

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, 1998

OR

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

Commission File Number 0-21180

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

California  
(State or other jurisdiction of  
incorporation or organization)

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

349 Oyster Point Boulevard, Suite 200, South San Francisco, California 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 None  
(Title of each class) (Name of each exchange on which registered)

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

Common Stock no par value  
Common Stock Purchase Warrants  
(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES X NO  
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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.

Registrant's revenues for the year ended December 31, 1998 were \$831,720.

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of March 16, 1999 was \$34,058,415 (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.

The number of shares of Common Stock outstanding as of March 16, 1999 was 10,173,294.

Documents Incorporated By Reference

The information called for by Part III is incorporated by reference to the definitive Proxy Statement for the Annual Meeting of Shareholders of the Company

to be held May 20, 1999, which will be filed with the Securities and Exchange Commission not later than 120 days after December 31, 1998.

CELLEGY PHARMACEUTICALS, INC. 10-K ANNUAL REPORT

FOR THE FISCAL YEAR ENDED DECEMBER 31, 1998

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PART I

ITEM 1: BUSINESS

Overview

Cellegy Pharmaceuticals, Inc. ("Cellegy" or the "Company"), incorporated in California in 1989, is a biopharmaceutical company engaged in the development of prescription drugs and high performance cosmeceutical products. The Company's products are all designed to be applied topically to address systemic medical conditions or skin diseases and other local conditions.

Cellegy's most advanced prescription product candidates include Anogesic(R), a nitroglycerin-based product for the treatment of anal fissures and hemorrhoids, and a transdermal testosterone gel for the treatment of male hypogonadism, a condition that frequently results in lethargy and reduced libido in men above the age of 40. Anogesic is currently undergoing a multi-center Phase III clinical trial in the United States for the treatment of chronic anal fissures. Cellegy's other prescription product, Glylorin(TM) (monolaurin), is a novel topical treatment for ichthyosis vulgaris and other severe dry skin conditions. In March 1999, Cellegy and Glaxo Wellcome Inc. ("Glaxo") announced their intention to terminate an existing license agreement with respect to Glylorin, thereby returning product rights to Cellegy.

In addition to prescription drugs, Cellegy is testing and developing a line of non-prescription cosmeceutical products which the Company believes will help reverse the signs of skin aging and address the skin care needs of an affluent and aging population. Cellegy's cosmeceutical products are expected to be marketed to dispensing dermatologists, cosmetic surgeons and prestige department stores by a separately established company, Cellisis Cosmeceuticals, Inc.

The Company's principal technologies consist of CELLEDIRM and PERMEATE. CELLEDIRM is a group of compounds identified by Cellegy's scientists and found in preclinical evaluations to reduce or eliminate irritation caused by many substances that come into contact with the skin. The Company's CELLEDIRM technology is currently being developed as an adjunct to its PERMEATE technology to mitigate skin irritation problems associated with transdermal drug delivery. Cellegy also believes that its CELLEDIRM technology can be used to develop a wide range of improved prescription and non-prescription products for the treatment of dermatological conditions, and can improve the performance of cosmeceutical products that are intended to enhance the appearance of the skin. PERMEATE is a patented topical drug delivery system which has been found in preclinical evaluations to permit delivery of larger or insoluble drugs into the blood stream or into the skin itself.

The Company has not yet completed the commercial development of any of its prescription drug candidates. It has completed development of a line of cosmeceutical products that it intends to commercialize in 1999. In 1998, the Company began selling an intensive moisturizer formulation for inclusion in a final product marketed by Bath and Body Works, a specialty retailer. There is no certainty that such sales will continue or that the Company's other cosmeceutical products will be commercialized within the expected time frame, if ever. In addition, the Company's business involves many other risks and uncertainties that could affect the Company's future financial position or results of operations. For further information regarding some of those factors, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Operating Results."

This Annual Report includes forward-looking statements. 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 concern matters that involve risks and uncertainties, including, but not limited to, those set forth below, that could cause actual results to differ materially from those in the forward-looking statements. The matters set forth below should be carefully considered when evaluating the Company's business and prospects.

#### Marketing and Commercialization Strategy

Cellegy intends to become a leader in the field of transdermal drug delivery and in the development and marketing of specialty pharmaceutical and cosmeceutical products that are applied to the skin. Key elements of its business and commercialization strategy include the following:

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Lower Risk Strategy for Selecting Product Candidates for Development. The Company does not intend to focus its near-term product development efforts on new chemical entities. Instead, the Company will focus on applying its proprietary technologies in the development of:

- (1) new or improved uses of topical and transdermal formulations of Food and Drug Administration ("FDA") containing approved or monographed pharmaceutical compounds. In all cases, Cellegy will attempt to achieve marketing exclusivity or patent protection for such products;
- (2) new cosmeceutical products that address the skin care needs of an increasing number of affluent middle-aged and older people;
- (3) new products, or sale of CELLEDIRM-based products, to corporate partners;
- (4) topical or transdermal formulations of new chemical entities in partnership with pharmaceutical or biotechnology companies.

Self Marketing to Specialty Physician and Dermatology Markets in U.S. Cellegy plans to market Anogesic and related products to a group of key physician specialists, either through the utilization of contract sales representatives or through the establishment of its own sales force. The Company plans to seek the support of a larger pharmaceutical company to assist in the promotion of these products to a broader physician audience. Cellegy also plans to retain exclusive or co-promotion rights in the United States to the dermatological and cosmeceutical products it develops, while outlicensing rights for other uses.

Outlicensing of Overseas Rights. The Company will initially pursue a policy of outlicensing the overseas rights for products it develops in exchange for upfront payments, royalties and/or product rights.

Leveraging of Corporate Alliances. Cellegy plans to enter into strategic alliances with established pharmaceutical companies for the development of certain products. These alliances generally will provide research or clinical funding and other support during the product development process. Cellegy's partners generally will provide established and trained marketing and sales forces. Cellegy generally will attempt to retain commercial rights to dermatological and other specialty pharmaceutical uses of products developed

under partner sponsored research collaborations.

Acquisition of Complementary Products. Although Cellegy is focusing primarily on the development of its own products and technologies, the Company may opportunistically acquire products, technologies or companies with products and distribution capabilities consistent with its commercial objectives.

#### Currently Marketed Products

##### High Performance Skin Care Products

The Company has completed development of certain consumer skin care and non-prescription products, including skin barrier repairing/fortifying moisturizers, skin protectant and anti-irritant lotions and creams. The Company is continuing to develop formulations in other related skin care consumer product categories. These products utilize certain of the Company's proprietary formulations. These formulations were tested for their moisturizing properties in humans compared with a leading commercial product. Results showed that the Cellegy formulations had more than a 50% higher moisturization effect 12 hours after application than the product tested.

The Company has incorporated this technology in a number of skin care formulations and is currently marketing one such formulation to specialty retailer Bath and Body Works, which incorporates them into their intensive moisturizing hand cream products. Cellegy revenues from sales of these products totaled \$458,000 in 1998.

Cellegy intends to expand the sale of such formulations to other specialty retailers which may market them under their own brand names through traditional, non-physician retail channels.

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#### Products Under Development

##### Prescription Products

##### Anogesic

The Company's leading product candidate is Anogesic, a topical prescription product for the treatment of anal fissures and hemorrhoids. Anogesic is a unique, nitroglycerin-based product which, based on published studies of trials in over 400 patients, appears to effectively heal anal fissures and is capable of dramatically reducing the pain of hemorrhoids. In a clinical study published in The Lancet it was shown that nitroglycerin promotes healing in over two-thirds of patients who would have required rectal surgery. The Company commenced a pivotal Phase III clinical trial for anal fissures in 1998 and expects to complete this study in 1999. In addition, Cellegy plans to initiate trials for complications of hemorrhoids in 1999.

Anal fissures are painful tears in the tissue of the anal mucosa and are common conditions affecting men and women of all age groups. Of the approximately 600,000 new cases of anal fissures each year in the U.S., Europe and Japan, approximately half require painful and expensive surgery, a procedure that sometimes leaves patients incontinent. A thrombosed external hemorrhoid is a dilated, swollen vein at the margin of the anus, resulting from clotting blood formed within the dilated external hemorrhoidal veins. In the United States alone, there are approximately nine million people who suffer from hemorrhoids each year.

Current drug therapies include anesthetics and anti-inflammatory agents that only partially relieve the symptoms of these conditions. Even though current treatments are only partially effective, sales of prescription products currently used to treat anal fissures and hemorrhoids have been estimated to be approximately \$500 million in the United States, Europe and Japan. Surgical procedures and hospitalization stays related to these conditions represent a substantial additional cost to the healthcare systems.

Anogesic is a proprietary formulation that includes nitroglycerin, a drug that has been used for many years in the treatment of certain heart diseases. Once administered, nitroglycerin causes relaxation of the sphincter muscle, which rapidly relieves pain and promotes the healing of the anal fissure or hemorrhoid. Anogesic is protected by two broad U.S. patents, both of which have been issued, the most recent in December 1997. In addition, numerous patent

applications have been filed in all major overseas markets.

The Company expects that the Phase III trials will generate the data required to pursue regulatory submission in the United States, and potentially, Europe. The clinical trials will include about 350 patients in several study centers in the United States. Patients receive one of three strengths of Anogesic or placebo. The product is administered on a daily basis until the patient's fissure is cured, up to a maximum administration period of eight weeks. The patient will then be observed for an additional 30-day period to determine whether any relapse occurs. Cellegy currently expects that the Phase III clinical trials for the fissure indication will be completed in 1999.

#### Testosterone Gel (male hormone replacement therapy)

The Company is currently developing a transdermal testosterone gel to address male hypogonadism (or andropause), a condition which results from a decline in the body's production 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 and bone mass can occur. Approximately 5 million men in the United States, primarily in the aging (over 40) male population group, have lower than normal levels of testosterone. Hypogonadism is the first indication for which the Company will seek regulatory approval in the U.S.

There are a number of companies currently marketing testosterone in several different product forms in domestic and certain international markets. Cellegy believes that a major market opportunity exists for an improved product, as the side effects and patient inconveniences associated with the currently marketed products have limited their use to less than 5% of potential patients. Current product forms include orals, injectables and transdermal patches.

Cellegy's patchless testosterone gel will incorporate the Company's CELLEDIRM technology. The gel product is expected to permit a once-a-day application of a metered dose to a small area of the skin without the irritation associated with current patch products. The current gel appears to be transparent, rapid drying and non-staining.

Based on preclinical studies to date, the Company believes its proprietary transdermal gel formulation is capable of delivering therapeutic levels of testosterone with reduced side effects and in a more convenient dosage form compared with other currently marketed products. Preclinical and human pharmacokinetic studies demonstrated transdermal testosterone delivery into the bloodstream at levels comparable to a leading patch product.

The Company has commenced a pharmacokinetic study at two prominent U.S. medical centers. If the study is successful, Phase III human trials for the treatment of hypogonadism are planned for late 1999. The Company believes that due to well-documented toxicology and efficacy data regarding the use of testosterone, regulatory approval of its transdermal testosterone gel may be achieved more quickly than would normally be associated with a new chemical entity.

#### Glylorin

Glylorin is a product developed by Dr. Carl Thornfeldt, Cellegy's founder and Chairman. The product is being developed for skin conditions which range from mild to severe ichthyosis vulgaris ("IV") and other severe dry skin conditions. In November 1996, Cellegy licensed Glylorin to Glaxo. In March 1999, Cellegy and Glaxo announced their agreement in principle to terminate the license agreement, at the request of Cellegy, with the return to Cellegy of Glylorin product rights. Cellegy will seek another partner to complete clinical development and regulatory approval of Glylorin in return for specifically defined geographic marketing rights, once it reacquires the product rights from Glaxo. If Cellegy is unable to find another corporate partner to develop Glylorin, it is not currently anticipated that Glylorin will be further developed by Cellegy, and the product may therefore not be commercialized.

#### Congenital Primary Ichthyosis

Ichthyosis is a family of related incurable skin diseases characterized by

a severe scaling of the skin that frequently affects large areas of the body. In all forms of ichthyosis, skin cells form a rigid, thick surface layer of scales that often discolor and crack. Congenital primary ichthyosis (CPI) is a group of the most severe and debilitating forms of ichthyosis, affecting all age and ethnic groups. Approximately 100,000 people in the United States and at least an equal number of persons outside the United States are afflicted with CPI. Glylorin has been granted Orphan Drug status by the FDA for the treatment of this condition.

In March 1998, the Company announced the results of a double-blind, placebo controlled Phase III clinical trial to evaluate the effectiveness of Glylorin in non-bullous congenital ichthyosiform erythroderma ("n-CIE"), a form of CPI. Utilizing the statistical method established in the original protocol for the trial, Glylorin did not show a statistical difference compared with the vehicle (placebo) in improving scaling, the primary outcome endpoint. However, the investigators' global assessment scores showed that 43% of the patients improved overall by more than 50% over time compared with only 19% of those receiving the vehicle. Moreover, when all the observations of each patient over the 12-week study were analyzed using a different statistical method, a significant improvement compared with the vehicle was observed for some outcome variables, including scaling at all timepoints. While the results of the study were encouraging overall, Cellegy has determined that it will not pursue the CPI indication at this time.

#### Ichthyosis Vulgaris

In 1998, Glaxo completed a Phase II clinical trial for the treatment of Ichthyosis Vulgaris, a milder form of ichthyosis which afflicts approximately one million people in the United States and a similar number in Europe. The disease is characterized by severe dry skin and scaling (although not as thick as the scaling present in CPI). Lac-Hydrin, the only currently approved prescription product for the treatment of IV, has certain side effects, including irritation and stinging on thinner skin areas such as the face. In addition, the product is not indicated for pediatric use. The results of the Phase II study, which were announced in August 1998, showed that Glylorin was able to completely clear 56% of the lesions treated, whereas only 33% of the lesions treated with the vehicle were cleared. Based on these results, the Company and Glaxo prepared a proposed Phase III clinical trial protocol which was discussed with, and approved in principle by, the FDA late in 1998.

#### Testosterone Gel (female hormone replacement therapy)

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%. Normal blood concentrations of testosterone in women range from

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10 to 20 times less than that of men. Nevertheless, in both sexes, testosterone plays a key role in building muscle or bone tissue, and the maintenance of sexual drive.

Cellegy's testosterone gel product (for the treatment of male hypogonadism) is being designed so that the dose can be readily reduced and customized to restore normal testosterone levels in women. The Company believes that this change may be accomplished by reducing the amount of gel delivered via a metered dose without a significant change in the product formulation. Thus, the Company believes that the same formulation can be developed and tested for use in both hypogonadism and menopause. Clinical studies for this indication are planned to commence once the initial studies in hypogonadal males are completed.

#### Estrogen-Testosterone Gel (female hormone replacement therapy)

Cellegy's third planned product in the area of hormone replacement therapy is a combination estrogen-testosterone gel which utilizes the Company's proprietary drug delivery technologies to restore the natural levels of both hormones in elderly or menopausal women. The Company believes that this product may offer significant advantages over the patches in terms of reduced side effects and patient convenience. The combination formulation is in the research stage with clinical trials planned following development of the mono-therapy testosterone products.

## Cosmeceutical Products

Cosmeceuticals (a hybrid of the words cosmetics and pharmaceuticals) are products that contain active ingredients which, when applied to the skin, will enhance appearance. Cosmeceuticals that satisfy the legal definition of a cosmetic under the Food Drug & Cosmetic Act, and that are not also drugs under that statute, are not subject to the same FDA regulations as drug products. Such cosmeceuticals may be marketed to consumers without prior approval by the FDA and without requiring a prescription from a physician. Cellegy also intends to use its formulation expertise to improve existing non-prescription topical medications.

