dyspareunia. Cellegy is now initiating a similar study and intends to conduct additional trials using Cellegesic for the treatment of vulvodynia.

Recent Cellegesic Clinical Trials Results

In January 2004, Cellegy announced results of a preliminary analysis of its third Cellegesic Phase 3 clinical trial showing a statistically significant ($p<0.05$) reduction in anal fissure pain compared with a placebo control during the first three weeks of the trial, the primary efficacy endpoint of the study. As observed in two earlier Phase 3 trials, the most common side effect was mild to moderate headache. The double blind, placebo controlled trial was conducted according to a Special Protocol Assessment ("SPA"), that was agreed to by the Company and the FDA. An SPA is intended to provide assurance that if the pre-specified primary endpoint is achieved and no unexpected safety issues are seen, the FDA will approve the product for commercial sale. We are now preparing an NDA submission for filing with the FDA in the second quarter of 2004.

Subjects who met the enrollment criteria for a chronic anal fissure were randomized to receive either the placebo ointment or 0.4% nitroglycerin ointment twice daily over an eight-week period. The daily records of average pain intensity from 187 intent-to-treat subjects (89 Cellegesic-treated and 98 placebo-treated) were analyzed for statistical evidence of pain reduction during the first 21 days of treatment as the primary efficacy endpoint. The primary endpoint was achieved ($p<0.05$).

A secondary endpoint and several tertiary endpoints were also analyzed. The secondary endpoint was time to 50% pain reduction. On average, the time to 50% pain reduction produced by Cellegesic was sooner than the reduction produced by the placebo, although the difference was not statistically significant. Tertiary endpoints included reduction of average pain over the eight-week (56 days) treatment period, reduction of pain upon defecation through days 21 and 56, and healing. Average pain reduction and defecation pain reduction were both statistically significant over 56 days ($p<0.05$). However, the significance achieved in these tertiary endpoints did not remain statistically significant after applying adjustment to the p-values for the analysis of multiple endpoints. These results were numerically superior to placebo and demonstrate an important positive trend. There was no significant difference in fissure healing between Cellegesic and the placebo control, as in earlier trials.

Side effects seen in the trial were consistent with those observed in the previous two Phase 3 studies, with mild to moderate headache the most common side effect. Five subjects dropped out of the study as a result of the headache. The SPA, as agreed to with the FDA, required that subjects discontinuing due to nitroglycerin related headache (one that occurs within 30 minutes of application) should have their last daily pain intensity score, as recorded on the day the subject dropped out, carried forward each day through day 21. Clinical judgment, based on each subject's entire record, was used to determine which of the five subjects discontinued due to nitroglycerin related headaches. Last daily pain intensity scores were carried forward for three of the five subjects. The other two subjects who withdrew from the trial due to headache had all of their available pain data prior to dropout included in the analysis. We believe we achieved the results specified in the SPA although the FDA will conduct its own analysis, and could disagree with our conclusion.

Cellegy is also conducting a Phase 2 clinical trial using Cellegesic to determine its effect on the symptoms of hemorrhoids. Hemorrhoids afflict an estimated nine million people annually in the United States alone, according to published data. We are also initiating a pilot study in dyspareunia, a painful condition afflicting up to five million women in the United States.

Previous Cellegesic Clinical Trial Results

We completed our initial Phase 3 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 compared with placebo, but did show significant pain reduction. Based on this outcome, we initiated a second Phase 3 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 3 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 daily 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.

In June 2001, we filed a rolling NDA with the FDA for the use of Cellegesic for the treatment of pain associated with chronic anal fissures. We amended the NDA upon completion of the second Phase 3 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 3 trial before considering approval of the product.

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 normal sexual desire. 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%. Testosterone deficiency in women frequently leads to diminished libido, decreased bone and muscle mass and reduced energy levels. 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, although it has been reported that testosterone treatment is frequently being prescribed off-label for women by Obstetricians and Gynecologists.

Based on the results of pharmacokinetic studies in men receiving Fortigel, Cellegy's product candidate for male hypogonadism, our scientists calculated the concentration of testosterone required to achieve normal pre-menopausal hormone levels in postmenopausal women. The result is Cellegy's Tostrelle, a product designed to safely restore normal testosterone levels in hormone deficient women.

Cellegy has successfully completed two Phase 1/2 pharmacokinetic studies in which we determined the proper dose necessary to restore normal testosterone levels to normally menopausal and surgically-induced menopausal women. In June 2003, we announced an interim analysis of a Phase 2 study in women with sexual dysfunction showing a favorable response rate of 71% with Tostrelle versus a 13% placebo response. Based on these results, we initiated an amended Phase 2 clinical study in 2003. We now plan to

meet with the FDA to review the trial results and the overall Tostrelle program. Subject to the outcome of this meeting, we intend to pursue advanced trials incorporating any reasonable protocol changes that might be required by the FDA.

Fortigel (testosterone replacement therapy for male hypogonadism)

Fortigel is a transdermal testosterone gel designed 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 five million men in the United States, primarily in the aging (over 40) male population group, have deficient levels Of testosterone.

There are a number of companies currently marketing testosterone in several different product forms in domestic and international markets. Cellegy believes there is an important medical and market need 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 10% of potential patients, according to published prescription data. Current product forms include injectables, a trans dermal patch, two testosterone gel products and a buccal tablet. The leading gel product currently priced at approximately $3,500 per year is now generating annual domestic revenues in excess of $350 million.

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 the results of a 201-patient Phase 3 trial announced in November 2001, Cellegy filed an NDA in June of 2002. However, Fortigel was subsequently the subject of a Not Approvable letter by the FDA in July 2003. In its letter, the FDA stated that in its opinion the following deficiencies in the Fortigel NDA were found: (1) there is insufficient information to establish that high supraphysiologic daily Cmax serum testosterone levels achieved in a significant portion of participants in the major clinical study supporting the NDA are safe under conditions of chronic administration; and, (2) there is insufficient information provided to demonstrate that the dose of the product can be adjusted to consistently preclude achieving these high supraphysiological testosterone levels. Cellegy has had discussion and exchanges with the FDA which Cellegy believes may lead to agreement on any remaining work required for approval of the product, although there can be no assurances regarding the timing and outcome of these interactions and the FDA's decision. We could be required to conduct further clinical trials or undertake other time consuming or costly actions necessary to satisfy the FDA's requirements.

Marketed Products

Rectogesic

Rectogesic™ (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 and is now on the market in New Zealand and South Korea. Rectogesic is the only approved product for the treatment of anal fissures and, although it is not indicated for hemorrhoids treatment, it has achieved the number 3 market position in the much larger hemorrhoid product category in Australia, with sales increasing by 27% in 2002 and another 40% in 2003. There have been no safety issues reported with use of the product since its introduction.

Skin Care

Cellegy has completed development of certain consumer skin care blends, including skin 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 its products. Our revenues from sales of C79 totaled $316,000 in 2003 with total sales of approximately $5 million since product introduction in 1998.

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 Physicians in United States.* Whenever practical, 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, initially on our own and subsequently through co-promotion agreements with partners in the United States as the use of Cellegesic expands beyond the specialists. In most cases, we plan to outlicense the overseas rights for products we develop.
- *Acquisition of Complementary Products and Companies.* As was done with the acquisitions of Vaxis Therapeutics Corporation ("Vaxis") in Canada in November 2001, of Rectogesic™ (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 PendoPharm Inc., ("PendoPharm") an FDA approved contract manufacturing company based in Canada. PendoPharm, previously called PanGeo and now an affiliate of Pharmasciences, has successfully manufactured Cellegesic, Fortigel and Tostrelle for our clinical trials and will be a commercial manufacturer for these products, when approved. We are actively working to validate a domestic contract manufacturer to serve as a second manufacturing source for our product candidates.
- *Distribution.* Cellegy has entered into distribution agreements for Rectogesic in New Zealand and South Korea. We intend to contract with additional distributors in Asia and other major overseas markets.

Research Programs

Cellegy's research and development programs focus on nitric oxide pharmacology and related 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 intellectual property and product candidate portfolio for the treatment of female sexual dysfunction, 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 expanded expertise in nitric oxide pharmacology has led to an understanding of the role of nitric oxide as a signaling molecule, operating at lower concentrations than is normally required for vasodilators, especially in tissue under an abnormally vaso-spasmatic 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 either in vivo animal testing or in pilot human studies.

We have also been investigating the role of nitric oxide in the development of chemo-resistance and in attenuating cancer metastasis induced by hypoxia (low oxygen), a condition that commonly exists in various difficult to treat cancers. Results published in various peer-reviewed journals show that the administration of nitric oxide donors, like nitroglycerin, prevented the development of chemo-resistance to several well-established chemotherapeutic agents such as 5-flurouracil and doxorubicin, and the metastasis of prostate, breast and other human cancer cell lines and in spheroid cultures. In addition to these mechanistic studies, Cellegy's collaborators at Queens University have also established an in vivo tumor model to test the effect of a nitric oxide donor in preventing the metastasis of existing tumors. A pilot human study using topical nitroglycerin to attenuate the progressive increase of PSA (prostate-specific antigen, a marker of biological failure in patients after a prostectomy procedure) was presented at the American Urological Association annual meeting in the second quarter of 2003.

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 is now initiating a clinical study using topical nitroglycerin in treating vulvar pain associated with vulvodynia and dyspareunia, which we intend to complete in 2004.

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 fissures and other anal diseases. While our European patent covering the Cellegesic product was challenged and subsequently revoked during the opposition proceedings in December 2003, Cellegy plans to file an appeal to the decision in the next several months. Two issued United States patents and over 25 pending patent applications relate to possible backup compounds for our Cellegesic product. As part of Cellegy's acquisition of Cellegy Canada, Cellegy gained rights to 5 issued United States patents, 3 issued foreign patents, and more than 40 pending patent applications. These patents and applications disclose methods of treatment of peripheral vascular conditions including male erectile dysfunction, female sexual dysfunction, and Raynaud's disease, as well as other conditions. United States and foreign patent applications disclosing novel store-operated calcium influx (SOC) inhibitors and their use in the treatment of various disorders are pending or have recently published. Additional patent applications are being prepared for filing that will cover methods or products currently under development. Corresponding patent applications for most of Cellegy's issued United States patents have been filed in countries of importance to us located in major world markets, including certain countries in Europe, Australia, South Korea, Japan, Mexico and Canada.

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

In November 2001, Cellegy acquired Vaxis Therapeutics Corporation, a private Canadian company for $4.1 million primarily in Cellegy common 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 supports our goals of expanding our product pipeline 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 common stock and warrants. Cellegy continues to self-market Rectogesic in Australia through its wholly-owned Cellegy Australia subsidiary and currently sells Rectogesic through distributors in New Zealand and South Korea. We plan to selectively sell Rectogesic through distributors in other Pacific Rim countries and potentially in other major markets around the world.

In December 1997, Cellegy acquired patent and related intellectual property rights relating to Cellegesic from Neptune Pharmaceuticals. Under 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. Cellegy has no future product royalty obligations to Neptune in connection with potential Cellegesic product 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. Clinical trials may begin 30 days after the IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. 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 3 studies are required. The FDA, upon request through a Special Protocol Assessment, can also provide specific written guidance on the acceptability of protocol designs for selected clinical trials.

