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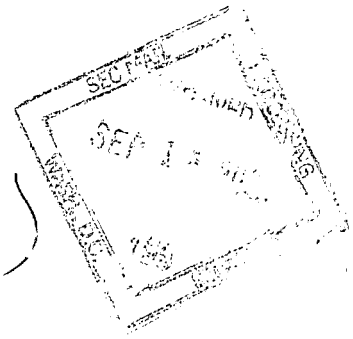
CELLEGY
PHARMACEUTICALS INC

2004 Annual Report to Shareholders



August 29, 2005

Dear Shareholder:

A number of significant accomplishments have been achieved for your Company during 2004 and in the first half of 2005. These include the following: the acquisition of Biosyn, Inc., a leader in the development of novel microbicide gel products for contraception and for the reduction in the transmission of HIV in women; the approval for marketing of two products in Europe, Rectogesic® and Tostrex®; and the consummation of European marketing agreements with ProStrakan to promote our approved products. The acquisition of Biosyn will allow us to become a more visible player in the women's preventive healthcare arena. Our new management team has a strong commitment to move Cellegy forward, and we have created a clear vision and solid foundation for greater advancement during 2005 and beyond.

Acquisitions and Key Personnel Additions

In October 2004, Cellegy acquired Biosyn, Inc., a privately-held biopharmaceutical company in Huntingdon Valley, Pennsylvania. The acquisition of Biosyn has expanded our near-term product pipeline and is a clear fit with Cellegy's focus on women's preventive health. Cellegy believes that Savvy® (C31G vaginal gel 1%), currently undergoing Phase 3 clinical studies in the United States and Africa, is one of the most clinically advanced products in development for the reduction in transmission of HIV. With this acquisition, we also gained a talented team of individuals who bring their focus and skill sets to support our drive forward.

Anne-Marie Corner, a co-founder of Biosyn, is Senior Vice President of Women's Preventive Health for Cellegy. Ms. Corner holds an MBA from the Wharton School of the University of Pennsylvania, and a BSc (honors) in Chemistry and Biology from Manchester Polytechnic, U.K. At the end of March 2005, Robert J. Caso joined us as Chief Financial Officer. Rob was previously Controller at Centocor prior to and after the Company's acquisition by Johnson & Johnson in 1999. He holds an MBA in finance from Lehigh University and a BS in accounting from Villanova University. He is also a CPA. In June 2005, Frank Malinoski, Ph.D., M.D., assumed the role of Vice President of Clinical Development for Women's Health. Most recently, Dr. Malinoski held positions of increasing responsibility with Wyeth Pharmaceuticals. He began his career at the U.S. Army Medical Research Center in Frederick, Maryland as Clinical Investigator and Chief of Viral Biology, and subsequently held positions in clinical and medical affairs for a number of large and small pharmaceutical companies. Dr. Malinoski holds an M.D. from Albany Medical College and a Ph.D. in microbiology and anti-viral drugs from Rutgers University. We are pleased to have these individuals join Cellegy as they bring tremendous knowledge, breadth and experience to our management team.

In January 2005, K. Michael Forrest resigned as President and CEO of Cellegy after having been with the Company since 1996. A. Richard Juelis, Vice President Finance and CFO, and David Karlin, M.D., Vice President, Clinical Development, also left the Company in the first half of 2005. The Board of Directors and I would like to thank them for the commitment, dedication and hard work that they have given to Cellegy during their many years of service.

Product Candidates

Savvy® (C31G vaginal gel)

Savvy is a contraceptive gel that also provides protection from HIV and other sexually transmitted diseases (known as STDs). Savvy is a clear, odorless, colorless gel that comes in a pre-filled applicator and is designed to offer protection to both the woman and her partner. The product is discreet and easy to use. We are currently running two Phase 3 HIV prevention trials in Africa; close to 2,000 women are enrolled in Ghana, and over 1,000 are enrolled in Nigeria. We have seen no drug-related serious adverse events in either trial. Biosyn is also running a Phase 3 contraception trial at 14 sites in the United States. Enrollment is on track and we are currently in the planning stages of the second trial needed for the New Drug Application (NDA). The development of Savvy has become a major objective of Cellegy. We also believe that it is the most advanced product in its class and is likely to be first to market. Data from our prior trials have shown that is well tolerated and highly acceptable. The worldwide potential market is estimated at over $1 billion, depending upon indications.

Cellegesic™ (nitroglycerin ointment, branded Rectogesic® outside of the US)

In January 2004, we announced positive results of a third Phase 3 trial for Cellegesic. An NDA was submitted to the U.S. Food and Drug Administration (FDA) covering the use of Cellegesic for the treatment of pain associated with chronic anal fissures in June 2004. In December 2004, we received a "Not Approvable" letter on Cellegesic from the FDA. In April 2005, we submitted a written response containing new analyses of data from our Cellegesic Phase 3 trials to the FDA, in response to their request resulting from an ongoing dialogue following receipt of the "Not Approvable" letter. In May 2005, Cellegy received a letter from the FDA indicating that it is reviewing the recently submitted amended NDA for Cellegesic. The FDA indicated a target response date of June 15, 2005 concerning the results of its analysis of the data. In August 2005, the FDA noted that it is still reviewing the amended NDA. We are currently awaiting their response.

Rectogesic® (nitroglycerin ointment, branded Cellegesic™ inside the US)

Rectogesic is a 0.4% topical nitroglycerin ointment indicated for the treatment of pain associated with chronic anal fissures. In August 2004, the product was approved by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for sale in the UK. Cellegy and ProStrakan Pharmaceuticals Ltd entered into an exclusive license agreement, in December 2004, for the commercialization of Rectogesic in Europe. Rectogesic was launched in May 2005 and has experienced excellent market reception, significantly outperforming initial projections. A similar formulation of Rectogesic is currently being sold in Australia, New Zealand and South Korea.

Tostrex® *(testosterone gel) 2% (branded Fortigel™ inside the US)*

Tostrex, our testosterone based product for the treatment of male hypogonadism, was approved in Sweden in December 2004. We entered into an exclusive license agreement for the commercialization of Tostrex in Europe with ProStrakan Pharmaceuticals Ltd in July 2004. We anticipate the launch of the product in the later part of 2005. We have also granted exclusive distribution rights for Tostrex to PT Kalbe Farma located in Jakarta, Indonesia for parts of the Far East.

Fortigel™ *(testosterone gel) 2% (branded Tostrex® overseas)*

In April 2005, we announced that we entered into a settlement agreement with PDI, Inc. resolving the lawsuits that the companies had filed against each other relating to an exclusive license agreement for Fortigel in North American markets. The settlement agreement resulted in return of all product rights to Cellegy, payment of certain amounts over time to PDI, and the dismissal of all pending litigation. We are currently in licensing discussions with prospective licensees.

Tostrelle® *(testosterone gel)*0.5%

Tostrelle, a testosterone product for treatment of female sexual dysfunction, has shown very encouraging results in Phase 2, demonstrating both safety and efficacy. The parameters of a Phase 3 study have been discussed with the FDA. Guidelines for female testosterone treatment products are under discussion at the FDA, and the Company expects to resume partnering discussions when these guidelines issue and there is greater clarity regarding the path to regulatory approval in the United States.

Going Forward

The Company completed a financing of $6 million on May 12, 2005. Five current and several new institutional shareholders participated in the financing. This provides the Company with funds to meet its needs into the first quarter of 2006. Most importantly, we have redefined our spending priorities and have taken action to reduce the Company's spending level in the later part of 2005 by approximately 30% from previous levels. We have also reduced discretionary spending in several areas. Our corporate headquarters will be located in Huntingdon Valley, Pennsylvania as of September 30, 2005. We will continue to evaluate the infrastructure for additional savings.

Through the Mutual Recognition Process led by ProStrakan, we have continued progress on filing throughout Europe, the dossiers of the Swedish-approved Tostrex and the UK-approved Rectogesic. We anticipate additional approvals of the products in early 2006.

In closing, we have had many substantial achievements during 2004 and into 2005. We look forward to further accomplishments in 2005 with our sharpened focus on women's healthcare and the development of Savvy. With new members added to the management team and the commitment of the entire Cellegy team, we are ready to move the Company forward. On behalf of the Board of Directors, I want to thank you, our shareholders, for your continued support.

Sincerely,

Richard C. Williams
Chairman and Interim CEO

The Company's 2004 Annual Report to Shareholders consists of this letter and the accompanying Annual Report on Form 10-K for the year ended December 31, 2004.

Forward-Looking Statement

This letter contains forward-looking statements. Investors are cautioned that these forward-looking statements are subject to numerous risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate to, among other factors: the timing and outcome of clinical trials, including reduction in transmission of HIV and contraception Phase 3 trials for Savvy. In addition, there is no certainty as to the timing and outcome of discussions with the FDA, particularly regarding additional requirements for clinical trials and marketing approval of Cellegesic, or the Company's ability to complete corporate partnerships and additional financings.

Readers are cautioned not to place undue reliance on forward-looking statements, and we undertake no obligation to update or revise statements made herein. For more information regarding risk factors, refer to the Company's Annual Report on Form 10-K for the year ending December 31, 2004, and to its other Securities and Exchange Commission filings.

BOARD OF DIRECTORS

Richard C. Williams
Chairman and Interim CEO
President, Conner-Thoele Ltd

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

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

Robert B. Rothermel
Partner, CroBern Management

Thomas M. Steinberg
Adviser, Tisch Family Interests

OFFICERS

Anne-Marie Corner
Sr. Vice President, Women's Preventive Health

Robert J. Caso
Vice President, Finance & CFO

John J. Chandler
Vice President, Corporate Development

GENERAL COUNSEL
Weintraub Genshlea Chediak Sproul
Sacramento, California

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

PATENT COUNSEL
Townsend and Townsend and Crew LLP
San Francisco, California

INDEPENDENT AUDITORS
PricewaterhouseCoopers LLP
San Jose, California

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

SHAREHOLDER INQUIRIES
If you have inquiries or wish to receive a copy of the Company's Annual Report on Form 10-K or other financial materials without charge, you may contact Robert J. Caso in our Corporate Office at 1800 Byberry Road, Bldg 13, Huntingdon Valley, PA 19006-3525, USA or you may call (215) 914-0900 x603.

CELLEGY
PHARMACEUTICALS INC

ANNUAL MEETING
Scheduled for Wednesday, September 28, 2005 at 10:00 a.m. E.S.T. at
Carter Ledyard & Millburn LLP
570 Lexington Avenue
41st Floor
New York, NY 10022
www.cellegy.com
NASDAQ: CLGY

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, 2004

OR

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

Commission File Number 000-26372

CELLEGY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

1000 Marina Boulevard, Suite 300, Brisbane, California 94005

(Address of Principal Executive Offices) (zip code)

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

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

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

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

Common Stock, $0.0001 par value

(Title of class)

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

YES ☒ **NO ☐**

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

YES ☐ **NO ☒**

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

YES ☐ **NO ☒**

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 30, 2004, the last business day of the Registrant's most recently completed second fiscal quarter, was $37,238,861, based on the closing price for the common stock on The Nasdaq Stock Market on such date. This calculation does not include a determination that persons are affiliates or non-affiliates for any other purpose.

As of March 18, 2005, there were 26,138,791 of shares of common stock outstanding.

Documents Incorporated By Reference:

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

CELLEGY PHARMACEUTICALS, INC. 10-K ANNUAL REPORT
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

TABLE OF CONTENTS

Unless the context otherwise requires, the terms "we", "our", "the Company", and "Cellegy" refer to Cellegy Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries. Savvy®, Cellegesic™, Fortigel™, Tostrelle®, Tostrex®, and Rectogesic® are our trademarks. We also refer to trademarks of other corporations and organizations in this document.

PART I

ITEM 1: BUSINESS

Cellegy Pharmaceuticals is a development stage specialty biopharmaceutical company, originally incorporated in California in 1989 and reincorporated in Delaware in 2004, that is primarily engaged in the development and commercialization of prescription drugs targeting women's health care, including reduction in transmission of HIV and female sexual dysfunction, and gastrointestinal conditions using proprietary topical formulations and nitric oxide, or NO, donor technologies. In October 2004, Cellegy completed the acquisition of Biosyn, Inc., a privately held Pennsylvania based biopharmaceutical company, with a late-stage product candidate, Savvy® (C31G vaginal gel), a contraceptive microbicide gel designed to reduce HIV/AIDS transmission in women. Savvy is currently undergoing three Phase 3 clinical trials in Africa and the United States.

Cellegy is developing two transdermal gel testosterone products, Fortigel™ (testosterone gel) and Tostrelle® (testosterone gel). Fortigel, a replacement therapy for male hypogonadism, was the subject of a Not Approvable letter by the U.S. Food and Drug Administration, or FDA, in July 2003. Cellegy has had extensive discussions with the FDA regarding additional Phase 3 trial work required for approval of the product and plans to initiate a Phase 3 clinical trial for Fortigel in 2005. Tostrex® (testosterone gel), which is the brand name for Fortigel in Europe, was approved by the Medical Products Agency (MPA) in Sweden for the treatment of male hypogonadism in December 2004. Approvals by the other member states of the European Union will be sought by our marketing partner, ProStrakan Group Limited, through the Mutual Recognition Procedure.

Tostrelle is for the treatment of female sexual dysfunction in postmenopausal women. In September 2004, we announced results of a second interim analysis of a Phase 2 study using Tostrelle for the treatment of female sexual dysfunction, which showed a 65% increase in sexual activity in women with hypoactive sexual desire disorder (HSDD), a 30% increase over placebo. We plan to seek a corporate partner during 2005 to assist in the development of Tostrelle, subject to agreement with the FDA on an acceptable clinical trial protocol. There are, however, no assurances regarding the timing and outcome of discussions with potential corporate partners for Tostrelle or the FDA discussions regarding our testosterone products.

Cellegy is also developing Cellegesic™ (nitroglycerin ointment) for the treatment of anal fissures and hemorrhoids. In January 2004, we announced results of preliminary analysis of our third Phase 3 clinical trial for Cellegesic. The trial showed a reduction in anal fissure pain, compared with a placebo control, during the first three weeks of the trial, the primary efficacy endpoint of the study. We submitted a New Drug Application, or NDA, to the FDA in June 2004. The FDA issued a Not Approvable letter for Cellegesic in December 2004. As a result, Cellegesic cannot be marketed in the United States unless and until the FDA at some future date grants marketing approval for the product. We are evaluating the FDA's letter, intend to have further discussions with the FDA concerning the letter and are considering our alternatives with respect to the product. The U.K. Medicines and Healthcare Products Regulatory Agency approved Cellegesic, branded Rectogesic in Europe, for sale in the United Kingdom in August 2004. In conjunction with our marketing partner ProStrakan Group Limited, we will seek approvals of Cellegesic by other member states of the European Union through the Mutual Recognition Procedure.

We also intend to develop Cellegesic for the treatment of a painful condition called dyspareunia, which prevents or inhibits sexual intercourse in more than five million women in the United States. Other early-stage NO donor product candidates in our pipeline address a number of conditions, including prostate cancer, Raynaud's Disease and Restless Legs Syndrome.

Biosyn is developing a portfolio of proprietary products known as microbicides. Biosyn's product candidates, which include both contraceptive and non-contraceptive microbicides, are used intravaginally

to reduce transmission of sexually transmitted diseases, or STDs, including HIV/AIDS. Biosyn's products include Savvy, which is currently undergoing Phase 3 clinical trials in Africa and the United States; UC-781 vaginal gel, in Phase 1 trials; and Cyanovirin-N, in pre-clinical development.

Products Under Development

Savvy (contraceptive vaginal gel for women, designed to prevent HIV/AIDS)

Cellegy obtained rights to the late-stage product candidate, Savvy, with the October 2004 acquisition of Biosyn. Cellegy believes that Savvy, which is part of a class of drugs known as microbicides, is one of the most clinically advanced product candidates in development for the reduction in transmission of HIV. Savvy has also shown promising results in the prevention of other STDs, including those caused by herpes simplex virus and chlamydia, and has shown activity against gonorrhea and syphilis.

Savvy is currently in two Phase 3 trials for reduction of HIV transmission. These trials are taking place in Africa, in populations of women at risk for HIV infection. Currently, approximately 1,600 women are enrolled in the African trials, with enrollment expected to reach 4,000 to 5,000 women by the second half of 2006. Additionally, a Phase 3 trial for contraception is ongoing in the United States, with about 200 women enrolled out of an expected total enrollment of 1,600 by the second half of 2006.

The active compound in Savvy is C31G, a broad-spectrum compound with antiviral, antibacterial and antifungal activity. Its mechanism of action is via immediate membrane disruption, and it is also spermicidal. Because of the mechanism of action, C31G has a low potential for resistance and is active against drug resistant pathogens.

Most of the Phase 3 trial expenses for Savvy, and certain other clinical and preclinical development costs for the Biosyn pipeline, are funded by significant grant and contract commitments through agencies including: the United States Agency for International Development; the International Partnership for Microbicides; the National Institute for Child Health and Development; the National Institute for Allergy and Infectious Disease; CONRAD; and other government and philanthropic organizations.

Fortigel (testosterone replacement therapy for male hypogonadism)

Fortigel is a transdermal gel testosterone product designed to treat male hypogonadism, a condition involving deficient levels of the sex hormone testosterone. Low levels of testosterone can result in lethargy, depression and a decline in libido. In severely deficient cases, loss of muscle mass and bone density can occur. Approximately five million men in the United States, primarily in the aging (over 40) male population group, have deficient levels of testosterone.

Fortigel is a transparent, rapid-drying and non-staining gel, designed as a once-a-day application from a unique metered dose dispenser to relatively small areas of the skin. Based on the results of a 201-patient Phase 3 trial announced in November 2001, Cellegy filed an NDA in June of 2002. However, Fortigel was subsequently the subject of a Not Approvable letter by the FDA in July 2003. In its letter, the FDA stated that in its opinion the following deficiencies in the Fortigel NDA were found: (1) there is insufficient information to establish that high supraphysiologic daily Cmax serum testosterone levels achieved in a significant portion of participants in the major clinical study supporting the NDA are safe under conditions of chronic administration; and (2) there is insufficient information provided to demonstrate that the dose of the product can be adjusted to consistently preclude achieving these high supraphysiological testosterone levels. Cellegy has had several discussions with the FDA which Cellegy believes has led to agreement on remaining work required for approval of the product, although there can be no assurances regarding the timing and outcome of these interactions and the FDA's decision. Cellegy now plans to initiate a Phase 3 trial for Fortigel in 2005, having reached agreement with the FDA on the protocol for the trial.

Tostrex® (testosterone gel), which is the brand name for Fortigel in Europe, was approved in December 2004 by the Medical Products Agency (MPA) in Sweden for the treatment of male hypogonadism. Approvals by the other member states of the European Union will be sought by our marketing partner, ProStrakan Group Limited, through the Mutual Recognition Procedure.

Tostrelle (testosterone gel for female hormone replacement therapy)

Normal blood concentrations of testosterone in women range from 10 to 20 times less than those of men. Nevertheless, in both sexes, testosterone plays a key role in building muscle tissue or bone and in maintaining normal sexual desire. In women, the ovaries and adrenal glands continue to synthesize testosterone after menopause, although the rate of production may diminish by as much as 50%. Testosterone deficiency in women frequently leads to diminished libido, decreased bone and muscle mass and reduced energy levels. Approximately 15 million women in the United States suffer from symptoms of testosterone deficiency. At the present time, there are no approved products for the treatment of this condition, although it has been reported that testosterone treatment is frequently being prescribed off-label for women by obstetricians and gynecologists.

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

Cellegy has successfully completed two Phase 1/2 pharmacokinetic studies in which we determined the proper dose necessary to restore normal testosterone levels to naturally menopausal and surgically induced menopausal women. In September 2004, we announced results of a second interim analysis of a Phase 2 study using Tostrelle for the treatment of female sexual dysfunction, which showed a 65% increase in sexual activity in women with hypoactive sexual desire disorder (HSDD), a 30% increase over placebo. Based on these results, we stopped enrollment in the Phase 2 clinical study. We met with the FDA to review the trial results and the overall Tostrelle program. The FDA informed Cellegy that specific guidelines regarding the long-term safety of testosterone for the treatment of female sexual dysfunction are under internal discussion by the Division of Reproductive and Urologic Drug Products. Cellegy is awaiting these guidelines before embarking upon a Phase 3 program. Depending, in part, on the outcome of these guidelines, we intend to pursue corporate partnering discussions for the development of Tostrelle. If the new FDA guidelines prove to be too onerous, limiting or too costly to implement, the Phase 3 program may be significantly delayed or we may decide not to pursue further developing of Tostrelle.

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

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

Anal fissures are painful tears in the lining of the anal canal. The condition is associated with increased pressure in the anal canal and a decrease in blood supply to the region. Many chronic cases require a surgical procedure (Lateral Internal Sphincterotomy) that is designed to reduce anal pressure by severing the inner anal sphincter muscle. This procedure, while highly effective, frequently leaves patients incontinent.

There are currently no FDA approved drug therapies for anal fissures, although topical anesthetics and anti-inflammatory agents, which only partially relieve the symptoms of the condition, are currently prescribed. According to Verispan audits, anal fissures afflict an estimated 750,000 Americans, resulting in over one million physician visits each year. The audit data for 2004 show about 75,000 annual uses of pharmacy-compounded nitroglycerin for the treatment of anal fissures.

Dyspareunia is a condition that is characterized by intense vaginal pain. The condition can be recurrent and frequently causes significant impairment to normal sexual functioning in women. Several publications have reported that between 7% to 15% of American women of sexually active age are affected by the condition. There are no approved treatments for dyspareunia and while many different approaches are used, none are completely satisfactory. In a non placebo controlled clinical study of nitroglycerin ointment conducted by Dr. Jennifer Berman of the University of California Los Angeles Medical Center, the product was reported to reduce the pain of women suffering from vulvodynia, a condition that is a major contributor to dyspareunia. Cellegy is now conducting a similar Phase 1/2 clinical study in Australia and may conduct additional clinical trials using Cellegesic for the treatment of vulvodynia.

Previous Cellegesic Clinical Trial Results. We completed our initial Phase 3 clinical trial using Cellegesic for the treatment of anal fissures and announced the results in November 1999. The trial, which included 304 patients, did not demonstrate a statistically significant rate of healing compared with placebo, but did show significant pain reduction. Based on this outcome, we initiated a second Phase 3 trial in 2000 to test the drug's ability to reduce fissure pain, the primary trial endpoint, with healing of chronic anal fissures as a secondary endpoint. The second Phase 3 clinical trial, which included 229 patients, was completed in September 2001. Positive results were achieved in the primary endpoint, which was pain reduction of chronic anal fissures. Statistical significance was not achieved in healing.

In June 2001, we filed a rolling NDA with the FDA for the use of Cellegesic for the treatment of pain associated with chronic anal fissures based on partial results of the second Phase 3 trial. We amended the NDA in November 2001 upon completion of the second Phase 3 study. In April 2002, we announced the withdrawal of our Cellegesic NDA after it became clear that the FDA was not going to approve the NDA. After several subsequent discussions and meetings with the FDA, the FDA indicated that it would require another Phase 3 trial before considering approval of the product.

In January 2004, Cellegy announced results of its third Cellegesic Phase 3 clinical trial showing a statistically significant ($p<0.05$) reduction in anal fissure pain compared with a placebo control during the first three weeks of the trial, the primary efficacy endpoint of the study. As observed in two earlier Phase 3 trials, the most common side effect was mild to moderate headache. The double blind, placebo controlled trial was conducted according to a Special Protocol Assessment, or SPA, that was agreed to by Cellegy and the FDA. Based on these trial results we filed an NDA with the FDA in July 2004.