### Anti-Wrinkling Products \*

The Company's core cosmeceutical program, includes anti-wrinkling products which, based on human studies to date, appear to mitigate the visible effects of photoaging and skin wrinkling. Cellegy's anti-wrinkling products will be included in a line of products that the Company believes has a different mechanism of action which is expected to produce greater improvement to the skin's appearance and cause less irritation than current market leading products.

Signs of aging and photoaging usually become visible when people reach their early thirties, with fine lines and roughness, loss of suppleness and elasticity of the skin becoming apparent. In subsequent decades, there is further deterioration marked by coarse wrinkles, spotty irregular pigmentation, leathery texture or thinning of the skin. Many of the skin changes associated with aging are due to ultraviolet light exposure, referred to as "photoaging." At the retail level, the non-prescription market for products which are used to mitigate the effects of aging and photodamage upon the skin is estimated to be in excess of \$1 billion in annual sales in the United States and growing at approximately 14% per year. The current high performance cosmeceutical anti-wrinkling market in the United States consists of a few broad categories of products, utilizing the following active ingredients: alpha and beta hydroxy acids, retinols and anti-oxidants.

Many of the currently marketed department store cosmeceutical products contain low concentrations of one or more of the above mentioned active ingredients and, to the Company's knowledge, their efficacy has not generally been supported by clinical studies. Low concentrations of the active ingredients are frequently employed in order to avoid side effects which can include stinging, redness and skin irritation, which generally increase with the concentration of the active ingredient used. However, the low concentrations of the active ingredient generally limit the efficacy of the products. Most of the cosmeceutical lines marketed to physicians contain higher concentrations of actives, yet the formulations are not substantiated by clinical study results.

Cellegy's high performance anti-wrinkling products incorporate CELLEDIRM, together with an active ingredient having multi-action capability exhibiting many of the attributes of several of the active cosmeceutical ingredients listed above. Certain human studies already completed and others in progress may provide stronger

comparative measurement data versus certain leading cosmeceutical products. If development continues successfully, the Company believes the product line could be available for launch in 1999. The products are planned to be marketed and distributed by Cellisis Cosmeceuticals Inc., a company recently established by Cellegy. Marketing efforts will be focused on the professional market segment (dermatologists, cosmetic and plastic surgeons), as well as the prestige department store market segment, capitalizing on the Company's research and human studies and its expertise in skin biology.

\* References in this Report to "anti-wrinkling," "anti-wrinkling products" or the "anti-wrinkling market" are intended to refer to a product category that the Company believes is generally understood in the marketplace or to products in that category, and are not intended to describe any claims that the Company's cosmeceutical products act in any way other than as cosmetics as defined under applicable laws. The term "cosmeceuticals" refers to products that, if they satisfy the definition of a cosmetic under applicable federal laws and if they are not also drugs under those laws, are not subject to the same requirements as



drug products. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Operating Results -- Possible FDA Regulation of Cosmeceutical Products as Drugs" and "Government Regulation."

## Technology

### Background in Skin Biology

Cellegy's technologies and products have been developed based on its research in skin biology and knowledge of the physical functions of the skin, particularly the epidermis. The epidermis is comprised mainly of cells known as keratinocytes that are continually regenerated and move toward the skin surface where they flatten, lose their nucleus, and become the outermost layer of the epidermis, the stratum corneum. The stratum corneum acts as a protective barrier against physical injuries and disease, and regulates the loss of moisture from the body. It consists of an array of flattened cells suspended in highly organized lipid structures, similar conceptually to a brick and mortar arrangement. Most importantly, these lipids regulate the permeability properties of the skin and, therefore, the movement of topically applied drugs into the body.

In addition to its physical role as barrier, the epidermis is biologically active, capable of initiating a full inflammatory reaction (characterized by redness and swelling). Normally, this process is a protective reaction in response to various noxious stimuli such as sunlight, irritants or mechanical injury (i.e., abrasions and burns). The same reaction, however, can result following the topical application of many drugs.

Similarly, certain dermatologic diseases can also be linked to environmental influences. Psoriasis, for example, which is characterized by inflammation and accelerated growth of the epidermis, can sometimes be triggered by a simple cut or abrasion to the skin. Nonetheless, despite material differences in appearance and symptoms, this disease and the other inflammatory reactions described above all share fundamental similarities in the underlying biological processes mediated by the epidermis.

### Core Technology

Cellegy's focus on the biological functioning of the skin has permitted development of two novel technologies: (i) CELLEDIRM, which appears to be capable of mitigating the irritation and inflammation caused when drugs, solvents and other substances come into contact with the skin, and (ii) PERMEATE, which appears to be capable of enhancing the delivery of drugs applied to the skin for systemic delivery or for the treatment of local skin conditions.

### CELLEDIRM Technology

CELLEDIRM (Cellegy's Dermal Inflammatory Response Modulators) is a group of compounds identified by Cellegy's scientists that have been found to be capable of reducing the inflammation associated with the topical application of drugs, solvents or other physiologically active substances. These compounds consist of specially processed or purified excipients that have been shown in preclinical studies to significantly reduce skin inflammation following challenge with a number of irritating or allergenic substances.

The Company has conducted a number of research studies investigating the utility of CELLEDIRM in mitigating the symptoms of skin inflammation. These compounds have been shown to reduce inflammation by up to 40% in animal models challenged with either a potent irritant or an allergen. These effects are comparable to those achieved with topical corticosteroids.

The Company expects its proprietary CELLEDIRM technology to complement its PERMEATE drug delivery system and to provide a unique platform for the development of novel topical products which could benefit from the anti-inflammatory or anti-allergic activities of CELLEDIRM. Since the active ingredients within CELLEDIRM are either GRAS (generally regarded as safe) or used as excipients in various pharmaceutical or cosmetic products, the Company believes the use of these compounds will not lengthen the United States Food and Drug Administration ("FDA") review time of therapeutic drug products in which

they are used. Accordingly, the Company plans to utilize these compounds in the development of its testosterone product and certain other prescription and cosmeceutical products.

#### PERMEATE Technology

PERMEATE is a patented technology which employs bioactive permeation enhancers to permit the passage of larger molecule drugs into or through the skin. This technology consists of a variety of methods to manipulate the three primary lipids which characterize the properties of the stratum corneum: cholesterol, ceramides and free fatty acids. Normal barrier function requires a specific critical ratio of these three lipids. The Company has shown that its newly identified enhancers can alter these lipid ratios to increase the permeability of the skin by inhibiting specific enzymes responsible for the synthesis of these lipids, or by inducing defects in the rigid lipid structures of the stratum corneum.

Cellegy's PERMEATE system has the potential of being able to open the stratum corneum barrier wider than previously believed possible, and to keep it open longer than conventional solvent approaches. This has been found in preclinical studies to facilitate the permeation of larger or more insoluble drugs into the skin or into the bloodstream. Cellegy's studies to date have also shown that these enhancers can exert their effect when formulated as topical creams or gels or in conventional transdermal patches.

The Company's research findings include the evaluation of selected PERMEATE systems in conjunction with the following drugs: testosterone, vasopressin, luteinizing hormone releasing hormone ("LHRH"), lidocaine, cimetidine, hydrocortisone and caffeine. Two of these compounds (LHRH and vasopressin), delivered using the Company's PERMEATE technology, are peptides which, to the Company's knowledge, have never before been delivered transdermally using conventional solvent technologies. The molecular weights of LHRH and vasopressin (approximately 1000 and 1200, respectively) are significantly greater than the (approximately 400 molecular weight) molecular weights of drugs delivered using currently approved transdermal patches. Because of other priorities, Cellegy does not expect to undertake significant research and development on PERMEATE during 1999.

#### Product Opportunities

##### Prescription Products

Cellegy seeks to capitalize on its knowledge of skin biology to develop treatments for a wide range of conditions which can be addressed by the topical application of prescription drugs. This includes the incorporation of CELLEDIRM to complement the anti-inflammatory activity of known drugs including corticosteroids.

##### Consumer and Cosmeceutical Products

Cellegy researchers are developing consumer and cosmeceutical products that fortify the protective function of the skin barrier and may improve the skin's ability to protect against environmental and occupational skin damage, thus preventing and/or reversing the signs of aging. Studies conducted to date by Cellegy and its collaborators suggest that these products may help alleviate inflamed skin conditions, as well as help reverse signs of photoaging, including fine lines, roughness, irregular pigmentation and wrinkling.

#### Drug Delivery Applications

Transdermal delivery involves the topical administration of drugs to the skin for the treatment of systemic diseases or localized skin conditions, generally using patches. Transdermal delivery systems may offer significant advantages over many conventional oral dosage forms and most parenteral (injectable) dosage forms. Those advantages include increased convenience, less pain (compared to injections), improved patient compliance, and potentially reduced side effects. Transdermal delivery systems can also offer certain advantages to pharmaceutical companies, including brand extension, product differentiation and additional patent protection.

Transdermal delivery has historically been limited to those drugs which are small in size, highly potent and can easily penetrate the skin due to their physical and chemical characteristics. Specifically, the Company believes that drugs with molecular weights larger than 400, or those drugs requiring daily doses greater than five milligrams or that are too lipid soluble, will be difficult to deliver transdermally with currently marketed systems. Although many companies have experimented with different transdermal drug delivery methods, they have enjoyed only limited success. Of all the prescription drugs in the United States, less than ten drugs are currently approved by the FDA for transdermal administration. Although reasonably successful compared with other non-oral routes of drug administration (for example, nasal, implants or liposomal-based systems), transdermal delivery has proved more difficult than initially anticipated.

The principal reason for the limited number of transdermal products relates to irritation caused by solvents designed to ease the passage of drugs through the skin. These solvents dissolve the lipid-rich stratum corneum membranes, while many also damage the keratinocytes, permitting the passage of the therapeutic agent into the lower levels of the skin, where it can be absorbed into the bloodstream. However, the interaction of the solvents with the metabolically active stratum corneum and the resulting inflammatory responses have been greater than anticipated. Several currently marketed transdermal patches utilize these solvents with, in many cases, high incidence of adverse skin reactions.

Recent efforts to expand the number and type of drugs delivered transdermally include the use of iontophoresis (mild electrical charges) or ultrasound waves in order to help drive the drug through the skin. While these approaches may prove successful for a few drugs, the Company believes that the resulting inflammatory skin reactions and higher product costs are likely to limit the use of these techniques.

With the advent of biotechnology, the discovery and development of larger molecular size drugs (including proteins, peptides and oligonucleotides) has increased significantly. As many of these potentially breakthrough new drugs are amenable only to injectable administration, the Company believes that transdermal methods to deliver these products represent an increasingly large commercial opportunity. Cellegy's approach to this challenge has been to develop novel technologies which (i) do not rely on solvent permeation enhancers, (ii) increase the size of molecules deliverable through the skin and (iii) mitigate skin irritation.

The Company's research and development expenses were \$6,668,000 in 1998, \$3,788,000 in 1997, and \$2,712,000 in 1996. See "Management's Discussion and Analysis of Financial Condition and Results of Operation."

#### Patents and Trade Secrets

The Company's success depends, in part, on its ability to obtain patent protection for its products and methods, both in the United States and in other countries. The patent position of companies engaged in businesses such as the Company's business generally is uncertain and involves complex legal and factual questions. There is a substantial backlog of patent applications at the U.S. Patent and Trademark Office ("USPTO"). Patents in the United States are issued to the party that is first to invent the claimed invention. Since patent applications in the United States are maintained in secrecy until patents issue, the Company cannot be certain that it was the first inventor of the invention covered by its pending patent applications or patents or that it was the first to file patent applications for such inventions. Further, issued patents can later be held invalid by the patent office issuing the patent or by a court. There can be no assurance that any patent applications relating to the Company'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 a competitive advantage to the Company. In addition, many other entities are engaged in research and product development efforts in drug delivery, skin biology and cosmeceutical fields that may overlap

with the Company's currently anticipated and future products. A substantial number of patents have been issued to such companies, and such companies may have filed applications for, or may have been issued patents or may obtain

additional patents and proprietary rights relating to, products or processes competitive with those of the Company. Such entities 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 the Company. These rights may prevent the Company from commercializing technology, or may require the Company to obtain a license from the entity to practice the technology. There can be no assurance that the Company will be able to obtain any such licenses that may be required on commercially reasonable terms, if at all, or 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, the Company is subject to the risk that persons located in such countries will engage in development, marketing or sales activities of products that would infringe the Company's patent rights if such activities were in the United States.

Several of the Company's products are based on existing compounds with a history of use in humans but which are being developed by the Company for new therapeutic use in skin diseases unrelated to the systemic diseases for which the compounds were previously approved. The Company cannot obtain composition patent claims on the compound itself, 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. The Company will not be able to prevent a competitor from using that formulation or compound for a different purpose. No assurance can be given that any additional patents will be issued to the Company, that the protection of any patents that may be issued in the future will be significant, or that current or future patents will be held valid if subsequently challenged.

The agreements with the University of California pursuant to which the Company has exclusive license rights to certain barrier repair and drug delivery and other technology contain certain development and performance milestones which the Company must satisfy in order to retain such rights. While the Company currently believes it will be able to satisfy the revised milestone dates, a loss of rights to these technologies could have a material adverse effect on the Company.

As of the end of March 1999, the Company has 16 issued United States patents, more than 35 issued foreign patents, and over 70 pending patent applications. The majority of these patents are for the use of certain compounds to treat common or severe inflammatory dermatologic diseases including dermatitis, psoriasis, rosacea and acne, as well as disorders such as various ichthyoses, signs and symptoms of skin aging and premalignant actinic keratoses. Three issued United States patents and 22 issued foreign patents relate to the Company's Glylorin product for the treatment of ichthyosis and certain other skin diseases and conditions. Two issued United States patents and more than 10 pending patent applications relate to the Company's Anogesic(R) product for the treatment of anal fissures. Two issued United States patents and 8 pending patent applications relate to the Company's PERMEATE drug delivery technology, and one issued United States patent and 5 issued foreign patents relate to the barrier repair technology licensed from the University of California. Additional patent applications are being prepared for filing that will cover methods or products currently under development. Corresponding patent applications for most of the Company's issued United States patents have been filed in countries of importance to the Company located in major world markets, including certain countries in Europe, Australia, South Korea, Japan, Mexico and Canada.

Federal patent law provides that for any inventions that have been developed with government funding that are the subject of a license, the government has the right to require the assignor or the licensee to grant a license to third parties upon the occurrence of certain events, such as if the government determines that no effective steps have been taken to achieve practical application of the invention, or if health or safety needs or requirements for public use are not reasonably satisfied.

The Company's policy is to protect its technology by, among other things, filing patent applications for technology that it considers important to the development of its business. The Company intends to file additional patent applications, when appropriate, relating to its technology, improvements to its technology and to specific products that it develops. It is impossible to anticipate the breadth or degree of protection that any such patents will

afford, or whether the Company can meaningfully protect its rights to its unpatented trade secrets. The Company also relies upon unpatented trade secrets and know-how, and no assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to the Company's trade secrets or disclose such technology, or that the Company can meaningfully protect its rights to its unpatented trade secrets. It is the Company's policy to require its employees to execute an invention assignment and confidentiality agreement upon employment. Cellegy's consultants are required to execute a confidentiality agreement upon the commencement of their consultancy to the Company. 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 the Company. In addition, it is the Company's policy to require the collaborators and potential collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for the Company's trade secrets.

#### Product Acquisitions

In December 1997, the Company acquired patent and related intellectual property rights relating to Anogesic (the "Agreement"), a topical product candidate for the treatment of anal fissures and hemorrhoids from Neptune Pharmaceutical Corporation. Pursuant to the Agreement and a subsequent letter of intent between the parties, the Company issued 462,809 shares of Common Stock to Neptune in 1997. The Agreement calls for a series of additional payments, payable in shares of Common Stock, upon successful completion of various milestones which, if achieved, would occur over the next several years. The Agreement does not provide for the payment by the Company of any future product royalties in connection with sales of Anogesic.