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, 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. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approvals of NDA's or other product applications if deficiencies are found at the facility. Vendors that supply us finished products or components used to manufacture, package and label products are subject to similar regulation and periodic inspection. We have used and intend to continue 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. Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for European Union member states. This authorization is called a marketing authorization approval ("MAA"). The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the application and assessment report, each member state must make their own determination regarding approval. This procedure is referred to as the mutual recognition procedure. 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 payers. 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, if commercialized, are subject to competition from existing products. Cellegesic, which is a prescription product, is expected to compete with over-the-counter products, such as Preparation H marketed by Wyeth, and various other prescription products. Cellegy's Fortigel product, if commercialized, is expected to compete with a currently marketed transdermal patch product sold by Watson Pharmaceuticals, two transdermal testosterone gel products marketed by Unimed/Solvay and Auxilium Pharmaceuticals and a buccal tablet marketed by Columbia Laboratories. As a result, we cannot assure you that Cellegy's products under development will be able to compete successfully with existing products or possible generic 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, and many large companies currently market and are developing a wide variety of products in these markets. 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. We believe there

are other pharmaceutical companies that are developing prescription testosterone replacement products for women, other generic manufacturers developing testosterone replacement products for men, and that competition will be intense for all of its female and male sexual dysfunction product candidates.

Employees

As of March 21, 2004, we had seventeen full-time and three part-time employees. Eleven of these employees, including one M.D. and three 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 clinical 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.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC), including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning us may be obtained at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549 or accessed through the SEC's website at http://www.sec.gov. The SEC's Public Reference Room phone number is 1-800-SEC-0330. In addition, electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are posted to our website (www.cellegy.com). Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

ITEM 2: PROPERTIES

Cellegy currently leases 65,340 square feet of space located in South San Francisco, California with an estimated total 2004 rental cost of approximately $109,000 per month or $1,311,000 for 2004. Approximately 49,920 square feet of this space is currently subleased to one tenant with estimated 2004 offsetting total rental income of approximately $98,000 per month or $1,176,000 for 2004. We believe our current facilities will be adequate for our needs for expansion for the foreseeable future.

ITEM 3: LEGAL PROCEEDINGS

Except as described below, Cellegy is not a party to any material legal proceedings.

In December 2002, Cellegy entered into an exclusive license agreement with PDI, Inc. ("PDI") to commercialize Fortigel in North American markets. Under the terms of the agreement, PDI's Pharmaceutical Products Group is responsible for the marketing and sale of Fortigel, if approved, utilizing its existing sales and marketing infrastructure. Cellegy received a payment of $15.0 million upon signing the agreement and is entitled to receive a milestone payment on FDA approval and royalties following a successful product launch. Cellegy is responsible for supplying finished product to PDI through Cellegy's contract manufacturer. In July 2003, the FDA issued a Not Approvable letter for our Fortigel NDA. In October 2003, Cellegy announced that it received a mediation notice from PDI. The dispute resolution provisions of the license agreement require non-binding mediation before either party may initiate further legal proceedings. The communication asserted several claims relating to the agreement, including Cellegy's breach of several provisions of the agreement and failure to disclose relevant facts, and PDI claimed several kinds of alleged damages, including return of the initial license fee that PDI paid to Cellegy when the agreement was signed. The parties subsequently conducted mediation as contemplated by the agreement but did not reach any resolution of the claims.

In December 2003, Cellegy and PDI then both initiated legal proceedings against each other relating to the agreement. Cellegy filed a declaratory judgment action in federal district court in San Francisco

against PDI, and PDI initiated an action in federal district court in New York against Cellegy. In its action, Cellegy seeks, among other things, a declaration that it has fully complied with the license agreement and that PDI's claims are without merit. There can be no assurances regarding the outcome of either proceeding. The Company could be required to devote significant time and resources to the proceedings, and an adverse outcome could have a material adverse impact on our business and financial position.

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, 2003.

ITEM 4A: EXECUTIVE OFFICERS OF THE REGISTRANT

Name	Age	Position
K. Michael Forrest	60	President and Chief Executive Officer, Director
John J. Chandler	62	Vice President, Corporate Development
A. Richard Juelis	55	Vice President, Finance and Chief Financial Officer
David A. Karlin, M.D.	60	Vice President, Clinical Research

K. Michael Forrest. Mr. Forrest has been President, CEO, and a director since December 1996. He also held the position of the Chairman of the Board from May 2000 to November 2003. 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 anticancer products. Mr. Forrest holds a B.S. in Business Administration from Georgetown University, with concentrations in Marketing, Finance and Economics.

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, now Wyeth. During 1994, he was Area Director, Europe/Latin America for Wyeth. 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 October 1990 to September 1994 he served as Vice President, Finance and Chief Financial Officer for two other publicly-traded biotechnology companies. 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.

Executive officers are chosen by and serve at the discretion of the Board of Directors, subject to any written employment agreements with Cellegy.

PART II

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

Price Range of Common Stock

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

2002	High	Low
First Quarter	$ 8.80	$ 5.15
Second Quarter	6.90	2.02
Third Quarter	2.44	1.66
Fourth Quarter	4.35	1.50
2003		
First Quarter	$ 5.60	$ 3.71
Second Quarter	5.54	3.81
Third Quarter	5.22	2.25
Fourth Quarter	3.20	2.45

Holders

As of March 21, 2004, there were approximately 450 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. We currently intend to retain our earnings, if any, for future growth. Future dividends on our common stock or other securities, if any, will be at the discretion of our board of directors and will depend on, among other things, our operations, capital requirements and surplus, general financial condition, contractual restrictions and such other factors as our board of directors may deem relevant.

Information with respect to equity compensation plans that is required by this Item will be included in our Proxy Statement for the 2004 annual meeting of shareholders under the heading "Equity Compensation Plans" and is hereby incorporated by reference.

ITEM 6: SELECTED FINANCIAL DATA

The following unaudited selected historical information has been derived from audited consolidated financial statements of Cellegy. The financial information as of December 31, 2003 and 2002 and for each of the three consolidated years in the period ended December 31, 2003 are derived from our audited consolidated financial statements included elsewhere in this Form 10-K. 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.

Statements of Operations Data:

(In thousands, except per share data)

	Years ended December 31,				
	2003	2002	2001	2000	1999
Revenues	$ 1,620	$ 1,402	$ 877	$ 1,586	$ 1,045
Costs and expenses(1)	15,512	17,163	21,847	13,573	10,847
Operating loss	(13,892)	(15,761)	(20,970)	(11,987)	(9,802)
Other income (expense)	360	520	1,505	569	501
Net loss	$(13,532)	$(15,241)	$(19,465)	$(11,418)	$(9,301)
Basic and diluted net loss per common share	$ (0.68)	$ (0.86)	$ (1.26)	$ (0.91)	$ (0.85)
Weighted average common shares used in computing basic and diluted net loss per common share	19,964	17,643	15,503	12,542	10,914

(1) For the year ended December 31, 2003, Cellegy recorded total non-cash compensation of $579,000 associated primarily with the modification of certain stock options and bonuses paid in stock.

For the year ended December 31, 2002, Cellegy recorded net non-cash credits of $504,000 of which non-cash compensation expense totaled $322,000. These were more then offset by a non-cash credit of $826,000 relating to the termination of the Ventiv Health marketing and sales agreement for Cellegesic in the third quarter of 2002.

During the year ended December 31, 2001, we recorded non-cash charges totaling $4,257,000, consisting of $3,507,000 for in-process research and development associated with the Vaxis acquisition and $750,000 in non-cash charges for two milestones paid in Cellegy stock to Neptune Pharmaceuticals.

Data for 2002 has been adjusted in a Form 10-K/A filing in March 2004 to reflect the Company's adjustment to the accounting treatment associated with certain employee and director stock options that had been cancelled in the fourth quarter of 2002. See also Note 13 to the Financial Statements. The adjustment reversed $695,000 of non-cash expense previously recorded in the fourth quarter of 2002 related to the intrinsic value of the vested options.

Quarterly Statements of Operations Data (unaudited):

(in thousands, except for per share data)

	2003(2)							
	First Quarter		Second Quarter		Third Quarter		Fourth Quarter	Total
	(Previously reported)	(Restated)	(Previously reported)	(Restated)	(Previously reported)	(Restated)		
Revenues	$ 392	$ 392	$ 263	$ 263	$ 414	$ 414	$ 551	$ 1,620
Operating loss	(2,636)	(3,284)	(4,769)	(4,352)	(1,974)	(2,676)	(3,580)	(13,892)
Net loss	(3,132)	(3,113)	(4,582)	(4,165)	(1,968)	(2,670)	(3,584)	(13,532)
Basic and diluted net loss per common share	$ (0.16)	$ (0.16)	$ (0.23)	$ (0.21)	$ (0.10)	$ (0.13)	$ (0.18)	$ (0.68)

(2) Quarterly financial data for 2003 has been adjusted in amended Form 10-Q/A filings in March 2004.

	2002				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter(3)	Total
Revenues	$ 267	$ 150	$ 145	$ 840	$ 1,402
Operating loss	(4,642)	(5,753)	(1,756)	(3,610)	(15,761)
Net loss	(4,387)	(5,624)	(1,623)	(3,607)	(15,241)
Basic and diluted net loss per common share	$ (0.25)	$ (0.32)	$ (0.09)	$ (0.20)	$ (0.86)

(3) The financial data for the fourth quarter of 2002 has been adjusted in an amended Form 10-K/A filing in March 2004. The adjustment reversed $695,000 of non-cash expense previously reported in the fourth quarter of 2002.

Balance Sheet Data:

(In thousands)

	December 31,				
	2003	2002 (Restated)	2001	2000	1999
Cash, cash equivalents, restricted cash and investments(4)	$ 11,564	$ 23,858	$ 17,190	$ 15,923	$ 16,737
Total assets	15,331	28,379	22,367	21,259	20,913
Long term portion of deferred revenue	13,335	14,168	—	—	—
Deficit accumulated during the development stage(5)	(99,149)	(85,617)	(70,377)	(50,912)	(39,494)
Total shareholders' equity (deficit)	$ (1,580)	$ 10,534	$ 19,845	$ 18,794	$ 15,839

(4) Includes restricted cash of $227,500 in 2003 and 2002, and $614,000 in 2001.

(5) The financial data for 2002 has been adjusted in a Form 10-K/A filing in March 2004. The adjustment reduced the accumulated deficit by $695,000.

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 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. These forward-looking statements are not guarantees of future performance and concern matters that could subsequently differ materially from those described in the forward-looking statements. Actual events or results may also differ materially from those discussed in this Annual Report. 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.

Cellegy Pharmaceuticals is a development stage specialty biopharmaceutical company that develops and commercializes prescription drugs targeting primarily gastrointestinal conditions and sexual dysfunction using proprietary topical formulations and nitric oxide donor technologies. In January 2004, Cellegy reported positive results from a confirmatory Phase 3 clinical trial using Cellegesic(tm) (nitroglycerin ointment) for the treatment of chronic anal fissure pain. We now plan to submit an NDA to the FDA in the second quarter of this year. We are also developing other prescription drugs, including two transdermal testosterone gel products: Fortigel for the treatment of male hypogonadism and Tostrelle for the treatment of sexual dysfunction in menopausal women.

The Consolidated Financial Statements as of and for the year ended December 31, 2002 included in this Form 10-K have been restated. For additional information regarding the restatement, please refer to

Note 13 to the Consolidated Financial Statements included in this Item 8. All applicable financial information presented in this Item 7 takes into account the effects of the restatement described in Note 13 to the Consolidated Financial Statements.

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 with the purchase price allocated to: net tangible assets of $250,000, intangible assets of $350,000 and $3,507,000 of in-process research and development. The intangibles of $350,000 are being amortized over five years and the in-process research and development was expensed in the fourth quarter of 2001. The results of operations of Cellegy Canada are included in our consolidated financial statements since the acquisition date.

In September 2002, Cellegy and Ventiv Health, Inc., a leading contract sales organization, terminated their services and funding Agreements related to Cellegesic based on the delay in commercialization of Cellegesic due to the withdrawal of the NDA and Cellegy's subsequent decision to conduct another Phase 3 trial. Cellegy and Ventiv originally signed a six-year Agreement in August 2001 to collaboratively commercialize Cellegesic in the United States. 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. Along with shares acquired in other open market purchases SJ Strategic Investments currently owns 5,828,993 shares or about 29% of Cellegy's outstanding shares.