Side effects seen in the trial were consistent with those observed in the previous two Phase 3 studies, with mild to moderate headache the most common side effect. Five subjects dropped out of the study as a result of headache. The SPA required that subjects discontinuing due to nitroglycerin related headache, defined as one that occurs within 30 minutes of application, should have their last daily pain intensity score, as recorded on the day the subject dropped out, carried forward each day through day 21. Clinical judgment, based on each subject's entire record, was used to determine which of the five subjects discontinued due to nitroglycerin related headaches. Last daily pain intensity scores were carried forward for three of the five subjects. The other two subjects who withdrew from the trial due to headache had all of their available pain data prior to dropout included in the analysis. We believe we achieved the results specified in the SPA. However, the FDA, after conducting its own analysis and raising other issues not covered in the SPA, issued a Not Approvable letter in December 2004. We are evaluating the FDA's letter, intend to have further discussion with the FDA concerning the letter and are considering alternatives with respect to the product.

Rectogesic® (nitroglycerin ointment), which is the brand name for Cellegesic outside of the United States, was approved by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) for sale in the United Kingdom in September 2004. Approvals by other member states of the European Union will be sought by our marketing partner ProStrakan Group Limited through the Mutual Recognition Procedure. We expect sales to commence in the United Kingdom through ProStrakan in 2005.

Marketed Products

Rectogesic (nitroglycerin ointment for the treatment of anal fissures)

Rectogesic was approved by the Australian Therapeutic Goods Administration, has been successfully marketed in Australia since 1999 and is now also marketed in New Zealand, Singapore and South Korea. Rectogesic is the only approved product for the treatment of anal fissures and, although it is not indicated for hemorrhoid treatment, it has achieved the number 3-market position in the anal fissure/hemorrhoid product category in Australia, according to recently published market research data. Sales have increased by 40% in 2003 and another 46% in 2004. There have been no serious safety issues reported with use of the product since its introduction.

Skin Care

Cellegy has completed development of certain consumer skin care blends, including skin moisturizers. We are currently selling our C79 Intensive Moisturizer formulation to a major specialty retailer, which incorporates C79 into its products. Our revenues from sales of C79 totaled $181,000 in 2004 with total sales of approximately $5 million since product introduction in 1998. See note 16 to the consolidated financial statements which describes our skin care product segment, including how this segment differs from our pharmaceutical products.

Marketing and Commercialization Strategy

Cellegy intends to become a leader in the development and commercialization of selected specialty biopharmaceutical products that are directed towards the treatment of HIV prevention and contraception, female sexual dysfunction and gastrointestinal disorders. Key elements of our business and commercialization strategy include the following:

- *Self-Marketing to Specialty Physicians in the United States.* If economically viable, we plan to self-market our products to a targeted audience of key physician specialists, including Gastroenterologists and Obstetrician-Gynecologists, through the establishment of our own sales force.
- *Outside the United States.* In most cases, we plan to out-license the overseas rights for the products we develop. During 2004 in two separate transactions, we out-licensed commercial rights to our Tostrex and Rectogesic products in Europe to ProStrakan Group Limited, a privately held specialty pharmaceutical company located in the United Kingdom with European-wide marketing capability.
- *Acquisition of Complementary Products and Companies.* We have successfully completed and integrated several acquisitions including: Biosyn, Inc. in October 2004; Vaxis Therapeutics Corporation in Canada in November 2001; Quay Pharmaceuticals Pty, Ltd. in Australia in June 2000; Neptune Pharmaceuticals in the United States in December 1997. We may selectively acquire other products, technologies or companies with products and distribution operations consistent with our commercial objectives and financial capability.
- *Manufacturing.* Cellegy has manufacturing arrangements with PendoPharm Inc., an FDA approved contract-manufacturing company based in Canada. PendoPharm, an affiliate of Pharmasciences, has successfully manufactured Cellegesic, Fortigel and Tostrelle for our clinical trials and will be the commercial manufacturer for these products. We are planning to validate a domestic contract manufacturer to serve as a second manufacturing source for our product candidates. Our products sold in Australia, New Zealand, Singapore and South Korea are currently supplied by a pharmaceutical manufacturer in Australia, and our skin care products are currently manufactured by a contractor in the United States.

- *Distribution.* Cellegy has entered into distribution agreements for Rectogesic in New Zealand, Singapore and South Korea. Cellegy has also entered into distribution agreements for Tostrex in Israel, Australia, South Korea, South Africa and approximately 10 other Far East markets.

Research Programs

Cellegy's research and development programs focus on developing products in the area of women's health, prevention of HIV transmission, sexual function, anorectal disorders, peripheral vascular disorders and certain cancers. To complement its topical drug delivery knowledge and intellectual property portfolio, Cellegy acquired Vaxis Therapeutics, now Cellegy Canada, Inc., in November 2001. The Cellegy Canada product pipeline includes potential products for the treatment of female sexual dysfunction and expands our research into potential oncology treatments. Cellegy has rights to future discoveries, technologies and products developed by Cellegy Canada. The acquisition of Biosyn in 2004 expanded our pipeline into the area of women's health. Most of our current research programs are now being conducted at Biosyn, in Huntingdon Valley, Pennsylvania, and at Queen's University in Kingston, Ontario, Canada.

Biosyn. Biosyn's topical microbicide technology expands our product pipeline in women's health care. In 2004, Biosyn's lead product, Savvy, entered two concurrent Phase 3 clinical studies in Africa where its effectiveness in preventing HIV transmission in women is being evaluated. A Phase 3 trial for contraception is also ongoing in the United States. If successful, Savvy could be the first product among many microbicide products in various stage of development to enter the commercial marketplace, although there can be no assurances that Savvy will be successfully commercialized or, if commercialized, that it would be the first, or one of the first, such products to enter the marketplace. A second-generation product, UC-781, is a non-nucleoside reverse transcriptase (RT) inhibitor that has demonstrated efficacy against a wide range of HIV-1 isolates, including laboratory adapted strains, T cell and macrophage tropic isolates, and primary isolates of all major clades (A through G and isolates that are resistant to other RT inhibitors). Phase 1 human safety studies of UC-781 are currently under way. Biosyn's expanded microbicides portfolio also includes a naturally occurring protein, Cyanovirin-N, or CV-N, that may be effective in blocking viral fusion *in vitro*. CV-N has demonstrated *in vivo* efficacy in vaginal and rectal prevention of HIV infection in animal models.

Nitric Oxide Donor Technology. In a pilot clinical study conducted by Cellegy Canada's collaborating scientists, the co-administration of nitric oxide releasing agent blocked nociceptive pain response triggered by PGE1 injection. This concept is further supported by the July 2002 publication of a pilot study in Journal of Gender Specific Medicine reporting the efficacy of treating vulvar pain and pain with sexual activity in women with vulvodynia using 0.2% topical nitroglycerin ointment. Cellegy is currently conducting a clinical study in Australia using topical nitroglycerin in treating vulvar pain associated with vulvodynia and dyspareunia.

Expanded expertise in nitric oxide pharmacology has led to an understanding of the role of nitric oxide as a signaling molecule, operating at lower concentrations than is normally required for vasodilators, especially in tissue under an abnormally vaso-spasmatic or vaso-constrictive state. This discovery presents various potential approaches to treat conditions caused by vaso-constriction, such as peripheral vascular insufficiency found in Raynaud's disease, male erectile dysfunction and selected aspects of female sexual dysfunction.

Patents and Trade Secrets

Cellegy has 22 issued United States patents, more than 40 issued foreign patents, and over 80 pending patent applications worldwide. Two issued United States patents, 4 issued foreign patents, and 11 pending patent applications relate to our testosterone gel products for males and females. Two issued United States patents; over 25 issued foreign patents, and over more than 5 pending patent applications relate to

Cellegesic for the treatment of anal fissures and other anal diseases. While our European patent covering our Cellegesic product was challenged and subsequently revoked during the opposition proceedings in December 2003, Cellegy has filed an appeal to the decision, and the patent stands on appeal. Four issued United States patents, 3 issued foreign patents, and over 25 pending patent applications relate to possible backup compounds for our Cellegesic product. In the area of treatment of female sexual disorders along with various conditions relating to vascular insufficiency such as Raynaud's Syndrome, Cellegy has 6 issued United States patents, 2 issued foreign patents, and over 15 pending patent applications worldwide. Over 12 pending United States and foreign patent applications relate to the use of nitric oxide donors in the treatment of cancer.

With its acquisition of Biosyn, Cellegy gained rights to an additional 21 issued United States patents, more than 90 issued foreign patents, and over 25 pending patent applications worldwide. Two issued United States patents and 39 issued foreign patents relate to Savvy contraceptive gel for the reduction in transmission of HIV infection in women. Rights licensed from Crompton Corporation to 4 issued US patents, over 30 issued foreign patents, and over 20 pending applications relate to UC-781, a non-nucleoside reverse transcriptase inhibitor under development as a second-generation microbicide. Rights licensed by Biosyn from the National Institutes of Health, or NIH, to 9 issued United States patents and 3 pending applications relate to the microbicide Cyanovirin-N.

With Cellegy's acquisition of Vaxis Therapeutics, now Cellegy Canada, Cellegy gained rights to 5 issued United States patents, 3 issued foreign patents, and more than 40 pending patent applications. These patents and applications disclose methods of treatment of peripheral vascular conditions, female sexual dysfunction and Raynaud's disease, as well as other conditions. United States and foreign patent applications disclosing store-operated calcium influx (SOC) inhibitors and their use in the treatment of various disorders are pending or have recently published. Additional patent applications are being prepared for filing that will cover methods or products currently under development. Corresponding patent applications for most of Cellegy's issued United States patents have been filed in countries of importance to us located in major world markets, including certain countries in Europe, Australia, South Korea, Japan, Mexico and Canada.

Our policy is to protect our technology by, among other things, filing patent applications for technology that we consider important to the development of our business. We intend to file additional patent applications, when appropriate, relating to our technology, improvements to our technology and to specific products that we develop. It is impossible to anticipate the breadth or degree of protection that any such patents will afford, or whether we can meaningfully protect our rights to our unpatented trade secrets. Cellegy also relies upon unpatented trade secrets and know-how, and no assurance can be given that competitors will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets or disclose such technology. It is our policy to require our employees to execute an invention assignment and confidentiality agreement upon employment. Our consultants are required to execute a confidentiality agreement upon the commencement of their consultancy. Each agreement provides that all confidential information developed or made known to the employee or consultant during the course of employment or consultancy will be kept confidential and not disclosed to third parties except in specific circumstances. The invention assignment generally provides that all inventions conceived by the employee shall be the exclusive property of Cellegy. In addition, it is our policy to require collaborators and potential collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection of our trade secrets. For additional risks and uncertainties relating to our patents and intellectual property, particularly the European opposition to our Cellegesic patents, see the discussion of our patents and intellectual property under the heading, "Management's Discussion and Analysis of Financial Condition and Results of Operation—Factors That May Affect Future Operating Results."

Product and Company Acquisitions

In October 2004, Cellegy acquired Biosyn, Inc., a privately held biopharmaceutical company. Under the terms of the agreement, Cellegy issued approximately 2,462,000 shares of Cellegy's common stock for all of Biosyn's issued and outstanding capital stock. In addition, outstanding Biosyn stock options and warrants were assumed by Cellegy and converted into options and warrants to purchase approximately 318,504 shares of Cellegy common stock. The options issued to acquire Cellegy common stock are fully vested and exercisable. The exercise prices of the options and warrants were adjusted by the exchange ratio in the transaction; the expiration date and other terms of the converted options and warrants remain the same. The purchase price does not include any provisions for contingent milestone payments of up to $15 million which would be payable to Biosyn shareholders on the achievement of C31G marketing approval in the United States and a portion of which would be payable earlier upon commercial launch in certain major overseas markets.

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

In June 2000, Cellegy acquired Quay Pharmaceuticals, an Australian company marketing Rectogesic, for the treatment of anal fissures. The acquisition cost totaled $1,835,000, consisting primarily of Cellegy common stock and warrants. Cellegy continues to self-market Rectogesic in Australia through its wholly-owned subsidiary, Cellegy Australia.

License Agreements

Cellegy

In December 2002, Cellegy entered into a license agreement, or the PDI Agreement, with PDI, Inc. or PDI, granting PDI the exclusive right to store, promote, sell and distribute Fortigel in North American markets. Cellegy received an upfront payment of $15.0 million on the effective date of December 31, 2002 with an additional $10.0 million payable no later than thirty days after Cellegy certifies to PDI that Fortigel has received all FDA approvals required to manufacture, sell and distribute the product in the United States. Cellegy recorded costs of $947,000 to selling, general and administrative expenses associated with an investment banking fee for the year ended December 31, 2002 related to the PDI Agreement. Under the PDI Agreement, Cellegy would also receive royalties each year until the expiration of the last patent right related to Fortigel of 20% - 30% of net sales and Cellegy would be reimbursed for 110% of burdened costs for any product supplied to PDI. In October 2003, Cellegy received a mediation notice from PDI. In December 2003, Cellegy and PDI initiated legal proceedings against each other. See "Legal Proceedings" below and in Note 10 to our consolidated financial statements.

In July 2004, Cellegy and ProStrakan Group Limited, or ProStrakan, entered into to an exclusive license agreement for the future commercialization of Tostrex® (testosterone gel) in Europe. Under the terms of the agreement, ProStrakan will be responsible for regulatory filings, sales, marketing and distribution of Tostrex throughout the European Union and in certain nearby non-EU countries. Cellegy will be responsible for supplying finished product to ProStrakan through Cellegy's contract manufacturer. Assuming successful commercial launch, Cellegy could receive up to $5.75 million in total payments, including a $500,000 non-refundable upfront payment made in July 2004, and a royalty on net sales of Tostrex.

In December 2004, Cellegy and ProStrakan entered into an exclusive license agreement for the commercialization of Cellegesic, branded Rectogesic outside of the United States, in Europe. Under the

terms of the agreement, Cellegy received a non-refundable upfront payment of $1.0 million and is entitled to receive up to an additional $4.6 million in milestone payments, along with additional payments based on net sales of Rectogesic in Europe. ProStrakan will be responsible for additional regulatory filings, sales, marketing and distribution of Rectogesic throughout Europe. In all, the agreement covers 38 European territories, including all EU member states. Cellegy will be responsible for supplying finished product to ProStrakan through its contract manufacturer. In addition, ProStrakan has granted a right of first negotiation to Cellegy for its oral estradiol-glucoside product, which is currently in Phase 1 clinical development or an alternative product in the area of gastroenterology.

Biosyn

In October 1996, Biosyn acquired the C31G Technology from the entity that originally licensed the technology to Biosyn. As part of the agreement, Biosyn is required to make annual royalty payments equal to the sum of 1% of net product sales of up to $100 million, 0.5% of the net product sales over $100 million and 1% of any royalty payments received by Biosyn under license agreement. The term of the agreement lasts until December 31, 2011 or upon the expiration of the C31G Technology's patent protection, whichever is later. Biosyn's current C31G patents expire between 2006 and 2018.

In May 2001, Biosyn entered into an exclusive license agreement with Crompton Corporation under which Biosyn obtained the rights to develop and commercialize UC-781, a non-nucleoside reverse transcriptase inhibitor, as a topical microbicide. Under the terms of the agreement, Biosyn paid Crompton a nonrefundable, upfront license fee that was expensed in research and development. Crompton also received a warrant to purchase Biosyn common stock, which converted into a Cellegy warrant in connection with the acquisition and is exercisable for a period of two years upon initiation of Phase 3 trials of UC-781. Crompton is entitled to milestone payments upon the achievement of certain development milestones and royalties on product sales. If UC-781 is successfully developed as a microbicide, then Biosyn has exclusive worldwide commercialization rights.

In February 2003, Biosyn acquired exclusive worldwide rights from the National Institutes of Health, or NIH, for the development and commercialization of Cyanovirin-N as a vaginal gel to prevent the sexual transmission of HIV. Under the terms of the agreement, Biosyn paid to NIH a nonrefundable, upfront license fee that was charged to research and development. NIH is entitled to milestone payments upon the achievement of certain development milestones and royalties on product sales.

Under the terms of certain of its funding agreements, Biosyn has been granted the right to commercialize products supported by the funding in developed and developing countries, and is obligated to make its commercialized products, if any, available in developing countries, as well as to public sector agencies in developed countries, at prices reasonably above cost or at a reasonable royalty rate.

Biosyn has entered into various other research and technology agreements. Under these other agreements, Biosyn is working in collaboration with various other parties. Should any discoveries be made under such arrangements, Biosyn may be required to negotiate the licensing of the discovery for the development of the respective technologies.

Government Regulation

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

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

The results of preclinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA before commencement of human clinical trials. Clinical trials may begin 30 days after the IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. In some instances, the IND application process can result in substantial delay and expense. Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are concerned primarily with the safety and pharmacokinetics of the product. Phase 2 trials are designed primarily to demonstrative effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various dose and regiments. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship, discover less common side effects and adverse reactions, and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4 or post-marketing, studies to be conducted. The FDA, upon request through a Special Protocol Assessment, can also provide specific written guidance on the acceptability of protocol designs for selected clinical trials.

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

manufacturer may result in restrictions or sanctions on such product or manufacturer, including withdrawal of the product from the market.

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

Manufacturing. Each domestic drug manufacturing facility must be registered with the FDA. Domestic drug manufacturing establishments are subject to routine inspection by the FDA and other regulatory authorities and must comply with GMP requirements and any applicable state or local regulatory requirements. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approvals of NDA's or other product applications if deficiencies are found at the facility. Vendors that supply us finished product or components used to manufacture, package and label products are subject to similar regulation and periodic inspection. We have used and intend to continue to use contract manufacturers that operate in conformance with these requirements to produce our compounds and finished products in commercial quantities. Nevertheless, there can be no assurances that manufacturing or quality control problems will not arise at the manufacturing plants of our contract manufacturers or that such manufacturers will have the financial capabilities or management expertise to be able to adequately supply product or maintain compliance with the regulatory requirements necessary to continue manufacturing our products.

Foreign Regulation of Drugs. Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities may be necessary in foreign countries before the commencement of marketing of the product in such countries. The approval procedures vary among countries, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for European Union member states. This authorization is called a marketing authorization approval. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Each member state must then make its own determination regarding approval. This procedure is referred to as the mutual recognition procedure. There can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. We expect to rely principally on corporate partners, licensees and contract research organizations, along with our expertise, to obtain governmental approval in foreign countries of drug formulations utilizing our compounds.

Other Government Regulation. In addition to regulations enforced by the FDA, Cellegy is also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other similar federal and state laws regarding, among other things, occupational safety, the use and handling of radioisotopes, environmental protection and hazardous substance control. Although we believe that we have complied

with these laws and regulations in all material respects and have not been required to take any action to correct any noncompliance, there can be no assurance that Cellegy will not be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, Cellegy could be held liable for any damages that result and any such liability could exceed our resources.

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

Competition

The pharmaceutical industry is characterized by extensive research efforts and rapid and significant technological change. In the development and marketing of topical prescription drugs, Cellegy faces intense competition. Cellegy is much smaller in terms of size and resources than many of its competitors in the United States and abroad, which include, among others, major pharmaceutical, chemical, consumer product, and biotechnology companies, specialized firms, universities and other research institutions. Cellegy's competitors may succeed in developing technologies and products that are safer, more effective or less costly than any which are being developed by us that would render our technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience than we have.

In addition, Cellegy's products, if commercialized, are subject to competition from existing products. Cellegesic, which is a prescription product, is expected to compete with over-the-counter products, such as Preparation H marketed by Wyeth, and various other prescription products. Cellegy's Fortigel product, if approved for marketing, is expected to compete with several products, including a currently marketed transdermal patch product sold by Watson Pharmaceuticals, two transdermal testosterone gel products marketed by Unimed/Solvay and Auxilium Pharmaceuticals and a buccal tablet marketed by Columbia Laboratories. In addition, there may be generic product competition for these prescription products in the future. As a result, Cellegy's products under development may not be able to compete successfully with existing products or possible generic products under development by other organizations.

Savvy is subject to competition from other microbicides that are currently undergoing clinical trials and which may be sold by prescription or over the counter, as well as non-microbicide products such as condoms. Additionally, if a vaccine for HIV/AIDS is made available, this could limit the potential market for Savvy and Biosyn's other products. As a result, we cannot assure you that Biosyn's products under development will be able to compete successfully with existing products or other innovative products under development.

Therapies for sexual dysfunction and women's health products represent a potentially large market opportunity. If this market potential is realized, competition will expand. The approval and marketing of

competitive products and other products that treat the indications targeted by Cellegy could adversely affect the market acceptance of Cellegy's products. The presence of directly competitive products could also result in more intense price competition than might otherwise exist. We are aware of other pharmaceutical companies that are developing prescription testosterone replacement products for women, including a female testosterone patch from Procter & Gamble, a testosterone gel product from BioSante Pharmaceuticals, Inc. and a spray product from VIVUS, Inc.

Employees

As of March 18, 2005, we had 26 full-time and 6 part-time employees, including 14 full-time and 2 part-time employees (one M.D. and two Ph.D.'s) at our Brisbane, California headquarters, and 12 full-time and 4 part-time employees (five Ph.D.'s) at our Biosyn subsidiary in Huntingdon Valley, Pennsylvania.

In addition, we utilize the services of several professional consultants, as well as contract manufacturing and clinical research organizations to supplement our internal staff's activities. None of our employees are represented by a labor union. We have experienced no work stoppages and we believe that our employee relations are good.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission, or SEC, including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning us may be obtained at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549 or accessed through the SEC's website at *http://www.sec.gov*. The SEC's Public Reference Room phone number is 1-800-SEC-0330. In addition, electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are posted to our website (*www.cellegy.com*). Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC. Upon written request to the Company at Cellegy Pharmaceuticals, Inc., 1000 Marina Boulevard, Suite 300, Brisbane, CA 94005, Attention: Chief Financial Officer, Cellegy will provide a copy of the 10-K to any stockholder.

ITEM 2: PROPERTIES

Cellegy has recently relocated its South San Francisco headquarters to the nearby city of Brisbane where we are leasing approximately 5,800 square feet of office space, pursuant to a sublease, with an expiration date of February 28, 2006. At Biosyn's Huntingdon Valley, Pennsylvania facilities, we are currently leasing approximately 10,000 square feet of laboratory and office space with an expiration date of October 31, 2008. We believe our new headquarters in Brisbane, California and current facilities at Biosyn will be adequate for our current needs and any future expansion.

ITEM 3: LEGAL PROCEEDINGS

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

In October 2003, we received a communication from PDI, Inc. ("PDI") invoking mediation procedures under the exclusive license agreement between PDI and Cellegy relating to Fortigel. After mediation was completed in December 2003, both PDI and Cellegy initiated litigation proceedings against each other. Cellegy filed a declaratory judgment action in federal district court in San Francisco against

PDI, and PDI initiated an action in federal district court in New York against Cellegy. In its action, Cellegy seeks, among other things, a declaration that it has fully complied with the license agreement and that PDI's claims are without merit. The federal court in New York decided that the case would be consolidated in the Northern District of California and that future proceeding would be held in that jurisdiction.

Cellegy has devoted and may continue to devote significant time and resources to the litigation. There can be no assurances regarding the outcome of the proceedings. Trial is currently scheduled to take place during the second quarter of 2005. An unfavorable outcome could have a material adverse impact on our business and financial position.

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

No matters were submitted to a vote of our stockholders during the fourth quarter of the year ended December 31, 2004.