#### Principal License Agreements

Glaxo. In November 1996, the Company entered into an agreement with Glaxo for licensing rights to Glylorin, Cellegy's lipid compound for the treatment of ichthyosis. Under the terms of the agreement, Cellegy provided Glaxo with an exclusive license of patent rights and know-how covering Glylorin in most of the world's major markets. In exchange for this license, Cellegy received from Glaxo an initial license fee. Since the signing of the agreement and through December 31, 1998, the Company had recognized total revenues of approximately \$1.3 million relating to licensing fees and development funding under the agreement. In March 1999, Cellegy and Glaxo announced their intention to terminate the license agreement with the return to Cellegy of Glylorin product rights.

University of California. In October 1993, the Company entered into a license agreement with the University of California (the "Licensor") providing for an exclusive, worldwide, royalty bearing license, subject to customary government rights, for patent rights relating to barrier repair formulations jointly held by the Licensor and the Company, in consideration of the issuance to the Licensor of certain shares of preferred stock (which subsequently converted into shares of Common Stock) and the payment by the Company of a licensing fee. In March 1994, the Company entered into a second exclusive, worldwide, royalty bearing license agreement with the Licensor for patent rights, jointly held by the Licensor and Cellegy, relating to drug delivery technologies, in consideration of the payment by the Company of a licensing fee, and an annual maintenance fee payable each year until the Company is commercially selling a licensed product. Both agreements require the Company to pay the Licensor royalties based on net sales of consumer and prescription products (with minimum annual royalty payment). The Company has the right to grant sublicenses to third parties under both agreements. In May and October 1997, the Licensor and the Company amended these agreements. The amendments, among other things, modified and extended certain development and commercialization milestones contained in the original agreements. The revised milestones are tied to the achievement of certain clinical, regulatory or product commercialization goals over the next several years. Although there can be no assurance that such goals will be achieved, the Company believes its development programs in place will result in the satisfaction of such milestones.

## Government Regulation

FDA Requirements for Human Drugs. The research, testing, manufacturing, labeling, distribution, and marketing of drug products are extensively regulated by numerous governmental authorities in the United States and

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other countries. In the United States, drugs are subject to rigorous FDA regulation. The Food, Drug and Cosmetic Act (the "FD&C Act") and the regulations promulgated thereunder, and other federal and state regulations govern, among other things, the research, development, testing, manufacture, distribution, storage, record keeping, labeling, advertising, promotion and marketing of pharmaceutical products. The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and the expenditure of substantial resources. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all. Moreover, additional government regulations may be established that could prevent or delay regulatory approval of the Company's products. Delays in obtaining regulatory approvals could have a material adverse effect on the Company. If the Company fails to comply with applicable regulatory requirements for marketing drugs, or if the Company's cosmeceutical products are deemed to be drugs by the FDA, the Company could be subject to administrative or judicially imposed sanctions such as warning letters, fines, products 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 the Company, its officers or its employees.

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include: (i) preclinical laboratory tests, animal studies and formulation studies; (ii) the submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before clinical testing may 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 ("NDA") to the FDA; and (v) FDA review and approval of the NDA prior to any commercial sale or shipment of the drug. Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and functionality of the product. Compounds must be produced according to the FDA's current Good Manufacturing Practice ("cGMP") requirements, and preclinical tests must be conducted in compliance with the FDA's Good Laboratory Practice regulations. The results of preclinical testing are submitted to the FDA as part of an IND. The FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials may not commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with good clinical practice ("GCP") requirements under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Clinical trials to support NDAs are typically conducted in three sequential phases, which may overlap. In Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug generally is tested to assess metabolism, pharmacokinetics, pharmacological action and safety, including side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. Phase II usually involves studies in a limited patient population to (i) determine the efficacy of the drug for a specific indication, (ii) determine dosage tolerance and optimal dosage and (iii) identify possible short-term adverse effects and safety risks. If a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical study sites. A clinical trial may combine the elements of more than one phase, and typically two or more Phase III studies are required. There can be no assurance that Phase I, Phase II or Phase III testing will be completed within any specific time period, if at all, with respect to any of the Company's products subject to such testing.

New and Abbreviated New Drug Applications. After completion of the required clinical testing, generally an NDA is submitted. FDA approval of the NDA (or, in the alternative, an Abbreviated New Drug Application ("ANDA"), as described below) is required before marketing may begin in the United States. The NDA must include the results of extensive clinical and other testing and the compilation of data relating to the product's chemistry, pharmacology and manufacture, the cost of all of which is substantial. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than filing an NDA. In such an event, the NDA must be resubmitted with the additional information and, again, is subject to review before 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

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in compliance with applicable cGMP and GCP requirements. If FDA evaluations of the NDA application, manufacturing facilities, and clinical sites are favorable, the FDA may issue either an approval letter or an 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 approval 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 FDA may also require postmarketing testing and surveillance programs to continuously monitor the drug's usage and effects. Side effects resulting from the use of drug products may prevent or limit the further marketing of products.

Certain of the Company's mid and late term products utilize its drug delivery technologies formulated with an active ingredient that is included in a drug product that is already the subject of an NDA approved by the FDA. In connection with obtaining FDA approval of such Company products which require an NDA, it is possible in certain instances that clinical and preclinical testing requirements may not be as extensive. Limited additional data about the safety or effectiveness of the proposed new drug formulation, along with chemistry and manufacturing information and public information about the active ingredient, may be satisfactory for product approval. Consequently, the new product formulation may receive marketing approval more rapidly than a traditional full NDA, although there can be no assurance that a product will be granted such treatment by the FDA.

Once patent and other statutory protections covering a drug approved under an NDA have expired or have been demonstrated not to apply, a generic equivalent to that drug may be approved under an ANDA. An ANDA is ordinarily based upon bioequivalence data that demonstrate that the rate and extent of absorption of the active drug ingredient of the generic drug, usually measured in the blood stream, is equivalent to that of the drug approved under an NDA. The demonstration of bioequivalence and, therefore, ANDA approval, generally requires less time than safety and efficacy studies and NDA approval.

Until an NDA or ANDA is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. It is impossible to anticipate the amount of time that will be required to obtain approval from the FDA to market any product.

Possible Regulation of Cosmeceutical Products as Drugs. "Cosmeceuticals" are not defined in the FD&C Act. The FDA has not defined the term by regulation

and may consider use of the term to imply drug-like qualities. The FDA will regulate a particular cosmeceutical product as a drug or a cosmetic (or both a drug and a cosmetic) depending primarily upon the manufacturer's intended use for such product. Such intent may be determined from labeling, advertising, promotional and marketing materials, and any other source attributable to the manufacturer or its employees, representatives or agents. Under the FD&C Act, drugs are articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body. By comparison, cosmetic products are defined as articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the body for cleansing, beautifying, promoting attractiveness or altering its appearance. Some products, however, may satisfy the definition of a drug and a cosmetic, and the FDA has generally regulated as drugs products that are intended to have a physiological effect on the body, for example, to alter the skin in more than a temporary way. Unlike drugs, products that constitute cosmetics (but not drugs as well) under the FD&C Act do not require premarket review or approval of the FDA, but cosmetics must be safe under normal conditions of use, and comply with FDA labeling and manufacturing requirements. Furthermore, the Federal Trade Commission ("FTC"), as well as state and local authorities, oversees the advertising of cosmetic products and prohibits false, misleading, deceptive or unsubstantiated advertising. The FTC has the authority to seek a number of remedies against a company that it believes fails to comply with its requirements, including, but not limited to, preliminary injunctive relief.

The Company plans to label, market, promote, advertise and distribute its cosmeceutical products with claims intended to be within the statutory definition of cosmetic. There can be no assurance, however, that the FDA will

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not determine that some or all of the Company's cosmeceutical products are drugs, and are therefore subject to more stringent regulatory oversight, including premarket approval, based on their intended use or ingredients.

The FDA has at times in the past contended, and may in the future contend, that one or more cosmeceutical products, including the Company's or competitors' anti-wrinkling or skin rejuvenating products that are currently marketed or may in the future be marketed, are not cosmetics but instead are subject to regulation as drugs. Even if the FDA were not ultimately to prevail with regard to such a contention, such a claim by the FDA could have a material adverse effect on the Company's ability to market its proposed cosmeceutical products and could significantly delay or prohibit marketing of such products. The inability of the Company to market its proposed cosmeceutical products as cosmetics without prior FDA approval could have a material adverse effect on the Company's business and financial condition.

OTC Monograph. Most over the counter ("OTC") drug products marketed in the United States are not subjected to the FD&C Act's premarket approval requirements. In 1972, the FDA instituted the ongoing OTC Drug Review to evaluate the safety and effectiveness of OTC drugs then on the market. Through this process, the FDA issues monographs that set forth the specific active ingredients, dosages, indications and labeling statements for OTC drugs that the FDA will consider generally recognized as safe and effective and therefore not subject to premarket approval. For certain categories of OTC drugs not yet subject to a final monograph, the FDA usually will not take regulatory action against such a product unless failure to do so poses a potential health hazard to consumers. OTC drugs not covered by pending or final OTC monographs, however, are subject to premarket review and approval by the FDA through the NDA/ANDA mechanism. Even if the Company seeks FDA approval of a product for OTC consumer sales, the FDA could instead require that the product be distributed by prescription only. Such a requirement could delay for several years, or indefinitely, distribution of the Company's products directly to consumers.

Manufacturing. Each domestic drug manufacturing facility must be registered with the FDA. Domestic drug and, to a lesser extent, cosmetic manufacturing establishments are subject to routine inspection by the FDA and other regulatory authorities and must comply with cGMP requirements (albeit less extensive ones for cosmetics than for drugs). Drug manufacturing facilities located in California must be licensed by the State of California in compliance with local regulatory requirements. The Company intends to use contract manufacturers that operate in conformance with these requirements to produce its compounds and finished products in commercial quantities. There can be no assurance that



manufacturing or quality control problems will not arise at the manufacturing plants of the Company's contract manufacturers or that such manufacturers will be able to maintain the compliance with the FDA's cGMP requirements necessary to continue manufacturing the Company's products.

Foreign Regulation of Drugs. Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities may be necessary in foreign countries before the commencement of marketing of the product in such countries. The approval procedures vary among countries, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. The Company expects to rely principally on corporate partners, licensees and contract research organizations, along with Company expertise, to obtain foreign governmental approval in foreign countries of drug formulations utilizing its compounds.

Other Government Regulation. In addition to regulations enforced by the FDA, the Company also is 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. In connection with its research and development activities and any manufacturing of clinical trial materials in which the Company may engage, the Company is subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes. Although the Company believes that it has complied with these laws and regulations in all material respects and has not been required to take any action to correct any noncompliance, there can be no assurance that the Company will not be required to incur significant costs to comply with environmental and health and safety regulations in the future. The Company's research and development involves the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although the

Company believes that its 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, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Operating Results - Environmental Regulation."

Health Care Reform. In the United States, there have been, and the Company 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 the Company cannot predict whether any legislative or regulatory proposals will be adopted or the effect such proposals may have on its business, the uncertainty of such proposals could have an adverse effect on the Company's 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 the Company. In both domestic and foreign markets, sales of the Company's therapeutic products, if any, will depend in part on the availability of reimbursement from third-party payors. Third-party payors and others increasingly are challenging the prices charged for medical products and services. There can be no assurance that the Company's products will be considered cost effective, that reimbursement will be available. The Company cannot predict the outcome of any government or industry reform initiatives or the impact thereof on the Company's financial position or results of operations.

Restriction of Physician Marketing. The American Medical Association is questioning the ethics of physicians selling cosmeceutical products for a significant profit. Hearings on the motion by state medical organizations are occurring and will continue to occur over the next years. Mandating sale of product at cost may reduce the number of physicians selling such products.

## Competition

The pharmaceutical and cosmeceutical industries are subject to rapid and significant technological change. In the development and marketing of topical prescription drugs, cosmeceutical and skin care products, and drug delivery systems, Cellegy faces intense competition. Competitors of the Company in the United States and abroad are numerous and include, among others, major pharmaceutical, cosmetic, chemical, consumer product, and biotechnology companies, specialized firms, universities and other research institutions. There can be no assurance that the Company's competitors will not succeed in developing technologies and products that are more effective than any which are being developed by the Company or that would render the Company's technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, production and marketing capabilities and regulatory experience than the Company. In addition, many of the Company's competitors have significantly greater experience than the Company in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA and other regulatory approvals of products for use in health care. In addition, these companies and academic and research institutions compete with Cellegy in recruiting and retaining highly qualified scientific and management personnel.

## Employees

As of March 16, 1999, the Company had twenty-seven full-time and three part-time employees. Ten of these employees, of whom three are M.D.s and another seven are Ph.D.s, are engaged in research and development. In addition, the Company utilizes the services of several professional consultants, as well as contract manufacturing and research organizations to supplement its internal staff's activities. None of the Company's employees is represented by a labor union. The Company has experienced no work stoppages and believes that its employee relations are good.

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## ITEM 2: PROPERTIES

The Company currently leases 65,340 square feet of space located in South San Francisco. Approximately 30,914 square feet of this space, is in turn, subleased to another company. The sublease expires December 17, 2001, but may be extended under certain circumstances described in the sublease agreement. Total rent payments to Cellegy by the sublessee are \$63,905.70 per month. The Company believes its current facilities will be adequate for at least the next five years.

The Company also subleases its previous administrative offices in Foster City, California to another company. The rent is currently \$11,368.50 per month. Cellegy's lease and the sublease term expires on July 31, 2000.

## ITEM 3: LEGAL PROCEEDINGS

The Company is not a party to any material legal proceedings.

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

No matters were submitted to a vote of the Company's shareholders during the fourth quarter of the year ended December 31, 1998.

## ITEM 4A: EXECUTIVE OFFICERS OF THE REGISTRANT

### MANAGEMENT

The directors and executive officers of the Company are as follows:

Name	Age	Position
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K. Michael Forrest	55	President, Chief Executive Officer and Director
Carl R. Thornfeldt, M.D.	47	Medical Director and Chairman of the Board
Daniel L. Azarnoff, M.D.	72	Vice President, Clinical and Regulatory Affairs
John J. Chandler	58	Vice President, Business Development
A. Richard Juelis	50	Vice President, Finance and Chief Financial Officer
Jack L. Bowman (1)	66	Director
Tobi B. Klar, M.D.	44	Director
Alan A. Steigrod (1)	61	Director
Larry J. Wells (2)	56	Director

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- (1) Member of the Compensation Committee.
- (2) Member of the Audit Committee.

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K. Michael Forrest. Mr. Forrest became President, CEO, and a director in December 1996. From January 1996 to November 1996, he served as a biotechnology consultant. From November 1994 to December 1995, he served as President and CEO of Mercator Genetics, a public biotechnology company. From March 1991 to June 1994, he served as President and CEO of Transkaryotic Therapies, Inc., a public biotechnology company. From 1968 to 1991, Mr. Forrest held a series of positions with Pfizer, Inc. and senior management positions with American Cyanamid, including Vice President of Lederle U.S. and Lederle International. He is a director of AlphaGene Inc., a private functional genomics company, and INEX Pharmaceuticals.

Carl R. Thornfeldt, M.D. Dr. Thornfeldt is the Chairman of the Board of Directors and a co-founder of the Company, as well as a physician, board certified in dermatology. He has been Medical Director of the Company since its inception. Dr. Thornfeldt served as acting CEO from July 1996 to December 1996. In addition, Dr. Thornfeldt served as Vice President, Research and Development from October 1994 until May 1996. Since 1983, Dr. Thornfeldt has maintained a private dermatology practice and is an Assistant Clinical Professor in Dermatology

at the University of Oregon Health Sciences Center. Dr. Thornfeldt received his M.D. from the University of Oregon.