In January 2004, Cellegy entered into a Structured Secondary Offering ("SSO") facility agreement with Kingsbridge Capital Limited. The facility requires Kingsbridge to purchase up to 3.74 million shares of newly issued common stock at times and in amounts selected by Cellegy over a period of up to two years, subject to certain restrictions.

Critical Accounting Policies and Estimates

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, judgements 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 substantive and at risk non-refundable 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 and risk of loss have been transferred to the customer. There is no right of return for our skin care product sales.

Up-front payments, such as the $15.0 million payment received from PDI for the Fortigel 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 and other intangible assets are included in our December 31, 2003 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. Based on management's analysis, no impairment was deemed to have occurred through December 31, 2003. 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 based on actual activity including 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.

Investment Policy. Cellegy is subject to certain credit risks 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 has been approved and is 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. Non-government 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).

Results of Operations

Years Ended December 31, 2003, 2002 and 2001

Revenues. Cellegy had revenues of $1,620,000, $1,402,000 and $877,000 in 2003, 2002 and 2001, respectively. Revenues in 2003 consisted of $385,000 in Australian Rectogesic ointment sales, $67,000 in initial Rectogesic sales in South Korea, $316,000 in skin care product sales to Gryphon Development, the product development arm of a major specialty retailer, $19,000 in Canadian government grants and $833,000 in licensing revenue for Fortigel. Revenues in 2002 consisted of $275,000 in Australian Rectogesic sales, $1,081,000 in product sales primarily to Gryphon and $46,000 in Canadian government grants. Revenues in 2001 were comprised of $217,000 in Australian Rectogesic sales and $660,000 in Gryphon sales.

Rectogesic revenues in Australia increased 40% in 2003, compared with 2002 following a 27% year over year increase in 2002 compared with 2001. The Company believes it has the potential to continue to gain market share and increase revenues in the future. Rectogesic was launched in the fourth quarter of 2003 in South Korea. We are not yet able to assess the market acceptance and revenue potential in South Korea. Skin Care moisturizer sales to Gryphon decreased by $765,000 or about 71% in 2003, compared with 2002. Gryphon sales will likely continue to fluctuate from period to period depending on their seasonal ordering patterns. We do not now expect any Gryphon sales orders through, at least, the first quarter of 2004. In 2003, Cellegy recorded total licensing revenue of $833,000 from PDI, with about $208,000 realized in each of the four quarters of 2003 reflecting the amortization over the expected commercial life of Fortigel of the initial $15.0 million received from PDI on the agreement date in December 2002. The Company expects the balance to be recorded as licensing revenue at the same quarterly rate in subsequent periods. See also Item 3: "Legal Proceedings."

Research and Development Expenses. Research and development expenses were $10,558,000 in 2003, compared with $10,403,000 in 2002 and $14,098,000 in 2001. Total research and development expenses, which are primarily related to the costs of clinical trials and regulatory filings, represented 69%, 62% and 65% of our total operating expenses in 2003, 2002 and 2001, respectively. Total research and development expenses in 2003, compared with 2002, increased by $155,000 or about 2%. The increase was due to clinical expenses relating to the completion of a third Phase 3 Cellegesic clinical trial, primarily in the second half of 2003, as well as the write down of certain tenant improvements in our South San Francisco facility. These expenses were partially offset by Fortigel Phase 3 clinical trial costs and FDA user fees associated with the Fortigel NDA filing in 2002. Total research and development expenses in 2002, compared with 2001, decreased by $3,695,000 or about 26%. The decrease was due to higher spending levels associated with a second Cellegesic Phase 3 clinical trial and other clinical trials in 2001 and non-cash charges of $750,000 relating to Cellegesic milestone payments made in stock to Neptune Pharmaceuticals in 2001. In addition, during the second half of 2002, we eliminated our domestic research operations and reduced our research staff. We have continued to operate at these reduced staffing levels through 2003.

Current research and development expenses consist primarily of internal salaries and allocated costs as well as external clinical costs, including: clinical site payments, costs of manufacturing, testing and shipping clinical supplies and service fees to clinical research organizations ("CROs") that monitor the clinical sites and perform other related trial support services. Additionally, research expenses consist of regulatory costs, including the cost of filing product approval applications around the world, particularly NDAs in the United States, and the costs of various functional consultants to support the filings. We expect our clinical trial and regulatory filing expenses to continue to constitute the majority of our operating expenses in 2004. Excluding non-cash compensation expenses, we anticipate that our research and development expenses will decline during the first half of 2004 and increase thereafter with total 2004 clinical and regulatory expenses at about the 2003 level. Additional increases in clinical trial and regulatory filing expenses may occur if the FDA requires extensive additional clinical trials to support Fortigel marketing approval.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $4,768,000 in 2003, compared with $6,390,000 in 2002, and $4,042,000 in 2001. Total selling, general and administrative expenses in 2003 decreased by $1,622,000 or about 25%, compared with 2002 and were in turn $2,348,000 higher in 2002, compared with 2001. The higher spending level in 2002, compared with both 2003 and 2001, resulted primarily from Cellegesic pre-launch sales and marketing expenses of $2,094,000 in the first half of 2002. In addition, we incurred certain higher non-cash compensation expenses and investment banking fees in 2002.

Our selling, general and administrative expenses are expected to increase in the later half of 2004 in support of our business development programs and product commercialization efforts for Cellegesic, assuming a favorable response from the FDA on the Cellegesic NDA that we plan to file in the second quarter of 2004.

Non-cash Charges and Credits. Operating expenses for 2003, 2002 and 2001 were impacted by various non-cash charges and credits. Some of the non-cash compensation charges are subject to periodic remeasurements and on-going charges and credits are expected to vary in subsequent quarters.

Acquired-In-Process Research and Development. There were no acquired-in-process research and development expenses for 2003 and 2002. Acquired-in-process research and development expenses of $3,507,000 were incurred during 2001 as a result of the Vaxis acquisition.

Other Income (Expense). Cellegy recognized a net interest and other income of $360,000 for 2003, compared with net interest and other income of $521,000 and $1,505,000 for 2002 and 2001, respectively. The net interest and other income in 2003 consisted of $212,000 in interest income from cash and investments and $148,000 in rental and other income. In 2002, other income consisted primarily of $342,000 in interest income from cash and investments, $119,000 in rental income and a gain of $87,000 from disposal of certain laboratory equipment, offset by interest expense of $27,000. In 2001, other income was comprised of $635,000 in interest income on cash and investments and $897,000 in rental

income, offset by interest expense of $27,000. Reductions in interest income over the last three years were due to lower average investment balances and interest rates. Interest expenses for 2002 and 2001 were related to the Ventiv loan and a commercial bank loan, respectively. Cellegy incurred no interest expense in 2003.

Net Loss. The net loss in 2003 was $13,532,000 or $0.68 per share based on 19,964,000 weighted average shares outstanding, compared with a net loss in 2002 of $15,241,000 or $0.86 per share based on 17,643,000 weighted average shares outstanding, and a net loss in 2001 of $19,465,000 or $1.26 per share based on 15,503,000 weighted average shares outstanding.

Liquidity and Capital Resources

We have experienced net losses from operations each year since our inception. Through December 31, 2003, we had incurred an accumulated deficit of $99.1 million and had consumed cash from operations of $65.6 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, restricted cash and investments were $11.6 million at December 31, 2003 compared with $23.9 million at December 31, 2002 and $17.2 million at December 31, 2001, including $227,000 of restricted cash in 2003 and 2002 and $614,000 of restricted cash, at year end 2001. The increase in cash, restricted cash and investments of $6.7 million in 2002 was principally due to the net proceeds from the $5.2 million financing completed in November and $15.0 million in payments from the licensing agreement with PDI in December, partially offset by other net cash used in operating activities of approximately $13.5 million. Cash, restricted cash and investments decreased by $12.3 million in 2003 principally due to cash used in support of operating activities of $12.5 million. The Company did not complete any financings in 2003.

During the fourth quarter of 2003 our cash, restricted cash and investment balance declined by $2.9 million. This is in line with Cellegy's goal to preserve cash and focus on key clinical and product development programs. We expect our cash use for the first quarter of 2004 to be at approximately the same monthly level as in the fourth quarter of 2003. Our cash needs throughout the rest of 2004 are expected to decrease due to a reduction in clinical trial activity followed by an increase in cash use in 2005. 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 progress and outcome of the Cellegy/PDI litigations, the costs of filing, prosecuting, defending and enforcing patent claims, oppositions and appeals, our ability to establish new collaborative arrangement and the initiation of commercialization activities and working capital increases associated with the scale up and manufacture of Cellegesic.

At December 31, 2003, the Company had a deficit accumulated during the development stage of $99.1 million. The Company expects negative cash flow from operations to continue for at least the next two years, with the need to continue or expand their development programs and to commercialize products once regulatory approvals have been obtained. Management believes that its existing cash balances will be sufficient to meet the Company's capital and operating requirements through December 31, 2004.

However, expenditures required to achieve the Company's growth and profitability in the long term may be greater than projected or the cash flow generated from operations may be less than projected. As a result, the Company's long-term capital needs may require the Company to seek to obtain additional funds through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources. There can be no assurance that the Company will be able to obtain additional

debt or equity financing on terms acceptable to the Company, or at all. If adequate funds are not available, the Company could be required to delay development or commercialization of certain products, to license to third parties the rights to commercialize certain products that the Company would otherwise seek to commercialize internally, or to reduce resources devoted to product development. Accordingly, the failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's ability to achieve its longer term business objectives.

In the fourth quarter of 1998, we entered into a ten-year operating lease commitment on our facility with our current landlord. Our operating lease commitments are $1,337,000 for 2004 and $5,700,000 thereafter in annual amounts of approximately $1.3 to $1.5 million. Information about this commitment as of December 31, 2003 is presented in the table below (in thousands):

Contractual Obligations	Total	2004	2005	2006	2007	2008
Operating lease	$7,037	$1,337	$1,377	$1,415	$1,433	$1,475

We sublease a portion of our facility and receive rental income from our sublease. Future sublease income is approximately $1,176,000 for 2004 and $4,843,000 thereafter in annual amounts of approximately $1.0 to $1.3 million.

In January 2004, Cellegy entered into a Structured Secondary Offering ("SSO") facility agreement with Kingsbridge Capital Limited. The facility requires Kingsbridge to purchase up to 3.74 million shares of newly issued common stock at times and in amounts selected by Cellegy over a period of up to two years, subject to certain restrictions. Cellegy may begin to draw down funds after the effectiveness of a registration statement that the Company intends to file with the Securities and Exchange Commission. The dollar amount of stock that Cellegy may require Kingsbridge to purchase will depend in part on the market price of the common stock at the time that the registration statement is filed and that shares are sold. The agreement does not prohibit Cellegy from conducting additional debt or equity financings, including PIPEs, shelf offerings, secondary offerings or any other non-fixed or future priced securities. The timing and amount of any draw downs are at Cellegy's sole discretion, subject to certain timing conditions, and are limited to certain maximum amounts depending in part on the then current market capitalization of the Company. Kingsbridge is not obligated to purchase shares at market prices below $1.25 per share. The purchase price of the common stock will be at discounts ranging from 8% to 12% of the average market price of the common stock prior to each future draw down. The lower discount applies to higher stock prices. In connection with the agreement, Cellegy issued warrants to Kingsbridge to purchase 260,000 common shares at an exercise price of $5.27 per share. Cellegy can, at its discretion and based on its cash needs, determine how much, if any, of the equity line it will draw down in the future, subject to the other conditions in the agreement.

In order to complete the research and development and other activities necessary to commercialize our products, financings in addition to the Kingsbridge SSO will likely be required. As a result, we may seek private or public equity investments and future collaborative arrangements or other transactions with third parties to meet such needs. However, there is no assurance that financing will be available for us to fund our operations on acceptable terms, if at all. We believe that available cash resources and the interest thereon will be adequate to satisfy our capital needs through, December 2004, assuming no material adverse financial impact associated with PDI litigation and any subsequent legal proceedings.

Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force ("EITF") reached a consensus on Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We do not expect the adoption of EITF issue No. 00-21 to have a material impact on our financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities

to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. During December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities, to the first reporting period ending after March 15, 2004. We do not expect the adoption of FIN 46 to have a material impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability or an asset in some circumstances. Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. While the effective date of certain elements of SFAS No. 150 has been deferred, we do not expect the adoption of SFAS No. 150 to have a material impact on our financial statements.

In December 2003, the SEC issued Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition," which codifies, revises and rescinds certain sections of SAB No. 101, "Revenue Recognition," in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The changes noted in SAB No. 104 did not have a material adverse effect on the Company's financial position or results of operations.

Factors That May Affect Future Operating Results

Risks Relating to Our Business

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, Fortigel 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 ("PDUFA"), 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 that file NDAs, there is no obligation on the FDA's part to do so. 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 substantial expenditures. 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.

One or more of our ongoing or planned clinical trials could be delayed, or the FDA could issue a Not Approvable letter with respect to our future NDAs, as it did with our Fortigel NDA in July 2003. Such

actions could result in further clinical trials or necessitate other time consuming or costly actions to satisfy regulatory requirements. The FDA may decide to have an Advisory Panel review the submission of our product candidates with an uncertain outcome of such panel's recommendation, or take other actions having the effect of delaying or preventing commercial introduction of our products. Similarly, the FDA or other regulatory agencies could impose requirements on future trials that could delay the regulatory approval process for our products. There can be no assurance that the FDA or other regulatory agencies will find any of our trial data, including our soon to be filed NDA for Cellegesic or other sections of our regulatory submissions, sufficient to approve any of our product candidates for marketing in the United States or in other overseas markets.

In January 2004, Cellegy reported positive results from its confirmatory Phase 3 study using Cellegesic for the treatment of chronic anal fissure pain. We now plan to submit an NDA to the FDA in the second quarter of 2004. The trial was conducted according to a Special Protocol Assessment ("SPA"), that was agreed upon by Cellegy and the FDA. An SPA is intended to provide assurance that if the pre-specified primary endpoint is achieved and no unexpected results are seen, the FDA will approve the product for commercial sale. Cellegy believes that it achieved the primary endpoint specified in the SPA; however, the FDA will conduct its own analysis and may reach a different conclusion. Failure of the FDA to approve Cellegesic for marketing or imposition by the FDA of significant additional studies or other requirements before granting marketing approval, could have a material adverse effect on Cellegy's business and stock price.

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 Phase 2 study for Tostrelle or the Cellegesic Phase 2 hemorrhoid trial, will demonstrate the results required to continue advanced trial development and allow us to seek marketing approval for these 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. Cellegy and other pharmaceutical companies have believed that their products performed satisfactorily in early tests, only to find their performance in later tests, including Phase 3 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 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;
- 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. We could be subject to delisting by the Nasdaq National Market.

Our accumulated deficit as of December 31, 2003 was approximately $99.1 million. We have never operated profitably and, given our planned level of operating expenses, we expect to continue to incur losses through at least 2004. 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 through development, 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.

Cellegy's common stock is currently listed on the NASDAQ National Market. There are several requirements for the continued listing of our common stock on the NASDAQ National Market, including requirements relating to stock price and to compliance with certain financial standards. If we fail to satisfy one or more of the criteria for continued listing and are unable to demonstrate compliance within the time periods permitted by NASDAQ, our common stock would be delisted from the NASDAQ National Market and we would likely seek a listing on the NASDAQ SmallCap Market or some other market. Delisting from the NASDAQ National Market would have a material adverse effect on our business and stock price.

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 continue or expand our 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 and skin care moisturizers and access to funding through the Kingsbridge SSO. The amount of cash required will depend on numerous factors including, without limitation: requirements in support of our development programs, the progress and results of pre-clinical and clinical testing, the time and costs involved in obtaining regulatory approvals, including the cost of complying with potential additional FDA information and/or clinical trial requirements to obtain marketing approval of our Fortigel product candidate, the costs of filing, prosecuting, defending and enforcing our intellectual property rights, the outcome of the PDI litigation, and legal costs and/or potential settlement payments associated with these legal proceedings. In order to complete the development, manufacturing and other pre-launch marketing activities necessary to commercialize our products, additional financing will be required.

In addition to the Kingsbridge SSO facility, Cellegy may seek private or public equity investments and future collaborative arrangements with third parties to help fund future cash needs. There is no assurance that such funding will be available for us to finance our operations on acceptable terms, if at all, and any future equity funding may involve significant dilution to our shareholders. Under certain circumstances we could be prevented from or be limited in fully utilizing planned funding from the Kingsbridge SSO. Insufficient funding may require us to delay, reduce or eliminate some or all of our research and development activities, planned clinical trials, administrative programs, personnel, outside services and facility costs. In addition, Cellegy would be subject to de-listing by the NASDAQ National Market if certain financial standards are not maintained. Cellegy believes that available cash resources together with the Kingsbridge SSO financing and interest earned thereon will be adequate to satisfy its capital needs through, at least, June 2005, assuming no material adverse financial impact associated with PDI litigation and any subsequent legal proceedings.

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, Fortigel 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 Fortigel. 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. For example, oppositions have 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. In December 2003, we reported that the Board of Opposition of the European Patent Office had rendered a verbal decision revoking Cellegy's European patent relating to its Cellegesic product and related compounds for the treatment of anal disorders, including fissures and various hemorrhoidal conditions. Although Cellegy intends to appeal this decision, an additional adverse outcome in the appeal process could have a negative effect on Cellegy, impacting the success of our marketing and corporate licensing efforts in Europe and adversely affecting our business and stock price.

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.

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. Besides the Fortigel license agreement with PDI, which is currently subject to litigation between the parties, Cellegy currently has a limited number of other agreements with third parties to commercialize our product candidates. Cellegy may not be able to establish other collaborative arrangements and we may not have the resources or the experience to successfully commercialize any

such products on our own, particularly in overseas markets. Failure to enter into other arrangements could prevent, delay or otherwise have a material adverse effect on our ability to develop and market products, including our Cellegesic product in the United States, and our Tostrex and Rectogesic products, in markets outside of North America.

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. 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 or may be subject to dispute or litigation between the parties.

In October 2003, Cellegy announced that it had received a communication on behalf of PDI invoking mediation procedures under the exclusive license agreement between PDI and Cellegy relating to Fortigel. The dispute resolution provisions of the agreement required non-binding mediation before either party could initiate further legal proceedings. Mediation proceedings were completed in early December 2003, after which both PDI and Cellegy initiated litigation proceedings. Although Cellegy believes PDI's claims are without merit, there can be no assurances regarding the outcome of any such proceedings, or any potential counterclaims by PDI, and the Company could be required to devote significant time and resources to the proceedings. An adverse outcome in any such proceeding could have a material adverse financial impact on Cellegy.

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 PendoPharm Inc., and certain other suppliers to manufacture our formulations. Although we are developing other contract manufacturers, there can be no assurance that we will be able to enter into acceptable agreements with them or successfully validate their facilities on a timely basis. 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 limit our ability to produce clinical or commercial product and otherwise adversely affect Cellegy's business and stock price.

In July 2003, PanGeo Pharma, Cellegy's major contract manufacturer, filed for bankruptcy protection under Canadian law. Under a re-organization plan, PanGeo sold its facilities to an affiliate of Pharmasciences, another Canadian manufacturer, and was re-named PendoPharm Inc. Uncertainty exists concerning the future operations of the manufacturing plant that is used to manufacture products for Cellegy, and there can be no assurance that PendoPharm will be able to meet Cellegy's clinical and product requirements on a timely basis, if at all, in the future. Cellegy is engaged in establishing production arrangements at a domestic location, although this is an expensive and time consuming process. There may be delays and additional costs relating to the technical transfer and validation of alternate suppliers.

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 have the financial capability to successfully establish a direct sales force or our collaborators may not effectively market our products. Either circumstance could have a material adverse effect on the successful commercialization of our products and ultimate profitability.

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 and staff. We have employment agreements and a severance/retention plan in place with certain executives, but none of our executives are legally bound to remain employed for any specific term. 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, which makes it difficult to attract and retain the qualified personnel necessary for the development and growth of our business.

Risks Relating to Our Industry

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 safer and 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 Fortigel product, if ever commercialized in the United States, is expected to compete with two currently marketed testosterone gel products sold by Unimed/Solvay and Auxilium Pharmaceuticals, a transdermal patch product sold by Watson Pharmaceuticals, a Buccal tablet from Columbia Laboratories and potential generic products which may be introduced before or after Fortigel is commercialized.

Cellegy's Cellegesic product, if commercialized, is expected to compete with over-the-counter products, such as Preparation H marketed by Wyeth, and various 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 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.

Risks Relating to Our Stock

Our stock price could be volatile.

Our stock price has from time to time experienced significant price and volume fluctuations. Since becoming a public company, our stock price has fluctuated in conjunction with the Nasdaq Stock Market

generally and sometimes on 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 particularly Fortigel and Cellegesic;
- Clinical trial results, particularly the outcome of our more advanced studies; or negative responses from regulatory authorities with regard to the approvability of our products;
- Period-to-period fluctuations in our financial results, including our cash and investment balance, operating expenses, cash burn rate or revenues;
- Negative announcements, additional legal proceeding or financial problems of our key suppliers, particularly relating to our Canadian manufacturer and our service providers;
- A negative outcome in litigation or other potential legal proceedings with PDI relating to the Fortigel license agreement; or
- Other potentially negative financial announcements, including delisting from the Nasdaq National Market or SEC, review of any of our filings by the Securities and Exchange Commission, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

The Kingsbridge SSO financing arrangement may have a dilutive impact on our stockholders. The SSO arrangement imposes certain limitations on our ability to issue equity or equity-linked securities

There are 4,000,000 shares of our common stock that are reserved for issuance under the Kingsbridge SSO, 260,000 of which is related to the warrant issued to Kingsbridge. In certain circumstances where the registration statement covering these shares that the Company is obligated to file is not effective or available to Kingsbridge, additional shares may be issuable to Kingsbridge under the agreement. The issuance of shares under the SSO, at a discount to the market price of the common stock, and upon exercise of the warrants will have a dilutive impact on other shareholders and the issuance or even potential issuance of such shares, if any, could have a negative effect on the market price of our common stock. If we sell stock to Kingsbridge when our share price is decreasing, such issuance will have a more dilutive effect and may further decrease our stock price.

To the extent that Kingsbridge sells shares of our common stock issued under the SSO to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares or encourage short sales. This could contribute to decline in our stock price.

During the two-year term of the Kingsbridge SSO, we are subject to certain restrictions on our ability to engage in certain equity or equity-linked financings without the consent of Kingsbridge. These restrictions primarily relate to non-fixed, future-priced securities. We may not issue securities that are, or may become, convertible or exchangeable into shares of common stock where the purchase, conversion or exchange price for such common stock is determined using a floating or otherwise adjustable discount to the market price of the common stock during the two year term of our agreement with Kingsbridge. However, the agreement does not prohibit us from conducting most kinds of additional debt or equity financings, including PIPES, shelf offerings, and secondary offerings.

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, 2003 will mature in 2004, 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, 2003, our investment portfolio consisted of $3,687,000 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 2003 levels, the fair value of our portfolio would decline by no more than $5,000. 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-26** of this report.

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

The disclosure called for by this Item has previously been provided by the Company on a Report on Form 8-K filed with the Securities and Exchange Commission on November 4, 2003, as amended by a report on Form 8-K/A filed November 20, 2003.

ITEM 9A: CONTROLS AND PROCEDURES (Additional language forthcoming from PWC)

(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-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2003. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures were effective as of December 31, 2003.