ITEM 4A: EXECUTIVE OFFICERS OF THE REGISTRANT

Richard C. Williams	61	Chairman and Interim Chief Executive Officer, Director
John J. Chandler	63	Vice President, Corporate Development
Anne-Marie Corner	43	Senior Vice President, Women's Preventive Health
A. Richard Juelis	56	Vice President, Finance and Chief Financial Officer
David A. Karlin, M.D.	61	Vice President, Clinical Research

Richard C. Williams. Mr. Williams became Chairman and Interim Chief Executive Officer in January 2005. He first joined Cellegy as Chairman of the Board in November 2003. He is President and Founder of Conner-Thoele Ltd., a consulting and financial advisory firm specializing in health care acquisition analysis, strategy formulation and post-merger consolidation and restructuring. Mr. Williams served as Vice Chairman, Strategic Planning of King Pharmaceuticals following the acquisition by King of Medco Research where he was Chairman. He has held a number of executive level positions with other pharmaceutical companies. Mr. Williams is a director of EP Med Systems, a public electrophysiology diagnostic company and is Chairman and a director of ISTA Pharmaceuticals, a public emerging ophthalmology company. Mr. Williams received a B.A. degree in economics from DePauw University and an M.B.A. from the Wharton School of Finance.

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

Anne-Marie Corner. Ms. Corner became Senior Vice President, Women's Preventive Health in October 2004, when Cellegy acquired Biosyn. Ms. Corner was the Chief Executive Officer and member of the Board of Directors of Biosyn prior to its acquisition by Cellegy. Before joining Biosyn, Ms. Corner was a researcher at the University of Pennsylvania, Department of Biochemistry. Ms. Corner sits on the Board of Directors of the Women's Investment Network, the Pennsylvania Biotechnology Association and the Alliance for Microbicide Development. Ms. Corner holds a B.S.C. (honors) in Chemistry and Biology from Manchester Polytechnic University and an M.B.A. from the Wharton School of Finance.

A. Richard Juelis. Mr. Juelis became Vice President, Finance and Chief Financial Officer in November 1994. From October 1990 to September 1994 he served as Vice President, Finance and Chief

Financial Officer for two other publicly traded biotechnology companies. Mr. Juelis has also held domestic and international financial and general management positions for seven years each with Hoffmann-LaRoche and Schering-Plough. He holds a B.S. in Chemistry from Fordham University and an M.B.A. from Columbia University.

David A. Karlin, M.D. Dr. Karlin joined Cellegy as Vice President, Clinical Research in October 2002. From February 2002 to July 2002, he served as Vice President, Clinical Development for Genteric, Inc., a privately held company specializing in gene therapy. From August 1999 to October 2001, Dr. Karlin was Senior Medical Director at Matrix Pharmaceuticals, a cancer and drug delivery company. He was Vice President, Clinical Research at SciClone Pharmaceuticals from 1995 to 1999. Prior to SciClone, Dr. Karlin held various positions at Syntex Corporation over a nine-year period. Before joining the pharmaceutical industry, Dr. Karlin was an Associate Professor at Temple University School of Medicine and an Assistant Professor at University of Texas M.D. Anderson Hospital and Tumor Institute. He was an instructor at the University of Chicago, where he received his medical degree, and had Gastroenterology and Gastrointestinal Oncology training at that University.

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

PART II

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Price Range of Common Stock

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

	High	Low
2003		
First Quarter	$5.60	$3.71
Second Quarter	5.54	3.81
Third Quarter	5.22	2.25
Fourth Quarter	3.20	2.45
2004		
First Quarter	$6.74	$3.14
Second Quarter	4.65	3.65
Third Quarter	4.62	3.46
Fourth Quarter	5.14	2.69

Holders

As of March 18, 2005, there were approximately 600 stockholders of record excluding beneficial holders of stock held in street name.

Dividend Policy

We have never paid cash or declared dividends on our common stock. We do not anticipate that we will declare or pay cash dividends on our common stock in the foreseeable future. We currently intend to retain our earnings, if any, for future growth. Future dividends on our common stock or other securities, if any, will be at the discretion of our board of directors and will depend on, among other things, our operations, capital requirements and surplus, general financial condition, contractual restrictions and such other factors as our board of directors may deem relevant.

Information with respect to equity compensation plans that is required by this Item will be included in our Proxy Statement for the 2005 annual meeting of stockholders under the heading "Equity Compensation Plans" and is hereby incorporated by reference.

Recent Sales of Unregistered Securities

Between June 17, 2004 and July 9, 2004, the Company issued 141,946 shares of common stock to Kingsbridge Capital Limited pursuant to a draw down under the Structured Secondary Offering, or SSO, that the Company entered into with Kingsbridge in January 2004. Proceeds from the issuance of shares were approximately $533,333. Between October 24, 2004 and December 9, 2004, we issued 104,453 shares of common stock to Kingsbridge pursuant to a second draw down under the SSO. Proceeds from the issuance of shares were approximately $466,663.

The sale and issuance of the securities described above were each effected without general solicitation or advertising and were deemed to be exempt from registration under the Securities Act of 1933, in light of, among other facts, the small number and sophistication of the entity receiving the shares and the

investment representations made by Kingsbridge. We previously filed a registration statement, which has been declared effective, registering possible resale of the shares of common stock issued pursuant to the Kingsbridge SSO.

Other sales of unregistered securities during the past year have previously been reported in quarterly reports on Form 10-Q or current reports on Form 8-K that we have filed with the Securities and Exchange Commission.

ITEM 6: SELECTED FINANCIAL DATA

The following unaudited selected historical information has been derived from the audited consolidated financial statements of Cellegy. The consolidated financial information as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004 are derived from our audited consolidated financial statements included elsewhere in this Form 10-K. The information set forth below should be read in conjunction with the financial statements, related Notes thereto, and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K.

	Years ended December 31,				
Statements of Operations Data:	**2004**	**2003**	**2002**	**2001**	**2000**
	(In thousands, except per share data)				
Revenues	$ 2,596	$ 1,620	$ 1,402	$ 877	$ 1,586
Costs and expenses(1)	31,370	15,512	17,163	21,847	13,573
Operating loss	(28,774)	(13,892)	(15,761)	(20,970)	(11,987)
Other income (expense)	620	360	520	1,505	569
Net loss	$(28,154)	$(13,532)	$(15,241)	$(19,465)	$(11,418)
Basic and diluted net loss per common share	$ (1.28)	$ (0.68)	$ (0.86)	$ (1.26)	$ (0.91)
Weighted average common shares used in computing basic and diluted net loss per common share	22,021	19,964	17,643	15,503	12,542

(1) Includes a charge of $14,982,000 for purchased research and development relating to the Biosyn acquisition in October 2004.

	December 31,				
Balance Sheet Data:	**2004**	**2003**	**2002**	**2001**	**2000**
			(In thousands)		
Cash, cash equivalents, restricted cash and investments(1)	$ 8,933	$ 11,564	$ 23,858	$ 17,190	$ 15,923
Total assets	13,863	15,331	28,379	22,367	21,259
Long term portion of deferred revenue	13,865	13,335	14,168	—	—
Long term payables	717	725	717	485	—
Deficit accumulated during the development stage	(127,303)	(99,149)	(85,617)	(70,377)	(50,912)
Total stockholders' equity (deficit)	$ (6,743)	$ (1,580)	$ 10,534	$ 19,845	$ 18,794

(1) Includes restricted cash of $227,500 in 2004, 2003 and 2002, and $614,000 in 2001.

On October 22, 2004, Cellegy completed the acquisition of Biosyn. The acquisition was accounted for as purchase of assets, with assets acquired and liabilities assumed recorded at their estimated fair values. The balance sheet data for 2004 above is consolidated to include Biosyn's acquired assets and liabilities.

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

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

Cellegy Pharmaceuticals is a development stage specialty biopharmaceutical company engaged in the development and commercialization primarily of prescription drugs targeting women's health care conditions, including HIV prevention and sexual dysfunction, as well as gastrointestinal conditions using proprietary topical formulations and nitric oxide donor technologies.

General

In January 2004, we entered into a Structured Secondary Offering, or SSO, agreement with Kingsbridge Capital Limited. The agreement requires Kingsbridge to purchase up to 3.74 million shares of newly issued common stock at times and in amounts selected by us over a period of up to two years, subject to certain restrictions. We filed a registration statement with the Securities and Exchange Commission relating to shares assumable under the SSO, which was subsequently declared effective on June 1, 2004. The SSO does not prohibit us from conducting most kinds of additional debt or equity financings, including Private Investments in Private Equity (PIPEs), shelf offerings, secondary offerings or any other non-fixed or future priced securities. If our common stock falls below $1.25 per share, we will not be able to conduct draw downs on the SSO. We completed two draw downs in 2004, issuing a total of 246,399 common shares resulting in net proceeds of approximately $0.8 million.

In July 2004, Cellegy announced that the United Kingdom's Committee on Safety of Medicines, or MHRA, recommended that marketing authorization be granted by the Medicines and Healthcare Products Regulatory Agency for Cellegesic™, branded Rectogesic® outside the United States. In August 2004, the MHRA issued an approvable letter for Rectogesic.

In July 2004, Cellegy and ProStrakan Group Limited, or ProStrakan, entered into an exclusive license agreement for the future commercialization of Tostrex® (testosterone gel) in Europe. Under the terms of the agreement, ProStrakan will be responsible for regulatory filings, sales, marketing and distribution of Tostrex throughout the European Union and in certain nearby non-EU countries. Cellegy will be responsible for supplying finished product to ProStrakan through Cellegy's contract manufacturer. Assuming successful commercial launch, Cellegy could receive up to $5.75 million in total payments, including a $500,000 non-refundable upfront payment received in July 2004, and a royalty on net sales of Tostrex.

In July 2004, Cellegy completed a private placement financing, primarily with a number of existing institutional stockholders, issuing 3,020,000 common shares and warrants to purchase 604,000 shares of common stock, resulting in net proceeds of $10.2 million. The offering price of the common shares sold was $3.42 per share and the exercise price of the warrants is $4.62 per share.

In October 2004, Cellegy acquired Biosyn, Inc., a privately held biopharmaceutical company. Under the terms of the agreement, Cellegy issued approximately 2,462,000 shares of Cellegy's common stock for

all of Biosyn's issued and outstanding capital stock. In addition, outstanding Biosyn stock options and warrants were assumed by Cellegy and converted into options and warrants to purchase approximately 318,504 shares of Cellegy common stock. The options issued to acquire Cellegy common stock are fully vested and exercisable. The exercise prices of the options and warrants were adjusted by the exchange ratio in the transaction; the expiration date and other terms of the converted options and warrants remain the same. The purchase price does not include any provisions for contingent milestone payments of up to $15.0 million, which would be payable to Biosyn shareholders on the achievement of C31G marketing approval in the United States and a portion of which would be payable earlier upon commercial launch in certain major overseas markets.

In December 2004, Cellegy and ProStrakan entered into an exclusive license agreement for the commercialization of Cellegesic, branded Rectogesic outside of the United States, in Europe. Under the terms of the agreement, Cellegy received a non-refundable upfront payment of $1.0 million and is entitled to receive up to an additional $4.6 million in milestone payments, along with additional payments based on net sales of Rectogesic in Europe. ProStrakan will be responsible for additional regulatory filings, sales, marketing and distribution of Rectogesic throughout Europe. In all, the agreement covers 38 European territories, including all EU member states. Cellegy will be responsible for supplying finished product to ProStrakan through its contract manufacturer. In addition, ProStrakan has granted a right of first negotiation to Cellegy for its oral estradiol-glucoside product, which is currently in Phase 1 clinical development or an alternative product in the area of gastroenterology

Critical Accounting Policies and Estimates

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

Revenue Recognition. Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects are incurred. Revenues related to substantive and at risk non-refundable milestone payments specified under development contracts are recognized as the milestones are achieved. We receive certain government and non-government grants that support our research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenues associated with these grants are recognized as costs under each grant are incurred. Advanced payments received under these agreements prior to completion of the related work are recorded as deferred revenue until earned. Should the research funded by federal grants result in patented technologies, the federal government would be entitled to a nonexclusive, nontransferable, irrevocable, paid-up license to utilize such technologies.

At December 31, 2004, $833,630 of grants receivable under research and development agreements were unbilled. These amounts represent billings by Cellegy for reimbursement of expenses funded by grants previously recorded in grant revenue. There were no unbilled grants at December 31, 2003.

Revenues related to product sales are recognized when title has been transferred to the customer and when all of the following criteria are met: a persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured. There is no right of return for our products.

Revenues under license and royalty agreements are recognized in the period the earnings process is completed based on the terms of the specific agreement. Advanced payments received under these agreements are recorded as deferred revenue at the time the payment is received and are subsequently

recognized as revenue on a straight-line basis over the longer of the life of the agreement or the life of the underlying patent.

Royalties payable to Cellegy under these license agreements will be recognized as earned when the royalties are no longer refundable under certain minimum royalty terms defined in the agreement.

Goodwill and Intangible Assets. Goodwill and intangible assets consist primarily of goodwill and acquired workforce related to the acquisition of the Company's subsidiary, Biosyn. In accordance with SFAS No. 142 "Goodwill and Other Intangible Assets", goodwill and other intangible assets are no longer systematically amortized, but rather the Company performs an annual assessment for impairment by applying a fair-value based test. Additionally, goodwill and intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount of the asset may not be recoverable. An impairment loss would be recognized based on the difference between the carrying value of the asset and its estimated fair value, which would be determined based on either discounted future cash flows or other appropriate fair value methods. The evaluation of goodwill and other intangibles for impairment requires management to use significant judgments and estimates including, but not limited to, projected future revenue, operating results and cash flows. Based on management's analysis, no impairments have been recorded to date. If an impairment were to occur, Cellegy would be required to charge to earnings the write-down in value of such assets.

Impairment of Long Lived Assets. The Company reviews long-lived assets for impairment whenever events or changes in business conditions indicate that these carrying values may not be recoverable in the ordinary course of business. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset.

Biosyn Obligation. Included in long-term liabilities is our assumed obligation to a non-profit economic development corporation, which is recorded at its estimated fair value. The repayment terms of the non interest-bearing obligation include the remittance of an annual fixed percentage of 3% applied to the future revenues of Biosyn, if any, until the principal balance of $777,902 is satisfied. Under the terms of the obligation, "revenues" are defined to exclude the value of unrestricted research and development funding received by Biosyn from non-profit sources. There is no obligation to repay the obligation in the absence of future Biosyn revenues. We will accrete the discount of $647,902 to earnings using the interest rate method over the discount period of five years, which was estimated in connection with the note's valuation at the time of the acquisition.

Research and Development Expenses. Research and development expenses, which include clinical study payments made to clinical sites and clinical research organizations, consulting fees, expenses associated with regulatory filings and internally allocated expenses such as rent, supplies and utilities, are charged to expense as they are incurred. Clinical study expenses are accrued based upon such factors as the number of subjects enrolled and number of subjects that have completed treatment for each trial.

Milestone payments that are made upon the occurrence of future contractual events prior to receipt of applicable regulatory approvals are charged to research and development expense. We may capitalize and amortize certain future milestone and other payments subsequent to the receipt of applicable regulatory approvals, if any.

Derivative Instruments. Cellegy accounts for the warrants issued in January 2004, in conjunction with the Kingsbridge financing, as a derivative financial instrument. As a derivative, the fair value of the warrant is recorded as a liability in the balance sheet and changes in the fair value of the warrant are recognized as other income or expense during each period. The fair value of the warrant is expected to change primarily

in response to changes in Cellegy's stock price. Significant increases in the fair value of our stock could give rise to significant expense in the period of the change. Likewise, a reduction in our stock price could give rise to significant income in the period of the change.

Results of Operations

Years Ended December 31, 2004, 2003 and 2002

Revenues. Cellegy had revenues of $2,596,000, $1,620,000, and $1,402,000 in 2004, 2003 and 2002, respectively. Revenues in 2004 consisted primarily of $563,000 in Australian Rectogesic sales, $1,005,000 in grant revenue from Cellegy's Biosyn subsidiary for the period from its acquisition on October 22, 2004 through year end 2004, $181,000 in skin care product sales to Gryphon Development, the product development arm of a major specialty retailer and $844,000 in licensing revenue from our Fortigel, Rectogesic and Tostrex products.

Revenues in 2003 consisted of $385,000 in Australian Rectogesic sales, $67,000 in initial Rectogesic sales in South Korea, $316,000 in skin care product sales to Gryphon, $833,000 in licensing revenue for Fortigel and $19,000 in Canadian government grants. Revenues in 2002 consisted of $275,000 in Australian Rectogesic sales, $1,081,000 in product sales primarily to Gryphon and $46,000 in Canadian government grants.

Rectogesic revenues in Australia increased 46% in 2004, compared with 2003, following a 40% increase in 2003, compared with 2002. We expect Australian Rectogesic sales to increase in 2005, but at a lower growth rate than the prior two years. Revenue growth in 2004 and 2003 was due primarily to effective advertising and selling programs for Rectogesic throughout Australia. Such programs will continue in 2005, but may not result in the same revenue growth as in the prior years.

Biosyn grant revenue of $1,005,000 for October 22nd to December 31, 2004 was primarily related to funding from several agencies in support of the following development programs: $562,000 for Cyanovirin-N, $273,000 for Savvy, $76,000 for UC-781 and $94,000 for a UC-781/Savvy combination product. We expect total grant revenues from various funding agencies for 2005 to be in the $3.0 to $5.0 million range for the development of our Savvy, UC-781 and Cyanovirin-N product candidates. In addition to the direct grants to Biosyn, Biosyn will benefit from agency funding paid to third party contractors in support of its ongoing Phase 3 clinical trials. Under the terms of certain of its funding agreements, Biosyn has been granted the right to commercialize products supported by the funding in developed and developing countries, and is obligated to make its commercialized products, if any, available in developing countries, as well as to public sector agencies in developed countries at prices reasonably above cost or at a reasonable royalty rate.

Skin care moisturizer sales to Gryphon decreased by $135,000 or about 43% in 2004, compared with 2003. The decrease was primarily attributable to a decline in overall retail sales of Gryphon's finished product of which our moisturizer is a component. We are unable to determine whether this decline reflects a trend that will continue although we do not now expect any Gryphon sales orders through the first quarter of 2005 and are not able to estimate full year 2005 sales at this time. Continued lower demand by Gryphon for our moisturizer in the future could impact our financial position, although other revenue sources, such as overseas sales of Rectogesic and Tostrex and grant revenue, are significantly larger than revenues from sales to Gryphon. Skin care sales to Gryphon decreased by $765,000 or about 71% in 2003, compared with 2002. The decline was primarily caused by lower retail sales by Gryphon in 2003 and corresponding lower moisturizer orders to Cellegy.

In 2004, Cellegy recorded licensing revenue of $833,000 from PDI, reflecting the amortization over the expected commercial life of Fortigel, of the initial $15.0 million received from PDI on the agreement date in December 2002. See also Item 3: "Legal Proceedings." We also recorded licensing revenue of

$11,000 in the second half of 2004 associated with upfront payments of $0.5 million and $1.0 million received from our European marketing partner ProStrakan for the licenses of Tostrex and Rectogesic, respectively. We expect to record about $240,000 in licensing revenue for each of the four quarters of 2005 reflecting the amortization of the upfront payments over the expected commercial life of the Fortigel, Rectogesic and Tostrex products. Cellegy expects to receive royalty revenues from ProStrakan in the second half of 2005 from initial product sales of Rectogesic and Tostrex in the United Kingdom and Sweden, respectively.

Research and Development Expenses. Research and development expenses were $9,599,000 in 2004, compared with $10,558,000 in 2003 and $10,403,000 in 2002. Research and development expenses, which are primarily related to the costs of clinical trials and regulatory filings, represented 31%, 69% and 62% of our total operating expenses in 2004, 2003 and 2002, respectively.

Total research and development in 2004, compared with 2003, decreased by approximately $959,000, or about 9%, due primarily to a reduction in clinical and regulatory costs in 2004 of about $2,865,000 relating, primarily, to higher Cellegesic Phase 3 clinical trial expenses and various Fortigel clinical costs in 2003. These were offset somewhat in 2004 by higher research and development expenses of $860,000 incurred by Biosyn primarily for Savvy development and included in the consolidated results during the fourth quarter of 2004, other Cellegy research expenditures of $635,000, primarily relating to the validation of Cellegesic and Fortigel manufacturing processes at a second contract manufacturer and non-cash expenses of $750,000 relating to common stock issued to Neptune for a milestone achieved during 2004.

Total research and development expenses in 2003, compared with 2002, increased by $155,000 or about 2%. The increase was primarily due to higher clinical and manufacturing costs of expenses of $703,000 relating principally to the completion of a third Phase 3 Cellegesic clinical trial in 2003 and this increase was partially offset by FDA user fees of $313,000 and other NDA related expenses associated with the Fortigel NDA filing in 2002.

Current research and development expenses consist primarily of internal salaries and allocated costs as well as external clinical costs, including: clinical site payments, costs of manufacturing, testing and shipping clinical supplies and service fees to clinical research organizations, or CROs, that monitor the clinical sites and perform other related trial support services. Additionally, research expenses consist of regulatory costs, including the cost of filing product approval applications around the world, and the costs of various consultants to support the filings. Excluding non-cash compensation expenses, we anticipate that our research and development expenses will increase during 2005 primarily relating to the first full annual effect of ongoing Phase 3 clinical trials for Savvy, which was acquired by Cellegy and included in our consolidated results for a portion of fourth quarter of 2004. In addition, increases in clinical trial and regulatory filing expenses will occur as planned additional Phase 3 clinical trials, to support Fortigel and/or Tostrelle, are initiated. We are planning to spend approximately $4.0 million for our clinical trial programs in 2005.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $6,641,000 in 2004, $4,768,000 in 2003, and $6,390,000 in 2002. These expenses in 2004 increased by $1,873,000,or about 39%, compared with 2003 resulting primarily from higher PDI litigation costs in 2004 of $1,215,000, accounting expenses of approximately $315,000 related to additional registration statement filings and to consulting cost associated with the Company's Sarbanes-Oxley compliance programs, pre-launch Cellegesic marketing expenses of $540,000, and the inclusion of Biosyn expenses of $266,000 from October 22, 2004 through December 31, 2004. These were offset somewhat by a net decrease in administrative expenses of $313,000 and a decrease in corporate development expenses of $150,000.

Selling, general and administrative expenses in 2003 decreased by $1,622,000 or about 25%, compared with 2002. The higher spending level in 2002, compared with 2003, resulted primarily from Cellegesic

pre-launch sales and marketing expenses of $2,094,000 and investment banking fees of approximately $947,000 in 2002.

Selling, general and administrative expenses are expected to increase in the first half of 2005 due to higher legal and litigation expenses, severance payments and the first half-year effect of additional Biosyn administrative expenses. For the second half of 2005, we expect lower legal expenses, assuming a resolution of current litigation, offset somewhat by higher professional and administrative fees related, in part, to our Sarbanes-Oxley compliance program.

Acquired-In-Process Technology. Included in the acquisition of Biosyn was purchased research and development with an allocated fair value of approximately $15.0 million. The valuation was based primarily on the income approach and applying risk-adjusted discount rates to the estimated future revenues and expenses attributable to in-process drug development programs. The most significant in-process program relates primarily to the development of Savvy® (C31G vaginal gel), a novel microbicide vaginal gel, which has the potential to reduce the transmission of HIV /AIDS and other sexually transmitted diseases in women. This product had an estimated fair value of $15.4 million for purposes of this valuation. Two other development programs, called UC-781 and Cyanovirin-N, had a combined estimated fair value of $1.6 million. The estimated fair value of the purchased research and development of $17.0 million was reduced by $2.0 million, the amount by which the allocated fair value of the net assets acquired exceeded the value of the acquisition consideration.