Daniel L. Azarnoff, M.D. Dr. Azarnoff became Vice President, Clinical and Regulatory Affairs in October 1997. Since January 1986, Dr. Azarnoff has been President of D.L. Azarnoff Associates and will continue consulting to the industry on a part-time basis. From August 1978 to December 1985, he served as President of Research and Development at G.D. Searle and Co. From July 1967 to August 1978, he was KUMC Distinguished Professor of Medicine and Pharmacology, as well as the Director of the Clinical Pharmacology-Toxicology Center at the University of Kansas Medical Center. Dr. Azarnoff has also served as a member of advisory and expert committees within the Food and Drug Administration, World Health Organization, American Medical Association, National Academy of Sciences and National Institutes of Health. He received his M.D. from the University of Kansas Medical School. Dr. Azarnoff was a director of Cibus Pharmaceutical through 1998, and is currently director of Western Center Clinical Trials, Entropin, Inc., Versaille Capital Managemet - Ameriumnone Inc., and Oread, Inc.

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 American Home Products. From January 1994 to December 1994, he was Area Director, Europe/Latin America for American Home Products. During this time, he oversaw the operations of nine European subsidiaries and three highly successful joint ventures. From 1968 to 1994 he held a series of management and senior management positions with American Cyanamid Company. Mr. Chandler holds a 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 March 1996. From November 1994 until March 1996, he worked as a financial consultant to the Company, as well as to other companies. From January 1993 to September 1994 he served as Vice President, Finance and Chief Financial Officer for VIVUS, Inc., a publicly traded drug delivery company. From October 1990 to December 1992, he served as Vice President, Finance and Chief Financial Officer at XOMA Corporation, a public biotechnology company. Mr.

Juelis has also held domestic and international financial and general management positions with Hoffmann-LaRoche from 1976 to 1982, and Schering-Plough from 1983 to 1990.

Jack L. Bowman. Mr. Bowman became a director in December 1996. He is currently a consultant to various pharmaceutical and biotechnology industry groups. From August 1987 to January 1994, he was Company Group Chairman at Johnson & Johnson, where he managed much of its global diagnostic and pharmaceutical businesses. Before then, Mr. Bowman held executive positions with CIBA-Geigy and American Cyanamid, where he had responsibility for worldwide pharmaceutical, medical device, and consumer product divisions. He is currently a director of NeoRx Corp., CytRx Corp., Cell Therapeutics, Inc., Targeted Genetics, Inc. and Osiris Therapeutics.

Tobi B. Klar, M.D. Dr. Klar became a director of the Company in June 1995. She is a physician, board certified in dermatology. Since 1986, Dr. Klar has maintained a private dermatology practice and has served as Co-Chairperson of the Department of Dermatology at New Rochelle Hospital Medical Center, New Rochelle, New York, and Associate Clinical Professor in dermatology at Albert Einstein Medical Center in New York City. Dr. Klar holds a M.D. from the State University of New York.

Alan A. Steigrod. Mr. Steigrod became a director in July 1996. Since January 1996 he has been Managing Director of Newport HealthCare Ventures, which invests in and advises biopharmaceutical companies. From March 1993 to November 1995, he served as President and CEO of Cortex Pharmaceuticals, Inc. From February 1991 to February 1993, he worked as a biotechnology consultant. From March 1981 through February 1991, Mr. Steigrod held a series of executive positions with Glaxo, Inc., serving as Chairman of Glaxo's operating committee, as well as on its board of directors. As Executive Vice President, he managed five divisions, including Glaxo Pharmaceuticals and Glaxo Dermatology Products. Prior to Glaxo, Mr. Steigrod held a number of senior management positions with Boehringer Ingelheim, Ltd. and Eli Lilly & Co. He is a director of Sepracor Inc. and NeoRx Corporation.

Larry J. Wells. Mr. Wells became a director of the Company in 1989. For the past five years, he has been a venture capitalist. He is the President of Wells Investment Group, the General Partner of Daystar Partners, and the

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founder of Sundance Venture Partners, L.P., a venture capital fund. Mr. Wells is a director of Identix, Inc., Novamed, Isonics Corp., Wings America and Legacy Brands.

Directors hold office until the next annual meeting of shareholders and until their respective successors have been elected and qualified. Executive officers are chosen by and serve at the discretion of the Board of Directors, subject to any written employment agreements with the Company.

Standing committees of the Board include an Audit Committee and a Compensation Committee. Mr. Wells is a current member of the Audit Committee. A second member appointment is pending. The Audit Committee reviews the Company's accounting practices, internal control systems and meets with the Company's outside auditors concerning the scope and terms of their engagement and the results of their audits. Messrs. Bowman and Steigrod are the current members of the Compensation Committee. The Compensation Committee recommends compensation for officers and employees of the Company, and grants options and stock awards under the Company's employee benefit plans.

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## 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 National 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.

1997 - ----	High ----	Low ---
First Quarter.....	5.13	4.13
Second Quarter.....	4.50	2.38
Third Quarter.....	6.56	2.44
Fourth Quarter.....	9.50	6.25
1998 - ----		
First Quarter.....	9.31	6.94
Second Quarter.....	7.63	5.00
Third Quarter.....	5.75	2.00
Fourth Quarter.....	5.38	2.88

Holders

As of March 16, 1999, there were approximately 96 shareholders of record. The Company believes that the actual number of shareholders of Common Stock substantially exceeds this number.

Dividend Policy

The Company has never paid cash or declared dividends on its Common Stock. Cellegy does not anticipate that it will declare or pay cash dividends on its Common Stock in the foreseeable future.

ITEM 6: SELECTED FINANCIAL DATA

The following balance sheet data as of December 31, 1997 and 1998 and the statement of operations data for the three years ended December 31, 1998 are derived from the Company's audited financial statements that are included elsewhere in this Document. The balance sheet data set forth below as of December 31, 1994, 1995 and 1996 and the statement of operations data for the years ended December 31, 1995 and 1996, are derived from the Company's audited financial statements which are not included herein. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements.

	Years Ended December 31,					Period From June 26, 1989 (Inception) Through December 31, 1998
	1994	1995	1996	1997	1998	
Statement of Operations Data:						
Revenues.....	\$ --	\$ 1,000	\$ 648	\$ 828	\$ 832	\$ 3,437
Costs and expenses.....	2,542	2,535	4,346	9,238	9,266	33,809
Loss from operations.....	(2,542)	(1,535)	(3,698)	(8,410)	(8,434)	(30,372)
Interest income (expense) and other, net.....	(1)	(617)	330	556	1,068	1,629
Net loss.....	(2,543)	(2,152)	(3,368)	(7,854)	(7,366)	(28,743)
Non-cash preferred dividends.....	--	--	1,414	35	--	1,449

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Net loss applicable to common Shareholders.....	\$ (2,543)	\$ (2,152)	\$ (4,782)	\$ (7,889)	\$ (7,366)	\$ (30,192)
	=====	=====	=====	=====	=====	=====
Pro forma net loss per share (1)...	\$ (0.76)	\$ (0.67)	\$ (1.11)	\$ (1.18)	\$ (0.73)	
	=====	=====	=====	=====	=====	
Shares used in computing pro forma net loss per share (1).....	3,344	3,206	4,307	6,670	10,160	

		1994	1995	1996	1997	1998
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Balance Sheet Data:						
Cash, cash equivalents and investments.....	\$	402	\$ 3,820	\$ 7,315	\$ 21,726	\$ 15,220
Total assets.....		555	4,028	7,696	22,751	19,484
Deficit accumulated during the development stage.....		(8,004)	(10,155)	(14,937)	(22,826)	(30,192)
Total shareholders' equity (deficit).....		(1,374)	3,648	7,387	21,354	14,218
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(1) See Note 1 of Notes to the Financial Statements for an explanation of the determination of the number of pro forma shares used in per share calculations.

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

This Annual Report on Form 10-K includes forward-looking statements. 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 concern matters that involve risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. Further, the Company undertakes no obligation to revise any forward-looking statements in order to reflect events or circumstances that may arise after the date of this report. Actual events or results may differ materially from those discussed in this Report. See "Factors That May Affect Future Operating Results."

Cellegy Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the development of prescription drugs and high performance cosmeceuticals to address a variety of skin diseases and conditions utilizing its patented transdermal and topical delivery technologies. The Company was incorporated in California in 1989. Cellegy is developing several prescription drugs, including Anogesic(R), a nitroglycerin-based product for the treatment of anal fissures and hemorrhoids, and a transdermal testosterone gel for the treatment of male hypogonadism, a condition that frequently results in lethargy and reduced libido in men above the age of 40. In addition to its prescription drugs, Cellegy is testing and developing a line of anti-wrinkling cosmeceutical products which the Company believes will address the skin care needs of an affluent and aging population.

General

In November 1997, the Company completed a \$15.1 million public offering of approximately 2.0 million shares of Common Stock. CIBC Oppenheimer Corp. acted as underwriter in connection with the offering. Simultaneously, the Company's stock was approved for listing on the Nasdaq National Market.

In December 1997, the Company completed an asset purchase agreement with Neptune Pharmaceutical Corporation ("Neptune") to acquire all patent and other intellectual property rights relating to Anogesic. The Company's expenses relating to product development and clinical trials are expected to increase during the remainder of 1999 as a result of the ongoing Phase III clinical trials initiated in July 1998. Although the purchase price for Anogesic is payable in Cellegy Common Stock, the Company recorded a non-cash charge to operations for in process technology of \$3,843,000 upon completion of the Anogesic acquisition in 1997.

In September 1998, Cellegy began initial shipments and product sales of its C79 intensive moisturizing formulation to Gryphon Development Inc., the product development arm of Bath & Body Works. C79 is a key ingredient in a new line of healing hand creams launched at most Bath & Body Works stores in the United States.

In March 1999, Cellegy and Glaxo announced their intention to terminate the license agreement with the return to Cellegy of Glylorin product rights. Subject to final termination agreement terms, Cellegy expects to receive any remaining development funding due from Glaxo through the date of termination. Cellegy intends to repay Glaxo approximately \$200,000 in funds previously advanced by Glaxo. Cellegy does not currently intend to develop Glylorin on its own, but will seek an appropriate partner for certain geographic territories to develop the product in exchange for certain upfront payments, milestones, and royalties on future sales.

#### Results of Operations

Years Ended December 31, 1998, 1997 and 1996

**Revenues.** The Company had revenues of \$832,000, \$828,000, and \$648,000 in 1998, 1997 and 1996, respectively. Revenues in 1998 consisted of \$458,000 in product sales to Gryphon Development, \$271,000 in licensing, milestone and development funding primarily from Glaxo Wellcome Inc. associated with the clinical development of Glylorin<sup>TM</sup>, and \$103,000 in Orphan Drug grant funding for Glylorin, received from the Food and Drug Administration.

**Research and Development Expenses.** Research and development expenses were \$6,668,000 in 1998, compared with \$3,786,000 in 1997 and \$2,712,000 in 1996. The increase of \$2,882,000 in 1998 was primarily due to clinical trial expenses related to Anogesic, including costs to manufacture clinical supplies, and to conduct product stability studies. Other factors contributing to the increase in expenses were personnel costs associated with the hiring of additional scientists, and costs of contract research work related to the Company's CELLEDIRM technology as well.

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as its cosmeceutical product line. Additionally, the Company incurred certain expenses to occupy and equip new laboratory and facilities in South San Francisco, California at the end of 1998.

The Company increased its research spending in 1998 and expects its research spending in 1999 to be equal to or higher than 1998 levels, primarily in support of its Anogesic and testosterone clinical trials and in support of its efforts to identify, develop and test compounds using the Company's CELLEDIRM technology.

**General and Administrative Expenses.** General and administrative expenses were \$2,485,000 in 1998, compared with \$1,608,000 in 1997 and \$1,634,000 in 1996. The increase of \$877,000 in 1998 was due to increased professional fees in connection with construction and design of the Company's new facility, as well as personnel related expenses in connection with Company's business development, sales and marketing programs. The Company's general and administrative expenses are expected to continue to increase in the future in support of its research and product commercialization efforts.

**Acquired in Process Technology.** Acquired in process technology expenses were not incurred during 1998, compared with \$3,843,000 in 1997. No such charges were recorded in 1996. This non-cash charge to operations resulted from Common Stock issued pursuant to the Anogesic purchase agreement the Company signed with Neptune. The Company expects to have additional non-cash charges in 1999 and

future years if and when certain milestones are achieved. Although the dollar amount of future milestone payments is fixed by the agreement, the amount of the non-cash accounting charge will vary as a function of the share price of Cellegy's Common Stock at the time the milestone is achieved. Such payments could result in issuance of a significant number of shares of Common Stock.

Interest Income and Other, Net. The Company recognized \$1,091,000 in interest income for 1998, compared with \$556,000 for 1997 and \$330,000 for 1996. The additional interest income earned in 1998 was due to a higher investment balance during the 1998 period resulting mainly from proceeds associated with a public offering of Common Stock completed in November 1997. Interest expense in 1998 was \$22,000 which reflected interest payments on a bank loan agreement. No interest expense was recorded in 1997 and 1996.

Net Loss. The net loss applicable to common shareholders was \$7,366,000 or \$0.73 per share in 1998 based on 10,160,000 weighted average shares outstanding, compared with a net loss of \$7,889,000 or \$1.18 per share in 1997 based on 6,670,000 weighted average shares outstanding, and \$4,782,000 or \$1.11 per share in 1996 based on 4,307,000 weighted average shares outstanding.

#### Liquidity and Capital Resources

The Company has experienced net losses and negative cash flow from operations each year since its inception. Through December 31, 1998, the Company had incurred an accumulated deficit of \$30.2 million and had consumed cash from operations of \$22.8 million. The Company's public financings included \$6.4 million in net proceeds from its 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, and \$13.8 million in net proceeds from a secondary public offering in November 1997. In June 1998, the Company secured a loan with a commercial bank to provide up to \$4.5 million with an initial interest rate tied to the bank's prime lending rate. As of December 31, 1998, \$3.2 million is outstanding under the arrangement.

The Company's cash and investments were \$15.2 million at December 31, 1998, compared with \$21.7 million at December 31, 1997. The decrease in cash and investments of \$6.5 million was principally due to net cash used in operating activities. The Company's operations have and will continue to use substantial amounts of cash. Future expenditures and capital requirements depend on numerous factors including, without limitation, the progress and focus of its research and development programs, the progress and results of preclinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, the ability of the Company to establish new collaborative arrangements, its ability to maintain existing collaborations, particularly with Glaxo, the initiation of commercialization activities, the purchase of capital equipment, and the availability of other financing.

In order to complete the research and development and other activities necessary to commercialize its products, additional financing will be required. As a result, the Company will seek private or public equity investments and

future collaborative arrangements with third parties to meet such needs. There is no assurance that such financing will be available for the Company to fund its operations on acceptable terms, if at all. Insufficient funding may require the Company to delay, reduce or eliminate some or all of its research and development activities, planned clinical trials and administrative programs. The Company believes that available cash resources and the interest thereon will be adequate to satisfy its capital needs through at least December 31, 1999.

#### Factors That May Affect Future Operating Results

Impact of Year 2000. The Company established a Y2K cross-function project team in August of 1998, chaired by the Company's Vice President, Finance and Chief Financial Officer. The Y2K project team reports to the Information Systems ("IS") committee which consists of the Company's Chief Executive Officer and all its other officers. The Y2K project team has developed a phased approach to identify and resolve any Year 2000 issues:

The first phase was to develop a corporate-wide strategy to address the



Year 2000 issue and to access the Company's state of readiness. This included a review of all Information Technology ("IT"), non-IT systems and laboratory instruments. The Company completed this initial phase in September 1998. The majority of hardware is Year 2000 compliant and the remaining was made Year 2000 compliant through BIOS upgrade or software patches. In the mean time, the Company has requested Year 2000 certification from hardware/software suppliers for all Year 2000 compliant products.