As discussed in Note 13 to the Consolidated Financial Statements, the Company has restated certain financial results and filed in an amended 2002 Annual Report on Form 10-K/A and amended quarterly reports on Form 10-Q/A for the first three quarters of 2003 in March 2004. The circumstances causing the restatement arose due to the complex nature of the accounting treatment of certain stock options that had been cancelled. As a result of the restatement, we reevaluated the effectiveness of our disclosure controls and procedures. Based upon this reevaluation we believe that our controls and procedures are effective and that no changes in such procedures or our internal controls are necessary or appropriate.

(b) Changes in Internal Controls

There were no changes in the Company's internal controls over financial reporting identified in connection with the evaluation by the Chief Executive Offer and Chief Financial Officer that occurred during the Company's fourth quarter that have materially affected or are reasonably likely to materially affect the Company's internal controls over financial reporting.

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 "2004 Proxy Statement") to be delivered to shareholders in connection with the Annual Meeting of Shareholders expected to be held in June 2004. 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 2004 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 2004 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 2004 Proxy Statement and is incorporated herein by reference.

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information with respect to this Item may be found in the section captioned "Principal Accountant Fees and Services" appearing in the 2004 Proxy Statement and is incorporated herein by reference.

PART IV

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

Exhibits

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

Exhibit Number	Exhibit Title
2.1	Asset Purchase Agreement dated December 31, 1997 between the Company and Neptune Pharmaceutical Corporation. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-3, file no. 333-46087, filed 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) filed 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 the fiscal quarter ended filed 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 the fiscal quarter ended March 31, 1998.)
*10.6	Employment Agreement, effective January 1, 2003, between the Company and K. Michael Forrest.
10.7	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 the fiscal year ended December 31, 2001.)
10.8	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.) (Incorporated herein by reference to Exhibit 10.10 to the Company's Form 10-K for the year ended December 31, 2002.)
10.9	Common Stock Purchase Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited.
10.10	Registration Rights Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited.
10.11	Warrant dated January 16, 2004 issued to Kingsbridge Capital Limited.
10.12	Retention and Severance Plan.

Exhibit Number	Exhibit Title
10.13	Form of Agreement of Plan Participation under Retention and Severance Plan.
*10.14	Letter agreement dated November 6, 2003 between Cellegy Pharmaceuticals, Inc. and Richard C. Williams.
*10.15	Stock option agreement dated November 6, 2003 between Cellegy Pharmaceuticals, Inc. and Richard C. Williams.
*10.16	Form of Indemnity Agreement between the Company and its directors and executive officers.
21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
23.2	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (See signature page.)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Represents a management contract or compensatory plan or arrangement.

(b) Reports on Form 8-K

Information regarding reports on Form 8-K and 8-K/A that we filed during our fourth quarter ended December 31, 2003, is as follows:

Date Filed or Furnished	Item Number	Description
October 27, 2003	Items 5 and 7	Initiation by PDI, Inc. of Non-Binding Mediation Proceedings
November 4, 2003	Items 4 and 7	Change in Registrant's Independent Accountant
November 6, 2003	Items 12 and 7	Third Quarter Financial Results
November 7, 2003	Items 5 and 7	Announcement of Changes to Cellegy's Board of Directors
November 20, 2003	Items 4 and 7	Change in Registrant's Independent Accountant
December 15, 2003	Items 4 and 7	Announcement of Resignation of Director, Dr. Ronald J. Saldarini; Filing of Declaratory Judgement Action against PDI, Inc.; European Patent Board's Decision regarding Cellegesic Patent

(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 6th of April, 2004.

CELLEGY PHARMACEUTICALS, INC.

K. Michael Forrest
President and Chief Executive Officer and Dire

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 confirming all that said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue thereof.

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

Name	Title	Date
Principal Executive Officer:		
/s/ K. Michael Forrest K. Michael Forrest	President, Chief Executive Officer and Director	April 6, 2004
Principal Financial Officer and Principal Accounting Officer:		
/s/ A. Richard Juelis A. Richard Juelis	Vice President, Finance, Chief Financial Officer and Secretary	April 6, 2004
Directors:		
/s/ Richard C. Williams Richard C. Williams	Chairman of the Board, Director	April 6, 2004
/s/ John Q. Adams, Sr. John Q. Adams, Sr.	Director	April 6, 2004
/s/ Tobi B. Klar, M.D. Tobi B. Klar, M.D.	Director	April 6, 2004
/s/ Robert B. Rothermel Robert B. Rothermel	Director	April 6, 2004
/s/ Thomas M. Steinberg Thomas M. Steinberg	Director	April 6, 2004

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

I, K. Michael Forrest, certify that:

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

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

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

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 6, 2004

K. Michael Forrest
President and 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 report on Form 10-K of Cellegy Pharmaceuticals, Inc.;

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

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

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors :

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 6, 2004

A. Richard Juelis
Vice President, Finance and Chief Financial Officer

Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with this annual report on Form 10-K of Cellegy Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2003, as filed with the United States Securities and Exchange Commission on the date hereof (the "Report"), K. Michael Forrest, as President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

i. The Report fully complied with the requirements of sections 13(a) or 15(d) of the Securities Exchange Act of 1934; and

ii. The information contained in the Report fairly presents, in all material respects, the financial Condition and results of operations of the Company:

/s/ K. Michael Forrest
President and Chief Executive Officer
Date: April 6, 2004

Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with this annual report on Form 10-K of Cellegy Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2003, as filed with the United States Securities and Exchange Commission on the date hereof (the "Report"), A. Richard Juelis, as Vice President, Finance and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

iii. The Report fully complied with the requirements of sections 13(a) or 15(d) of the Securities Exchange Act of 1934; and

iv. The information contained in the Report fairly presents, in all material respects, the financial Condition and results of operations of the Company

A. Richard Juelis
Vice President, Finance and Chief Financial Officer
Date: April 6, 2004

Index to Financial Statements

Report of Independent Auditors

To the Board of Directors and Shareholders of
Cellegy Pharmaceuticals, Inc.:

In our opinion, the consolidated financials statements listed in the accompanying index present fairly, in all material respects, the financial position of Cellegy Pharmaceuticals, Inc. and its subsidiaries (a development stage company) at December 31, 2003, and the results of their operations and their cash flows for the year then ended and, cumulatively for the period from January 1, 2003 to December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. 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 audit. We did not audit the cumulative totals of the Company for the period from June 26, 1989 (inception) to December 31, 2002, which totals reflect a deficit of 86.4 percent of the related total cumulative amount accumulated during the development stage. Those cumulative totals were audited by other auditors whose report, dated February 13, 2003 (except for Note 13, as to which the date is March 24, 2004), expressed an unqualified opinion on the cumulative amounts and included an explanatory paragraph that indicated that the consolidated financial statements as of and for the year ended December 31, 2002 have been restated as described in Note 13. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
April 6, 2004

Report of Ernst & Young LLP, Independent Auditors

The Board of Directors and Shareholders
Cellegy Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Cellegy Pharmaceuticals, Inc. (a development stage company) as of December 31, 2002, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2002, and for the period from June 26, 1989 (inception) through December 31, 2002 (not separately presented herein). 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 the consolidated results of its operations and its cash flows for each of the two 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.

The accompanying consolidated financial statements as of and for the year ended December 31, 2002 have been restated as discussed in Note 13.

/s/ Ernst & Young LLP

Palo Alto, California
February 13, 2003
(except for Note 13, as to which the date is March 24, 2004)

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Balance Sheets

	December 31, 2003	December 31, 2002 (Restated, see note 13)
Assets:		
Current assets		
Cash and cash equivalents	$ 7,649,878	$ 21,628,517
Short-term investments	3,686,919	2,002,123
Prepaid expenses and other current assets	508,123	608,313
Total current assets	11,844,920	24,238,953
Property and equipment, net	1,891,726	2,616,193
Restricted cash	227,500	227,500
Intangible assets, net	256,688	275,204
Goodwill	1,009,973	921,418
Other assets	100,000	100,000
Total assets	$ 15,330,807	$ 28,379,268
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 1,908,057	$ 2,005,279
Accrued compensation and related expenses	111,989	122,925
Current portion of deferred revenue	832,000	833,340
Total current liabilities	2,852,046	2,961,544
Long term liabilities	724,560	716,619
Deferred revenue	13,334,660	14,166,660
Total liabilities	16,911,266	17,844,823
Commitments and Contingencies (Note 4)		
Shareholders' equity (deficit):		
Preferred stock, no par value; 5,000,000 shares authorized: no shares issued or outstanding at December 31, 2003 and 2002	—	—
Common stock, no par value; 35,000,000 shares authorized: 20,045,000 shares issued and outstanding at December 31, 2003 and 19,652,356 shares issued and outstanding at December 31, 2002	97,293,984	96,139,764
Accumulated other comprehensive income	274,855	11,831
Deficit accumulated during the development stage	(99,149,298)	(85,617,150)
Total shareholders' equity (deficit)	(1,580,459)	10,534,445
Total liabilities and shareholders' equity (deficit)	$ 15,330,807	$ 28,379,268

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,
	2003	2002 (Restated, see note 13)	2001	2003
Revenues:				
Licensing and contract revenue from affiliate	$ —	$ —	$ —	$ 1,145,373
Licensing, milestone, and development funding	833,340	—	—	2,384,748
Government grants	18,833	45,798	566	566,966
Product sales	768,325	1,355,828	876,925	5,870,737
Total revenues	1,620,498	1,401,626	877,491	9,967,824
Costs and expenses:				
Cost of products sold	185,891	369,992	200,338	1,506,765
Research and development	10,558,174	10,403,214	14,097,746	72,175,558
Selling, general and administrative	4,768,529	6,389,847	4,041,642	31,719,125
Acquired in-process research and development	—	—	3,507,134	7,350,102
Total costs and expenses	15,512,594	17,163,053	21,846,860	112,751,550
Operating loss	(13,892,096)	(15,761,427)	(20,969,369)	(102,783,726)
Other income (expense):				
Interest expense	—	(27,136)	(27,283)	(1,503,729)
Interest income and other, net	359,948	547,961	1,531,929	6,586,662
Net loss	(13,532,148)	(15,240,602)	(19,464,723)	(97,700,793)
Non-cash preferred dividends	—	—	—	1,448,505
Net loss applicable to common shareholders	$(13,532,148)	$(15,240,602)	$(19,464,723)	$ (99,149,298)
Basic and diluted net loss per common share	$ (0.68)	$ (0.86)	$ (1.26)	
Weighted average common shares used in computing basic and diluted net loss per common share	19,963,552	17,642,640	15,502,918	

See accompanying notes.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Shareholders' Equity (Deficit)

	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 (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of convertible preferred stock, net of issuance cost through December 31, 2000	27,649	$ 6,801,730	—	$ —	477,081	$ 4,978,505	—	$ —	$ —	$ —	$11,780,235
Issuance of Series A convertible preferred stock and warrants to purchase 14,191 shares of Series A convertible preferred stock in exchange for convertible promissory notes and accrued interest through December 31, 2000	625,845	1,199,536	—	—	—	—	—	—	—	—	1,199,536
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 2000	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, 2000	(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
Issuance of common stock in connection with IPO in August 1995	—	—	—	—	—	—	1,322,500	6,383,785	—	—	6,383,785

See accompanying notes.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Shareholders' Equity (Deficit) (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 (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of common stock for cash through December 31, 2000	—	—	—	—	—	—	953,400	126,499	—	—	126,499
Issuance of common stock for services rendered through December 31, 2000	—	—	—	—	—	—	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
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
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
Compensation expense related to the extension of option exercise periods	—	—	—	—	—	—		338,481	—	—	338,481
Exercise of warrants to purchase common stock through December 31, 2000	—	—	—	—	—	—	59,086	918,479	—	—	918,479
Exercise of options to purchase common stock through December 31, 2000	—	—	—	—	—	—	371,574	1,342,291	—	—	1,342,291
Unrealized loss in investments through December 31, 2000	—	—	—	—	—	—	—	—	(27,270)	—	(27,270)
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
Foreign currency translation	—	—	—	—	—	—	—	—	(1,537)	—	(1,537)