The in-process C31G program requires significant additional scientific and clinical testing, which for purposes of the valuation, was assumed to be completed in the second half of 2006 with cash inflows from product sales in the United States forecasted to begin in 2007, assuming no unforeseen adverse events or delays and assuming that regulatory approvals are timely obtained. The C31G Phase 3 clinical trials are currently underway in the United States and Africa. The UC-781 and Cyanovirin-N development programs are at a much earlier stage than for C31G. Additional manufacturing optimization and development expenses associated with completing the clinical trials, as well as legal and regulatory expenses relating to the drug approval process will be required to gain marketing acceptance.

The primary risk in completing the projects is the successful completion of the clinical testing and the regulatory review process. This process is time consuming and expensive, subject to significant challenges and risks before the products can be approved and commercialized. Cellegy must demonstrate product safety and efficacy to standards agreed to with regulatory authorities. Unsuccessful clinical results or delays in the approval process could have significant consequences, jeopardizing marketing launch of the product resulting in lower potential revenues and lowered economic returns. Based on this risk assessment, management has concluded that the technological feasibility of the in-process research and development purchased from Biosyn had not yet been reached and that the technology had only limited alternative future uses. Accordingly, the amount allocated to purchased research and development of approximately $15.0 million has been charged to the Statement of Operations for the year ended December 31, 2004.

Other Income (Expense). Cellegy recognized net interest and other income of $620,000 for 2004, compared with $360,000 for 2003 and $521,000 for 2002. The 2004 total was comprised primarily of $110,000 in interest income, $149,000 in rental income and a derivative revaluation credit associated with the Kingsbridge warrants of $390,000. The net interest and other income in 2003 consisted of $212,000 in interest income from cash and investments and $148,000 in rental and other income. In 2002, other income consisted primarily of $342,000 in interest income from cash and investments and $119,000 in rental income, somewhat offset by interest expense of $27,000. Reductions in interest income over the last three years were due to lower average investment balances and interest rates.

Liquidity and Capital Resources

Our cash and cash equivalents were $8.7 million at December 31, 2004, compared with $7.6 million at December 31, 2003 and $21.6 million at December 31, 2002. Cash and cash equivalents increased $1.1 million during 2004. Cash used in operations of $13.6 million was somewhat offset primarily by net proceeds of the July private placement financing and two Kingsbridge SSO draw downs of approximately $11.2 million and of $1.5 million in payments received pursuant to the ProStrakan licenses. Additionally, maturing short term investments of $3.7 million were added to cash and cash equivalents during 2004.

Our net loss was $28.2 million and $13.5 million in 2004 and 2003, respectively. Net cash used in operating activities was $13.6 million and $12.8 million in 2004 and 2003, respectively. The $14.6 increase in net loss and the $0.8 million decrease in cash used in operations during 2004, compared with 2003, was primarily due to the $15.0 million non-cash purchased research and development charge associated with the Biosyn acquisition. This charge was included in the 2004 net loss. Other major changes in operating cash in 2004 included a non-cash milestone payment of $0.8 million to Neptune, a net decrease in accrued expenses and accounts payable of $1.4 million due to the extinguishment of certain Biosyn liabilities by Cellegy after the acquisition, partially offset by higher accrual of legal and consulting expenses, and an increase in deferred revenue of $1.3 million related primarily to the ProStrakan license agreements and the Biosyn acquisition. These were partially offset by a reduction in the loss on fixed assets of about $0.6 million primarily due to the write-off of tenant improvements at our South San Francisco corporate facility in 2003, lower equity compensation expense of $0.5 million relating to non-cash bonuses paid in stock in 2003 and a $0.5 million increase in accounts receivable.

Net cash used in operating activities was $12.8 million in 2003, compared with net cash provided by operating activities of $1.6 million in 2002. The $14.3 million increase in cash used in operations during 2003, compared with 2002, was primarily due to $15.0 million in upfront payments received under the PDI license agreement and recorded as deferred revenue in 2002, offset by an increase in the loss of fixed assets of $0.8 million relating primarily to the write-off of tenant improvements at our South San Francisco corporate facility in 2003. Net cash used in investing activities during 2003, compared with 2002, increased by $10.2 million, due primarily to investment purchases. Net cash provided by financing activities decreased by $5.5 million in 2003, compared with 2002, primarily due to a $5.2 million private placement financing in 2002.

We prepared the financial statements assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. At December 31, 2004, we had a deficit accumulated during the development stage of $127.3 million, negative cash flows from operations of $13.6 million, and cash and cash equivalents of $8.7 million. We expect negative cash flow from operations to continue for at least the next two years, with the need to continue or expand development programs and to commercialize products once regulatory approvals have been obtained. These factors raise substantial doubt about our ability to continue as a going concern. Our plans, with regard to these matters, include raising additional required funds through one or more of the following options, among others: making further Kingsbridge SSO draw downs, seeking partnerships with other pharmaceutical companies to co-develop and fund our research and development efforts, pursuing additional out-licensing arrangements with third parties, re-licensing and monetizing in the near term our future milestone and royalty payments expected from existing licensees and seeking equity or debt financing. In addition, we will continue to implement further cost reduction programs and reduce discretionary spending, if necessary, to meet our obligations as they become due for the foreseeable future.

There is no assurance that any of the above options will be implemented on a timely basis or that we will be able to obtain additional financing on acceptable terms, if at all. Alternatively, we may be required to accept less than favorable commercial terms in any such future arrangements. If adequate funds are not available on acceptable terms, we could be required to delay development or commercialization of certain products, to license to third parties the rights to commercialize certain products that we would otherwise

seek to commercialize internally or to reduce resources devoted to product development. In addition, if we do not receive all, or a portion, of the planned Biosyn grant funding, or if such funding is delayed, this could impact our ability to complete our Biosyn development programs on a timely basis, if at all. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect out ability to enter into collaborative relationships with business partners, make it more difficult to obtain required financing on favorable terms or at all, negatively affect the market price of our common stock and could otherwise have a material adverse effect on our business, financial condition and results of operations.

Future expenditures and capital requirements depend on numerous factors including, without limitation, the progress and focus of our research and development programs, the progress of pre-clinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the progress and outcome of the PDI litigation, the costs of filing, prosecuting, defending and enforcing patent claims, oppositions and appeals, the timing and level of grant funding to support Biosyn's clinical programs and operations and our ability to establish new collaborative arrangements.

Management believes that our existing cash balances will be sufficient to meet our capital and operating requirements through September 30, 2005, assuming no significant impact from the PDI litigation and any other subsequent legal proceedings.

Contractual Obligations

The table below summarizes certain of our future contractual obligations, which include obligations under our current South San Francisco lease and Biosyn's lease and capital obligations at December 31, 2004 (in thousands):

	Total	2005	2006	2007	2008
Operating lease	$6,387	$1,562	$1,590	$1,690	$1,626
Capital lease	120	56	48	16	—
Total	$6,507	$1,618	$1,638	$1,706	$1,626

In March 2005, we relocated our principal office from South San Francisco to Brisbane, California. Our sublease for our office in Brisbane has a term that expires February 28, 2006. Rent during the term is nominal. If we and the sublessor agree to extend the term of the Brisbane sublease beyond the initial one year term, rent would increase to approximately $17,200 per month. In connection with the Brisbane sublease, the sublessor intends to move into the space formerly occupied by us in South San Francisco and has agreed, subject to approval and execution of definitive agreements, to make a payment to us as consideration for moving. We expect to enter into definitive agreements with the landlord regarding the termination of our South San Francisco lease. Our operating lease payments were $1,337,000 for 2004.

Other obligations not reflected in the table are comprised primarily of employment agreements, license agreements and the fair value of an obligation to a non-profit economic development corporation pursuant to the acquisition of Biosyn. Severance payments of $597,000 and other healthcare cost reimbursements will be made to Cellegy's former Chief Executive Officer over an 18-month period ending in June 2006. License agreements generally provide for payment by us of annual license fees, milestones payments and royalties upon successful commercialization of products. The note repayment obligation is a non-interest bearing obligation with terms to remit an annual fixed percentage of 3% applied to future revenues of Biosyn if any, until the principle balance of $777,902 is satisfied. Under the terms of the obligation, "revenues" are defined to exclude the value of unrestricted research and development funding received by Biosyn from non-profit sources. There is no obligation to make payments in the absence of

future Biosyn revenues. The above table excludes milestone, royalty payments and the repayment obligation, as such amounts are not probable or estimable at this time.

Under the Kingsbridge SSO, if we do not issue and sell common stock pursuant to draw downs under the SSO at least equal to $2.66 million during the term of the agreement, which expires in January 2006, then we have agreed to pay approximately $266,000 to Kingsbridge. In addition, our December 1997 agreement with Neptune Pharmaceuticals Corporation pursuant to which we acquired the rights relating to Cellegesic calls for a series of payments, which may be paid in shares of common stock, upon successful completion of various development milestones. We issued shares to Neptune in 2001 and 2004 upon completion of certain milestones, valued at $750,000 for each milestone. The remaining milestone payments are contingent and become payable upon certain product development or commercialization milestones, the achievement and timing of which are subject to material uncertainties.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123R, "Share-Based Payment", which replaces SFAS No. 123 "Accounting for Stock Based Compensation". SFAS No. 123R requires public companies to recognize an expense for share-based payment arrangements including stock options and employee stock purchase plans. The statement eliminates a company's ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair-value based method. SFAS No. 123R requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant, and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. SFAS No. 123R is effective for the Company in the quarter ending September 30, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. Upon adoption of SFAS No. 123R, companies are allowed to select one of three alternative transition methods, each of which has different financial reporting implications. Management is currently evaluating the transition methods as well as valuation methodologies and assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately implemented by Cellegy upon adoption of SFAS No. 123R.

Factors That May Affect Future Operating Results

Risks Relating to Our Business

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

Cellegy's prescription product candidates, and our ongoing research and clinical activities such as those relating to our product candidates Savvy, Cellegesic, Fortigel and Tostrelle, are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. Before we obtain regulatory approval for the commercial sale of our potential drug products, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and efficacious for use in the clinical indication for which approval is sought. The timing of NDA submissions, the outcome of reviews by the FDA and the initiation and completion of other clinical trials are subject to uncertainty, change and unforeseen delays. Under the Prescription Drug User Fee Act, or PDUFA, the FDA establishes a target date to complete its review of an NDA. Although the FDA attempts to respond by the relevant PDUFA date to companies that file NDAs, there is no obligation on the FDA's part to do so. In addition, extensive current pre-clinical and clinical testing requirements and the current regulatory approval process of the FDA in the United States and of certain foreign regulatory authorities, or new government regulations, could prevent or delay regulatory approval of Cellegy's products.

The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and substantial expenditures. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all. Delays in obtaining regulatory approvals could delay receipt of revenues from product sales, increase our expenditures relating to obtaining approvals, jeopardize corporate partnership arrangements that we might enter into with third parties regarding particular products, or cause a decline in our stock price. If we fail to comply with applicable regulatory requirements, we could be subject to a wide variety of serious administrative or judicially imposed sanctions and penalties, any of which could result in significant financial penalties that could reduce our available cash, delay introduction of products resulting in deferral or elimination of revenues from product sales, and could result in a decline in our stock price.

One or more of our ongoing or planned clinical trials could be delayed, or the FDA could issue a Not Approvable letter with respect to our current or future product candidates, as it did with our Fortigel NDA in July 2003 and our Cellegesic NDA in December 2004. Such actions could result in further clinical trials or necessitate other time consuming or costly actions to satisfy regulatory requirements. For example, in January 2004, Cellegy reported positive results from its confirmatory Phase 3 study using Cellegesic for the treatment of chronic anal fissure pain, and we submitted an NDA to the FDA in June 2004. The Cellegesic trial was conducted in accordance with a Special Protocol Assessment, or SPA, agreed to with the FDA. In December 2004, the FDA concluded that the trial data did not satisfy the standards specified in the SPA and did not grant marketing approval for Cellegesic.

Similarly, although there is still no definitive agreement with the FDA regarding requirements for approval of Fortigel, the FDA will require an additional Phase 3 clinical trial. The FDA may also decide to have an Advisory Panel review the submission of our product candidates with an uncertain outcome of such panel's recommendation, or take other actions having the effect of delaying or preventing commercial introduction of our products. The FDA or other regulatory agencies could impose requirements on future trials that could delay the regulatory approval process for our products. Similarly, there are risks and uncertainties associated with our female clinical trial programs for Tostrelle and Savvy in that sufficient resources for clinical development of these product candidates may not be available or one or both drugs may not prove to be safe and effective by standards established by worldwide regulatory authorities. There can be no assurance that the FDA, or other regulatory agencies, will find any of our trial data or other sections of our regulatory submissions sufficient to approve any of our product candidates for marketing in the United States or in other overseas markets.

Sales of Cellegy's products outside the United States are subject to different regulatory requirements governing clinical trials and marketing approval. These requirements vary widely from country to country and could delay introduction of Cellegy's products in those countries. Cellegy may not be able to obtain marketing approval for one or more of its products in any countries in addition to those countries where approvals have already been obtained.

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

Results of pre-clinical studies and early clinical trials may not be good predictors of results that will be obtained in later-stage clinical trials. We cannot provide any assurances that Cellegy's present or future clinical trials, will demonstrate the results required to continue advanced trial development and allow us to seek marketing approval for these or our other product candidates. Because of the independent and blind nature of certain human clinical testing, there will be extended periods during the testing process when we will have only limited, or no, access to information about the status or results of the tests. Cellegy and other pharmaceutical companies have believed that their products performed satisfactorily in early tests, only to find their performance in later tests, including Phase 3 clinical trials, to be inadequate or

unsatisfactory, or that FDA Advisory Committees have declined to recommend approval of the drugs, or that the FDA itself refused approval, with the result that stock prices have fallen precipitously.

Clinical trials can be extremely costly. Certain costs relating to the Phase 3 trials for the Savvy product for contraception and reduction in the transmission of HIV, and other clinical and preclinical development costs for the Biosyn pipeline products acquired by Cellegy, are funded directly by certain grant and contract commitments from several governmental and non-governmental organizations, or NGOs. Nevertheless, these Phase 3 trials and Cellegy's other planned clinical trials could require Cellegy to provide trial funding of approximately $4.0 million in 2005 and additional amounts in future years. There can be no assurance that funding from governmental agencies and NGOs will continue to be available at previous levels or at all, and any other Phase 3 trials that Cellegy may commence in the future relating to its products could involve the expenditure of several million dollars through the completion of the clinical trials. In addition, delays in the clinical trial process can be extremely costly in terms of lost sales opportunities and increased clinical trial costs. The speed with which we complete our clinical trials and our regulatory submissions, including NDAs, will depend on several factors, including the following:

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

Adverse events in our clinical trials may force us to stop development of our product candidates or prevent regulatory approval of our product candidates, which could materially harm our business.

Patients participating in the clinical trials of our product candidates may experience serious adverse health events. A serious adverse health event includes death, a life-threatening condition, hospitalization, disability, congenital anomaly, or a condition requiring intervention to prevent permanent impairment or damage. The occurrence of any of these events could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA, or other regulatory authorities, denying approval of our product candidates for any or all targeted indications. An institutional review board or independent data safety monitoring board, the FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Our product candidates may prove not to be safe for human use. Any delay in the regulatory approval of our product candidates could increase our product development costs and allow our competitors additional time to develop or market competing products.

Due to our reliance on contract research organizations or other third-parties to assist us in conducting clinical trials, we are unable to directly control all aspects of our clinical trials.

Currently, we rely on contract research organizations, or CROs, and other third parties to conduct our clinical trials. As a result, we have had and will continue to have less control over the conduct of the clinical trials, the timing and completion of the trials and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with CROs can also be challenging, potentially leading to difficulties in coordinating activities. CROs may:

- have staffing difficulties;

- experience regulatory compliance issues;
- undergo changes in priorities or may become financially distressed; or
- not be able to properly control payments to government agencies or clinical sites, particularly in less developed countries.

These factors may adversely affect their ability to conduct our trials. We may experience unexpected cost increases or experience problems with the timeliness or quality of the work of the CRO. If we must replace these CROs or any other third party contractor, our trials may have to be suspended until we find another contract research organization that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of our product candidates or may cause us to incur significant expenses. Although we do not now intend to replace our CROs, such a change would make it difficult to find a replacement organization to conduct our trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of our product candidates, thereby limiting our ability to generate product revenue resulting in a decrease in our stock price.

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

We have incurred losses since our inception and negative cash flows from operations that raise substantial doubt about our ability to continue as a going concern. Our accumulated deficit as of December 31, 2004, was approximately $127.3 million. We have never operated profitably and, given our planned level of operating expenses, we expect to continue to incur losses through at least 2006. We plan to devote significant resources to pre-clinical studies, clinical trials, administrative, marketing, sales and patent activities. Accordingly, without substantial revenues from new corporate collaborations, royalties on product sales or other revenue sources, we expect to incur substantial operating losses in the foreseeable future as our potential products move through development and as we continue to invest in research and clinical trials. As a result of our continuing losses, we may exhaust our resources and may be unable to complete the development of our products, and our accumulated deficit will continue to increase as we continue to incur losses. Our losses may increase in the future, and even if we achieve our revenue targets, we may not be able to sustain or increase profitability on a quarterly or annual basis. The amount of future net losses, and the time required to reach profitability, are both highly uncertain. To achieve sustained profitable operations, we must, among other things, successfully discover, develop, and obtain regulatory approvals for and market pharmaceutical products. We cannot assure you that we will ever be able to achieve or sustain profitability.

We have received a "going concern" opinion from our independent auditors, which may negatively impact our business.

Our audit opinion from our independent auditors regarding the consolidated financial statements for the year ended December 31, 2004, included an explanatory paragraph indicating that there is substantial doubt about the Company's ability to continue as a going concern. As discussed in Note 1 to the financial statements, we have incurred losses from operations since inception and negative cash flows from operations that raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect our ability to enter into collaborative relationships with business partners, make it more difficult to obtain required financing on favorable terms or at all, negatively affect the market price of our common stock and could otherwise have a material adverse effect on our business, financial condition and results of operations.

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

Throughout our history, we have consumed substantial amounts of cash. Our cash needs may increase during the second half of 2005 in order to fund the additional expenses required to continue our development and administrative programs, and to fund future payments in support of Biosyn's operations to the extent these are not covered by various government and non-government organizations. In addition, one or more such organizations could withdraw, reduce the extent of, delay or terminate their funding commitments. Cellegy has no current source of significant ongoing revenues or capital beyond existing cash, certain product sales of Rectogesic and skin care moisturizers, grant funding supporting Biosyn's clinical trials and access to funding through the Kingsbridge SSO.

The amount of cash required to fund future expenditures and capital requirements will depend on numerous factors including, without limitation:

- requirements in support of our development programs;
- progress and results of pre-clinical and clinical testing;
- time and costs involved in obtaining regulatory approvals, including the cost of complying with additional FDA information and/or clinical trial requirements to obtain marketing approval of our Fortigel, Tostrelle and Cellegesic product candidates;
- the commercial success of our products that are approved for marketing by the United States or foreign regulatory authorities;
- the costs of filing, prosecuting, defending and enforcing patent claims, oppositions and appeals, and our other intellectual property rights;
- the progress and outcome of the litigation involving the Fortigel license agreement with PDI, Inc., and legal costs and/or potential settlement payments associated with the PDI litigation, as well as expenses associated with any other unforeseen litigation;
- our ability to establish new collaborative arrangements;
- the validation of a second contract manufacturing site; and
- the extent of expenses required to support Biosyn's operations that are not covered by government and non-government grants.

In order to complete the development, manufacturing and other pre-launch marketing activities necessary to commercialize our products, additional financing will be required. In addition to the Kingsbridge SSO to help fund future cash needs, Cellegy may seek other alternatives such as private or public equity investments, partnerships with other pharmaceutical companies to co-develop and fund our research and development efforts, additional out-licensing agreements with third parties, or agreements to monetize in the near term our future milestone and royalty payments expected from licenses. There is no assurance that such funding will be available for us to finance our operations on acceptable terms, if at all, and any future equity funding may involve significant dilution to our stockholders. Our ability to draw down funds under the SSO is dependent in part on our stock price and the satisfaction of other conditions of the SSO; under certain circumstances we could be prevented from or be limited in fully utilizing planned funding from the SSO.

Insufficient funding may require us to delay, reduce or eliminate some or all of our research and development activities, planned clinical trials, administrative programs, personnel, outside services and facility costs; reduce the size and scope of our sales and marketing efforts; delay or reduce the scope of, or eliminate, one or more of our planned commercialization or expansion activities; seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less

favorable than might otherwise be available; or relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. In addition, even if we do receive additional financing, we may not be able to complete planned clinical trials, development, manufacturing or marketing of any or all of our product candidates.

Cellegy believes that available cash resources and interest earned thereon together with the available funding from the Kingsbridge SSO, will be adequate to satisfy our capital needs through at least September 30, 2005, assuming no material adverse financial impact associated with the PDI litigation and any subsequent legal proceedings, although failure to obtain additional funds as described above may affect the timing of development, clinical trials or commercialization activities relating to certain products.

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

Cellegy's success depends, in part, on our ability to obtain patent protection for our products and methods, both in the United States and in other countries. Several of Cellegy's products and product candidates, such as Cellegesic, Fortigel and Tostrelle, are based on existing molecules with a history of use in humans but which are being developed by us for new therapeutic uses or in novel delivery systems which enhance therapeutic utility. We cannot obtain composition patent claims on the compounds themselves, and will instead need to rely on patent claims, if any, directed to use of the compound to treat certain conditions or to specific formulations. This is the case, for example, with our United States patents relating to Cellegesic and Fortigel. Such method-of-use patents may provide less protection than a composition-of-matter patent, because of the possibility of "off-label" use of the composition. Cellegy may not be able to prevent a competitor from using a different formulation or compound for a different purpose.

No assurance can be given that any additional patents will be issued to us, that the protection of any patents that may be issued in the future will be significant, or that current or future patents will be held valid if subsequently challenged. For example, oppositions have been filed with the European Patent Office regarding our European patent protecting the manufacture and use of nitroglycerin ointment and related compounds for the treatment of anal disorders, including fissures and various hemorrhoidal conditions. In December 2003, we reported that the Board of Opposition of the European Patent Office had rendered a verbal decision revoking Cellegy's European patent relating to its Cellegesic product and related compounds for the treatment of anal disorders, including fissures and various hemorrhoidal conditions. Although Cellegy has appealed this decision, an additional adverse outcome in the appeal process could have a negative effect on Cellegy, impacting the commercial success of our partner's marketing and corporate licensing efforts in Europe and adversely affecting our royalty revenues and stock price.

The patent position of companies engaged in businesses such as Cellegy's business generally is uncertain and involves complex legal and factual questions. There is a substantial backlog of patent applications at the United States Patent and Trademark Office, or USPTO. Patents in the United States are issued to the party that is first to invent the claimed invention. There can be no assurance that any patent applications relating to Cellegy's products or methods will issue as patents, or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us a competitive advantage.

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

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

Our product sales strategy involving corporate partners is highly uncertain.