The second phase of the Company's Year 2000 compliance program was to define a Year 2000 compliance standard and to develop uniform test plans. The Company is also evaluating its other critical non-IT facility systems with date sensitive operating controls for Year 2000 issue. While the Company believes that most of these systems will function without substantial Year 2000 compliance problems, the Company will continue to review, test and resolve Year 2000 issues during 1999.

The third phase of the Company's Year 2000 compliance program is the actual testing and correction of the Company's IT and non-IT systems. It is expected that the testing and correction phase will be completed by mid-year 1999. The Company is also evaluating each of its principal suppliers, service providers to determine each of such party's Year 2000 status.

Cellegy does not expect the cost of the Year 2000 compliance program to be material. The total cost is estimated at less than \$50,000.

The Company is also developing a contingency plan in the event that a business interruption caused by Year 2000 problems should occur and expects to complete the plan by the end of the second quarter of 1999. The contingency plans also include plans to address vendor and third parties' Year 2000 issues that may arise. Nevertheless, Year 2000 compliance is a complex project and it depends on many factors, some of which are not completely within the Company's control. Should either the Company's internal systems or the internal systems of one or more significant vendor or supplier fail to achieve Year 2000 compliance, the Company's business and its results of operations could be adversely affected.

History of Losses; Future Profitability Uncertain. The Company has a history of operating losses and expects to incur substantial additional expenses with resulting quarterly losses over at least the next several years as it continues to develop its potential products and to devote significant resources to preclinical studies, clinical trials and manufacturing. As of December 31, 1998, the Company had an accumulated deficit of approximately \$30.2 million. To date, the Company has not sought regulatory approval to distribute any products. The time and resource commitment required to achieve market success for any individual product is extensive and uncertain. No assurance can be given that the Company's product development efforts will be successful, that required regulatory approvals can be obtained, that potential products can be manufactured at an acceptable cost and with appropriate quality or that any approved products can be successfully marketed.

The Company has not generated any significant revenues from royalties from licenses of the Company's technology, and most of the potential prescription products that may be marketed by the Company, if any, are not expected to be marketed or approved for marketing for at least the next several years. Moreover, the Company anticipates that its operating expenses will continue to increase significantly as the Company increases its research and development, preclinical, clinical, administrative and patent activities. Accordingly, in the absence of

substantial revenues from new corporate collaborations, royalties on product sales or other sources, the Company expects to incur substantial and increased operating losses in the foreseeable future as certain of its earlier stage potential products move into clinical development, as additional potential products are selected as clinical candidates for further development, as the Company completes its move into its new facilities, and as the Company invests in research or acquires additional technologies, product candidates or businesses. The amount of net losses and the time required to reach sustained profitability are highly uncertain. To achieve sustained profitable operations, the Company must successfully discover, develop, obtain regulatory approvals for and market its potential pharmaceutical and cosmeceutical products. No

assurances can be given that the Company will be able to achieve or sustain profitability, and results are expected to fluctuate from quarter to quarter.

**Uncertainty of Clinical Trial Results.** Before obtaining regulatory approval for the commercial sale of many of its potential drug products, the Company must demonstrate through preclinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. There can be no assurance that the Company will be permitted to undertake or continue clinical trials for any of its potential products or, if such trials are permitted, that such products will be demonstrated to be safe and efficacious. Moreover, the results from preclinical studies and early clinical trials may not be predictive of results that will be obtained in later-stage clinical trials, as was the case with the Phase III trial results announced by Cellegy in March 1998 regarding Glylorin. Thus, there can be no assurance that the Company's present or future clinical trials, for example, the ongoing Phase III clinical trials relating to Anogesic or the dose ranging study for testosterone, will demonstrate the safety and efficacy required for approval to market these potential products. The failure of Anogesic to successfully complete its current Phase III or any future clinical testing, including toxicology studies, could have a material adverse effect on the Company.

Due to the independent and blind nature of certain human clinical testing, there will be extended periods during the testing process when the Company will have only limited, or no, access to information about the status or results of the tests. Other pharmaceutical companies have believed that their products performed satisfactorily in early tests, only to find their performance in later tests, including Phase III clinical trials, to be inadequate or unsatisfactory, or that FDA Advisory Committees have declined to recommend approval of the drugs, or that the FDA itself refused approval, with the result that such companies' stock prices have fallen precipitously.

**Early Stage of Product Development.** With the exception of certain skin care cosmeceutical products, Cellegy has not yet completed the development of its prescription products or sought regulatory approval for the marketing of drug products and has not begun to market or generate revenues from the commercialization of products. Development of most of the Company's products will require significant additional research and development. All of the Company's product development efforts are based upon technologies and therapeutic approaches that have not been widely tested or used. Moreover, the Company's beliefs regarding the therapeutic and commercial potential for its products are based on studies conducted to date, and later studies may not support the Company's current beliefs. In addition, results of certain of the Company's studies have not been published in medical journals or reviewed by independent third parties, and as a result have not been subjected to the same degree of scrutiny as results that have been published or subjected to review by independent parties.

The Company's potential products are subject to the risks of failure inherent in the development of products based on new technologies. These risks include the possibilities that the Company's therapeutic approaches will not be successful; that the results from future clinical trials may not correlate with any safety or effectiveness results from prior clinical studies conducted by the Company or others; that some or all of the Company's potential products will not be successfully developed or will not be found to be safe and effective by the FDA, or otherwise will fail to meet applicable regulatory standards or receive necessary regulatory clearances. There can be no assurance the Company's clinical and research and development activities will result in any commercially viable products.

**Possible FDA Regulation of Cosmeceutical Products as Drugs.** The Company intends to introduce products that will compete in the cosmeceutical market. "Cosmeceuticals" are not defined in the Food, Drug and Cosmetics Act (the "FD&C") Act. The FDA has not defined the term by regulation and may consider use of the term to imply drug-like qualities. Cosmeceuticals (a hybrid of the words "cosmetics" and "pharmaceuticals") are products that contain active ingredients which, when applied to the skin, will enhance appearance. Cosmeceuticals which satisfy the definition of a cosmetic under the FD&C Act and which are not also drugs under that statute are not subject to the same FDA requirements as drug products. For example, cosmeceutical products that constitute cosmetics (but

not drugs as well) as defined by applicable federal laws may be marketed to consumers without prior approval by the FDA, and without requiring a prescription from a physician. The Company intends to develop a number of cosmeceutical products, including a product line that will compete in what is generally referred to as the "anti-wrinkling" market.

The FDA has at times in the past contended, and may in the future contend, that one or more cosmeceutical products, including the Company's or competitors' anti-wrinkling products that are currently marketed or may in the future be marketed, are not cosmetics but instead are subject to regulation as drugs. The inability of the Company to market its proposed cosmeceutical products as cosmetics without prior FDA approval could have a material adverse effect on the Company's business and financial condition.

Competition and Technological Change. The pharmaceutical and cosmeceutical industries are subject to rapid and significant technological change. In the development and marketing of topical prescription drugs, skin care and other cosmeceutical products and drug delivery systems, Cellegy faces intense competition. Competitors of the Company in the United States and abroad are numerous and include, among others, major pharmaceutical, chemical, cosmetic, consumer product, and biotechnology companies, specialized firms, universities and other research institutions. There can be no assurance that the Company's competitors will not succeed in developing technologies and products that are more effective than any which are being developed by the Company or that would render the Company's technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, production and marketing capabilities and regulatory experience than the Company. In addition, many of the Company's competitors have significantly greater experience than the Company in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA and other regulatory approvals of products for use in health care. There can be no assurance that the Company's products under development will be able to compete successfully with existing products or products under development by other companies, universities and other institutions or that they will obtain regulatory approval in the United States or elsewhere. In addition, these companies and academic and research institutions compete with Cellegy in recruiting and retaining highly qualified scientific and management personnel.

Patents and Proprietary Technology. The Company's success depends, in part, on its ability to obtain patent protection for its products and methods, both in the United States and in other countries. Several of the Company's products are based on existing compounds with a history of use in humans but which are being developed by the Company for new therapeutic use in skin diseases unrelated to the systemic diseases for which the compounds were previously approved. The Company cannot obtain composition patent claims on the compound itself, 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. The Company may not be able to prevent a competitor from using that formulation or compound for a different purpose. No assurance can be given that any additional patents will be issued to the Company, that the protection of any patents issued in the future will be significant or that current or future patents will be held valid if subsequently challenged.

The patent position of companies engaged in businesses such as the Company'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. Further, issued patents can later be held invalid by the patent office issuing the patent or by a court. There can be no assurance that any patent applications relating to the Company'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 a competitive advantage to the Company. In addition, many other entities are engaged in research and product development efforts in drug delivery, skin biology and cosmeceutical fields that may overlap with the Company's currently anticipated and future products, and such other entities 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 the Company. These rights may prevent the Company from commercializing technology, or may require the Company to obtain a license from the entity to practice the technology. There can be no assurance that the Company will be able to obtain any such licenses that may be required on commercially reasonable terms, if at all, or 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. As with other companies in the pharmaceutical industry, the Company is subject to the risk that persons located in such countries will engage in development, marketing or sales activities of products that would infringe the Company's patent rights if such activities were in the United States.

The agreements with the University of California pursuant to which the Company has exclusive license rights to certain drug delivery and other technology contain certain development and performance milestones which the Company must satisfy in order to retain such rights. While the Company currently believes it will be able to satisfy the revised milestone dates, a loss of rights to these technologies could have a material adverse effect on the Company.

Dependence on Collaborative Partners. In view of the early stage of the Company and its research and development programs, the Company has restricted hiring to research and development scientists and a small administrative staff and has made limited investment in marketing, product sales and regulatory compliance resources. The Company may in the future enter into agreements with certain of its collaborative partners granting exclusive rights to commercialize one or more products for particular indications. The Company has collaborative agreements with certain third party companies or academic institutions, and intends to enter into other collaborative agreements in the future, relating to the research, development, manufacture and marketing of certain potential products. In some cases, the Company is relying, and in the future will rely, on its collaborative partners to conduct clinical trials, to compile and analyze the data received from such trials, to obtain regulatory approvals and, if approved, to manufacture and market these products. As a result, the Company may have little or no control over the development of these potential products and little or no opportunity to review clinical data before or after public announcement. There can be no assurance that the Company will be able to establish any such collaborative arrangements or that they will be successful. Failure to enter into any such arrangements that in the future might be necessary could have a material adverse effect on the Company's business and financial condition. If Cellegy is unable to find another corporate partner to develop Glylorin, it is not currently anticipated that Glylorin will be further developed by Cellegy, and the product may therefore not be commercialized.

Government Regulation and Drug Product Approvals. The research, development, testing, manufacture, labeling, distribution, marketing and advertising of products such as the Company's products and its ongoing research and development activities are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The extensive preclinical and clinical testing requirements and regulatory approval process of the FDA in the United States and of certain foreign regulatory authorities require a number of years and the expenditure of substantial resources. There can be no assurance that the Company will be able to obtain the necessary approvals for clinical testing or for the marketing of products on a timely basis or at all. Moreover, additional government regulations may be established that could prevent or delay regulatory approval of the Company's products. Delays in obtaining regulatory approvals could have a material adverse effect on the Company's business and results of operations. Even if regulatory approval of a product is granted, such approval may include significant limitations on the indicated uses of the product or the manner in which or conditions under which the product may be marketed. Moreover, failure to comply with regulatory requirements for marketing drugs, or if the Company's cosmeceutical products are deemed to be drugs by the FDA, could subject the Company to regulatory or judicial enforcement actions, including, but not limited to, product recalls or seizures, injunctions against production, distribution, sales and marketing, civil penalties, criminal prosecution of the Company, its officers or employees, refusals to approve new products and suspensions and withdrawals of existing approvals, as well as potentially increased product liability exposure. Sales of the Company's products outside the United States will be subject to regulatory requirements governing clinical trials and marketing approval. These requirements vary widely from country to country and could delay introduction of the Company's products in those countries. See "Business -- Government Regulation."

Limited Experience with Clinical Trials. The Company has conducted only a limited number of clinical trials to date. There can be no assurance that the Company will be able to successfully commence and complete its current and all

of its planned clinical trials without significant additional resources and expertise. In addition, there can be no assurance that the Company will meet its contemplated clinical trial schedule for any of its potential products, including its Phase III trial for Anogesic. The inability of the Company or its existing or any future collaborative partners to commence or continue clinical trials as currently planned, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of its potential products, would have a material adverse effect on the business and the financial condition of the Company.

**Future Capital Needs; Uncertainty of Additional Funding.** The Company's operations to date have consumed substantial amounts of cash. The Company's cash needs are expected to continue to increase significantly over at least the next several years in order to fund the additional expenses the Company will incur as it expands its current research and development programs, particularly in the prescription pharmaceutical and cosmeceutical product

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areas. The Company has no current source of significant ongoing revenues or capital beyond existing cash, product sales to Gryphon and payments, if any, that may be received pursuant to the existing licensing agreements with Glaxo. In order to complete the research and development and other activities necessary to commercialize its products, additional financing may be required.

The Company will seek private or public equity investments and future collaborative arrangements with third parties to help fund its future cash needs. There is no assurance that such funding will be available on acceptable terms, if at all. Insufficient funding may require the Company to delay, reduce or eliminate some or all of its research and development activities, planned clinical trials and administrative programs. The Company believes that available cash resources and the interest thereon will be adequate to satisfy its capital needs through at least December 31, 1999.

**Limited Sales and Marketing Experience.** The Company may market certain of its products, if successfully developed and approved, through a direct sales force in the United States and through sales and marketing partnership arrangements or distribution arrangements outside the United States. The Company has no history or experience in sales, marketing or distribution. To market its products directly, the Company must either establish a marketing group and direct sales force or obtain the assistance of one or more third parties. There can be no assurance that the Company will be able to establish sales and distribution capabilities or succeed in gaining market acceptance for its products. If the Company enters into marketing or licensing arrangements with established pharmaceutical companies, the Company's revenues will be subject to the payment provisions of such arrangements and will be dependent on the efforts of third parties. There can be no assurance that the Company will be able to successfully establish a direct sales force or that its collaborators will effectively market any of the Company's potential products, and the inability of the Company or its collaborators to do so could have a material adverse effect on the business and financial condition of the Company.

**Manufacturing Limitations; Suppliers.** The Company has no direct experience in manufacturing commercial quantities of its potential products and currently does not have any capacity to manufacture potential products on a large commercial scale itself. The Company currently relies on third parties to manufacture unprocessed compounds into therapeutic and cosmeceutical products. Although the Company believes that there will be adequate third party manufacturers, there can be no assurance that the Company will be able to enter into acceptable agreements with third party manufacturers, and the Company is and will be dependent upon third party contract manufacturers for such production. There can be no assurance that the Company will continue to be able to obtain contract manufacturing on commercially acceptable terms for compounds or products and quantities currently obtainable. There can be no assurance that manufacturing or quality control problems will not arise at the manufacturing plants of the Company's contract manufacturers or that such manufacturers will be able to maintain the compliance with the FDA's current good manufacturing practice requirements necessary to continue manufacturing the Company's products.

**Uncertainty Related to Health Care Industry.** The health care industry is subject to changing political, economic and regulatory influences that may

significantly affect the purchasing practices and pricing of human therapeutics. Cost containment measures, whether instituted by health care providers or enacted as a result of government health administration regulators or new regulations, such as pricing limitations or formulating eligibility for dispensation by medical providers, could result in greater selectivity in the availability of treatments. Such selectivity could have an adverse effect on the Company's ability to sell its prescription products and there can be no assurance that adequate third party coverage will be available for the Company to maintain price levels sufficient to generate an appropriate return on its investment in product development. The trend towards managed health care in the United States, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices or proposals to reform health care or reduce government insurance programs or result in lower prices or reduced markets for the Company's products. The adoption of any such measures or reforms could have a material adverse effect on the business and financial condition of the Company. However, cosmeceutical products generally are not reimbursed by third party payors.