See accompanying notes.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Shareholders' Equity (Deficit) (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 (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Net loss for the period June 26, 1989 (inception) to December 31, 2000	—	—	—	—	—	—	—	—	—	(49,463,320)	(49,463,320)
Total Comprehensive Loss through December 31,2000	—	—	—	—	—	—	—	—	—	—	(49,492,127)
Balances at December 31, 2000	—	—	—	—	—	—	13,838,053	69,735,022	(28,807)	(50,911,825)	18,794,390
Exercise of options to purchase common stock	—	—	—	—	—	—	60,803	203,437	—	—	203,437
Exercise of warrants to purchase common stock	—	—	—	—	—	—	12,000	48,000	—	—	48,000
Compensation expense related to warrants and options granted to non-employees	—	—	—	—	—	—	—	349,515	—	—	349,515
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
Common stock issued in connection with Vaxis acquisition	—	—	—	—	—	—	533,612	3,852,631	—	—	3,852,631
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

See accompanying notes.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Shareholders' Equity (Deficit) (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 (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of common stock in connection with the private placement of common stock in November 2002, net of issuance costs of $275,000	—	—	—	—	—	—	2,200,000	5,225,000	—	—	5,225,000
Compensation expense related to stock option modifications (restated)	—	—	—	—	—	—	—	249,746	—	—	249,746
Compensation expense for options related to non-employees	—	—	—	—	—	—	—	72,224	—	—	72,224
Unrealized gain (loss) on investments	—	—	—	—	—	—	—	—	(82,916)	—	(82,916)
Foreign currency translation	—	—	—	—	—	—	—	—	11,289	—	11,289
Net loss (restated)	—	—	—	—	—	—	—	—	—	(15,240,602)	(15,240,602)
Total Comprehensive Loss (restated)	—	—	—	—	—	—	—	—	—	—	(15,312,229)
Balances at December 31, 2002 (restated)	—	—	—	—	—	—	19,652,356	96,139,764	11,831	(85,617,150)	10,534,445
Exercise of options to purchase common stock	—	—	—	—	—	—	273,196	537,700	—	—	537,700
Compensation expense for options related to non-employees	—	—	—	—	—	—	—	153,784	—	—	153,784
Issuance of shares to CEO upon renewal of employment contract	—	—	—	—	—	—	107,118	425,000	—	—	425,000
Issuance of common stock for services	—	—	—	—	—	—	12,330	50,000	—	—	50,000
Financing fees	—	—	—	—	—	—	—	(12,264)	—	—	(12,264)
Changes in unrealized gain (loss) on investments	—	—	—	—	—	—	—	—	(424)	—	(424)
Gain on foreign currency translation	—	—	—	—	—	—	—	—	263,448	—	263,448
Net loss	—	—	—	—	—	—	—	—	—	(13,532,148)	(13,532,148)
Total Comprehensive Loss	—	—	—	—	—	—	—	—	—	—	(13,259,611)
Balances December 31, 2003	—	$ —	—	$ —	—	$ —	20,045,000	$97,293,984	$274,855	$(99,149,298)	$ (1,580,459)

See accompanying notes.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Cash Flows

	Years ended December 31,			Period from June 26, 1989 (inception) through December 31,
	2003	2002 (Restated, see note 13)	2001	2003
Operating activities				
Net loss	$(13,532,148)	$(15,240,602)	$(19,464,723)	$(97,700,793)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Acquired in-process technology	—	—	3,507,134	7,350,102
Depreciation and amortization	369,590	484,028	530,643	2,598,706
Intangible assets amortization	193,409	325,644	359,673	1,177,077
Loss (gain) on disposal of fixed assets	666,875	(86,476)	—	580,399
Non-cash equity compensation expense	578,784	321,970	349,516	2,190,499
Amortization of discount on notes payable and deferred financing costs	—	—	—	24,261
Issuance of common stock for services	50,000	—	—	1,040,918
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	100,190	229,032	18,732	(608,122)
Other assets	—	250,000	—	250,000
Accounts payable and accrued liabilities	(90,621)	112,026	450,023	1,914,658
Other long term liabilities	—	231,793	484,826	716,619
Deferred revenue	(832,000)	15,000,000	—	14,168,000
Accrued compensation and related expenses	(10,936)	(21,689)	5,541	111,989
Net cash provided by (used in) operating activities	(12,506,857)	1,605,726	(13,008,635)	(65,618,184)
Investing activities				
Purchases of property and equipment	(362,335)	(733,175)	(150,530)	(5,199,755)
Purchases of investments	(11,019,220)	—	(16,789,905)	(98,909,574)
Sales of investments	5,334,000	6,706,769	7,500,000	43,509,646
Maturities of investments	4,000,000	2,000,000	4,980,239	51,617,759
Proceeds from sale of property and equipment	50,337	187,337	—	237,674
Acquisition of Vaxis and Quay	—	—	(142,556)	(511,556)
Net cash provided by (used in) investing activities	(1,997,218)	8,160,931	(4,602,752)	(9,255,806)
Financing activities				
Proceeds from notes payable	—	—	—	8,047,424
Proceeds from restricted cash	—	386,499	—	386,499
Repayment of notes payable	—	—	(882,070)	(6,610,608)
Net proceeds from issuance of common stock	525,436	5,679,983	15,450,643	69,636,987
Other assets	—	—	—	(613,999)
Issuance of convertible preferred stock, net of issuance costs	—	—	—	11,757,735
Deferred financing costs	—	—	—	(80,170)
Net cash provided by financing activities	525,436	6,066,482	14,568,573	82,523,868
Net increase (decrease) in cash and cash equivalents	(13,978,639)	15,833,139	(3,042,814)	7,649,878
Cash and cash equivalents, beginning of period	21,628,517	5,795,378	8,838,192	—
Cash and cash equivalents, end of period	$ 7,649,878	$ 21,628,517	$ 5,795,378	$ 7,649,878

See accompanying notes.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Cash Flows (Continued)

	2003	2002 (Restated, see note 13)	2001	Period from June 26, 1989 through December 31, 2003
Supplemental cash flow information				
Interest paid	$ —	$27,136	$ 27,281	$ 639,987
Supplemental disclosure of non-cash transactions:				
Issuance of common stock in connection with acquired-in-process technology	$ —	$ —	$3,507,134	$ 7,350,102
Conversion of preferred stock to common stock	$ —	$ —	$ —	$14,715,474
Issuance of common stock for notes payable	$ —	$ —	$ —	$ 277,250
Issuance of warrants in connection with notes payable financing	$ —	$ —	$ —	$ 487,333
Issuance of convertible preferred stock for notes payable	$ —	$ —	$ —	$ 1,268,316
Issuance of common stock for milestone payments	$ —	$ —	$ 750,000	$ 750,000

See accompanying notes.

1. Accounting Policies

Description of Business and Principles of Consolidation

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

Cellegy Pharmaceuticals, Inc. 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.

Liquidity and Capital Resources

At December 31, 2003, the Company had a deficit accumulated during the development stage of $99.1 million. The Company expects negative cash flow from operations to continue for at least the next two years, with the need to continue or expand their development programs and to commercialize products once regulatory approvals have been obtained. Management believes that its existing cash balances will be sufficient to meet the Company's capital and operating requirements through December 31, 2004.

However, expenditures required to achieve the Company's growth and profitability in the long term may be greater than projected or the cash flow generated from operations may be less than projected. As a result, the Company's long-term capital needs may require the Company to seek to obtain additional funds through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources. There can be no assurance that the Company will be able to obtain additional debt or equity financing on terms acceptable to the Company, or at all. If adequate funds are not available, the Company could be required to delay development or commercialization of certain products, to license to third parties the rights to commercialize certain products that the Company would otherwise seek to commercialize internally, or to reduce resources devoted to product development. Accordingly, the failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's ability to achieve its longer term business objectives.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. 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 substantive and at risk non-refundable milestone payments specified under development contracts are recognized as the milestones are achieved. The Company may receive 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 and risk of loss have been transferred to the customer. There is no right of return for sales of our skin care products.

Research and development costs are expensed as incurred. The type of costs included in research and development expenses are salaries and benefits, laboratory supplies, external research programs, clinical studies, consulting and other expenses associated with regulatory filings and internally 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 based on actual activity including such factors as the number of subjects enrolled and number of subjects that have completed certain treatment phases 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, 2003 and 2002. 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 (deficit) as other comprehensive income (loss) until their disposition. The cost of securities sold is based on the specific identification method. Realized gains or losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest income and other, net.

The Company is subject to credit risk from its portfolio of marketable securities. By policy, the Company invests only in highly rated, liquid securities and 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. Depreciation and amortization of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets.

	Useful Life
Furniture and Fixtures	3 years
Office Equipment	3 years
Laboratory Equipment	5 years

Amortization for leasehold improvements is taken over the shorter of the estimated useful life of the asset or the remaining lease term. Upon sale or retirement, the assets' cost and related accumulated depreciation are removed from the accounts and only related gain or loss is reflected in operations.

Goodwill and Other Intangible Assets

Goodwill that is related to the purchase of Quay Pharmaceuticals in June 2000, represents the excess purchase price over the fair value of net assets acquired and 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 no longer amortizes the remaining balance of goodwill. The Company performed impairment tests of goodwill upon transition to Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets", and no impairment was identified at that time or in conjunction with the annual impairment test for fiscal years 2002 and 2003. The Company will continue to evaluate 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.

SFAS No. 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. The Company currently amortizes assets on a straight-line basis over their estimated useful lives of five years. Amortization recorded to date as of December 31, 2003 was approximately $1,177,000.

Reclassification

Certain prior year balances have been reclassified to conform to current year presentation.

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 United States 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 presented in the consolidated balance sheets consists of the accumulated net unrealized gain (loss) on available-for-sale investments and foreign currency translation adjustments.

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 SFAS No. 123, "Accounting for Stock-Based Compensation", as amended by SFAS No. 148 "Accounting for Stock-Based Compensation-Transition and Disclosure". 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 SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling Goods or Services," at the fair value of the equity instruments issued.

The Company has elected to follow APB Opinion No. 25 and related interpretations in accounting for its stock options since the alternative fair market value accounting provided for under SFAS No. 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 SFAS No. 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.

Had compensation cost for the Company's stock-based compensation plans been determined in a manner consistent with the fair value approach described in SFAS No. 123, the Company's pro forma net loss and net loss per share as reported would have been increased to the pro forma amounts indicated below:

	Year ended December 31,		
	2003	2002 (Restated, see note 13)	2001
Net loss as reported	$(13,532,148)	$(15,240,602)	$(19,464,723)
Add: Stock-based employee compensation costs included in reported net loss	425,000	249,746	—
Deduct: Stock-based employee compensation costs determined under the fair value based method for all awards	(1,839,447)	(2,227,933)	(2,687,751)
Net loss, proforma	$(14,946,595)	$(17,218,789)	$(22,152,474)
Basic and diluted net loss per share, as reported	$ (0.68)	$ (0.86)	$ (1.26)
Basic and diluted net loss per share, proforma	$ (0.75)	$ (0.98)	$ (1.43)

The Company valued its options on the date of grant using the Black-Scholes valuation model with the following weighted average assumptions:

	Year ended December 31,		
	2003	2002	2001
Risk-free interest rate	2.9%	2.5%	3.5%
Dividend yield	0%	0%	0%
Volatility	0.98	1.06	0.60
Expected life of options in years	4.3	4.3	4.3

The weighted average per share grant date fair value of options granted during the years ended December 31, 2003, 2002, and 2001 was $3.28, $3.80 and $5.33, respectively.