Cellegy is seeking to enter into agreements with corporate partners regarding commercialization of our lead product candidates. Besides the Fortigel license agreement with PDI, which is currently subject to litigation between the parties, Cellegy currently has a limited number of other agreements with third parties to commercialize our product candidates. In July 2004, Cellegy and ProStrakan Group Limited entered into an exclusive license agreement for the future commercialization of Tostrex in Europe and in December these parties also entered into an exclusive license agreement for commercialization of Rectogesic in Europe. However, Cellegy may not be able to establish other collaborative arrangements and we may not have the resources or the experience to successfully commercialize any such products on our own. Failure to enter into other arrangements could prevent, delay or otherwise jeopardize our ability to develop and market products in the United States and in markets outside of North America, reducing our revenues and profitability.

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

In October 2003, Cellegy announced that it had received a communication on behalf of PDI invoking mediation procedures under the exclusive license agreement between PDI and Cellegy relating to Fortigel. The dispute resolution provisions of the agreement required non-binding mediation before either party could initiate further legal proceedings. Mediation proceedings were completed in early December 2003, after which both PDI and Cellegy initiated litigation proceedings. The legal proceedings have been consolidated in the United States District Court for the Northern District of California. Trial is currently scheduled to take place during the second quarter of 2005. Although Cellegy believes PDI's claims are without merit, there can be no assurances regarding the outcome of any such proceedings and Cellegy has been and may continue to be required to devote significant time and additional resources to the proceedings. An adverse outcome in any such proceeding could require Cellegy to make a significant cash payment to PDI which would adversely affect Cellegy's ability to fund its business and product development efforts, could result in additional time and expenses relating to any appeal that might be pursued and could cause a decline in Cellegy's stock price.

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

Cellegy has no direct experience in manufacturing commercial quantities of products and currently does not have any capacity to manufacture products on a large commercial scale. We currently rely on a limited number of contract manufacturers, primarily PendoPharm Inc. and certain of Biosyn's suppliers, to manufacture our formulations. Although we are developing other contract manufacturers, there can be no

assurance that we will be able to enter into acceptable agreements with them or validate facilities successfully on a timely basis. This is an expensive and time-consuming process and there may be delays and additional costs relating to the technical transfer and validation of alternate suppliers. In the future, we may not be able to obtain contract manufacturing on commercially acceptable terms for compounds or product formulations in the quantities we need. Manufacturing or quality control problems, lack of financial resources or qualified personnel could occur with our contract manufacturers causing product shipment delays, inadequate supply, or causing the contractor not to be able to maintain compliance with the FDA's current good manufacturing practice requirements necessary to continue manufacturing. Such problems could limit our ability to produce clinical or commercial product, cause us to be in breach of contract obligations with our distributors to supply product to them, reduce our revenues from product sales, and otherwise adversely affect our business and stock price.

PendoPharm, Inc. is Cellegy's contract manufacturer for our North American and European clinical supplies and future commercial supplies of prescription products in those territories, while the Australian and South Korean product sales are sourced by a pharmaceutical manufacturer in Australia and the Gryphon skin care product sales are sourced by a manufacturer in the New York area. In July 2003, PanGeo Pharma, our former contract manufacturer, filed for bankruptcy protection under Canadian law. Under a reorganization plan, PanGeo sold its facilities to an affiliate of Pharmascience, another Canadian manufacturer, and was renamed PendoPharm Inc. Cellegy has not experienced any material adverse impact to date from the previous bankruptcy filing, the manufacturing facility was inspected and re-certified by Canadian regulatory authorities after its acquisition by PendoPharm, and PendoPharm has continued to supply product from the manufacturing facility without interruption. Nevertheless, uncertainty exists concerning the future operations of PendoPharm manufacturing plant and whether PendoPharm will be able to meet Cellegy's clinical and product requirements on a timely basis, if at all, in the future. In addition, there can be no assurances relating to PendoPharm's ability to continue to produce product under Good Manufacturing Practices required by the FDA or other regulatory agencies. There could be difficulty or delays in importing raw materials or exporting product into or out of Canada resulting in delays in our clinical trials or commercial product sale. Cellegy has started the process of establishing an alternative production site at a domestic location. This is an expensive and time consuming process and there may be delays and additional costs relating to the technical transfer and validation of alternate suppliers.

We have limited sales and marketing experience.

We may market some of our products, if successfully developed and approved, through a direct sales force in the United States. Cellegy has very limited experience in sales, marketing or distribution. To market these products directly, we may seek to establish a direct sales force in the United States or obtain the assistance of a marketing partner. However, Cellegy may not have the financial capability or the experience to successfully establish a direct sales force, marketing or distribution operations, which could delay or prevent the successful commercialization of our products and could reduce the ultimate profitability to Cellegy of such products if we needed to rely on a third party marketing partner to commercialize the products.

If medical doctors do not prescribe our products or the medical profession does not accept our products, our product sales and business would be adversely affected.

Our business is dependent on market acceptance of our products by physicians, healthcare payers, patients and the medical community. Medical doctors' willingness to prescribe our products depends on many factors, including:

- perceived efficacy of our products;
- convenience and ease of administration;

- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and
- our ability to obtain third-party coverage or reimbursement.

Even if we receive regulatory approval and satisfy the above criteria, physicians may not prescribe our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

- the experience, skill and effectiveness of the sales force and our sales managers;
- the effectiveness of our production, distribution and marketing capabilities;
- the success of competing products; and
- the availability and extent of reimbursement from third-party payors.

Failure of our products or product candidates to achieve market acceptance would limit our ability to generate revenue and could harm our business.

If testosterone replacement therapies are perceived to create health risks, our testosterone gel product candidates may be jeopardized.

Recent studies of female hormone replacement therapy products have reported an increase in certain health risks with long-term use. As a result of such studies, some companies that sell or develop female hormone replacement products have experienced decreased sales of these products, and in some cases, a decline in the value of their stock. Publications have, from time to time, suggested potential risks associated with testosterone replacement therapy, or TRT. Potential health risks were described in various articles, including a 2002 article published in Endocrine Practice and a 1999 article published in the International Journal of Andrology. It is possible that further studies on the effects of TRT could demonstrate other health risks. This, as well as negative publicity about the risks of hormone replacement therapy, including TRT, could adversely affect patient or prescriber attitudes and impact the development and successful commercialization of our Fortigel, Tostrex and Tostrelle product candidates. In addition, in a recent meeting with the FDA, the FDA informed Cellegy that specific guidelines regarding the long-term safety of testosterone for the treatment of female sexual dysfunction are under internal discussion by the Division of Reproductive and Urologic Drug Products. Cellegy is awaiting these guidelines before embarking on a Phase 3 program. If the new FDA guidelines prove to be too onerous, limiting or too costly to implement, the Phase 3 program may be significantly delayed or we may decide not to pursue further development of Tostrelle. The above factors could adversely affect investor attitudes and the price of our common stock.

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

Our success is dependent upon the efforts of a small management team and staff. We have compensation or employment arrangements and a severance/retention plan in place with all of our executive officers, but none of our executive officers is legally bound to remain employed for any specific term. Our key personnel include Richard C. Williams, our Chairman and Interim Chief Executive Officer, and Anne-Marie Corner, Senior Vice President, Women's Preventive Health. Mr. Williams has a written arrangement describing his compensation and we have a written employment agreement with Ms. Corner.

Either arrangement may be terminated by either Cellegy or the officer at any time upon notice. We do not have key man life insurance policies covering any of our executive officers or key employees. If key individuals leave Cellegy, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the development and growth of our business. Our future success depends upon our ability to continue to attract and retain qualified scientific, clinical and administrative personnel.

Our corporate compliance programs cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company and we rely heavily on third parties to conduct many important functions. We also have significantly fewer employees than many other companies that have the same or fewer product candidates in late stage clinical development. In addition, as a publicly traded company we are subject to significant regulations, including the Sarbanes-Oxley Act of 2002, some of which have either only recently been adopted or are currently proposals subject to change. While we have developed and instituted a corporate compliance program and continue to update the program in response to newly implemented or changing regulatory requirements, we cannot assure you that we are now or will be in compliance with all such applicable laws and regulations. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation. Failure to comply with potentially applicable laws and regulations could also lead to the imposition of fines, cause the value of our common stock to decline, impede our ability to raise capital or lead to the de-listing of our stock.

We are evaluating our internal control systems in order to allow management to report on, and our independent auditors to attest to, our internal controls, as required by the Sarbanes-Oxley Act. We will be performing the system and process evaluation and testing (and any necessary remediation) required in an effort to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, we expect to incur significant additional expenses and diversion of management's time. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 by our compliance deadline, which is currently expected to be December 2006, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there are few or no precedents available by which to measure compliance adequacy. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission or the Nasdaq National Market. In addition, we may be required to incur a substantial financial investment to improve our internal systems and the hiring of additional personnel or consultants.

Risks Relating to Our Industry

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

The pharmaceutical industry is subject to rapid and significant technological change. In the development and marketing of prescription drugs, Cellegy faces intense competition. Cellegy is much smaller in terms of size and resources than many of its competitors in the United States and abroad, which include, among others, major pharmaceutical, chemical, consumer product, specialty pharmaceutical and

biotechnology companies, universities and other research institutions. Cellegy's competitors may succeed in developing technologies and products that are safer and more effective than any that we are developing and could render Cellegy's technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience. In addition, Cellegy's products are subject to competition from existing products. For example, Cellegy's Fortigel product, if ever commercialized in the United States, is expected to compete with several products, including two currently marketed testosterone gel products sold by Unimed/Solvay and Auxilium Pharmaceuticals, a transdermal patch product sold by Watson Pharmaceuticals, a Buccal tablet from Columbia Laboratories and potential generic products which may be introduced before or after Fortigel is commercialized.

Cellegesic, if ever commercialized, is expected to compete with over-the-counter products, such as Preparation H marketed by Wyeth, and various prescription products. As a result, we cannot assure you that Cellegy's products under development may not be able to compete successfully with existing products or with innovative products under development by other organizations.

Savvy is subject to competition from other microbicides that are currently undergoing clinical trials and which may be sold by prescription or over the counter, as well as non-microbicide products such as condoms. Additionally, if a vaccine for HIV/AIDS is successfully developed and made available, this could limit the potential market for Savvy and Biosyn's other products. As a result, Biosyn's products under development may not be able to compete successfully with existing products or other innovative products under development.

We are subject to the risk of product liability lawsuits.

The testing, marketing and sale of human health care products entails an inherent risk of allegations of product liability. We are subject to the risk that substantial product liability claims could be asserted against us in the future. Cellegy has obtained insurance coverage relating to our clinical trials in an aggregate amount of $5 million and an aggregate amount of $7 million relating to the clinical trials relating to products acquired from Biosyn. If any of our product candidates are approved for marketing, we may seek additional coverage. There can be no assurance that Cellegy will be able to obtain or maintain insurance on acceptable terms, particularly in overseas locations, for clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities. Moreover, our current and future coverages may not be adequate to protect us from all of the liabilities that we may incur. If losses from product liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. In addition, a product liability action against us would be expensive and time-consuming to defend, even if we ultimately prevailed. If we are required to pay a product liability claim, we may not have sufficient financial resources and our business and results of operations may be harmed.

Risks Relating to Our Stock

Our stock price could be volatile.

Our stock price has from time to time experienced significant price and volume fluctuations. Since becoming a public company, our stock price has fluctuated in conjunction with the Nasdaq National Market generally and sometimes on matters more specific to Cellegy, such as an announcement of clinical trial or regulatory results or other corporate developments. For example, our high and low closing stock prices for the last three years have been as follows: 2002, high of $8.80 and low of $1.50; 2003, high of $5.60 and low of $2.25; 2004, high of $6.74 and low of $2.69; and 2005 through March 18, 2005, high of $3.05 and low of $2.01. Events or announcements that could significantly impact our stock price include:

- Publicity or announcements regarding regulatory developments relating to our products, as recently experienced with the Not Approvable letter from the FDA relating to Cellegesic;
- Clinical trial results, particularly the outcome of our more advanced studies; or negative responses from regulatory authorities with regard to the approvability of our products;
- Period-to-period fluctuations in our financial results, including our cash and investment balance, operating expenses, cash burn rate or revenues;
- Negative announcements, additional legal proceeding or financial problems of our key suppliers, particularly relating to our Canadian manufacturer and our service providers;
- Common stock sales in the public market by one or more of our larger stockholders, officers or directors;
- A negative outcome in litigation or other potential legal proceedings with PDI relating to the Fortigel license agreement; or
- Other potentially negative financial announcements, including delisting from the Nasdaq National Market, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

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

There are 4,000,000 shares of our common stock that are reserved for issuance under the structured secondary offering facility arrangement, or Kingsbridge SSO, that we entered into in January 2004 with Kingsbridge Capital Limited, or Kingsbridge, 260,000 shares of which are related to a warrant that we issued to Kingsbridge. In certain circumstances where the registration statement covering those shares is not effective or available to Kingsbridge, additional shares may be issuable to Kingsbridge under the agreement. Such circumstances could include, for example, suspending Kingsbridge's ability to sell shares pursuant to the registration statement because of the existence of material undisclosed developments relating to Cellegy. If within 15 trading days following any settlement date on which Cellegy issues shares under the Kingsbridge SSO, Cellegy suspends Kingsbridge's ability to sell shares by delivering a notice to Kingsbridge, referred to as a blackout notice, then if the volume weighted average market price of our common stock, or the VWAP, is higher on the trading day immediately before the blackout notice is delivered than it is on the first trading date after the blackout trading period is lifted, Cellegy is obligated to pay to Kingsbridge an amount based on a percentage, ranging from 75% to 25% depending on when the blackout notice is delivered, of the difference between the two VWAP prices multiplied by the number of shares purchased by Kingsbridge under the most recent drawn down and held by Kingsbridge immediately before the suspension was imposed. Cellegy may, in its discretion, pay this amount either in cash or in shares, the value of which is based on the market price of the common stock on the first trading date after the registration statement became available again. In addition, if we fail to issue and sell common stock to Kingsbridge pursuant to drawdowns at least equal to $2.66 million under the Kingsbridge SSO during the term of the agreement, then we have agreed to pay approximately $266,000 to Kingsbridge. The issuance of shares under the Kingsbridge SSO at a discount to the market price of the common stock, and upon exercise of the warrant, will have a dilutive impact on other stockholders, and the issuance or even potential issuance of such shares, if any, could have a negative effect on the market price of our common stock. If we sell stock to Kingsbridge when our share price is decreasing, such issuance will have a more dilutive effect and may further decrease our stock price. A decrease in our stock price or other consequences of issuing shares under the Kingsbridge SSO could potentially cause us not to satisfy one or more requirements for the continued listing of our common stock on the Nasdaq National Market, or

could impair or prevent our ability to obtain additional required financing, resulting in a damaged capital structure.

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

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

We could be subject to delisting by the Nasdaq National Market.

Cellegy's common stock is currently listed on the Nasdaq National Market. There are several requirements for the continued listing of our common stock on the Nasdaq National Market, including requirements relating to stock price, stockholders' equity and compliance with certain financial standards. If we fail to satisfy one or more of the criteria for continued listing and are unable to demonstrate compliance within the time periods permitted by Nasdaq, our common stock would be delisted from the Nasdaq National Market and we would likely seek a listing on the Nasdaq SmallCap Market or some other market. For example, during 2003 Cellegy had discussions with Nasdaq regarding satisfaction of a minimum $10 million stockholders' equity requirement under one of the alternative standards for continued listing, and a requirement under a different standard for continued listing of a minimum of $50 million aggregate market value of listed securities. Based on the number of shares of our common stock outstanding on the date of this annual report, if our stock price was less than approximately $1.90 per share for ten consecutive trading days, we might be subject to receiving a letter from Nasdaq notifying us that we did not satisfy the continued listing criteria, and if we did not regain compliance or satisfy another listing standard, our stock could be delisted. Delisting from the Nasdaq National Market could reduce the liquidity of our common stock, cause certain investors not to trade in our common stock and result in a lower stock price.

Future sales of shares of our common stock may negatively affect our stock price.

As a result of our acquisition of Biosyn, we issued approximately 2,462,000 shares and assumed options and warrants to purchase 318,504 shares of our common stock. In addition, from 2002 through December 31, 2004 we have issued 5,466,399 shares of our common stock in private placement transactions and through the Kingsbridge SSO. A substantial portion of these shares is held by a relatively small number of stockholders. Sales of a significant number of the above shares into the public markets, particularly in light of our relatively small trading volume, may negatively affect our stock price. We also have outstanding warrants and vested stock options that can be exercised by the holders to acquire up to approximately 4,860,802 shares of our common stock. The exercise of these options or warrants could result in significant dilution to our stockholders at the time of exercise.

In the future, we will likely issue additional shares of common stock or other equity securities, including but not limited to options, warrants or other derivative securities convertible into our common stock, which could result in significant dilution to our stockholders and adversely affect our stock price

Changes in the expensing of stock options could result in unfavorable accounting charges or require us to change our compensation practices.

For Cellegy, stock options are a significant component of compensation for existing employees and to attract new employees. We currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. The Financial Accounting Standards Board has issued a new accounting standard requiring recording of expense for the fair value of stock options granted. During 2005, when we change our accounting policy to record expense for the fair value of stock options granted our net loss will increase. We intend to continue to include various forms of equity in our compensation plans, such as stock options and other forms of equity compensation allowed under our plans. If we continue our reliance on stock options, our reported losses could increase.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Cellegy invests its excess cash in short-term, investment grade, fixed income securities under an investment policy. All of our investments are classified as available-for-sale. All of our securities owned as of December 31, 2004 were in money market funds and are classified as cash equivalents. We believe that potential near-term losses in future earnings, fair values or cash flows related to our investment portfolio are not significant.

At December 31, 2004, our investment portfolio consisted of $8.1 million in money market funds. We currently do not hedge interest rate exposure. If market interest rates were to increase or decrease, the fair value of our portfolio would not be affected.

We are incurring market risk associated with the issuance of warrants to Kingsbridge to purchase 260,000 shares of our common stock. We will continue to calculate the fair value at the end of each quarter and record the difference to other income or expense until the warrants are exercised. We are incurring risk associated with increases or decreases in the market price of our common stock, which will directly impact the fair value calculation and the non-cash charge or credit recorded to the income statement in future quarters. For example, if our stock price increases by 20% during the first quarter of 2005 from its December 31, 2004 value, and all other inputs into the Black-Scholes model remained constant, we would record approximately $110,000 of other expense for the period ended March 31, 2005. If our stock price decreased by 20% from its value for the same periods, we would record approximately the same amount as other income.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and financial information required by Item 8 are set forth below on **pages F-1** through **F-35** of this report.

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

None.

ITEM 9A: CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2004. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures were effective as of December 31, 2004.

(b) Changes in Internal Controls

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

ITEM 9B: OTHER INFORMATION

None.

PART III

ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information required by this Item with respect to directors and compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the sections captioned "Election of Cellegy Directors" and "Compliance under Section 16(a) of the Securities Exchange Act of 1934" appearing in the definitive Proxy Statement to be filed no later than 120 days after the end of the 2004 fiscal year and to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held in June 2005 (the "2005 Proxy Statement"). 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 forthcoming 2005 Proxy Statement and is incorporated herein by reference.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information with respect to this Item may be found in the section captioned "Security Ownership of Certain Beneficial Owners and Management" appearing in the forthcoming 2005 Proxy Statement and is incorporated herein by reference.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information with respect to this Item may be found in the section captioned "Certain Relationships and Related Transactions" appearing in the 2005 Proxy Statement and is incorporated herein by reference.

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information with respect to this Item may be found in the section captioned "Principal Accountant Fees and Services" appearing in the 2005 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibits

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

Exhibit Number	Exhibit Title
2.1	Asset Purchase Agreement dated December 31, 1997 between the Company and Neptune Pharmaceutical Corporation. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-3, file no. 333-46087, filed on February 11, 1998, as amended.)
2.2	Agreement and Plan of Share Exchange dated as of October 7, 2004, by and between the Company and Biosyn, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed October 26, 2004.)
3.1	Amended and Restated Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 8-K filed with the Commission on September 3, 2004 (the "September 2004 8-K").)
3.2	Bylaws of the Company. (Incorporated by reference to Exhibit 3.2 to the September 2004 8-K.)
4.1	Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.1 to the September 2004 8-K.)
*10.1	1995 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.03 to the Company's Registration Statement on Form S-8, file no. 333-91588, filed on June 28, 2002.)
*10.2	Form of Option Agreement under the 1995 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.05 to the Company's Post-effective Amendment No. 1 to Registration Statement on Form S-8, file no. 333-91588, filed on September 7, 2004 (the "2004 Form S-8").)
*10.3	1995 Directors' Stock Option Plan. (Incorporated by reference to Exhibit 10.8 to the Company's Form 10-Q for the fiscal quarter ended filed June 30, 2002.)
*10.4	Form of option agreement under the 1995 Directors' Stock Option Plan. (Incorporated by reference to Exhibit 4.07 to the 2004 Form S-8.)
10.5	Sublease Agreement, dated as of March 18, 2005, by and between the Company and VaxGen, Inc.
*10.6	Employment Agreement, effective January 1, 2003, between the Company and K. Michael Forrest. (Incorporated by reference to Exhibit 10.6 to the Annual Report on Form 10-K for the year ended December 31, 2003 (the "2003 Form 10-K".))
10.7	Share Purchase Agreement dated as of November 27, 2001, by and among the Company, Vaxis Therapeutics Corporation and certain stockholders of Vaxis. (Incorporated by reference to Exhibit 10.14 to the Company's Form 10-K for the fiscal year ended December 31, 2001.)
10.8	Exclusive License Agreement dated as of December 31, 2002, by and between the Company and PDI, Inc. (Confidential treatment has been requested with respect to portions of this agreement.) (Incorporated herein by reference to Exhibit 10.10 to the Company's Form 10-K for the year ended December 31, 2002.)
10.9	Common Stock Purchase Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited. (Incorporated by reference to Exhibit 10.9 to the 2003 Form 10-K.)
10.10	Registration Rights Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited. (Incorporated by reference to Exhibit 10.10 to the 2003 Form 10-K.)
10.11	Warrant dated January 16, 2004 issued to Kingsbridge Capital Limited. (Incorporated by reference to Exhibit 10.11 to the 2003 Form 10-K.)

Exhibit Number	Exhibit Title
10.12	Retention and Severance Plan. (Incorporated by reference to Exhibit 10.01 to the Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2003.)
10.13	Form of Agreement of Plan Participation under Retention and Severance Plan. (Incorporated by reference to Exhibit 10.01 to the Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2003.)
*10.14	Letter agreement dated November 6, 2003 between Cellegy Pharmaceuticals, Inc. and Richard C. Williams. (Incorporated by reference to Exhibit 10.14 to the 2003 Form 10-K.)
*10.15	Stock option agreement dated November 6, 2003 between Cellegy Pharmaceuticals, Inc. and Richard C. Williams. (Incorporated by reference to Exhibit 10.15 to the 2003 Form 10-K.)
*10.16	Form of Indemnity Agreement between the Company and its directors and executive officers. (Incorporated by reference to Exhibit 10.16 to the 2003 Form 10-K.)
10.17	Registration Rights Agreement dated as of October 1, 2004 between the Company and certain former stockholders of Biosyn, Inc. (Incorporated by reference to Exhibit 10.1 to the Form 8-K filed October 26, 2004.)
*10.18	Employment agreement dated as of October 7, 2004, between the Company and Anne-Marie Corner.
10.19	Exclusive License Agreement for Tostrex dated as of July 9, 2004, by and between Strakan International Limited and the Company. (Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004. (Confidential treatment has been requested for portions of this agreement.))
10.20	Exclusive License and Distribution Agreement for Rectogesic dated as of December 9, 2004, by and between Strakan International Limited and the Company. (Confidential treatment has been requested for portions of this agreement.)
10.21	Agreement dated as of October 8, 1996 by and among Biosyn, Inc., Edwin B. Michaels and E.B. Michaels Research Associates, Inc. (Confidential treatment has been requested with respect to portions of this agreement.)
10.22	Patent License Agreement by and among Biosyn, Inc., and certain agencies of the United States Public Health Service. (Confidential treatment has been requested with respect to portions of this agreement.)
10.23	License Agreement dated as of May 22, 2001, by and between Crompton Corporation and Biosyn, Inc. (Confidential treatment has been requested for portions of this agreement.)
21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (See signature page.)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Represents a management contract or compensatory plan or arrangement.