**Dependence Upon Key Employees.** The success of the Company is dependent upon the efforts of its senior management team. A change in the association of these individuals or other officers and directors of the Company could adversely affect the Company if suitable replacement personnel could not be employed. The success of the Company also depends upon its ability to

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continue to attract and retain qualified scientific and technical personnel. There is intense competition for qualified personnel in the areas of the Company's activities, and there can be no assurance that the Company will be able to continue to attract and retain the qualified personnel necessary for the development or expansion of its business.

**Environmental Regulation.** The Company is subject to federal, state and local laws and regulations governing the use, generation, manufacture, storage, discharge, handling and disposal of certain materials and wastes used in its operations, some of which are classified as "hazardous." There can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws, the Occupational Safety and Health Act, and state, local and foreign counterparts to such laws, rules and regulations as its activities are increased or that the operations, business and future profitability of the Company will not be adversely affected by current or future laws, rules and regulations. The risk of accidental contamination or injury from hazardous materials cannot be eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. In any event, the cost of defending claims arising from such contamination or injury could be substantial. In addition, the Company cannot predict the extent of the adverse effect on its business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

**Risk of Product Liability; Limited Product Liability Insurance.** The testing, marketing and sale of human health care products entails an inherent risk of allegations of product liability. There can be no assurance that substantial product liability claims will not be asserted against the Company. The Company has obtained limited amounts of insurance relating to its clinical trials. There can be no assurance that the Company will be able to obtain or maintain insurance on acceptable terms for its clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities.

**Anti-Takeover Provisions.** Certain provisions of the Company's Amended and Restated Articles of Incorporation, as well as the California General Corporation Law, could discourage a third party from attempting to acquire, or make it more difficult for a third party to acquire, control of the Company without approval of the Company's Board of Directors. Such provisions could also limit the price that certain investors might be willing to pay in the future for shares of the Common Stock. Certain of such provisions allow the Board of Directors to authorize the issuance of preferred stock with rights superior to those of the Common Stock and to accelerate vesting of employee stock options. The Company is also subject to the provisions of Section 1203 of the California General Corporation Law which requires that a fairness opinion be provided to the Company's shareholders in connection with their consideration of any proposed "interested party" reorganization transaction.

Volatility of Stock Price. The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. In addition, the market price of the Common Stock, like the stock prices of many publicly-traded pharmaceutical, chemical, consumer, and biotechnology companies, may prove to be highly volatile. Announcements of technological innovations or new commercial products by the Company or its competitors, developments or disputes concerning patent or proprietary rights, publicity regarding actual or potential medical results relating to products under development by the Company or its competitors, regulatory developments in both the United States and foreign countries, public concern as to the safety of pharmaceutical products, sales of a large number of shares of Common Stock in the market and economic and other external factors, as well as period-to-period fluctuations in financial results, among other factors, may have a significant impact on the market price of the Common Stock.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company invests its excess cash in short-term, investment grade, fixed income securities under an investment policy. All of the Company's investments are classified as available-for-sale (see Financial Statements - Note 2). Approximately 54% of the Company's securities will mature by the end of 1999. The Company believes that potential near-term losses in future earnings, fair values or cash flows related to their investment portfolio would not be significant. Cellegy has a long-term note payable outstanding (see Financial Statements - Note 4) with an interest rate which currently varies with the lender's prime rate.

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ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data required by item 7 are set forth below on pages F-1 through F-21 of this report.

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

Information with respect to this Item may be found in the section captioned "Executive Compensation - Certain Transactions" appearing in the definitive Proxy Statement to be delivered to Shareholders in connection with the Annual Meeting of Shareholders expected to be held on May 20, 1999. Such information is incorporated herein by reference.

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 to be delivered to shareholders in connection with the Annual Meeting of Shareholders expected to be held on May 20, 1999. 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 definitive Proxy Statement to be delivered to shareholders in connection with the Annual Meeting of Shareholders expected to be held on May 20, 1999. Such information 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 definitive Proxy Statement to be delivered to Shareholders in connection with the Annual Meeting of Shareholders expected to be held on May 20, 1999.

Such information is incorporated herein by reference.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None.

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PART IV

ITEM 14: 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 declared effective on February 19, 1998.)
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	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.)
4.2	Specimen Warrant Certificate. (Incorporated by reference to Exhibit 4.2 to the SB-2.)
4.3	Form of Warrant Agreement Between the Company and First Interstate Bank of California. (Incorporated by reference to Exhibit 4.3 to the SB-2.)
4.4	Form of Representatives' Warrant Agreement. (Incorporated by reference to Exhibit 27.2 to the SB-2.)
4.5	Certificate of Determination, as amended, relating to the Series A Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-QSB for the three months ended March 31, 1996 (the "Q1 1996 Form 10-QSB").)
4.6	Securities Subscription Agreement dated April 1996 relating to the Series A Preferred Stock. (Incorporated by reference to Exhibit 4.2 to the Q1 1996 Form 10-QSB.)
4.7	Registration Rights Agreement dated April 18, 1996 relating to the Series A Preferred Stock. (Incorporated by reference to Exhibit 4.3 to the Q1 1996 Form 10-QSB.)
10.1	Barrier Repair Formulations License Agreement, dated October 26, 1993 between the Company and the University of California. (Incorporated by reference to Exhibit 10.5 to the SB-2.)
10.2	License Agreement, dated March 4, 1994, regarding Drug Delivery by Skin Barrier Disruption, between the Company and University of California. (Incorporated by reference to Exhibit 10.6 to the SB-2.)



- \*10.3 Employment Agreement, dated as of January 21, 1996, between the Company and Dr. Carl Thornfeldt. (Incorporated by reference to Exhibit 10.7 to the Company's Form 10-KSB for fiscal year ended December 31, 1995 (the "1995 Form 10-KSB".))
- 10.4 Amended and Restated Registration Rights Agreement dated April 10, 1992. (Incorporated by reference to Exhibit 10.11 to the SB-2.)
- \*10.5 1992 Stock Option Plan. (Incorporated by reference to Exhibit 10.12 to the SB-2.)
- 10.6 Secured Debenture and Warrant Purchase Agreement dated as of February 10, 1995. (Incorporated by reference to Exhibit 10.13 to the SB-2.)
- 10.7 Amended and Restated Registration Rights Agreement dated as of February 10, 1995. (Incorporated by reference to Exhibit 10.14 to the SB-2.)

Exhibit Number -----	Exhibit Title -----
10.8	Warrant Agreement dated as of February 10, 1995. (Incorporated by reference to Exhibit 10.15 to the SB-2.)
10.9	Agency Agreement dated as of February 10, 1995. (Incorporated by reference to Exhibit 10.16 to the SB-2.)
*10.10	1995 Equity Incentive Plan (Incorporated by reference to Exhibit 10.17 to the 1995 Form 10-KSB.)
*10.11	1995 Directors' Stock Option Plan (Incorporated by reference to Exhibit 10.18 to the 1995 Form 10-KSB.)
10.12	Standard Industrial Lease dated April 6, 1992, between the Company and H&H Management. (Incorporated by reference to Exhibit 10.20 to the 1995 Form 10-KSB.)
10.13	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.)
10.14	Lease Agreement between the Company and TCNorthern California Inc. dated April 8, 1998 (Incorporated by reference to Exhibit 10.01 to the Company's Form 10-QSB for fiscal quarter ended March 31, 1998.)
*10.15	Employment Agreement dated November 20, 1996, between the Company and K. Michael Forrest. (Incorporated by reference to Exhibit 10.19 to the Company's Form 10-KSB for fiscal year ended December 31, 1996 (the "1996 Form 10-KSB".))
10.16	Exclusive Licensing Agreement for Glylorin between the Company and Glaxo Wellcome Inc. dated November 11, 1996. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 10.20 to the 1996 Form 10-KSB.)
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (See signature page.)
27.1	Financial Data Schedule.

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

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the last quarter of the year for when this report is filed.

(c) Financial Statement Schedules

All schedules are omitted because they are not applicable or are not required, 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 22nd day of March, 1999.

CELLEGY PHARMACEUTICALS, INC.

By: /s/ K. MICHAEL FORREST
-----
K. Michael Forrest
President and Chief Executive Officer

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

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

Table with 3 columns: Name, Title, Date. Rows include Principal Executive Officer (K. Michael Forrest), Principal Financial Officer (A. Richard Juelis), and Directors (Carl R. Thornfeldt, Jack L. Bowman, Tobi B. Klar, Alan A. Steigrod, Larry J. Wells).

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

-----

EXHIBITS

to

Form 10-K

Under

THE SECURITIES EXCHANGE ACT OF 1934

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CELLEGY PHARMACEUTICALS, INC.

INDEX TO EXHIBITS

Exhibit Number -----	Description -----	Page No. ---
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- 4.5 Certificate of Determination, as amended, relating to the Series A Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-QSB for the three months ended March 31, 1996 (the "Q1 1996 Form 10-QSB").)
- 4.6 Securities Subscription Agreement dated April 1996 relating to the Series A Preferred Stock. (Incorporated by reference to Exhibit 4.2 to the Q1 1996 Form 10-QSB.)
- 4.7 Registration Rights Agreement dated April 18, 1996 relating to the Series A Preferred Stock. (Incorporated by reference to Exhibit 4.3 to the Q1 1996 Form 10-QSB.)
- 10.1 Barrier Repair Formulations License Agreement, dated October 26, 1993 between the Company and the University of California. (Incorporated by reference to Exhibit 10.5 to the SB-2.)
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- 10.16 Exclusive Licensing Agreement for Glylorin between the Company and Glaxo Wellcome Inc. dated November 11, 1996. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 10.20 to the 1996 Form 10-KSB.)
- \*10.19 Consulting Agreement between the Company and Dr. Peter M. Elias dated May 1, 1996. (Incorporated by reference to Exhibit 10.21 to the 1996 Form 10-KSB.)
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.
- 24.1 Power of Attorney (See signature page.)
- 27.1 Financial Data Schedule.

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

</FN>

Index to Financial Statements

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Report of Ernst & Young LLP, Independent Auditors

The Board of Directors and Shareholders  
Cellegy Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Cellegy Pharmaceuticals, Inc. (a development stage company) as of December 31, 1998 and 1997, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 1998, and for the period from June 26, 1989 (inception) through December 31, 1998. 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 generally accepted auditing standards. 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 financial position of Cellegy Pharmaceuticals, Inc. at December 31, 1998 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1998, and for the period from June 26, 1989 (inception) through December 31, 1998, in conformity with generally accepted accounting principles.

Palo Alto, California  
February 5, 1999

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Balance Sheets

	December 31,	
	1998	1997
	-----	-----
Assets		
Current assets		
Cash and cash equivalents .....	\$ 1,610,826	\$ 1,821,791
Short-term investments .....	7,282,233	7,481,870
Inventory .....	52,977	--
Prepaid expenses and other current assets .....	1,380,417	1,011,913
	-----	-----
Total current assets .....	10,326,453	10,315,574
Property and equipment, net .....	2,830,808	13,663
Long-term investments .....	6,326,623	12,422,230
	-----	-----
Total assets .....	\$ 19,483,884	\$ 22,751,467
	=====	=====
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities .....	\$ 1,551,600	\$705,153
Deferred revenue .....	250,000	500,000
Accrued research fees .....	94,088	154,665
Accrued compensation and related expenses .....	69,097	37,220
Current portion of note payable .....	402,602	--
	-----	-----
Total current liabilities .....	2,367,387	1,397,038
Long-term liabilities		
Long-term portion of note payable .....	2,818,211	--
Other long-term liabilities .....	80,256	--
Commitments and contingencies		
Shareholders' equity		
Preferred stock, no par value; 5,000,000 shares authorized: Series A convertible preferred stock; 1,100 shares designated; no shares issued or outstanding at December 31, 1998 and 1997 .....	--	--
Common Stock, no par value; 20,000,000 shares authorized: 10,173,294 shares issued and outstanding at December 31, 1998, and 10,123,751 shares issued and outstanding at December 31, 1997 .....	44,363,133	44,192,387
Accumulated other comprehensive income (loss) .....	47,353	(11,833)
Deficit accumulated during the development stage .....	(30,192,456)	(22,826,125)
	-----	-----
Total shareholders' equity .....	14,218,030	21,354,429
	-----	-----
Total liabilities and shareholders' equity .....	\$ 19,483,884	\$ 22,751,467
	=====	=====

<FN>

See accompanying notes.

</FN>

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notes in 1992 .....	---	---	12,750	114,000	---	---	---	---
Issuance of Series C convertible preferred stock for cash, net of issuance cost, through December 31, 1995 .....	---	---	---	---	477,081	4,978,505	---	---

	Accumulated Other Comprehensive Income (Loss) -----	Deficit Accumulated During the Development Stage -----	Total Shareholders' Equity -----
Issuance of common stock for cash through December 31, 1995 .....	\$ ---	\$ ---	\$117,749
Issuance of common stock for services rendered through December 31, 1995 .....	---	---	24,261
Issuance of common stock in connection with merger with Pacific Pharmaceuticals, Inc. in April 1992 .....	---	---	8,750
Repurchase of common shares in 1992 .....	---	---	(324)
Issuance of Series A convertible preferred stock for cash through December 31, 1995 .....	---	---	48,500
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, 1995 .....	---	---	1,199,536
Issuance of Series A convertible preferred stock for services rendered through December 31, 1995 .....	---	---	73,198
Issuance of Series A convertible preferred stock in exchange for license agreement .....	---	---	100,000
Issuance of Series B convertible preferred stock in exchange for convertible promissory notes in 1992 .....	---	---	114,000
Issuance of Series C convertible preferred stock for cash, net of issuance cost, through December 31, 1995 .....	---	---	4,978,505

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Statements of Shareholders' Equity - (Continued)

Series A Convertible Preferred Stock -----	Series B Convertible Preferred Stock -----	Series C Convertible Preferred Stock -----	Common Stock -----
--	--	--	-----------------------



	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
	-----	-----	-----	-----	-----	-----	-----	-----
Issuance of common stock in exchange for notes payable ...	---	---	---	---	---	---	42,960	268,500
Issuance of warrants in connection with notes payable financing .....	---	---	---	---	---	---	---	487,333
Conversion of preferred stock to common stock in connection with IPO in August 1995 .....	(702,854)	(1,421,234)	(12,750)	(114,000)	(477,081)	(4,978,505)	1,192,685	6,513,739
Issuance of common stock in connection with IPO in August 1995 .....	---	---	---	---	---	---	1,322,500	6,383,785
Net loss for the period June 26, 1989 (inception) through December 31, 1995 ....	---	---	---	---	---	---	---	---
Balances at December 31, 1995 ...	---	---	---	---	---	---	3,777,075	13,803,793
Issuance of Series A convertible preferred stock, net of issuance costs .....	750	6,753,230	---	---	---	---	---	---
Conversion of preferred stock, including dividends, to common stock ...	(555)	(6,005,724)	---	---	---	---	1,234,077	6,005,724
Exercise of warrants to purchase common stock .....	---	---	---	---	---	---	135,256	51,814
Exercise of options to purchase common stock.....	---	---	---	---	---	---	6,344	11,553
Compensation expense related to the extension of option exercise periods .....	---	---	---	---	---	---	---	268,486
Non-cash preferred dividends ....	---	1,413,765	---	---	---	---	---	---
Unrealized gain on investments ..	---	---	---	---	---	---	---	---
Net loss - 1996 .....	---	---	---	---	---	---	---	---
Total Comprehensive Income-1996..	-----	-----	-----	-----	-----	-----	-----	-----
Balances at December 31, 1996 ...	195	2,161,271	---	---	---	---	5,152,752	20,141,370