Recent Accounting Pronouncements

In November 2002, the EITF reached a consensus on Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. During December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities, to the first reporting period ending after March 15, 2004. The Company does not expect the adoption of FIN 46 to have a material impact on its financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer

classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability or an asset in some circumstances. Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. While the effective date of certain elements of SFAS No. 150 has been deferred, the Company does not expect the adoption of SFAS No. 150 to have a material impact on its financial statements.

In December 2003, the SEC issued Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition," which codifies, revises and rescinds certain sections of SAB No. 101, "Revenue Recognition," in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The changes noted in SAB No. 104 did not have a material effect on the Company's financial position or results of operations.

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 6,426,899, 1,864,551, and 5,041,375 for the years ended December 31, 2003, 2002 and 2001, respectively.

2. Investments

At December 31, 2003 and 2002, investments consist of the following:

	2003			2002		
	Cost	Gross Unrealized Gains	Fair Value	Cost	Gross Unrealized Gains	Fair Value
Corporate notes	$3,686,800	$119	$3,686,919	$2,001,580	$543	$2,002,123

The Company's investments in corporate notes of $1,433,000 and $2,253,000 will mature in April and July 2004, respectively.

3. Property and Equipment, net

Property and equipment, net consist of the following:

	December 31,	
	2003	2002
Furniture and fixtures	$ 185,815	$ 184,305
Office equipment	238,550	238,822
Laboratory equipment	874,753	978,485
Leasehold improvements	2,063,636	2,919,390
	3,362,754	4,321,002
Less: accumulated depreciation and amortization	(1,471,028)	(1,704,809)
	$ 1,891,726	$ 2,616,193

4. Lease Commitments and Contingencies

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 on a straight-line basis over the term of the sublease. Future minimum lease payments, net of future minimum sublease income at December 31, 2003, are as follows:

Years ending December 31,	Lease Commitments	Sublease Income	Future Minimum Lease Commitments
2004	$1,337,194	$(1,176,166)	$ 161,028
2005	1,377,005	(1,211,451)	165,554
2006	1,414,747	(1,247,795)	166,952
2007	1,432,716	(1,285,228)	147,488
2008	1,475,700	(1,099,341)	376,359
	$7,037,362	$(6,019,981)	$1,017,381

Rent expense, net of sublease income, was $335,661, $891,620 and $1,653,337 for the years ended December 31, 2003, 2002, and 2001, respectively. The Company received $148,000, $405,000 and $897,000 in sublease income, which is reflected in other income (expense), during the year ended December 31, 2003, 2002 and 2001, respectively.

Restricted cash at December 31, 2003 and 2002 was $227,500 and represents amounts that secure a letter of credit related to the Company's leases.

Litigation

In December 2002, Cellegy entered into an exclusive license agreement with PDI, Inc. ("PDI") to commercialize Fortigel in North American markets. Under the terms of the agreement, PDI's Pharmaceutical Products Group is responsible for the marketing and sale of Fortigel, if approved, utilizing its existing sales and marketing infrastructure. Cellegy received a payment of $15.0 million upon signing the agreement and is entitled to receive a milestone payment on FDA approval and royalties following a successful product launch. Cellegy is responsible for supplying finished product to PDI through Cellegy's contract manufacturer. In July 2003, the FDA issued a Not Approvable letter for our Fortigel NDA. In October 2003, Cellegy announced that it received a mediation notice from PDI. The dispute resolution provisions of the license agreement require non-binding mediation before either party may initiate further legal proceedings.

The communication asserted several claims relating to the agreement, including Cellegy's breach of several provisions of the agreement and failure to disclose relevant facts, and PDI claimed several kinds of alleged damages, including return of the initial license fee that PDI paid to Cellegy when the agreement was signed. The parties subsequently conducted mediation as contemplated by the agreement but did not reach any resolution of the claims.

In December 2003, Cellegy and PDI both initiated legal proceedings against each other relating to the agreement. Cellegy filed a declaratory judgment action in federal district court in San Francisco against PDI, and PDI initiated an action in federal district court in New York against Cellegy. In its action, Cellegy seeks, among other things, a declaration that it has fully complied with the license agreement and that PDI's claims are without merit. There can be no assurances regarding the outcome of either proceeding. The Company could be required to devote significant time and resources to the proceedings, and an adverse outcome could have a material adverse impact on our business and financial position. Such potential loss is not estimatable at this time.

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, 2003, 2002 and 2001 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 of 2002, the Company recorded severance and other related charges of $210,000 and $143,000, respectively. In the fourth quarter of 2002, the Company recorded a stock based compensation charge of $250,000 related to the extension of the exercise period of certain options held by terminated employees. All these amounts were paid and there is no remaining accrual balance as of December 31, 2003.

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, the Company issued 33,057 shares of common stock to Neptune. The Agreement calls for a series of additional payments, payable in shares of common stock, upon successful completion of various development milestones. Upon completion of milestones in 2001, the Company issued 104,113 shares of common stock valued at $750,000 which has been recorded to research and development expenses. The remaining milestones, if achieved, would become payable over the next several years. Depending on several factors, including the market price of the common stock, such payments, which are fixed based on the Agreement, could result in the issuance of a significant number of shares of common stock or cash. Future potential milestones, if all paid in Cellegy common stock could result in the issuance of up to an additional 1,285,000 shares of Cellegy common stock based on the closing price of Cellegy stock at time of issuance. The Agreement does not provide for the payment by the Company of any future product royalties in connection with sales of Cellegesic.

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

On November 27, 2001, Cellegy acquired Vaxis Therapeutics Corporation ("Vaxis"), 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 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 and therefore was expensed. 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, 2003 was $144,000. The expected amortization expense for Vaxis for the next three years will be approximately $82,217 per year. Amortization for Quay was fully recognized in May 2003.

Other Agreements

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 3 clinical trial.

In December 2002, Cellegy entered into a license agreement with PDI, Inc. ("PDI") granting PDI the exclusive right to store, promote, sell and distribute Fortigel, one of the Company's products awaiting FDA approval, in North American markets. Cellegy received an upfront payment of $15.0 million on the effective date of December 31, 2002 with an additional of $10.0 million payable no later than thirty days after the Company certifies to PDI that Fortigel has received all FDA approvals required to manufacture, sell and distribute the product in the United States. The Company recorded costs of $947,000 to selling, general and administrative expenses for the year ended December 31, 2002 related to this agreement. If the $10.0 million payment is received, the Company will incur additional financing costs of $600,000 payable to an investment bank. Under the PDI agreement, the Company would also receive royalties each year until the expiration of the last patent right related to Fortigel of 20% - 30% of net sales and the Company would be reimbursed for 110% of burdened costs for any product supplied to PDI. The $15.0 million up front payment was initially included as deferred revenue as of December 31, 2002 and is being recognized as revenue over the 18 year term of the agreement. As of December 31, 2003, total remaining deferred revenue of $14.2 million relates to this payment.

In October 2003, Cellegy received mediation notice from PDI. In December 2003, Cellegy and PDI initiated legal proceedings against each other. See also Note 4: "Litigation".

8. Shareholders' Equity (Deficit)

Common Stock Private Placements

In October 2000, the Company completed a private placement of 1.5 million 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, the Company completed a private placement of approximately 2.7 million shares of common stock at a price of $5.60 per share. Participants included two existing investors, as well as five new investors. Net proceeds were $15,199,206.

In November 2002, the Company completed a private placement of approximately 2.2 million shares of 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

The Company has two stock option plans that were approved by the Board and the shareholders of the Company in 1995: the 1995 Equity Incentive Plan (the "Plan") and the 1995 Directors' Stock Option Plan (the "Directors' Plan"). Both plans are administered by the Board. Subject to the overall supervision of the Board, the Board has designated the Compensation Committee as the administrator of both plans.

The Plan provides for the grant of options and other awards to employees, directors and consultants. Options granted under the Plan may be either incentive stock options or nonqualified stock options. Incentive stock options may be granted only to employees. The Compensation Committee determines who will receive options or other awards under the Plan and their terms, including the exercise price, number of shares subject to the option or award, and the vesting and exercisability thereof. Options granted under the Plan generally have a term of ten years from the grant date, and exercise price typically is equal to the closing price of the common stock on the grant date. Options typically vest over a three-year or four-year period. Options granted under the Plan typically expire if not exercised within 90 days (or such other period not to exceed five years) from the date on which the optionee is no longer an employee, director or consultant. The vesting and exercisability of options may also be accelerated upon certain change of control events.

Equity Incentive Plan

When the Plan was established in 1995, the Company reserved 700,000 shares for issuance. From 1996 to 2003, a total of 4,150,000 additional shares were reserved for issuance under the Plan.

Activity under the Plan is summarized as follows:

	Shares Under Option	Weighted Average Exercise Price
Balance at January 1, 2001	2,150,641	$5.00
Granted	476,000	$7.96
Canceled	(123,634)	$5.71
Exercised	(60,803)	$3.35
Balance at December 31, 2001	2,442,204	$5.59
Granted	1,898,789	$3.84
Canceled	(221,869)	$5.97
Exercised	(156,632)	$2.90
Balance at December 31, 2002	3,962,492	$4.83
Granted	363,500	$3.05
Canceled	(1,123,080)	$5.11
Exercised	(273,196)	$1.97
Balance at December 31, 2003	2,929,716	$4.77

At December 31, 2003, options to purchase 2,173,078 shares of common stock were vested and exercisable at exercise prices ranging from $1.80 to $15.00 per share. At December 31, 2002 and 2001, options to purchase 2,362,446 and 1,576,834 shares of common stock were vested and exercisable, respectively. At December 31, 2003, 882,850 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, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$1.80 - $ 3.90	1,538,836	7.5 years	$2.78	1,073,404	$2.87
$4.00 - $ 6.50	691,180	4.2 years	$5.18	626,608	$5.18
$7.00 - $15.00	699,700	6.1 years	$8.75	473,066	$8.55
Total	2,929,716	6.4 years	$4.77	2,173,078	$4.77

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 2003, a total of 350,000 shares were reserved for issuance under the Directors' Plan.

The Directors' Plan provides for the grant of initial and annual non-qualified stock options to non-employee directors. Initial options vest over a four-year period and subsequent annual options vest over three years. The exercise price of options granted under the Directors' Plan is the fair market value of the common stock on the grant date. Options generally expire 10 years from the Grant Date, and generally expire within 90 days of the date the optionee is no longer a director. The vesting and exercisability of options may also be accelerated upon certain change of control events.

Activity under the Directors' Plan is summarized as follows:

	Shares Under Option	Weighted Average Exercise Price
Balance at January 1, 2001	182,500	$5.01
Granted	46,000	$5.85
Balance at December 31, 2001	228,500	$7.26
Granted	64,000	$2.56
Balance at December 31, 2002	292,500	$4.61
Granted	60,000	$5.00
Canceled	(84,000)	$4.41
Balance at December 31, 2003	268,500	$4.75

At December 31, 2003, options to purchase 251,167 shares of common stock were vested and exercisable at exercise prices ranging from $2.56 to $8.50 per share. At December 31, 2003, options to purchase 60,833 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, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$2.56 - $3.25	44,000	8.0 years	$2.62	38,667	$2.63
$4.50 - $5.50	206,500	6.1 years	$5.04	194,500	$5.04
$6.50 - $8.50	18,000	6.9 years	$6.72	18,000	$6.72
Total	268,500	6.4 years	$4.75	251,167	$4.79

In November 2003, the Company granted an initial stock option to Mr. Richard Williams, on his appointment to become Chairman of the Board, to purchase 1,000,000 shares of common stock. 400,000 of the options have an exercise price equal to $2.89 per share, the closing price of the stock on the grant date and 600,000 of the options have an exercise price of $5.00 per share. The option is vested and exercisable in full on the grant date, although a portion of the option, covering up to 600,000 shares initially and declining over time, is subject to cancellation if they have not been exercised, in the event that Mr. Williams voluntarily resigns as Chairman and a director within certain future time periods.