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 Brisbane, State of California, on the 30 of March, 2005.

CELLEGY PHARMACEUTICALS, INC.

By: /s/ RICHARD C. WILLIAMS
Richard C. Williams
Chairman and Interim Chief Executive Officer

Power of Attorney

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

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

Name	Title	Date
Principal Executive Officer:		
/s/ RICHARD C. WILLIAMS Richard C. Williams	Chairman, Interim Chief Executive Officer and Director	March 30, 2005
Principal Financial Officer and Principal Accounting Officer:		
/s/ A. RICHARD JUELIS A. Richard Juelis	Vice President, Finance, Chief Financial Officer and Secretary	March 30, 2005
Directors:		
/s/ JOHN Q. ADAMS, SR. John Q. Adams, Sr.	Director	March 30, 2005
/s/ TOBI B. KLAR, M.D. Tobi B. Klar, M.D.	Director	March 30, 2005
/s/ ROBERT B. ROTHERMEL Robert B. Rothermel.	Director	March 30, 2005
/s/ THOMAS M. STEINBERG Thomas M. Steinberg	Director	March 30, 2005

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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

In our opinion, the consolidated financial statements listed in the index appearing under Item 8 present fairly, in all material respects, the financial position of Cellegy Pharmaceuticals, Inc. and its subsidiaries (a development stage company) at December 31, 2004 and December 31, 2003, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2004, and cumulatively, for the period from January 1, 2003 to December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. These consolidated 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 did not audit the cumulative totals of the Company for the period from June 26, 1989 (date of inception) to December 31, 2002, which totals reflect a deficit of 67.3 percent of the related total cumulative deficit accumulated during the development stage. Those cumulative totals were audited by other auditors whose report dated February 13, 2003, expressed an unqualified opinion on the cumulative amounts. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses from operations since its inception and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 28, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Cellegy Pharmaceuticals, Inc.

We have audited the accompanying consolidated statements of operations, stockholders' equity, and cash flows of Cellegy Pharmaceuticals, Inc. (a development stage company) for the year ended December 31, 2002, and for the period from June 26, 1989 (inception) through December 31, 2002 (not separately presented herein). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

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

/s/ Ernst & Young LLP

Palo Alto, California
February 13, 2003

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Balance Sheets

	December 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 8,705,120	$ 7,649,878
Short-term investments	—	3,686,919
Accounts receivable	885,810	158,476
Prepaid expenses and other current assets	282,184	349,647
Total current assets	9,873,114	11,844,920
Restricted cash	227,500	227,500
Property and equipment, net	1,952,408	1,891,726
Goodwill	1,031,311	1,009,973
Intangible assets	778,992	256,688
Other assets	—	100,000
Total assets	$ 13,863,325	$ 15,330,807
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,691,952	$ 779,796
Accrued expenses and other current liabilities	2,724,808	1,240,250
Current portion of deferred revenue	1,196,260	832,000
Total current liabilities	5,613,020	2,852,046
Long-term payables	717,257	724,560
Derivative instrument	410,800	—
Deferred revenue	13,865,064	13,334,660
Total liabilities	20,606,141	16,911,266
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock, no par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2004 and 2003	—	—
Common stock, par value $.0001; 50,000,000 shares authorized; 26,120,440 shares issued and outstanding at December 31, 2004; 20,045,000 shares issued and outstanding at December 31, 2003	2,612	97,293,984
Additional paid-in capital	120,253,688	—
Accumulated other comprehensive income	304,244	274,855
Deficit accumulated during the development stage	(127,303,360)	(99,149,298)
Total stockholders' deficit	(6,742,816)	(1,580,459)
Total liabilities and stockholders' deficit	$ 13,863,325	$ 15,330,807

The accompanying notes are an integral part of these financial statements.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Operations

	Years Ended December 31,			Period from June 26, 1989 (inception) to December 31,
	2004	2003	2002	2004
Revenues:				
Licensing and contract revenue from affiliates	$ —	$ —	$ —	$ 1,145,373
Licensing, milestone and development funding	844,044	833,340	—	3,228,792
Grants	1,007,500	18,833	45,798	1,574,466
Product sales	744,833	768,325	1,355,828	6,615,570
Total revenues	2,596,377	1,620,498	1,401,626	12,564,201
Costs and expenses:				
Cost of product sales	147,849	185,891	369,992	1,654,614
Research and development	9,599,310	10,558,174	10,403,214	81,774,868
Selling, general and administrative	6,641,205	4,768,529	6,389,847	38,360,330
Acquired in-process technology	14,981,816	—	—	22,331,918
Total costs and expenses	31,370,180	15,512,594	17,163,053	144,121,730
Operating loss	(28,773,803)	(13,892,096)	(15,761,427)	(131,557,529)
Interest and other income	258,693	359,948	547,961	6,845,355
Interest and other expense	(28,952)	—	(27,136)	(1,532,681)
Derivative revaluation	390,000	—	—	390,000
Net loss	(28,154,062)	(13,532,148)	(15,240,602)	(125,854,855)
Non-cash preferred dividends	—	—	—	1,448,505
Net loss applicable to common stockholders	$(28,154,062)	$(13,532,148)	$(15,240,602)	$(127,303,360)
Basic and diluted net loss per common share	$ (1.28)	$ (0.68)	$ (0.86)	
Weighted average common shares used in computing basic and diluted net loss per common share	22,020,689	19,963,552	17,642,640	

The accompanying notes are an integral part of these financial statements.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Stockholders' Equity (Deficit)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Issuance of convertible preferred stock, net of issuance cost through December 31, 2001	27,649	$ 6,801,730	—	$ —	477,081	$ 4,978,505	—	$ —	—	$—	$ —	$11,780,235
Issuance of Series A convertible preferred stock and warrants to purchase 14,191 shares of Series A convertible preferred stock in exchange for convertible promissory notes and accrued interest through December 31, 2001	625,845	1,199,536	—	—	—	—	—	—	—	—	—	1,199,536
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 2001	50,110	173,198	—	—	—	—	—	—	—	—	—	173,198
Issuance of Series B convertible preferred stock in exchange for convertible promissory notes	—	—	12,750	114,000	—	—	—	—	—	—	—	114,000
Non-cash preferred dividends	—	1,448,505	—	—	—	—	—	—	—	—	(1,448,505)	—
Conversion of preferred stock including dividends to common stock through December 31, 2001	(703,604)	(9,622,969)	(12,750)	(114,000)	(477,081)	(4,978,505)	3,014,644	14,715,474	—	—	—	—
Issuance of warrants in connecton with notes payable in financing	—	—	—	—	—	—	—	487,333	—	—	—	487,333
Issuance of common stock in connection with private placement of common stock in July, 1997, net of issuance costs	—	—	—	—	—	—	1,547,827	3,814,741	—	—	—	3,814,741

The accompanying notes are an integral part of these financial statements.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Stockholders' Equity (Deficit) (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Issuance of common stock in connection with the public offering of common stock in November 1997, net of issuance cost	—	—	—	—	—	—	2,012,500	13,764,069	—	—	—	13,764,069
Issuance of common stock in connection with the acquisition of Neptune Pharmaceuticals	—	—	—	—	—	—	462,809	3,842,968	—	—	—	3,842,968
Issuance of common stock in connection with IPO in Aug. 1995	—	—	—	—	—	—	1,322,500	6,383,785	—	—	—	6,383,785
Issuance of common stock for cash through December 31, 2001	—	—	—	—	—	—	953,400	126,499	—	—	—	126,499
Issuance of common stock for services rendered through December 31, 2001	—	—	—	—	—	—	269,115	24,261	—	—	—	24,261
Issuance of common stock in connection with the private placement of common stock in July 1999, net of issuance cost	—	—	—	—	—	—	1,616,000	10,037,662	—	—	—	10,037,662
Issuance of common stock in connection with the private placement of common stock in October 2000, net of issuance cost of $22,527	—	—	—	—	—	—	1,500,000	11,602,473	—	—	—	11,602,473
Repurchase of common shares in 1992	—	—	—	—	—	—	(3,586)	(324)	—	—	—	(324)
Issuance of common stock in exchange for notes payable	—	—	—	—	—	—	42,960	268,500	—	—	—	268,500
Fair value of warrants issued in Quay acquisition	—	—	—	—	—	—	—	489,477	—	—	—	489,477
Compensation expenses related to the extension of option exercise periods	—	—	—	—	—	—	—	338,481	—	—	—	338,481
Common stock issued in connection with Quay acquisition	—	—	—	—	—	—	169,224	977,105	—	—	—	977,105
Exercise of options to purchase common stock through December 31, 2001	—	—	—	—	—	—	432,377	1,545,728	—	—	—	1,545,728

The accompanying notes are an integral part of these financial statements.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Stockholders' Equity (Deficit) (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Exercise of warrants to purchase common stock through December 31, 2001	—	—	—	—	—	—	571,086	966,479	—	—	—	966,479
Compensation expense related to options and warrants issued to non-employees through December 31, 2001	—	—	—	—	—	—	—	951,263	—	—	—	951,263
Issuance of common stock in connection with the public offering of common stock in June 2001, net of issuance costs of $184,795	—	—	—	—	—	—	2,747,143	15,199,206	—	—	—	15,199,206
Issuance of common stock in connection with Vaxis acquisition	—	—	—	—	—	—	533,612	3,852,631	—	—	—	3,852,631
Issuance of common stock in connection with the achievement of Neptune milestones	—	—	—	—	—	—	104,113	750,000	—	—	—	750,000
Components of comprehensive loss												
Unrealized gain/(loss) on investments through December 31, 2001	—	—	—	—	—	—	—	—	—	103,385	—	103,385
Gain/(loss) on foreign currency translation through December 31, 2001	—	—	—	—	—	—	—	—	—	(19,927)	—	(19,927)
Net loss through December 31, 2001	—	—	—	—	—	—	—	—	—	—	(68,928,043)	(68,928,043)
Total Comprehensive Loss through December 31, 2001	—	—	—	—	—	—	—	—	—	—	—	(68,844,585)
Balances at December 31, 2001	—	—	—	—	—	—	17,295,724	90,137,811	—	83,458	(70,376,548)	19,844,721
Exercise of options to purchase common stock	—	—	—	—	—	—	156,632	454,983	—	—	—	454,983
Issuace of common stock in connection with the private placement of common stock in November 2002, net of issuance costs of $275,000	—	—	—	—	—	—	2,200,000	5,225,000	—	—	—	5,225,000
Compensation expense related to option modifications	—	—	—	—	—	—	—	249,746	—	—	—	249,746
Compensation expense for options related to non-employees	—	—	—	—	—	—	—	72,224	—	—	—	72,224
Components of comprehensive loss												
Unrealized gain/(loss) on investments	—	—	—	—	—	—	—	—	—	(82,916)	—	(82,916)
Gain/(loss) on foreign currency translation	—	—	—	—	—	—	—	—	—	11,289	—	11,289
Net loss	—	—	—	—	—	—	—	—	—	—	(15,240,602)	(15,240,602)
Total Comprehensive Loss	—	—	—	—	—	—	—	—	—	—	—	(15,312,229)
Balances at December 31, 2002	—	—	—	—	—	—	19,652,356	96,139,764	—	11,831	(85,617,150)	10,534,445

The accompanying notes are an integral part of these financial statements.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Stockholders' Equity (Deficit) (Continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Exercise of options to purchase common stock	—	—	—	—	—	—	273,196	537,700	—	—	—	537,700
Compensation expense for options related to non-employees	—	—	—	—	—	—	—	153,784	—	—	—	153,784
Issuance of shares to CEO upon renewal of employment contract	—	—	—	—	—	—	107,118	425,000	—	—	—	425,000
Issuance of common stock for services	—	—	—	—	—	—	12,330	50,000	—	—	—	50,000
Financing fees	—	—	—	—	—	—	—	(12,264)	—	—	—	(12,264)
Components of comprehensive loss												
Unrealized gain/(loss) on investments	—	—	—	—	—	—	—	—	—	(424)	—	(424)
Gain/(loss) on foreign currency translation	—	—	—	—	—	—	—	—	—	263,448	—	263,448
Net loss	—	—	—	—	—	—	—	—	—	—	(13,532,148)	(13,532,148)
Total Comprehensive Loss	—	—	—	—	—	—	—	—	—	—	—	(13,269,124)
Balances at December 31, 2003	—	—	—	—	—	—	20,045,000	97,293,984	—	274,855	(99,149,298)	(1,580,459)
Conversion of common stock to shares with 0.0001 par value	—	—	—	—	—	—		(97,291,979)	97,291,979	—	—	—
Exercise of options to purchase common stock	—	—	—	—	—	—	142,174	14	303,815	—	—	303,829
Compensation expense for options related to non-employees	—	—	—	—	—	—	—	—	28,288	—	—	28,288
Compensation expense related to option modifications	—	—	—	—	—	—	—	—	80,860	—	—	80,860
Issuance of common stock and warrants in connection with the private placement of common stock in July 2004, net of issuance cost of $57,480	—	—	—	—	—	—	3,020,000	302	10,310,402	—	—	10,310,704
Kingsbridge drawdown, net of issuance cost of $116,192	—	—	—	—	—	—	246,399	25	843,043	—	—	843,068
Derivative instrument in connection with Kingsbridge warrants		—	—						(800,800)			(800,800)
Issuance of common stock in connection with the achievement of Neptune milestones	—	—	—	—	—	—	204,918	20	749,980	—	—	750,000
Shares issued in connection with the Biosyn acquisition	—	—	—	—	—	—	2,461,949	246	10,478,026	—	—	10,478,272
Options issued in connection with the Biosyn acquisition	—	—	—	—	—	—	—	—	968,095	—	—	968,095
Components of comprehensive loss												
Gain/(loss) on foreign currency translation	—	—	—	—	—	—	—	—	—	29,389	—	29,389
Net loss	—	—	—	—	—	—	—	—	—	—	(28,154,062)	(28,154,062)
Total Comprehensive Loss	—	—	—	—	—	—	—	—	—	—	—	(28,124,673)
Balances at December 31, 2004	—	—	—	—	—	—	26,120,440	$ 2,612	$120,253,688	$304,244	$(127,303,360)	$ (6,742,816)

The accompanying notes are an integral part of these financial statements.

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Cash Flows

	Years ended December 31,			Period from June 26, 1989 (inception) to December 31,
	2004	2003	2002	2004
Operating activities				
Net loss	$(28,154,062)	$(13,532,148)	$(15,240,602)	$(125,854,855)
Adjustments to reconcile net loss to net cash provided by (used in) operating activties:				
Acquired in-process technology	14,981,816	—	—	22,331,918
Depreciation	415,078	373,507	484,028	3,017,701
Intangible assets amortization	164,066	193,409	325,644	1,341,143
Loss (gain) on sale of fixed assets	30,710	666,875	(86,476)	611,109
Equity compensation expense	109,149	578,784	321,970	2,299,648
Derivative revaluation	(390,000)	—	—	(390,000)
Amortization of discount on notes payable and deferred financing costs	—	—	—	24,261
Issuance of common stock for services	—	50,000	—	1,040,918
Issuance of common stock for services rendered, interest and Neptune milestones	750,000	—	—	1,317,503
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	142,077	(3,566)	56,096	(305,404)
Accounts receivable	(398,900)	72,833	172,936	(590,464)
Other assets	—	—	250,000	250,000
Accounts payable	(285,952)	720,061	(307,112)	390,926
Other long term liabilities	(261,807)	—	231,793	454,812
Deferred revenue	476,075	(832,000)	13,000,000	14,644,075
Accrued expenses and other current liabilities	(1,179,173)	(1,057,540)	397,449	(65,326)
Net cash provided by operating activities	(13,600,923)	(12,769,785)	1,605,726	(79,482,035)
Investing activities				
Purchases of property and equipment	(203,988)	(362,335)	(733,175)	(5,403,743)
Purchases of investments	—	(11,019,220)	—	(98,909,574)
Sale of investments	—	5,334,000	6,706,769	43,509,646
Maturity of investments	3,686,919	4,000,000	2,000,000	55,304,678
Proceeds from sale of property	—	50,337	187,337	237,674
Acquisition of Vaxis, Quay and Biosyn	(303,966)	—	—	(815,522)
Net cash provided by (used in) investing activities	3,178,965	(1,997,218)	8,160,931	(6,076,841)
Financing activities				
Proceeds from notes payable	—	—	—	8,047,424
Proceeds from restricted cash	—	—	386,499	386,499
Repayment of notes payable	—	—	—	(6,610,608)
Net proceeds from issuance of common stock	11,457,601	525,436	5,679,983	81,094,588
Other assets	—	—	—	(613,999)
Issaunce of convertible preferred stock, net of issuance cost	—	—	—	11,757,735
Deferred financing costs	—	—	—	(80,170)
Net cash provided by (used in) financing activities	11,457,601	525,436	6,066,482	93,981,469
Effect of exchange rate changes on cash	19,599	262,928	—	282,527
Net increase (decrease) in cash and cash equivalents	1,055,242	(13,978,639)	15,833,139	8,705,120
Cash and cash equivalents, beginning of period	7,649,878	21,628,517	5,795,378	—
Cash and cash equivalents, end of period	$ 8,705,120	$ 7,649,878	$ 21,628,517	$ 8,705,120

The accompanying notes are an integral part of these financial statements

Celegy Pharmaceuticals, Inc.
(a development stage company)

Consolidated Statements of Cash Flows (Continued)

	Years ended December 31,			Period from June 26, 1989 (inception) to December 31,
	2004	2003	2002	2004
Supplemental cash flow information				
Interest paid	$ —	$ —	$27,136	$ 639,987
Supplemental disclosure of non-cash transactions:				
Issuance of common stock in connection with acquired-in-process technology	—	—	—	7,350,102
Conversion of preferred stock to common stock	—	—	—	14,715,474
Issuance of common stock for notes payable	—	—	—	277,250
Issuance of warrants in connection with Kingsbridge financing	800,800	—	—	800,800
Issuance of warrants in connection with notes payable financing	—	—	—	487,333
Issuance of convertible preferred stock for notes payable	—	—	—	1,268,316
Issuance of common stock for milestone payments	750,000	—	—	1,500,000
Fair value of assets acquired net of liabilities assumed for Biosyn acquisition	11,856,000	—	—	11,856,000

The accompanying notes are an integral part of these financial statements

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements

1. Accounting Policies

Description of Business and Principles of Consolidation

The consolidated financial statements include the accounts of Cellegy Pharmaceuticals, Inc. and its wholly owned subsidiaries, Biosyn, Inc. ("Biosyn"), Cellegy Australia Pty, Ltd. and Cellegy Canada, Inc. (collectively the "Company" or "Cellegy"). Biosyn was acquired on October 22, 2004. Biosyn's results were included in consolidation from its date of acquisition. All inter-company balances and transactions have been eliminated in consolidation.

Cellegy is a development stage specialty biopharmaceutical company, originally incorporated in California in 1989 and reincorporated in Delaware in 2004, that develops and intends to commercialize prescription drugs targeting primarily women's health care, including the reduction in transmitting of HIV, female sexual dysfunction and gastrointestinal conditions using proprietary topical formulations and nitric oxide donor technologies. In October 2004, Cellegy completed the acquisition of Biosyn which is developing a portfolio of proprietary product candidates known as microbicides that are used intravaginally to reduce transmission of sexually transmitted diseases, or STDs, including HIV/AIDS. Biosyn's product candidates, which include both contraceptive and non-contraceptive microbicides, include Savvy® (C31G vaginal gel), which is undergoing Phase 3 clinical trials in the United States and Africa; UC-781 vaginal gel, in Phase 1 trials; and Cyanovirin-N, in pre-clinical development.

The Company's other products under development, Cellegesic™ (nitroglycerin ointment) for the treatment of anal fissures and hemorrhoids, and Fortigel™ (testosterone gel), a replacement therapy for male hypogonadism, have not yet been approved for marketing by the United States FDA. However, Cellegesic is currently approved for marketing in Australia, New Zealand, Singapore and South Korea under the brand name Rectogesic®. The product has also been approved by the United Kingdom's Medicines and Healthcare Products Regulatory Agency in August 2004 for sale in the United Kingdom. Fortigel was approved by the Swedish Medical Products Agency in December 2004 for the treatment of male hypogonadism under the brand name Tostrex. In addition to pharmaceutical products, Cellegy also manufactures and sells skin care product ingredients to the product development division of a major specialty retailer.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. At December 31, 2004, the Company had a deficit accumulated during the development stage of $127.3 million and recurring, negative cash flows from operations. The Company expects negative cash flow from operations to continue for at least the next two years, with the need to continue or expand development programs and to commercialize products once regulatory approvals have been obtained. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is presently considering financing and corporate options to fund its operations for 2005 and 2006. These options include, but are not limited to: further Kingsbridge Capital Limited Structured Secondary Offering, or SSO, draw downs, seeking partnerships with other pharmaceutical companies to co-develop and fund research and development efforts, pursue additional out-licensing arrangements with third parties, re-licensing and monetizing near term future milestone and royalty payments expected from existing licensees. In addition, the Company will continue to implement further cost reduction programs. There is no assurance that any of the above options will be implemented on a

1. Accounting Policies (Continued)

timely basis. Alternatively, Cellegy may be required to accept less than favorable commercial terms in any such future arrangements.

If adequate funds are not available, the Company could be required to delay development or commercialization of certain products, to license to third parties the rights to commercialize certain products that the Company would otherwise seek to commercialize internally, or to reduce resources devoted to product development. Accordingly, the failure of the Company to obtain sufficient funds could have a material adverse effect on the Company's business, results of operations and financial condition. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

Revenues related to cost reimbursement provisions under development contracts are recognized as the costs associated with the projects are incurred. Revenues related to substantive and at risk non-refundable milestone payments specified under development contracts are recognized as the milestones are achieved. The Company receives certain government and non-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. Advanced payments received under these agreements prior to completion of the related work are recorded as deferred revenue until earned. Should the research funded by federal grants result in patented technologies, the federal government would be entitled to a nonexclusive, nontransferable, irrevocable, paid-up license to utilize such technologies.

At December 31, 2004, $833,630 of grants receivable under research and development agreements were unbilled. These amounts represent future billings by the Company for reimbursement of expenses funded by grants previously recorded in grant revenue. There were no unbilled grants at December 31, 2003.

Revenues related to product sales are recognized when title has been transferred to the customer and when all of the following criteria are met: a persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured. There is no right of return for our products.

Revenues under license and royalty agreements are recognized in the period the earnings process is completed based on the terms of the specific agreement. Advanced payments received under these agreements are recorded as deferred revenue at the time the payment is received and are subsequently

1. Accounting Policies (Continued)

recognized as revenue on a straight-line basis over the longer of the life of the agreement or the life of the underlying patent.

Royalties payable to Cellegy under these license agreements will be recognized as earned when the royalties are no longer refundable under certain minimum royalty terms defined in the agreement. The various licensing agreements currently in effect are described in Note 13.