	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	-----	-----	-----
Issuance of common stock in exchange for notes payable ...	---	---	268,500
Issuance of warrants in connection with notes payable financing .....	---	---	487,333
Conversion of preferred stock to common stock in connection with IPO in August 1995 .....	---	---	---
Issuance of common stock in connection with IPO in August 1995 .....	---	---	6,383,785
Net loss for the period June 26, 1989 (inception) through December 31, 1995 ....	---	(10,155,456)	(10,155,456)
Balances at December 31, 1995 ...	---	(10,155,456)	3,648,337
Issuance of Series A convertible preferred stock, net of issuance costs .....	---	---	6,753,230
Conversion of preferred stock, including dividends, to common stock ...	---	---	---
Exercise of warrants to purchase common stock .....	---	---	51,814
Exercise of options to purchase common stock.....	---	---	11,553
Compensation expense related to the extension of option exercise periods .....	---	---	268,486
Non-cash preferred dividends ....	---	(1,413,765)	---
Unrealized gain on investments .....	22,167	---	22,167
Net loss - 1996 .....	---	(3,368,096)	(3,368,096)
Total Comprehensive Income - 1996 .....	---	---	(3,345,929)

Balances at December 31, 1996 ... 22,167 (14,937,317) 7,387,491

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Statements of Shareholders' Equity - (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Exercise of warrants to purchase common stock .....	---	---	---	---	---	---	227,847	930
Non-cash preferred dividends ...	---	34,740	---	---	---	---	---	---
Conversion of preferred stock, including dividends, to common stock ..	(195)	(2,196,011)	---	---	---	---	587,879	2,196,011
Exercise of options to purchase common stock .....	---	---	---	---	---	---	132,137	362,303
Compensation expense related to the extension of option exercise periods .....	---	---	---	---	---	---	---	69,995
Issuance of common stock in connection with the private placement in July 1997, net of issuance costs .....	---	---	---	---	---	---	1,547,827	3,814,741
Issuance of common stock in connection with the public offering of common stock in November 1997, net of issuance costs .....	---	---	---	---	---	---	2,012,500	13,764,069
Issuance of common stock in connection with the acquisition of product rights from Neptune Pharmaceutical Corp. ....	---	---	---	---	---	---	462,809	3,842,968
Unrealized loss on investments .....	---	---	---	---	---	---	---	---
Net loss - 1997 .....	---	---	---	---	---	---	---	---
Total Comprehensive Income - 1997 .....	-----	-----	-----	-----	-----	-----	-----	-----
Balances at December 31, 1997 ..	---	---	---	---	---	---	10,123,751	44,192,387
Exercise of warrants to purchase common stock .....	---	---	---	---	---	---	13,979	47,740
Exercise of options to purchase common stock .....	---	---	---	---	---	---	35,564	123,006
Unrealized gain on investments .	---	---	---	---	---	---	---	---
Net loss - 1998 .....	---	---	---	---	---	---	---	---
Total Comprehensive Income - 1998 .....	-----	-----	-----	-----	-----	-----	-----	-----
Balances at December 31, 1998 ..	---	\$ ---	---	\$ ---	---	\$ ---	10,173,294	\$44,363,133

	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
Exercise of warrants to purchase common stock .....	---	---	930
Non-cash preferred dividends ...	---	(34,740)	---
Conversion of preferred stock, including dividends, to common stock ..	---	---	---
Exercise of options to purchase common stock .....	---	---	362,303
Compensation expense related to the extension of option exercise periods .....	---	---	69,995

Issuance of common stock in connection with the private placement in July 1997, net of issuance costs . . . . .	---	---	3,814,741
Issuance of common stock in connection with the public offering of common stock in November 1997, net of issuance costs . . . . .	---	---	13,764,069
Issuance of common stock in connection with the acquisition of product rights from Neptune Pharmaceutical Corp. . . . .	---	---	3,842,968
Unrealized loss on investments . . . . .	(34,000)	---	(34,000)
Net loss - 1997 . . . . .	---	(7,854,068)	(7,854,068)
Total Comprehensive Income - 1997 . . . . .			(7,888,068)
	-----	-----	-----
Balances at December 31, 1997 ..	(11,833)	(22,826,125)	21,354,429
Exercise of warrants to purchase common stock . . . . .	---	---	47,740
Exercise of options to purchase common stock . . . . .	---	---	123,006
Unrealized gain on investments . . . . .	59,186	---	59,186
Net loss - 1998 . . . . .	---	(7,366,331)	(7,366,331)
			-----
Total Comprehensive Income - 1998 . . . . .			(7,307,145)
	-----	-----	-----
Balances at December 31, 1998 ..	\$47,353	\$(30,192,456)	\$14,218,030
	=====	=====	=====

See accompanying notes.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Statements of Cash Flows

	Years ended December 31,			Period from
	1998	1997	1996	June 26, 1989 (inception) through December 31, 1998
	-----	-----	-----	-----
Operating activities				
Net loss . . . . .	\$ (7,366,331)	\$ (7,854,068)	\$ (3,368,096)	\$ (28,743,951)
Adjustment to reconcile net loss to net cash used in operating activities:				
Acquired in process technology . . . . .	--	3,842,968	--	3,842,968
Depreciation and amortization . . . . .	15,015	17,618	35,384	279,271
Compensation expense related to the extension of option exercise periods . . . . .	--	69,995	268,486	338,481
Loss on sale of property and equipment . . . . .	--	--	--	3,724
Amortization of discount on notes payable and deferred financing costs . . . . .	--	--	--	567,503
Issuance of common shares for services . . . . .	--	--	--	24,261
Issuance of Series A convertible preferred stock for services rendered . . . . .	--	--	--	73,198
Issuance of Series A convertible preferred stock for interest . . . . .	--	--	--	67,720
Issuance of Series A convertible preferred stock for license agreement . . . . .	--	--	--	100,000
Changes in operating assets and liabilities:				
Inventory . . . . .	(52,977)	--	--	(52,977)
Prepaid expenses and other current assets . . . . .	(368,504)	(661,352)	(201,521)	(1,380,417)
Accounts payable and accrued liabilities . . . . .	846,447	435,140	77,781	1,551,600
Deferred revenue . . . . .	(250,000)	500,000	--	250,000
Accrued research fees . . . . .	(60,577)	133,665	21,000	94,088
Accrued compensation and related expenses . . . . .	31,877	19,262	(169,308)	69,097
	-----	-----	-----	-----
Net cash used in operating activities . . . . .	(7,205,050)	(3,496,772)	(3,336,274)	(22,915,434)
Investing activities				
Purchase of property and equipment . . . . .	(2,832,160)	--	(8,000)	(3,005,053)
Purchases of investments . . . . .	(5,039,440)	(18,915,933)	(9,576,000)	(40,577,893)

Sales of investments .....	5,893,870	--	--	5,893,870
Maturities of investments .....	5,500,000	6,256,000	3,820,000	21,122,520
	-----	-----	-----	-----
Net cash provided by (used in) investing activities .....	3,522,270	(12,659,933)	(5,764,000)	(16,566,556)

<FN>

See accompanying notes.

</FN>

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Statements of Cash Flows - (Continued)

	Years ended December 31,			Period from
	1998	1997	1996	June 26, 1989 (inception) through December 31,
	-----	-----	-----	-----
Financing activities				
Proceeds from notes payable .....	\$ 3,220,813	\$ --	\$ --	\$ 6,768,237
Repayment of notes payable .....	--	--	--	(2,110,608)
Other long-term liabilities .....	80,256	--	--	80,256
Net proceeds from issuance of Common Stock .....	170,746	17,942,043	63,367	24,677,690
Repurchase of Common Stock .....	--	--	--	(324)
Issuance of convertible preferred stock, net of issuance costs .....	--	--	6,753,230	11,757,735
Deferred financing costs .....	--	--	--	(80,170)
Net cash provided by financing activities .....	3,471,815	17,942,043	6,816,597	41,092,816
Net increase (decrease) in cash .....	(210,965)	1,785,338	(2,283,677)	1,610,826
Cash and cash equivalents, beginning of period .....	\$ 1,821,791	36,453	2,320,130	--
Cash and cash equivalents, end of period .....	\$ 1,610,826	\$ 1,821,791	\$ 36,453	\$ 1,610,826
	=====	=====	=====	=====
Supplemental disclosure of non-cash transactions:				
Issuance of Common Stock in connection with acquired in process technology .....	--	\$ 3,842,968	\$ --	\$ 3,842,968
Conversion of preferred stock to Common Stock .....	\$ --	\$ 2,196,011	\$ 6,005,724	\$ 14,715,474
Issuance of Common Stock for notes payable .....	\$ --	\$ --	\$ --	\$ 268,500
Issuance of warrants in connection with notes payable financing .....	\$ --	\$ --	\$ --	\$ 487,333
Issuance of Series A convertible preferred stock for notes payable .....	\$ --	\$ --	\$ --	\$ 1,153,316
Issuance of Series B convertible preferred stock for notes payable .....	\$ --	\$ --	\$ --	\$ 115,000
Issuance of Common Stock for Pacific Pharmaceuticals, Inc .....	\$ --	\$ --	\$ --	\$ 8,750

<FN>

See accompanying notes.

</FN>

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements

1. Accounting Policies

Description of Business

Cellegy Pharmaceuticals, Inc., incorporated in California in June 1989,

is a development stage company. Since its inception, the Company has engaged primarily in research and development activities based upon its patented transdermal and topical drug delivery technologies and its expertise in skin biology. The Company has conducted a number of clinical trials for its products, including the preparation of manufactured clinical materials. Laboratory equipment has been purchased and installed in support of its research and development activities. A number of sponsored, external research programs were undertaken. Pre-launch commercialization activities, including packaging design are ongoing for its cosmeceutical products.

#### Basis of Presentation

In the course of its development, the Company has incurred significant losses and will continue to incur additional losses during its development phase. As a result, the Company will require substantial additional funds for its operational activities and may seek private or public equity financings and future collaborative arrangements with third parties to meet its cash needs. There is no assurance that such additional funds will be available on acceptable terms or available at all. Insufficient funding may require the Company to delay, reduce, or eliminate some or all of its research and development, planned clinical trials, and administrative programs.

#### Use of Estimates

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

#### Revenues and Research and Development Expenses

Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects are incurred. Revenues related to milestones specified under development contracts are recognized as the milestones are achieved. Research and development costs are expensed as incurred.

The Company receives certain United States government grants that support the Company's research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenues associated with these grants are recognized as costs under each grant are incurred.

Revenues related to cosmeceutical product sales are recognized upon shipment.

#### 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, 1998 and 1997. The Company considers all its investments as available-for-sale and reports these investments at estimated fair market value. Unrealized gains or losses on available-for-sale securities are included in shareholders' equity until their disposition. The cost of securities sold is based on the specific identification method. Realized gains or losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest income and other, net.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

#### Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. At December 31, 1998, inventories consisted entirely of raw materials.

#### Property and Equipment

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

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 Opinion No. 25") and has elected to follow the disclosure-only alternative prescribed by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123").

Comprehensive Income (Loss)

The Company has adopted Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income," as of the first quarter of 1998. SFAS No. 130 establishes new rules for the reporting and display of comprehensive income and its components. It has no impact on net loss or shareholders' equity.

Segment Reporting

Effective January 1, 1998, the Company adopted the Financial Accounting Standards Board's Statement of Financial Accounting Standards ("SFAS") No. 131, "Disclosures about Segments of an Enterprise and Related Information." SFAS No. 131 supersedes FASB Standard No. 14, "Financial Reporting for Segments of a Business Enterprise." SFAS No. 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. SFAS No. 131 also establishes standards for related disclosures about products and services, geographic areas, and major customers. The adoption of SFAS No.131 did not affect results of operations or financial position, but did affect the disclosure of segment information. See note 10.

Advertising Costs

Advertising costs are accounted for as expenses in the period in which they are incurred. Advertising expense for the year ended December 31, 1998 was \$175,815. There were no advertising costs in 1997 and 1996.

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 (see note 6) are anti-dilutive.

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

2. Investments

At December 31, 1998, available-for-sale securities consist of the following:

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	-----	-----	-----	-----
Corporate Notes .....	\$ 9,337,751	\$ 45,080	\$ (7,020)	\$ 9,375,811
U.S. Government Notes .....	3,996,252	9,293	--	4,005,545
Time Deposits .....	227,500	--	--	227,500
Money Market .....	1,463,698	--	--	1,463,698

	-----	-----	-----	-----
Total available-for-sale securities .....	15,025,201	54,373	(7,020)	15,072,554
Less amounts classified as cash equivalents .....	1,463,698	--	--	1,463,698
Total investments .....	\$13,561,503	\$ 54,373	\$ (7,020)	\$13,608,856

At December 31, 1997, available-for-sale securities consist of the following:

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	-----	-----	-----	-----
Corporate Notes .....	\$10,406,917	\$ 3,327	\$ (23,987)	\$10,386,257
U.S. Government Notes .....	5,030,259	5,589	(197)	5,035,651
Time Deposits .....	1,999,948	1,202	(122)	2,001,028
Money Market .....	1,788,853	--	--	1,788,853
Variable Rate Securities .....	1,500,000	--	--	1,500,000
Commercial Paper .....	978,809	2,355	--	981,164
Total available-for-sale securities .....	21,704,786	12,473	(24,306)	21,692,953
Less amounts classified as cash equivalents .....	1,788,853	--	--	1,788,853
Total investments .....	\$19,915,933	\$ 12,473	\$ (24,306)	\$19,904,100

The amortized cost and estimated fair value of available-for-sale securities in debt securities at December 31, 1998, by contractual maturity, were as follows:

	Cost	Estimated Fair Value
	-----	-----
Due in 1 year or less .....	\$ 8,734,694	\$ 8,745,931
Due in 1 - 3 years .....	6,290,507	6,326,623
Total available-for-sale securities .....	15,025,201	15,072,554
Less amounts classified as cash equivalents .....	1,463,698	1,463,698
Total investments .....	\$13,561,503	\$13,608,856

There have been no significant realized gains or losses on the sale of securities for the years ended December 31, 1998, 1997 and 1996.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

3. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	1998	1997
	-----	-----
Furniture and fixtures .....	\$ 145,395	\$ 49,702
Office equipment .....	100,872	39,142
Laboratory equipment .....	373,767	65,310
Leasehold improvements .....	2,369,890	3,610
	2,989,924	157,764
Less accumulated depreciation and amortization ...	(159,116)	(144,101)

\$ 2,830,808      \$ 13,663  
 =====            =====

4. Note Payable

In June 1998, the Company entered into an agreement with a bank to provide up to \$4.5 million through December 1999 with interest at the bank's prime rate plus one percentage point or a rate equal to four and one quarter percentage points above the yield of the 48 month treasury bill. The note is secured by the Company's cash and investments. Interest only payments are due during the first twelve months of the agreement. After the initial 12-month period of the agreement, the Company is required to repay the amount then borrowed in 48 equal monthly installments. The fair value of the note payable is estimated based on current interest rates available to the Company for debt instruments with similar terms, degrees of risk, and remaining maturities. The carrying value of the note approximates its fair value. As of December 31, 1998, a total of \$3,220,813 is outstanding under the arrangement.

5. Lease Commitments

The Company leases its facilities and equipment under non-cancelable operating leases. Future minimum lease payments, net of future minimum sublease rentals at December 31, 1998, are as follows:

	Lease Commitments	Sublease Rentals	Lease Commitments Net of Sublease Rentals
	-----	-----	-----
1999 .....	\$ 1,419,313	\$ 850,284	569,029
2000 .....	1,542,248	930,420	611,828
2001 .....	1,432,448	852,217	580,231
2002 .....	1,302,739	--	1,302,739
2003 .....	1,279,608	--	1,279,608
2004 and thereafter .....	6,997,428	--	6,997,428
	-----	-----	-----
	\$13,973,784	\$ 2,632,921	\$11,340,863
	=====	=====	=====

Lease expense was \$437,245, \$362,532 and \$209,715 for the years ended December 31, 1998, 1997 and 1996, respectively. For the year ended December 31, 1998, such lease expense included \$200,749 of office rent expense and \$236,496 of equipment lease expense, compared with office rent and equipment lease expense of \$207,299 and \$155,233, respectively for the year ended December 31, 1997, and office rent and equipment lease expense of \$145,879 and \$63,836, respectively, for the year ended December 31, 1996.