Shares reserved

As of December 31, 2003, the Company has reserved shares of common stock for future issuance as follows:

Equity Plan	3,812,566
Directors' Plan	329,333
Chairman Options	1,000,000
Neptune Agreement	1,285,000
Total	6,426,899

Non-cash Compensation Expense Related to Stock Options

For the year ended December 31, 2003, the Company recorded non-cash stock compensation expense of $579,000 associated primarily with the modification of certain stock options and the renewal of employment contract of the CEO paid in stock. For the year ended December 31, 2002, the Company recorded non-cash compensation expense of $322,000.

9. Income Taxes

At December 31, 2003 the Company had net operating loss carryforwards of approximately $70,715,000 and $ 15,817,000 for federal and state purposes, respectively. The federal net operating loss carryforwards expire between the years 2004 and 2023. The state net operating loss carryforwards expire between the years 2004 and 2023. The state net operating loss carryforwards expire between the years 2004 and 2013. At December 31, 2003, the Company also had research and development credit carryforwards of approximately $1,757,000 and $995,000 for federal and state purposes, respectively. The federal credits expire between the years 2006 and 2023 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,	
	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 25,000	$ 19,300
Deferred revenue	5,600	6,000
Credit carryforwards	2,400	1,600
Capitalized intangibles	2,100	1,900
Other, net	20	—
Depreciation and amortization	1,120	800
Total deferred tax assets	36,240	29,600
Valuation allowance	(36,240)	(29,600)
Net deferred tax assets	$ —	$ —

Reconciliation of the statutory federal income tax to the Company's effective tax :

	2003	
	$	%
Net loss	($13,532)	
Tax at Federal statutory rate'	(4,601)	34.00%
State, net of Federal benefit	(832)	6.15%
Meals and entertainment	9	-0.07%
Stock compensation expense	46	-0.34%
Foreign rate differential	85	-0.63%
Research credits	(542)	4.00%
Deferred taxes not benefited	5,968	-44.10%
True up	(134)	0.99%
Provision for taxes	$ —	—%

The valuation allowance for deferred tax assets for 2003, 2002, and 2001 increased by approximately $6,640,000, $5,400,000, and $5,700,000, respectively.

10. Segment Reporting

The Company has two business segments: pharmaceuticals and skin care. 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 and South Korea, in addition to the PDI license revenue for Fortigel. 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 skin care business segment includes development expenses for non-prescription moisturizer and anti-aging products. During 2001, Cellegy incurred development expenses for its skin care products. No development expenses were incurred in 2003 and 2002. The Company's product sales are to 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 skin care 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 skin care product.

The following table contains information regarding revenues and operating income (loss) of each business segment for the years ended December 31, 2003, 2002, and 2001:

	Years ended December 31,		
	2003	2002 (Restated see note 13)	2001
Revenues:			
Pharmaceuticals	$ 1,304,498	$ 320,339	$ 217,439
Skin care	316,000	1,081,287	660,052
	$ 1,620,498	$ 1,401,626	$ 877,491
Operating income (loss):			
Pharmaceuticals	$(14,039,351)	$(16,462,264)	$(21,021,796)
Skin care	147,255	700,837	52,427
	$(13,892,096)	$(15,761,427)	$(20,969,369)

Total assets were minimal for the skin care segment.

Revenue from Major Customer

Revenues from product sales to one customer represented approximately 20%, 70% and 75% of total revenue for 2003, 2002 and 2001, respectively.

Geographic data

Approximately 28%, 20% and 25% of total revenues in 2003, 2002 and 2001, respectively, are from sales of Rectogesic in Australia and South Korea. All other sales are in the United States. Most of the Company's assets are located in the United States.

11. Related Party Transactions

The Company has paid fees to their board members for their services on the board, audit committee and compensation committee. The total fees paid to these directors during 2003, 2002 and 2001 were $103,000, $10,000 and $30,000, respectively. Cash compensation paid to the Chairman of the Board in 2003 was $15,300.

There were no consulting fees paid in cash to any board members in 2003 and 2002. For 2001, consulting fees of $80,000 were paid in cash to two board members based on consulting agreements. In addition, the Company recognized $131,000 and $33,000 in non-cash compensation expense during 2003 and 2002, respectively, associated with the valuation of vested stock options previously issued under a consulting agreement to a former board member.

Cellegy had an interest bearing $100,000 loan outstanding to a non-officer employee, which was issued in 1999 in conjunction with the purchase of his home. This loan had an interest rate of 5% and repayment was due at the end of the 15 year term of the loan or sooner. The loan was paid in full in April 2004.

12. Subsequent Events

In January 2004, Cellegy entered into a Structured Secondary Offering ("SSO") facility agreement with Kingsbridge Capital Limited. The facility requires Kingsbridge to purchase up to 3.74 million shares of newly issued common stock at times and in amounts selected by Cellegy over a period of up to two years, subject to certain restrictions. Cellegy may begin to draw down funds after the effectiveness of a registration statement that the Company intends to file with the Securities and Exchange Commission. The dollar amount of stock that Cellegy may require Kingsbridge to purchase will depend in part on the

market price of the common stock at the time that the registration statement is filed and that shares are sold. The agreement does not prohibit Cellegy from conducting additional debt or equity financings, including PIPEs, shelf offerings, secondary offerings or any other non-fixed or future priced securities. The timing and amount of any draw downs are at Cellegy's sole discretion, subject to certain timing conditions, and are limited to certain maximum amounts depending in part on the then current market capitalization of the Company. Kingsbridge is not obligated to purchase shares at market prices below $1.25 per share. The purchase price of the common stock will be at discounts ranging from 8% to 12% of the average market price of the common stock prior to each future draw down. The lower discount applies to higher stock prices. In connection with the agreement, Cellegy issued warrants to Kingsbridge to purchase 260,000 common shares at an exercise price of $5.27 per share. Cellegy can, at its discretion and based on its cash needs, determine how much, if any, of the equity line it will draw down in the future, subject to the other conditions in the agreement.

13. Restatement

In the course of preparing its financial statements for the year ended December 31, 2003, the Company determined that it was necessary to adjust the accounting treatment for certain employee and director stock options that had been cancelled during the fourth quarter of 2002. The Company initially accounted for the cancellation of certain unvested options as a modification to the stock options and applied variable accounting treatment to the uncancelled portion of the stock options. Subsequently, the Company determined that was not the appropriate application under generally accepted accounting principles, and reversed the $695,000 of expense previously recorded in the fourth quarter of 2002. Cellegy has filed an amended annual report on Form 10-K/A for 2002 and amended quarterly reports on Form 10-Q/A for each of the first three quarters of 2003.

A summary of the effect of this adjustment on the 2002 financial statements is as follows: in the statement of operations, research and development expense, selling, general and administrative expense and the net loss were reduced by $269,000, $426,000 and $695,000, respectively; on the consolidated balance sheet, common stock and the accumulated deficit were both reduced by $695,000.

Further changes to the Board included the addition of John Q. Adams, Sr., Thomas M. Steinberg and Robert B. Rothermel. John Adams is a 45-year veteran of the pharmaceutical industry adding operational, marketing, sales and regulatory skills. Tom Steinberg brings multi-industry financial experience supporting our goal of achieving long-term growth, financial strength and shareholder value. Bob Rothermel has extensive experience in the public accounting arena bringing much needed expertise to the Board and Audit Committee.

The combined and varied experience of these new directors, and the continuing contributions of Dr. Tobi Klar, will help us achieve our ambitious goals. At the same time, I would like to thank directors Jack Bowman, Alan Steigrod, Larry Wells and Ron Saldarini who stepped down from the Board late in 2003 for their invaluable contributions and tireless support over the past several years.

Financial Position

Cellegy's cash use continues to be in sync with the achievement of our focused corporate goals and reflective of efficient operational execution. In order to support Cellegy's development objectives, we entered into a structured secondary offering (SSO) agreement with Kingsbridge Capital Limited early in 2004 permitting us to sell up to 3.74 million shares of common stock, at our discretion and subject to various terms and conditions. With this standby source of capital in place, we believe Cellegy is well positioned and sufficiently funded to accomplish our goals for 2004. We are exploring other financing and corporate licensing options, which could supplement the SSO funding facility.

In closing, we believe the markets for NO donor technologies and prescription drugs targeting gastrointestinal conditions and sexual dysfunction continue to offer tremendous potential. Our progress in 2003, as it relates to our most mature pipeline product, Cellegesic, was a testament to the dedication and persistence of not only Cellegy's clinical personnel, but the entire Cellegy team. We look forward to keeping you, our shareholders, apprised of our progress. On behalf of Cellegy's Board of Directors and my talented colleagues, I thank you for your continued support.

Sincerely,

K. Michael Forrest
President and Chief Executive Officer
May 10, 2004

The Company's 2003 Annual Report to Shareholders consists of this letter and the accompanying Annual Report on Form 10-K for the year ended December 31, 2003.

Forward-Looking Statement

This letter contains forward-looking statements, subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed in this letter. Such risks and uncertainties relate to, among other factors, completion and timing of the NDA filing of Cellegesic Phase 3 clinical trial data and the completion of trials for hemorrhoids and dyspareunia. There can be no assurance that the FDA will find the Cellegesic trial data, the statistical analysis methodology used by the Company, or other sections of the NDA acceptable. The FDA may not agree that the trial data satisfied the standards specified in the Special Protocol Assessment and may not ultimately grant marketing approval for Cellegesic. In addition, there is no certainty as to the outcome and timing of discussions with the FDA, particularly with regard to additional requirements for marketing approval of Fortigel.

In December 2003, both PDI and Cellegy initiated litigation proceedings against each other relating to the Fortigel License Agreement. The Company believes PDI's claims are without merit. However, there can be no assurances regarding the outcome of litigation proceedings by Cellegy and PDI. The Company could be required to devote significant time and resources to the proceedings and an adverse outcome could have a material adverse financial impact on Cellegy. For more information regarding risk factors, refer to the Company's Annual Report on Form 10-K for the year ending December 31, 2003, and other company filings with the Securities and Exchange Commission.

BOARD OF DIRECTORS

Richard C. Williams
Chairman
President, Conner-Thoele Ltd.

K. Michael Forrest
President and CEO

John Q. Adams, Sr.
President, J.Q. Enterprises, Inc.

Tobi B. Klar, M.D.
Associate Clinical Professor Dermatology
Albert Einstein Medical Center

Robert B. Rothermel
Partner, CroBern Management

Thomas M. Steinberg
President, Tisch Family Interests

GENERAL COUNSEL

Weintraub Genshlea Chediak Sproul
Sacramento, California

PATENT COUNSEL

Townsend and Townsend and Crew LLP
San Francisco, California

REGULATORY COUNSEL

Hyman, Phelps & McNamara, P.C.
Washington, D.C.

OFFICERS

K. Michael Forrest
President and CEO

John J. Chandler
Vice President, Corporate Development

A. Richard Juelis
Vice President, Finance & CFO

David A. Karlin, M.D.
Vice President, Clinical Research

TRANSFER AGENT

Mellon Investor Services
Phone: (800) 522-6645
www.mellon-investor.com

INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP
San Jose, California

SHAREHOLDER INQUIRIES

If you have inquiries or wish to receive a copy of the Company's Annual Report on Form 10-K or other financial materials without charge, you may contact A. Richard Juelis in our Corporate Office at the address below.

CELLEGY
PHARMACEUTICALS INC

ANNUAL MEETING

Scheduled for Tuesday, June 15, 2004 at 8:30 a.m. at our Corporate Office.
349 Oyster Point Boulevard, Suite 200
South San Francisco, California 94080
(650) 616-2200
www.cellegy.com
NASDAQ: CLGY