Research and Development

Research and Development expenses, which include clinical study payments made to clinical sites and clinical research organizations, consulting fees, expenses associated with regulatory filings and internally allocated expenses such as rent, supplies and utilities are charged to expense as they are incurred. Clinical study expenses are accrued based upon such factors as the number of subjects enrolled and number of subjects that have completed treatment for each trial.

Milestone payments that are made upon the occurrence of future contractual events prior to receipt of applicable regulatory approvals are charged to research and development expense. The Company may capitalize and amortize certain future milestones and other payments subsequent to the receipt of applicable regulatory approvals, if any.

Cash and Cash Equivalents

Cash and cash equivalents consist of demand deposits and 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, 2004 and 2003. The Company's cash and cash equivalents are maintained at three financial institutions in the United States, one financial institution in Australia and one financial institution in Canada. Deposits in these financial institutions may, from time to time, exceed federally insured limits.

Short Term Investments

The Company considers all of its investments as available-for-sale securities and reports these investments at their estimated fair market value using available market information. Unrealized gains or losses on available-for-sale securities are included in stockholders' deficit as other comprehensive income (loss) until their disposition. The cost of securities sold is based on the specific identification method.

Realized gains or losses and declines in value deemed to be other than temporary on available-for-sale securities are included in other income or expense.

Restricted Cash

Cash held by financial institutions to secure a letter of credit related to the Company's long-term lease (see Note 10) is classified as restricted cash and is shown separately in the balance sheet as a non-current asset. Restricted cash at December 31, 2004 and 2003 was $227,500.

Concentration of Credit Risk

At December 31, 2004, the Company has all of their excess cash in money market funds and have no short or long-term investments.

1. Accounting Policies (Continued)

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets.

	Estimated Useful Life
Furniture and fixtures	3 years
Office equipment	3 years
Laboratory equipment	5 years

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

Goodwill and Intangible Assets

Goodwill and intangible assets are included in our December 31, 2004 balance sheet. Management reviews goodwill for impairment either on an annual basis or quarterly if an event occurs that might reduce the fair value of the long-lived asset below its carrying value. All other long-lived and intangible assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount of the asset may not be recoverable. An impairment loss would be recognized based on the difference between the carrying value of the asset and its estimated fair value, which would be determined based on either discounted future cash flows or other appropriate fair value methods. The evaluation of goodwill and other intangibles for impairment requires management to use significant judgments and estimates including, but not limited to, projected future revenue, operating results and cash flows.

Although management currently believes that the estimates used in the evaluation of goodwill and other intangibles are reasonable, differences between actual and expected revenue, operating results and cash flow could cause these assets to be deemed impaired. Based on management's analysis, no impairment was deemed to have occurred through December 31, 2004. If an impairment were to occur, Cellegy would be required to charge to earnings the write-down in value of such assets.

SFAS No. 142 also requires that intangible assets with definite lives be amortized over their estimated useful lives. The Company currently amortizes assets on a straight-line basis over their estimated useful lives. Amortization recorded for the year ended December 31, 2004, 2003 and 2002 were approximately $111,000, $176,000 and $326,000, respectively (see Note 4).

Impairment of Long Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in business conditions indicate that these carrying values may not be recoverable in the ordinary course of business. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset.

1. Accounting Policies (Continued)

Derivative Instruments

Cellegy accounts for the warrants issued in January 2004, in conjunction with the Structured Secondary Offering, or SSO, agreement with Kingsbridge Capital Ltd., as a derivative financial instrument. As a derivative, the fair value of the warrant is recorded as a liability in the balance sheet and changes in the fair value of the warrant are recognized as other income or expense during each period. The fair value of the warrant is expected to change primarily in response to changes in the Company's stock price. Significant increases in the fair value of the Company's stock could give rise to significant expense in the period of the change. Likewise, a reduction in the Company's stock price could give rise to significant income in the period of the change (see Note 8).

The Company is subject to market risk associated with the issuance of warrants to Kingsbridge Capital to purchase 260,000 shares of our common stock, as more fully described in Note 8. The Company will continue to calculate the fair value at the end of each quarter and record the difference to other income or expense until the warrants are exercised.

Reclassification

Certain prior year balances have been reclassified to conform to current year presentation. Prior year's accounts receivable was included in prepaid expenses and other current assets. Accounts payable, accrued expenses and other payables were combined under two separate current liability accounts. Balances within the statement of cash flows have been reclassed to adjust for the effect of exchange rate changes on cash. There is no impact on working capital or the statement of operations as a result of these reclassifications.

Foreign Currency Translation

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

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' deficit except those resulting from investments or contributions by stockholders. The Company's unrealized gains and losses on available-for-sale securities and foreign currency translation adjustments represent the only components of comprehensive loss that are excluded from the Company's net loss. Total accumulated other comprehensive income consists of the following:

	December 31,		
	2004	2003	2002
Gain (loss) on foreign exchange translation	$284,199	$254,810	$ (8,638)
Unrealized gain (loss) on investments	20,045	20,045	20,469
Accumulated other comprehensive income (loss) ..	$304,244	$274,855	$11,831

1. Accounting Policies (Continued)

Stock-Based Compensation

The Company accounts for its stock option grants in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related Interpretations. The Company has elected to follow the disclosure-only alternative prescribed by SFAS No. 123, "Accounting for Stock-Based Compensation", as amended by SFAS No. 148 "Accounting for Stock-Based Compensation-Transition and Disclosure". Under APB 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company's common stock and the option's exercise price.

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

	Years ended December 31,		
	2004	2003	2002
Net loss, as reported	$(28,154,062)	$(13,532,148)	$(15,240,602)
Add: Stock based employee costs included in reported net loss	80,860	425,000	249,746
Deduct: Stock-based employee compensation costs determined under the fair value based method for all awards	(790,518)	(1,839,447)	(2,227,933)
Net loss, pro forma	$(28,863,720)	$(14,946,595)	$(17,218,789)
Basic and diluted net loss per common share, as reported	$ (1.28)	$ (0.68)	$ (0.86)
Basic and diluted net loss per common share, pro forma	$ (1.31)	$ (0.75)	$ (0.98)

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

	Years ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.6%	2.9%	2.5%
Dividend yield	0%	0%	0%
Volatility	0.86	0.98	1.06
Expected life of options in years	4.3	4.3	4.3

The weighted average per share grant date fair value of options granted during the years ended December 31, 2004, 2003, and 2002 was $4.37, $3.28 and $3.80 respectively.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Under EITF Issue No. 96-18, the fair value of the equity instrument is calculated using the Black-Scholes valuation model at each reporting period with charges amortized to the results of operations over the instrument's vesting period.

1. Accounting Policies (Continued)

Recent Accounting Pronouncement

In December 2004, the FASB issued SFAS No. 123R, "Share-Based Payment", which replaces SFAS No. 123. SFAS No. 123R requires public companies to recognize an expense for share-based payment arrangements including stock options and employee stock purchase plans. The statement eliminates a company's ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair value based method. SFAS No. 123R requires an entity to measure the cost of employee services received in exchanged for an award of equity instruments based on the fair value of the award on the date of the grant, and to recognize the cost over the period during which the employee is to provide service in exchange for the award. SFAS No. 123R is effective for the Company in the quarter ending September 30, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. Upon adoption of SFAS No. 123R, companies are allowed to select one of three alternative transition methods. Management is currently evaluating the transition methods, as well as valuation methodologies and assumptions for employee stock options in light of SFAS No. 123R. Current estimates of option values using the Black-Scholes method (as shown under "Stock Based Compensation") may not be indicative of results from valuation methodologies ultimately implemented by the Company upon adoption of SFAS No. 123R.

Basic and Diluted Net Loss per Common Share

Basic net loss per common share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per common share incorporates the incremental shares issued upon the assumed exercise of stock options and warrants, when dilutive. There is no difference between basic and diluted net loss per common share, as presented in the statement of operations, because all options and warrants are anti-dilutive. The total number of shares that had their impact excluded were:

	Years ended December 31,		
	2004	2003	2002
Options	4,345,777	4,198,216	4,254,992
Warrants	945,869	—	300,000
Total number of shares excluded	5,291,646	4,198,216	4,554,992

2. Accounts Receivable

Accounts receivable consists of the following:

	Years ended December 31,	
	2004	2003
Unbilled grants receivable	$833,630	$ —
Trade receivables	26,036	34,651
Other receivables	26,144	123,825
Total	$885,810	$158,476

3. Short-term Investments

At December 31, 2004, the Company had no investments. At December 31, 2003, investments consisted of the following:

	2003		
	Cost	Gross Unrealized Gains	Fair Value
Corporate notes	$3,686,800	$119	$3,686,919

4. Intangible Assets, net

The Company's intangible assets and related accumulated amortization at December 31, 2004 and December 31, 2003, respectively, were as follows:

	December 31, 2004			December 31, 2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Capitalized non-compete agreement with Vaxis	$ 463,544	$(293,578)	$169,966	$400,280	$(143,592)	$256,688
Capitalized workforce—Biosyn acquisition	635,504	(26,478)	609,026	—	—	—
	$1,099,048	$(320,056)	$778,992	$400,280	$(143,592)	$256,688

The amortization periods of the Company's intangible assets are as follows:

Capitalized non-compete agreement with Vaxis	5 years
Capitalized work force—Biosyn acquisition	4 years

The aggregate amortization expense for the year ended December 31, 2004 and estimated amortization expense for each of the four years ended December 31, 2005 through 2008 is as follows:

Aggregate amortization expense:	
For the twelve months ended December 31, 2004	$111,000
Estimated future amortization expense:	
For the twelve months ended December 31:	
2005	$247,000
2006	$240,000
2007	$159,000
2008	$132,000

5. Property and Equipment, net

Property and equipment, net consist of the following:

	Years ended December 31,	
	2004	2003
Furniture and fixtures	$ 199,202	$ 185,815
Office equipment	261,718	238,550
Laboratory equipment	1,296,113	874,753
Leasehold improvements	2,081,313	2,063,636
	3,838,346	3,362,754
Less: accumulated depreciation and amortization	(1,885,938)	(1,471,028)
Total	$ 1,952,408	$ 1,891,726

Depreciation expense for the years ended December 31, 2004 and 2003 was $420,000 and $370,000, respectively.

6. Long-Term Payables

Included in long-term payables is our assumed obligation to a non-profit economic development corporation, which is recorded at its estimated fair value $130,000 and a capital lease obligation of $56,000 (see Note 10), each of which was assumed by Cellegy in connection with its acquisition of Biosyn. The long-term obligation of $130,000 represents the fair value of an assumed obligation for funds received by Biosyn from a non-profit economic development corporation from 1989 through 1993. The repayment terms of the non-interest bearing obligation include the remittance of an annual fixed percentage of 3% applied to future revenues of Biosyn, if any, until the principal balance of $777,902 is satisfied. Under the terms of the obligation, "revenues" are defined to exclude the value of unrestricted research and development funding received by Biosyn from non-profit sources. There is no obligation to repay the amounts in the absence of future Biosyn revenues. The Company will accrete the discount of $647,902 to earnings using the interest rate method over the discount period of five years, which was estimated in connection with the note's valuation at the time of the acquisition.

7. Accrued Expenses and Other Current Liabilities

The Company accrues for goods and services received but for which billings have not been received. Accrued expenses and other current liabilities at December 31, 2004 and 2003 were as follows:

	Years ended December 31,	
	2004	2003
Accrued clinical expenses	$ 612,937	$ 667,344
Accrued legal fees	453,953	$ 282,782
Accrued employee bonuses	507,723	121,695
Accrued consulting fees	339,142	18,643
Other	811,053	149,786
Total	$2,724,808	$1,240,250

8. Derivative Instrument

In January 2004, the Company entered into a Structured Secondary Offering, or SSO, agreement with Kingsbridge Capital Limited The agreement requires Kingsbridge to purchase up to 3.74 million shares of newly issued common stock at times and in amounts selected by Cellegy over a period of up to two years, subject to certain restrictions. The warrants issued in connection with the Kingsbridge SSO qualify as a non-hedge derivative instrument, due to liquidating damages provisions included in the warrant agreement in the event the Company fails to maintain an effective registration statement. This derivate instrument has been valued based on a Black-Scholes model. The factors used to perform Black-Scholes calculation were the following: volatility of 94%, risk free interest rate of 2.86%, dividend yield of 0% and the closing stock price of $4.39 at January 21, 2004, the date of the agreement. The fair value of $800,800 was recorded as a liability upon the warrants issuance in January 2004. The derivative instrument will be revalued at each reporting period, as long as it remains outstanding, with the changes in the estimated fair value recorded in other income or expense in the income statement. For year ended December 31, 2004, the Company recognized $390,000 in derivative revaluation income in the income statement related to changes in the valuation of the warrants. The fair value of this derivative instrument at December 31, 2004 is $410,800.

9. Deferred Revenue

Current and long-term deferred revenue totaling $15.1 million at December 31, 2004 and $14.2 million at December 31, 2003 represents the remaining unamortized and unearned portion of upfront licensing fees received from licensees for the right to store, promote, sell and /or distribute the Company's products. These amounts are being amortized into income over the life of the licensing agreement or the life of the patent for the product being licensed, whichever is longer. The various licensing agreements currently in effect are described in Note 13.

10. Commitments and Contingencies

Operating Leases

The Company leases its facilities and certain equipment under non-cancelable operating leases. Rent expense is recorded on a straight-line basis over the term of the lease. During the third quarter of 2002, the Company subleased a portion of its facility. Rental income is recorded on a straight-line basis over the term of the sublease. Future minimum lease payments, net of future minimum sublease income at December 31, 2004, are as follows:

Years ended December 31,	Lease Commitments	Sublease Income	Future Minimum Lease Commitments
2005	$1,562,402	$(1,211,451)	$ 350,951
2006	1,590,191	(1,247,795)	342,396
2007	1,608,616	(1,285,228)	323,388
2008	1,626,117	(1,099,341)	526,776
Total	$6,387,326	$(4,843,815)	$1,543,511

Rent expense, net of sublease income, was $382,000, $336,000, and $892,000 for the years ended December 31, 2004, 2003, and 2002, respectively. The Company received $149,000, $148,000 and $405,000 in sublease income, which is reflected in other income (expense), during the year ended December 31, 2004, 2003 and 2002, respectively.

10. Commitments and Contingencies (Continued)

Restricted cash at December 31, 2004 and 2003 was $227,500 and represents an amount that secures a letter of credit related to the lease for the Company's facilities in South San Francisco, California.

Capital Leases

Included in property, plant and equipment is laboratory equipment and computer equipment under long-term leases of $107,000, with related accumulated depreciation of $830 which included an option to purchase the assets for a nominal cost at the termination of the lease. There were no capital lease assets and amortization expenses prior to the Biosyn acquisition. Future minimum lease payments for assets under capital leases at December 31, 2004 are as follows:

Years ended December 31:	
2005	$ 56,000
2006	48,000
2007	16,000
Total minimum lease payments	120,000
Less amount representing interest	20,000
Present value of minimum lease payments	100,000
Less current maturities	44,000
Long-term obligation	$ 56,000

Other Agreements

In December 1997, the Company acquired patent and related intellectual property rights relating to Cellegesic, a topical product candidate for the treatment of anal fissures and hemorrhoids from Neptune Pharmaceuticals Corporation. The agreement calls for a series of additional payments, payable in shares of common stock, upon successful completion of various development milestones. Upon completion of certain milestones in 2001 and 2004, the Company issued 104,113 and 204,918 shares of common stock, respectively, valued at $750,000 for each of those milestones. These were charged to research and development expense. The remaining milestones, if achieved, would become payable over the next several years.

On November 27, 2001, Cellegy acquired Vaxis Therapeutics Corporation ("Vaxis"), a private Canadian company. The Vaxis purchase agreement contains earn-out provisions through 2008 that are based on commercial sales of any products developed by the Company or other revenues generated from the acquired research. There have been no earn-out payments made under this agreement through December 31, 2004.

Legal Proceedings

In December 2002, Cellegy entered into an exclusive license agreement with PDI, Inc., or PDI, to commercialize Fortigel in North American markets. Under the terms of the agreement, PDI's Pharmaceutical Products Group is responsible for the marketing and sale of Fortigel, if approved, utilizing its existing sales and marketing infrastructure. Cellegy received a payment of $15.0 million upon signing the agreement and is entitled to receive a milestone payment on FDA approval and royalties following a successful product launch. Cellegy is responsible for supplying finished product to PDI through Cellegy's

10. Commitments and Contingencies (Continued)

contract manufacturer. In July 2003, the FDA issued a Not Approvable letter for the Company's Fortigel NDA. In October 2003, Cellegy announced that it received a mediation notice from PDI. The dispute resolution provisions of the license agreement require non-binding mediation before either party may initiate further legal proceedings.

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

In December 2003, Cellegy and PDI both initiated legal proceedings against each other relating to the agreement. Cellegy filed a declaratory judgment action in federal district court in San Francisco against PDI, and PDI initiated an action in federal district court in New York against Cellegy. In its action, Cellegy seeks, among other things, a declaration that it has fully complied with the license agreement and that PDI's claims are without merit. There can be no assurances regarding the outcome of proceedings. Trial is currently scheduled to take place during the second quarter of 2005. The Company has been and may continue to devote significant time and resources to the proceedings, and an adverse outcome could have a material adverse impact on its business and financial position. Such potential loss is not estimable at this time.

11. 401(k) Plan

The Company maintains a savings and retirement plan under Section 401(k) of the Internal Revenue Code. All employees are eligible to participate on their first day of employment with the Company. Under the plan, employees may contribute up to 15% of salaries per year subject to statutory limits. The Company provides a matching contribution equal to 25% of the employee's rate of contribution, up to a maximum contribution rate of 4% of the employee's annual salary. Expenses related to the plan for the years ended December 31, 2004, 2003 and 2002 were not significant.

12. Acquisitions

Biosyn Acquisition

On October 22, 2004, Cellegy completed its 100% acquisition of Biosyn, developer of a contraceptive gel product for the reduction in transmission of HIV/AIDS in women. The acquisition both compliments Cellegy's womens's health care focus and expands the product pipeline to include products for the reduction in transmission of HIV and other sexually transmitted diseases. The acquisition was accounted for as an acquisition of assets as the operations of Biosyn did not meet the definition of a business as defined in Emerging Issues Task Force Issue No. 98-3 "Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business". Assets acquired and liabilities assumed were recorded at their estimated fair values. The value of the merger consideration, including certain acquisition and closing costs, exceeded the fair value of the net assets acquired. In accordance with paragraph 9 of Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets", such excess was allocated among the relative fair values of the assets acquired. Amounts allocated to identifiable intangible assets are amortized over their estimated useful lives. Amounts allocated to purchased research and development were expensed immediately. Under the terms

12. Acquisitions (Continued)

of the acquisition, 12,000 preferred shares and 5,031,267 shares of Biosyn common stock outstanding at the closing of the acquisition were exchanged for approximately 2,462,000 shares of Cellegy's common stock. In addition, outstanding Biosyn stock options and warrants were assumed by Cellegy and converted into options and warrants to purchase 318,504 shares of Cellegy common stock. The options issued to acquire Cellegy common stock are fully vested and exercisable. The exercise prices of the options and warrants were adjusted by the exchange ratio in the transaction. The expiration date and other terms of the converted options and warrants remain the same.

The purchase price is as follows:

Issuance of Cellegy common stock	$10,478,000
Value of replacement options and warrants to acquire Cellegy common stock	968,000
Transaction costs	410,000
Total purchase price	$11,856,000

The total purchase price above does not include any provisions for contingent milestone payments of up to $15.0 million, which would be payable to Biosyn shareholders on the achievement of C31G marketing approval in the United States and a portion of which will be payable upon commercial launch in major overseas markets.

The fair value of the Cellegy shares used in determining the purchase price was $4.26 per common share. The fair value of the converted options and warrants issued by Cellegy was determined using the Black-Scholes option pricing model assuming a market price of $4.26 per share, exercise prices ranging from $0.06 to $21.02 per share and averaging $5.89 per share, expected lives ranging from 0.2 to 4.3 years and averaging 3.7 years, risk free interest rates ranging from 1.50% to 3.36% and averaging 3.13%, and volatility ranging from 27% to 92% and averaging 77%.

The allocation of purchase price at the acquisition date of October 22, 2004 is as follows:

Current assets	$ 300,000
Property and equipment	299,000
Acquired work force	635,000
Purchased research and development	14,982,000
Current liabilities	(4,225,000)
Long term debt and capital leases	(135,000)
Net assets	$11,856,000

The purchase price allocation was based on the estimated fair values of the assets and liabilities assumed at the date of the closing of the acquisition.

The results of the valuation of the purchased research and development was $17.0 million using primarily the income approach and applying risk-adjusted discount rates to the estimated future revenues and expenses attributable to in-process drug development programs. The most significant in-process program relates primarily to the development of a microbacidal vaginal gel, which may have the potential to prevent HIV / AIDS and other sexually transmitted diseases in women. This product candidate, called

12. Acquisitions (Continued)

Savvy® (C31G vaginal gel) has an estimated fair value of $15.4 million. Two other development programs, called UC-781 and Cyanovirin-N, have a combined estimated fair value of $1.6 million. The in-process C31G program requires significant additional scientific and clinical testing, which for purposes of this valuation, is expected to be completed in the second half of 2006 with cash inflows from product sales in the United States forecasted to begin in 2007, assuming no unforeseen adverse events or delays and assuming that regulatory approvals are obtained. The C31G Phase 3 clinical trials are approximately 40% complete based on cost and patient enrollment. The UC-781 and Cyanovirin-N development programs are at a much earlier stage than for C31G. Additional manufacturing optimization and development expenses associated with completing the clinical trials, as well as legal and regulatory expenses relating to the drug approval process will be required to gain marketing acceptance.

The primary risk in completing the projects is the successful completion of the clinical testing and the regulatory review process. This process is time consuming and expensive, subject to significant challenges and risks before the products can be approved and commercialized. The Company must demonstrate product safety and efficacy to standards agreed to with regulatory authorities. Unsuccessful clinical results or delays in the approval process could have significant consequences, jeopardizing marketing launch of the product resulting in lower potential revenues and lowered economic returns.

Under the income approach, value is based on the calculation of the present value of future economic benefits to be derived from the ownership of the assets, analyzing the earnings potential of the in-process development programs while factoring in the underlying risk associated with obtaining those earnings. Value indications were developed by discounting future net cash flows to their present value using market-based rates of return. For C31G, discount rates ranging from 34% - 37% were applied to cash flows with an additional approximate 52% probability applied to the cash flows representing, for purposes of this valuation, the estimated probability of the C31G Phase 3 trials beings successful and ultimately receiving FDA approval in the United States. These factors are commensurate with the overall risk and percent complete of the C31G program. Because of the earlier development stage of the UC-781 and Cyanovirin-N in-process programs, the primary valuation method used for these potential products was the current transaction approach. This uses management's estimated value of the consideration paid for the acquisition.

Management has concluded that technological feasibility of the purchased in-process research and development has not yet been reached and that the technology had only limited alternative future uses, if any. Accordingly, the amount allocated to purchased research and development was charged to the statement of operations. In addition to the income and the current transaction approaches, other methodologies including the cost and comparable transaction approaches, were considered to validate the results obtained. These other approaches were, however, given a minor weighting in achieving the valuations. The results of these approaches do not necessarily indicate what a third party would be willing to pay to acquire the in-process projects.

An aggregate amount of $15.0 million was allocated to purchased research and development. The estimated fair the value of the purchased research and development was reduced by $2.0 million of the amount by which fair value of the net asset acquired exceeded the value of the acquisition consideration. The Company recorded a non-cash charge to operations in the fourth quarter of 2004 of $15.0 million for the purchased research and development.