Cellegy Pharmaceuticals, Inc.  
 (a development stage company)

Notes to Financial Statements - (Continued)

6. Shareholders' Equity

Convertible Series A Preferred Stock Offering

For the year ended December 31, 1997, the Company had non-cash preferred dividends of \$34,740 reflecting the 8% per annum mandatory preferred dividends of the Series A preferred stock. For the year ended December 31, 1996, the Company had non-cash preferred dividends of \$1,125,000 reflecting the 15% discount in conjunction with the Common Stock variable conversion price of the Series A preferred stock, and non-cash preferred dividends of \$288,765 reflecting the 8% per annum mandatory preferred dividends of the Series A preferred stock.

Common Stock Private Placement

On July 23, 1997, the Company completed a \$3,850,000 private placement of 1,547,827 shares of Common Stock. Net proceeds were \$3,814,741. The purchase



price for all investors, except the Company's chief executive officer, was \$2.375 per share. The purchase price for the shares purchased by the Company's chief executive officer in the private placement was \$2.875 per share, which is equal to the closing price of the Common Stock on the Nasdaq SmallCap Market on the date immediately preceding the closing date of the private placement.

#### Secondary Public Offering

On November 24, 1997, the Company completed a public offering of 2,012,500 shares of Common Stock at \$7.50 per share. Net proceeds were \$13,764,069.

#### 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 numbers of shares to be included in, and the designation of, any such shares to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon any wholly unissued series of preferred stock and to increase or decrease the number of shares of any such series without any further vote or action by the shareholders.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

#### Warrants

The Company has the following warrants outstanding to purchase Common Stock at December 31, 1998:

Number of Shares	Exercise Price per Share	Date Issued	Expiration Date
35,496	4.51	October 1994	December 31, 1999
22,368	0.01	February 1995	December 31, 1999
365,728	7.81	February 1995	December 31, 1999
44,604	9.02	March 1995	December 31, 1999
42,960	5.19	August 1995	December 31, 1999
115,000	10.31	August 1995	August 11, 2000
57,500	15.47	August 1995	August 11, 2000
661,250	9.38	August 1995	August 11, 2000
86,005	7.23	April 1996	April 18, 2001
24,000	10.50	October 1997	October 1, 2002
24,000	8.75	October 1997	October 1, 2002
94,063	9.75	November 1997	November 24, 2002
-----			
1,572,974			
=====			

Included in the table above are warrants to acquire 661,250 shares of Common Stock at a price of \$9.375 per share that were issued in connection with the Company's initial public offering. The warrants are exercisable at any time unless previously redeemed until August 11, 2000. The Company may redeem the warrants, in whole or in part, at any time upon at least thirty days prior written notice to the warrant holders at a price of \$0.05 per warrant provided that the closing price of the Common Stock has been at least \$12.50 for at least ten consecutive trading days ending on a date within 30 days before the date of the notice of redemption. No warrants have been redeemed through December 31, 1998.

#### Stock Option Plans

In 1995, the Company adopted the Equity Incentive Plan (the "Plan") to

provide for the issuance of incentive stock options and non-statutory stock options. When the Plan was established, the Company reserved 700,000 shares for issuance. In 1996, 1997 and 1998, an additional 300,000 shares, 450,000 shares, and 1,000,000 shares were reserved for issuance under the Plan, respectively. Under the Plan, incentive stock options may be granted at a price per share of not less than the fair market value of Common Stock on the date of grant. Nonqualified options may be granted at a price per share of not less than 85% of fair market value on the date of grant. Options are exercisable to the extent vested. The Compensation Committee establishes the vesting schedules.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

Activity under the Plan is summarized as follows:

	Shares Under Option	Price Range Per Share	Weighted Average Exercise Price
Balance at December 31, 1995 .....	650,685	\$0.45 - \$6.66	\$ 3.35
Granted .....	605,447	\$4.56 - \$8.25	\$ 5.43
Canceled .....	(253,443)	\$1.39 - \$6.38	\$ 4.49
Exercised .....	(6,344)	\$1.81 - \$2.09	\$ 1.82
Balance at December 31, 1996 .....	996,345	\$0.45 - \$8.25	\$ 4.34
Granted .....	430,500	\$3.00 - \$8.81	\$ 5.17
Canceled .....	(213,371)	\$3.07 - \$8.25	\$ 5.58
Exercised .....	(132,138)	\$0.45 - \$5.69	\$ 2.74
Balance at December 31, 1997 .....	1,081,336	\$0.46 - \$8.81	\$ 4.62
Granted .....	544,000	\$3.25 - \$8.50	\$ 6.68
Canceled .....	(46,344)	\$3.07 - \$8.25	\$ 6.19
Exercised .....	(35,564)	\$0.46 - \$5.50	\$ 3.46
Balance at December 31, 1998 .....	1,543,428	\$0.46 - \$8.81	\$ 5.32

At December 31, 1998, options to purchase 552,306 shares of Common Stock were vested and exercisable at exercise prices ranging from \$0.46 to \$8.81 per share. At December 31, 1998, options to purchase 45,000 shares of Common Stock at an exercise price of \$4.56 per share vest in the year of 2001 but are subject to earlier vesting if certain performance criteria are met. At December 31, 1998, options to purchase 36,750 shares of Common Stock at an exercise price of \$3.75 per share vest in the year of 2002 but are subject to earlier vesting if certain performance criteria are met. At December 31, 1998, 711,801 options to purchase 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, 1998:

Range of Exercise Price	Options Outstanding		Options Exercisable		
	Outstanding at December 31, 1998	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at December 31, 1998	Weighted Average Exercise Price
\$0.46 - \$3.75 .....	398,198	7.6 years	\$3.05	189,149	\$2.59
\$4.38 - \$6.66 .....	716,730	8.1 years	\$5.25	315,822	\$5.09
\$7.00 - \$8.81 .....	428,500	9.2 years	\$7.57	47,335	\$8.19
Total .....	1,543,428	8.3 years	\$5.32	552,306	\$4.50

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

Activity under the Directors' Plan is summarized as follows:

	Shares Under Option	Price Range Per Share	Weighted Average Exercise Price
Balance at December 31, 1995 .....	20,000	\$5.00	\$5.00
Granted .....	50,000	\$4.50 - \$8.50	\$5.31
Balance at December 31, 1996 .....	70,000	\$4.50 - \$8.50	\$5.22
Granted .....	6,000	\$3.25	\$3.25
Balance at December 31, 1997 .....	76,000	\$3.25 - \$8.50	\$5.07
Granted .....	40,000	\$5.50	\$5.50
Canceled .....	(2,000)	\$3.25 - \$8.50	\$5.88
Balance at December 31, 1998 .....	114,000	\$3.25 - \$8.50	\$5.20

At December 31, 1998, options to purchase 47,000 shares of Common Stock were vested and exercisable at exercise prices ranging from \$3.25 to \$8.50 per share. At December 31, 1998, options to purchase 36,000 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, 1998:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Outstanding at December 31, 1998	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at December 31, 1998	Weighted Average Exercise Price
\$3.25 .....	5,000	8.4 years	\$3.25	1,250	\$3.25
\$4.50 - \$5.50 .....	105,000	8.2 years	\$5.17	43,750	\$4.97
\$8.50 .....	4,000	7.4 years	\$8.50	2,000	\$8.50
Total .....	114,000	8.2 years	\$5.20	47,000	\$5.08

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

Pro forma information regarding net loss and net loss per common share is required by FAS 123, which requires that the information be determined as if the Company has accounted for its Common Stock options granted subsequent to December 31, 1994 under the fair market value method. The fair market value for options granted in 1998, 1997 and 1996 was estimated at the date of the grant using a Black-Scholes option-pricing model.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

The Company valued its options using the following weighted average assumptions for the years ended December 31, 1998, 1997 and 1996:

	1998	1997	1996
Risk-free interest rate .....	5.14%	6.20%	6.23%
Dividend yield .....	0%	0%	0%
Volatility .....	0.531	0.487	0.517

Expected life of options in years ..... 4.6                      4.9                      4.8

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

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information follows:

	1998	1997	1996
	-----	-----	-----
Pro forma net loss applicable to common shareholders .....	\$ (8,220,952)	\$ (8,221,875)	\$ (5,494,675)
Pro forma basic and diluted net loss per share applicable to common shareholders ...	\$ (0.81)	\$ (1.23)	\$ (1.29)

The weighted average grant date fair value of options granted during the years ended December 31, 1998, 1997 and 1996 was \$2.88, \$2.57 and \$2.79, respectively.

As a result of FAS 123 only being applicable to options granted subsequent to December 31, 1994, its pro forma effect will not be fully reflected until the year ending December 31, 1999.

Shares reserved

As of December 31, 1998, the Company has reserved shares of Common Stock for future issuance as follows:

Warrants .....	1,543,428
Stock Option Plans .....	2,405,229
Neptune Agreement (see note 7) .....	1,537,191
	-----
Total .....	5,485,848
	=====

Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

7. Product Acquisitions

In December 1997, the Company acquired patent and related intellectual property rights relating to "Anogesic" (the "Anogesic Acquisition"), a topical product candidate for the treatment of anal fissures and hemorrhoids from Neptune Pharmaceutical Corporation. Under the terms of the Agreement, the Company issued 429,752 shares of Common Stock to Neptune on December 31, 1997. Upon the signing of a letter of intent on November 3, 1997, 33,057 shares of Common Stock had been issued to Neptune. The Agreement calls for a series of additional payments, payable in shares of Common Stock, upon successful completion of various milestones which, if achieved, would occur over the next several years. Depending on several factors, including the market price of the Common Stock, such payments could result in issuance of a significant number of shares of Common Stock. The Agreement does not provide for the payment by the Company of any future product royalties in connection with sales of Anogesic.

8. License Agreements

In November 1996, the Company entered into an agreement with Glaxo Wellcome Inc. ("Glaxo") for licensing rights to Glylorin, Cellegy's compound for

the treatment of ichthyoses. Under the terms of the agreement, Cellegy provided Glaxo with an exclusive license of patent rights and know-how covering Glylorin in most of the world's major markets. In exchange for this license, the Company received from Glaxo an initial license fee payment. In March 1999, Cellegy and Glaxo announced their agreement in principle to terminate the license agreement with the return to Cellegy of Glylorin product rights.

In October 1993, the Company entered into a license agreement with the University of California (the "Licensor") providing for an exclusive, worldwide, royalty-bearing license, subject to customary government rights, for patent rights relating to barrier repair formulations, jointly held by the Licensor and the Company, in consideration of the issuance to the Licensor of certain shares of preferred stock (which subsequently converted into shares of Common Stock) and the payment by the Company of a licensing fee. In March 1994, the Company entered into a second exclusive, worldwide, royalty-bearing license agreement with the Licensor for patent rights jointly held by the Licensor and the Company, relating to drug delivery technologies, in consideration of the payment by the Company of a licensing fee, and an annual maintenance fee payable each year until the Company is commercially selling a licensed product. Both agreements require the Company to pay the Licensor royalties based on net sales of consumer and prescription products (with minimum annual royalty payments). The Company has the right to grant sublicenses to third parties under both agreements. In May and October 1997, the Licensor and the Company amended these agreements. The amendments modified and extended certain development and commercialization milestones contained in the original agreements. The revised milestones are tied to the achievement of certain clinical, regulatory, or product commercialization goals over the next several years. Although there can be no assurance that such goals will be achieved, the Company believes its development programs in place will result in the satisfaction of such milestones.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

9. Income Taxes

At December 31, 1998, the Company has net operating loss carryforwards of approximately \$23,900,000 and \$8,200,000 for federal and state purposes, respectively. The federal net operating loss carryforwards expire between the years 2004 and 2018. The state net operating loss carryforwards expire between the years 1999 and 2003. At December 31, 1998, the Company also has research and development credit carryforwards of approximately \$600,000 and \$300,000 for federal and state purposes, respectively. The federal credits expire between the years 2006 and 2018.

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:

	December 31,	
	1998	1997
	-----	-----
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 8,600,000	\$ 5,986,000
Credit carryforwards .....	700,000	477,000
Capitalized intangibles .....	2,200,000	510,000
Other, net .....	(200,000)	169,000
	-----	-----
Total deferred tax assets .....	11,300,000	7,142,000
Valuation allowance.....	(11,300,000)	(7,142,000)

Net deferred tax assets.....	----- \$     -- =====	----- \$     -- =====
------------------------------	-----------------------------	-----------------------------

The valuation allowance for deferred tax assets increased by approximately \$4,158,000 and \$1,827,000 during the years ended December 31, 1998 and 1997, respectively.

10. Segment Reporting

The Company has two business segments: pharmaceuticals and cosmeceuticals. Pharmaceuticals include primarily research and development expenses for potential prescription products to be marketed directly by the Company or through corporate partners. Current pharmaceutical revenues consist primarily of licensing, milestones and development funding from one licensee, Glaxo Wellcome Inc. The Company expects to complete other corporate collaborations in the future for a number of its potential pharmaceutical products, which may result in milestones, development funding and royalties on sales. Cellegy expects to generate future revenues on potential products it intends to self-market.

The cosmeceutical business segment includes primarily development expenses for non-prescription anti-aging products. Using related technologies, Cellegy is currently incurring development expenses and receiving all of its product sales from one customer, Gryphon Development, Inc., which is selling product through Bath and Body Works specialty retail stores exclusively in the United States.

Cellegy allocates its research expenses and personnel to each business segment, but does not assess segment performance or allocate resources based on a segment's assets and, therefore, assets 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.

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Cellegy Pharmaceuticals, Inc.  
(a development stage company)

Notes to Financial Statements - (Continued)

The Company's segments are business units that will, in some cases, distribute products to different types of customers through different marketing programs. The potential future sales of cosmeceutical products to prestige department stores requires 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 more a extensive level of development, manufacturing and compliance than a cosmeceutical product.

The following table contains information regarding revenues and operating income (loss) of each business segment for the years ended December 31, 1998, 1997 and 1996:

	Years ended December 31,		
	----- 1998 -----	----- 1997 -----	----- 1996 -----
Revenues:			
Pharmaceuticals .....	\$ 373,750	\$ 827,695	\$ 647,660
Cosmeceuticals .....	457,970	--	--
	----- \$ 831,720 =====	----- \$ 827,695 =====	----- \$ 647,660 =====
Loss from Operations:			
Pharmaceuticals .....	\$ (8,011,630)	\$ (8,066,973)	\$ (3,698,265)
Cosmeceuticals .....	(423,078)	(343,030)	--
	----- \$ (8,434,708) =====	----- \$ (8,410,003) =====	----- \$ (3,698,265) =====



EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-06065), the Registration Statement (Form S-8 No. 333-32301), and the Registration Statement (Form S-8 No. 333-60343) pertaining to the 1992 Stock Option Plan, 1995 Equity Incentive Plan, and 1995 Directors' Stock Option Plan, and in the Registration Statement (Form SB-2 No. 33-93288 LA), the Registration Statement (Form SB-2 No. 33-03401), the Registration Statement (Form S-1 No. 333-38179), the Registration Statement (Form S-3 No. 33-11457), the Registration Statement (Form S-3 No. 333-36057), and the Registration Statement (Form S-3 No. 333-46087) of Cellegy Pharmaceuticals, Inc. of our report dated February 5, 1999, with respect to the financial statements of Cellegy Pharmaceuticals, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 1998.

ERNST & YOUNG LLP

Palo Alto, California  
March 22, 1999



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