12. Acquisitions (Continued)

The acquisition was completed on October 22, 2004 and Biosyn's results of operations subsequent to that date are included in the Company's consolidated statements of operations for the twelve months ended December 31, 2004. However, the Company has prepared unaudited pro forma financial information showing revenues and net loss for the combined entity for the years ended December 31, 2004 and 2003, respectively, as if the merger occurred as of the beginning of those periods. The following unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations of the Company that would have been reported had the acquisition been completed as of the dates presented and should not be taken as representative of the future consolidated results of operations or financial condition of the Company.

	Years Ended December 31,	
	2004	2003
Revenues	$ 6,304,377	$ 6,847,023
Net loss	$(14,028,996)	$(16,444,850)
Basic and diluted net loss per common share	$ (0.64)	$ (0.73)

13. License and Other Agreements

Cellegy

In December 2002, Cellegy entered into a license agreement, or the PDI Agreement, with PDI, Inc., or PDI, granting PDI the exclusive right to store, promote, sell and distribute Fortigel in North American markets. Cellegy received an upfront payment of $15.0 million on the effective date of December 31, 2002 with an additional $10.0 million payable no later than thirty days after the Company certifies to PDI that Fortigel has received all FDA approvals required to manufacture, sell and distribute the product in the United States. The Company recorded costs of $947,000 to selling, general and administrative expenses associated with an investment banking fee for the year ended December 31, 2002 related to the PDI Agreement. Under the PDI Agreement, the Company would also receive royalties each year until the expiration of the last patent right related to Fortigel of 20% - 30% of net sales and the Company would be reimbursed for 110% of burdened costs for any product supplied to PDI. In October 2003, Cellegy received mediation notice from PDI. In December 2003, Cellegy and PDI initiated legal proceedings against each other. See Note 10.

In July 2004, Cellegy and ProStrakan Group Limited, or ProStrakan, entered into to an exclusive license agreement for the future commercialization of Tostrex® (testosterone gel) in Europe. Under the terms of the agreement, ProStrakan will be responsible for regulatory filings, sales, marketing and distribution of Tostrex throughout the European Union and in certain nearby non-EU countries. Cellegy will be responsible for supplying finished product to ProStrakan through Cellegy's contract manufacturer. Assuming successful commercial launch, Cellegy could receive up to $5.75 million in total payments including a $500,000 non-refundable upfront payment made in July 2004, and a royalty on net sales of Tostrex. The advanced payment received by the Company was recorded as deferred revenue to be amortized to income over eighteen years, which represents the estimated life of the underlying patent and has a balance of $493,000 in deferred revenue at December 31, 2004.

In December 2004, Cellegy and ProStrakan entered into an exclusive license agreement for the commercialization of Cellegesic, branded Rectogesic outside of the United States, in Europe. Under the terms of the agreement, Cellegy received a non-refundable upfront payment of $1.0 million and is entitled

13. License and Other Agreements (Continued)

to receive up to an additional $4.6 million in milestone payments, along with additional based on net sales of Rectogesic in Europe. ProStrakan will be responsible for additional regulatory filings, sales, marketing and distribution of Rectogesic throughout Europe. In all, the agreement covers 38 European territories, including all EU member states. Cellegy will be responsible for supplying finished product to ProStrakan through its contract manufacturer. In addition, ProStrakan has granted a right of first negotiation to Cellegy for its oral estradiol-glucoside product, which is currently in Phase 1 clinical development or an alternative product in the area of gastroenterology. The $1.0 million upfront fee received by the Company is being amortized to income over 10 years, which represents the estimated life of the underlying patent and has a balance of $996,000 in deferred revenue at December 31, 2004.

Biosyn

In October 1989, Biosyn entered into an agreement whereby it obtained an exclusive license to develop and market products using the C31G Technology. As amended, the agreement now requires Biosyn to make certain royalty payments assuming successful product commercialization.

In October 1996, Biosyn acquired the C31G Technology from the entity that originally licensed the technology to Biosyn. As part of the agreement, Biosyn is required to make annual royalty payments equal to the sum of 1% of net product sales of up to $100 million, 0.5% of the net product sales over $100 million and 1% of any royalty payments received by Biosyn under license agreements. The term of the agreement lasts until December 31, 2011 or upon the expiration of the C31G Technology's patent protection, whichever is later. Biosyn's current C31G patents expire between 2006 and 2018.

In May 2001, Biosyn entered into an exclusive license agreement with Crompton Corporation under which Biosyn obtained the rights to develop and commercialize UC-781, a non-nucleoelostide reverse transcriptase inhibitor, as a topical microbicide. Under the terms of the agreement, Biosyn paid Crompton a nonrefundable, upfront license fee that was expensed in research and development. Crompton also received a warrant to purchase Biosyn common stock, which converted into a Cellegy warrant in connection with the acquisition and is exercisable for a period of two years upon initiation of Phase 3 trials of UC-781. Crompton is entitled to milestone payments upon the achievement of certain development milestones and royalties on product sales. If UC-781 is successfully developed as a microbicide, then Biosyn has exclusive worldwide commercialization rights.

In February 2003, Biosyn acquired exclusive worldwide rights from the National Institutes of Health, or NIH, for the development and commerclization of protein Cyanovirin-N as a vaginal gel to prevent the sexual transmission of HIV. NIH is entitled to milestone payments upon achievement of certain development milestones and royalties on product sales.

Under the terms of certain of its funding agreements, Biosyn has been granted the right to commercialize products supported by the funding in developed and developing countries, and is obligated to make its commercialized products, if any, available in developing countries, as well as to public sector agencies in developed countries at prices reasonably above cost or at a reasonable royalty rate.

Biosyn has entered into various other research and technology agreements. Under these other agreements, Biosyn is working in collaboration with various other parties. Should any discoveries be made under such arrangements, Biosyn may be required to negotiate the licensing of the technology for the

13. License and Other Agreements (Continued)

development of the respective discoveries. There are no significant funding commitments under any of these other agreements.

14. Stockholders' Equity (Deficit)

Common Stock Private Placements

In January 2004, the Company entered into a Structured Secondary Offering, or "SSO", facility agreement with Kingsbridge Capital Limited. The SSO requires Kingsbridge to purchase up to 3.74 million shares of newly issued common stock at times and in amounts selected by Cellegy over a period of up to two years, subject to certain restrictions. The Company filed a registration statement with the SEC, which was subsequently amended and declared effective on June 1, 2004. The SSO agreement does not prohibit additional debt or equity financings, including Private Investment in Public Equity ("PIPEs"), shelf offerings, secondary offerings or any other non-fixed or future priced securities. If the common stock falls below $1.25 per share, Cellegy will not be able to conduct drawdowns on the Kingsbridge SSO. The timing and amount of any draw downs are at Cellegy's sole discretion, subject to certain timing conditions, and are limited to certain maximum amounts depending in part on the then current market capitalization of the Company. The purchase price of the common stock will be at discounts ranging from 8% to 12% of the average market price of the common stock prior to each future draw down. The lower discount applies to higher stock prices. In connection with the agreement, Cellegy issued warrants to Kingsbridge to purchase 260,000 common shares at an exercise price of $5.27 per share. Cellegy can, at its discretion and based on its cash needs, determine how much, if any, of the equity line it will draw down in the future, subject to the other conditions in the agreement. The Company completed two drawdowns in 2004, issuing a total of 246,399 common shares resulting in net proceeds of approximately $0.8 million.

In July 2004, Cellegy completed a private placement financing, primarily with existing institutional stockholders, issuing 3,020,000 common shares and warrants to purchase 604,000 shares of common stock, with an offering price of the common shares of $3.42 per share and the exercise price of the warrants of $4.62 per share. Net proceeds were $10.3 million.

Delaware Reincorporation

In September 2004, the Company reincorporated in the state of Delaware. In connection with the reincorporation, each outstanding share of Cellegy California common stock, no par value, was automatically converted into one share of Cellegy Delaware common stock, $0.0001 par value per share. Each stock certificate representing issued and outstanding shares of Cellegy California common stock continues to represent the same number of shares of Cellegy Delaware common stock. The Company recorded as additional paid-in capital, the cumulative excess value of the no par common shares that were converted to shares with par value of $.0001 as of the reincorporation date.

Preferred Stock

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

14. Stockholders' Equity (Deficit) (Continued)

Stock Option Plans

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

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

Equity Incentive Plan

When the Plan was established in 1995, the Company reserved 700,000 shares for issuance. From 1996 to 2004, a total of 4,150,000 additional shares were reserved for issuance under the Plan. Activity under the Plan is summarized as follows:

	Shares Under Option	Weighted Average Exercise Price
Balance at January 1, 2002	2,442,204	$5.59
Granted	1,898,789	$3.84
Canceled	(221,869)	$5.97
Exercised	(156,632)	$2.90
Balance at December 31, 2002	3,962,492	$4.83
Granted	363,500	$3.05
Canceled	(1,123,080)	$5.11
Exercised	(273,196)	$1.97
Balance at December 31, 2003	2,929,716	$4.77
Granted	35,000	$4.47
Canceled	(29,900)	$3.73
Exercised	(133,174)	$2.10
Balance at December 31, 2004	2,801,642	$4.90

The following table summarizes those stock options outstanding and exercisable related to the Plan at December 31, 2004:

14. Stockholders' Equity (Deficit) (Continued)

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Weighted Average Number of Options	Weighted Average Remaining Contractual Life	Exercise Price	Number of Options	Weighted Average Exercise Price
$1.80 - $2.30	525,528	7.4 years	$ 1.84	509,857	$ 1.83
$2.89 - $4.00	868,884	5.9 years	$ 3.45	670,426	$ 3.61
$4.38 - $6.50	707,930	3.4 years	$ 5.17	663,713	$ 5.19
$7.00 - $8.93	627,050	4.8 years	$ 8.02	513,218	$ 7.90
$15.00	72,250	6.0 years	$15.00	72,250	$15.00
Total	2,801,642	5.3 years	$ 4.90	2,429,464	$ 4.91

At December 31, 2003 and 2002, options to purchase 2,173,078 shares of common stock with an average price of $4.77 and 2,362,446 shares of common stock with an average price of $4.72 were vested and exercisable, respectively. At December 31, 2004, 877,750 shares of common stock were available for future option grants under the Plan.

Director's Stock Option Plan

In 1995, Cellegy adopted the 1995 Directors' Stock Option Plan (the "Directors' Plan") to provide for the issuance of non-qualified stock options to eligible outside Directors. When the plan was established, Cellegy reserved 150,000 shares for issuance. From 1996 to 2004, a total of 350,000 shares were reserved for issuance under the Directors' Plan.

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

Activity under the Directors' Plan is summarized as follows:

	Shares Under Option	Weighted Average Exercise Price
Balance at January 1, 2002	228,500	$7.26
Granted	64,000	$2.56
Balance at December 31, 2002	292,500	$4.61
Granted	60,000	$5.00
Canceled	(84,000)	$4.41
Balance at December 31, 2003	268,500	$4.75
Granted	48,000	$4.30
Exercised	(9,000)	$2.64
Balance at December 31, 2004	307,500	$4.74

14. Stockholders' Equity (Deficit) (Continued)

The following table summarizes those stock options outstanding and exercisable related to the Directors' Plan at December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$2.56 - $3.25	35,000	4.5 years	$2.62	32,334	$2.62
$4.30 - $5.50	254,500	4.8 years	$4.90	198,500	$5.04
$6.50 - $8.50	18,000	3.6 years	$6.72	18,000	$6.72
Total	307,500	4.7 years	$4.74	248,834	$4.85

At December 31, 2003 and 2002, options to purchase 251,167 shares of common stock with a weighted average exercise price of $4.79 and 179,330 shares of common stock with a weighted average exercise price of $5.13 were vested and exercisable, respectively. At December 31, 2004, options to purchase 12,833 shares of common stock were available for future option grants under the Directors' Plan.

Non-Plan Options

In November 2003, the Company granted an initial stock option to Mr. Richard Williams, on his appointment to become Chairman of the Board, to purchase 1,000,000 shares of common stock. 400,000 of the options have an exercise price equal to $2.89 per share, the closing price of the stock on the grant date and 600,000 of the options have an exercise price of $5.00 per share. The option was vested and exercisable in full on the grant date, although a portion of the option, covering up to 600,000 shares initially and declining over time, is subject to cancellation if they have not been exercised, in the event that Mr. Williams voluntarily resigns as Chairman and a director within certain future time periods. As of December 31, 2004, none of these options have been exercised.

In October 2004, in conjunction with its acquisition of Biosyn, Cellegy issued stock options to certain Biosyn option holders to purchase 236,635 shares of Cellegy common stock. All options issued were immediately vested and exercisable. The following table summarizes information about stock options outstanding and exercisable related to Biosyn option grants at December 31, 2004:

	Options Outstanding and Exercisable		
Range of Exercise Prices	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$0.06	74,651	1.8 years	$ 0.06
$0.29	77,705	8.8 years	$ 0.29
$1.46 - $6.83	17,128	9.5 years	$ 1.46
$8.76	37,170	7.8 years	$ 8.76
$14.60 - $21.02	29,981	4.8 years	$17.98
Total	236,635	6.0 years	$ 3.87

14. Stockholders' Equity (Deficit) (Continued)

Shares reserved

As of December 31, 2004, the Company has reserved shares of common stock for future issuance as follows:

Biosyn options	236,635
Directors' Plan	320,333
Warrants	945,869
Non-plan options	1,000,000
Neptune agreement	1,080,082
Kingsbridge SSO	3,493,601
Equity Incentive Plan	3,679,392
Total	10,755,912

Warrants

The Company has the following warrants outstanding to purchase common stock as of December 31, 2004:

	Warrant Shares	Exercise Price Per Share	Date Issued	Expiration Date
PIPE Financing	604,000	$ 4.62	July 27, 2004	July 27, 2009
Biosyn warrants	81,869	$5.84 - $17.52	Oct. 22, 2004	2013 - 2014
Kingsbridge SSO	260,000	$ 5.27	Jan. 16, 2004	Jan. 16, 2009
Total	945,869			

Non-cash Compensation Expense Related to Stock Options

For the year ended December 31, 2004, Cellegy recorded non-cash stock compensation expense of $109,000 related primarily to the modification of options to employees and non-employees. For the year ended December 31, 2003, the Company recorded non-cash stock compensation expense of $579,000 associated primarily with the modification of certain stock options and stock paid relating to the renewal of the employment contract for the CEO. For the year ended December 31, 2002, the Company recorded non-cash compensation expense of $322,000 out of which $72,000 related to options issued to non-employees under the Equity Incentive Plan, and $250,000 related to the extension of the exercise period of certain options issued to employees who were terminated in December 2002.

15. Income Taxes

At December 31, 2004 the Company had net operating loss carryforwards of approximately $101.1 million and $41.8 million for federal and state purposes, respectively. The federal net operating loss carryforwards expire between the years 2005 and 2024. The state net operating loss carryforwards expire between the years 2005 and 2014. At December 31, 2004, the Company also had research and development credit carryforwards of approximately $2.7 million and $1.4 million for federal and state purposes,

15. Income Taxes (Continued)

respectively. The federal credits expire between the years 2006 and 2024 and the state credits do not expire. Pursuant to the "change in ownership" provisions of the Tax Reform Act of 1986, utilization of the Company's net operating loss and research and development tax credit carryforwards may be limited if a cumulative change of ownership of more than 50% occurs within any three-year period. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax liabilities and assets are as follows (in thousands):

	December 31, 2004	December 31, 2003
Deferred tax assets:		
Net operating loss carryforwards	$ 36,900	$ 25,000
Deferred revenue	6,000	5,600
Credit carryforwards	3,600	2,400
Capitalized intangibles	2,100	2,100
Depreciation and amortization	1,700	1,120
Other, net	1,100	20
Total deferred tax assets	51,400	36,240
Valuation allowance	(51,400)	(36,240)
Net deferred tax assets	$ —	$ —

Reconciliation of the statutory federal income tax to the Company's effective tax (dollars in thousands):

	2004 $	2004 %	2003 $	2003 %
Net loss	$(28,154)		$(13,532)	
Tax at Federal statutory rate	(9,572)	34.00%	(4,601)	34.00%
State, net of Federal benefit	(2,164)	7.70%	(832)	6.15%
Meals and entertainment	9	-0.03%	9	-0.07%
Stock compensation expense	(240)	0.85%	46	-0.34%
Purchased research and development	5,349	-18.97%	—	0.00%
Foreign rate differential	59	-0.21%	85	-0.63%
Research credits	(121)	0.43%	(542)	4.00%
Deferred taxes not benefited	6,975	-24.83%	5,968	-44.10%
Other	(295)	1.05%	(133)	0.99%
Provision for taxes	$ —	0%	$ —	0%

The valuation allowance for deferred tax assets for 2004, 2003, and 2002 increased by approximately $15.2 million, $6.6 million, and $5.4 million, respectively.

16. Segment Reporting

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

16. Segment Reporting (Continued)

Current pharmaceutical revenues consist primarily of Rectogesic sales in Australia, New Zealand, Singapore and South Korea, as well as, PDI license revenue relating to Fortigel and the ProStrakan license revenues for Rectogesic and Tostrex. The Company's skin care product sales are to one customer, Gryphon Development, Inc., which is selling one of the Company's skin care products, exclusively in the United States, through a major specialty retailer.

Cellegy allocates its revenues and operating expenses to each business segment. Management regularly assesses segment operating performance and makes decisions on how resources are allocated based upon segment performance. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

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

The following table contains information regarding revenues and operating income (loss) of each business segment for the years ended December 31, 2004, 2003, and 2002:

	Years ended December 31,		
	2004	2003	2002
Revenues:			
Pharmaceuticals	$ 2,414,991	$ 1,304,498	$ 320,339
Skin care	181,386	316,000	1,081,287
	$ 2,596,377	$ 1,620,498	$ 1,401,626
Operating income (loss):			
Pharmaceuticals	$ (28,891,704)	$(14,039,351)	$(16,462,264)
Skin care	117,901	147,255	700,837
	$(28,773,803)	$(13,892,096)	$(15,761,427)

Total assets were minimal for the skin care segment.

Revenue from Major Customer

Revenues from product sales to one customer represented approximately 7%, 20% and 70% of total revenue for 2004, 2003 and 2002, respectively.

Geographic data

Approximately 22%, 28% and 20% of total revenues in 2004, 2003 and 2002, respectively, are from sales of Rectogesic in Australia, New Zealand and South Korea. All other sales are in the United States. Most of the Company's assets are located in the United States.

17. Related Party Transactions

The Company has paid fees to their board members for their services to the board including the audit, nominating, and compensation committees. The total fees paid to these directors during 2004, 2003 and 2002 were $180,703, $103,000, and $10,000, respectively.

There were no consulting fees paid in cash to any board members in 2004, 2003 and 2002. The Company recognized $131,000 and $33,000 in non-cash compensation expense during 2003 and 2002, respectively, associated with the valuation of vested stock options previously issued under a consulting agreement to a former board member.

Cellegy had an interest bearing $100,000 loan outstanding to a non-officer employee, which was issued in 1999 in conjunction with the purchase of his home. The loan was repaid in full in April 2004.

18. Subsequent Events

In January 2005, Cellegy announced the resignation of K. Michael Forrest as Chief Executive Officer and Director. Richard C. Williams, the Company's Chairman was appointed as interim Chief Executive Officer. The Company has a contractual obligation to pay Mr. Forrest severance over an 18-month period ending in June 2006. Severance compensation cost of $597,000 will be accrued in 2005.

In March 2005, Cellegy relocated its principal office from South San Francisco to Brisbane, California. Cellegy's sublease for its offices in Brisbane has a term that expires February 28, 2006. Rent during the term is nominal. If Cellegy and the sublessor agree to extend the term of the Brisbane sublease beyond the initial one year term, rent would increase to approximately $17,200 per month.

19. Quarterly Financial Data

(Unaudited)

	2004			
	First Quarter	Second Quarter	Third Quarter	Fouth Quarter
	(Amounts in thousands, except per share data)			
Revenues	$ 338	$ 430	$ 483	$ 1,345
Operating loss	(3,245)	(2,837)	(3,194)	(19,498)
Net loss	(3,058)	(2,708)	(3,143)	(19,245)
Basic and diluted net loss per common share	$ (0.15)	$ (0.13)	$ (0.14)	$ (0.76)

	2003			
	First Quarter	Second Quarter	Third Quarter	Fouth Quarter
	(Amounts in thousands, except per share data)			
Revenues	$ 392	$ 263	$ 414	$ 551
Operating loss	(3,284)	(4,352)	(2,676)	(3,580)
Net loss	(3,113)	(4,165)	(2,670)	(3,584)
Basic and diluted net loss per common share	$ (0.16)	$ (0.21)	$ (0.13)	$ (0.18)

(1) Includes a charge of $14,982,000 for acquired in-process technology relating to the Biosyn acquisition in October 2004.

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-06065, 333-32301, 333-60343, 333-42840, 333-91588, 333-114229 and 333-121838), Form S2 (No. 333-114247) and Form S-3 (Nos. 333-11457, 333-36057, 333-46087, 333-86193, 333-49466, 333-64864, 333-102485 and 333-118841) of Cellegy Pharmaceuticals, Inc. of our report dated March 28, 2005 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 28, 2005

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-11457, 333-36057, 333-46087, 333-86193, 333-49466, 333-64864, 333-102485, 333-118841 and 333-121836) of Cellegy Pharmaceuticals, Inc. and in the related Prospectuses,

(2) Registration Statement (Form S-2 No. 333-114247) of Cellegy Pharmaceuticals, Inc. and in the related Prospectus, and

(2) Registration Statements (Form S-8 Nos. 33-96384, 333-06065, 333-32301, 333-60343, 333-42840, 333-91588, 333-114229 and 333-121838) pertaining to the 1992 Stock Option Plan, the 1995 Equity Incentive Plan, the 1995 Directors' Stock Option Plan and the Director Stock Option Agreement of Cellegy Pharmaceuticals, Inc. and options to purchase common stock granted under the Biosyn, Inc. 1999 Stock Option Plan, as amended, and non-plan options granted to Biosyn, Inc.,

of our report dated February 13, 2003 with respect to the 2002 consolidated financial statements of Cellegy Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Palo Alto, California
March 28, 2005

Exhibit 31.1

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

I, Richard C. Williams, certify that:

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

Date: March 30, 2005

By: /s/ RICHARD C. WILLIAMS
Chairman and Interim Chief Executive Officer

Exhibit 31.2

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

I, A. Richard Juelis, certify that:

1. I have reviewed this report on Form 10-K of Cellegy Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and (15d-15(e)) for the registrant and we have:
   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
   a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2005

By: /s/ A. RICHARD JUELIS
Vice President, Finance and Chief Financial Officer

Exhibit 32.1

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

In connection with this annual report on Form 10-K of Cellegy Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2004, as filed with the United States Securities and Exchange Commission on the date hereof (the "Report"), Richard C. Williams, Chairman and Interim Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

By: /s/ RICHARD C. WILLIAMS
Richard C. Williams
Chairman and Interim Chief Executive Officer
Date: March 30, 2005

Exhibit 32.2

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

In connection with this annual report on Form 10-K of Cellegy Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2004, as filed with the United States Securities and Exchange Commission on the date hereof (the "Report"), A. Richard Juelis, as Vice President, Finance and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

By: /s/ A. RICHARD JUELIS
A. Richard Juelis
Vice President, Finance and Chief Financial Officer
Date: March 30, 2005