

**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, 2005

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**  
(State or other jurisdiction of  
incorporation or organization)

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

**1800 Byberry Rd., Building 13, Huntingdon Valley, PA 19006**

(Address of Principal Executive Offices) (zip code)

Registrant's telephone number, including area code: **(215) 914-0900**

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

None  
(Title of each class)

None  
(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

**YES**

**NO**

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

**YES**

**NO**

**Note** - Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those sections.

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

**YES**

**NO**

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

**YES**

**NO**

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 30, 2005 was \$43,547,000.

As of March 24, 2006, there were 29,831,625 shares of common stock outstanding.

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### **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.

*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 “Risk Factors” 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.*

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CELLEGY PHARMACEUTICALS, INC. 10-K ANNUAL REPORT

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2005

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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 primarily engaged in the development and commercialization of prescription drugs targeting women's health care, including the reduction in transmission of HIV, and gastrointestinal conditions using proprietary topical formulations and nitric oxide ("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<sup>®</sup> (C31G vaginal gel), a contraceptive microbicide gel designed to reduce HIV/AIDS transmission in women.

Cellegy is developing Cellegesic<sup>™</sup> (nitroglycerin ointment) for the treatment of anal fissures and hemorrhoids. In January 2004, the results of preliminary analysis of our third Phase 3 clinical trial for Cellegesic 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. The company submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA" or the "Agency") in June 2004. The FDA issued a Not Approvable letter for Cellegesic in December 2004.

Cellegy submitted an amended NDA containing new analyses of data from its trials to the FDA in April 2005 and the submission has been under review at the FDA since then. In January 2006, the FDA indicated that the Company's submission will be reviewed April 25, 2006 by the Cardiovascular and Renal Drug Products Advisory Committee (the "Committee"), an independent panel of external experts. The Committee's recommendation for approval or non-approval of Cellegesic is expected to be rendered at the conclusion of its review. While the FDA will consider the findings of the Committee, the final regulatory decision rests with the Agency. The FDA has not indicated when its final decision will be communicated. Cellegesic cannot be marketed in the United States unless and until the FDA grants marketing approval for the product.

The U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") approved Cellegesic (branded Rectogesic in Europe) for sale in the United Kingdom in August 2004 and the product was launched by our European marketing partner, ProStrakan Group Limited ("ProStrakan"), in May 2005. ProStrakan is seeking additional approvals of Rectogesic by other member states of the European Union through the Mutual Recognition Procedure. The Mutual Recognition Procedure has been successfully completed, although additional national licenses will be sought and are expected to be issued in the 19 additional countries included in the submission.

Cellegy is developing two transdermal gel testosterone products, Fortigel<sup>™</sup> (testosterone gel) and Tostrelle<sup>®</sup> (testosterone gel). Fortigel, a replacement therapy for male hypogonadism, was the subject of a Not Approvable letter by the FDA in July 2003. Tostrex<sup>®</sup> (testosterone gel), which is the brand name for Fortigel in Europe, was approved by the Medical Products Agency in Sweden ("MPA") for the treatment of male hypogonadism in December 2004 and was launched by ProStrakan in September, 2005. ProStrakan is currently seeking additional approvals of Tostrex by other member states of the European Union through the Mutual Recognition Procedure.

Tostrelle is for the treatment of female sexual dysfunction in postmenopausal women and has completed Phase 2 development. In 2004, the FDA indicated 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. The company is awaiting these guidelines before embarking upon a Phase 3 program.

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 ("STD's") including HIV/AIDS. Biosyn's products include Savvy, which is currently undergoing Phase 3 clinical trials in Africa and in the United States; UC-781 vaginal gel, in Phase 1 trials; and Cyanovirin-N, in pre-clinical development.

#### Products Under Development

##### *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 up to 35% of patients incontinent.

There are currently no FDA approved drug therapies for anal fissures, although topical anesthetics and anti-inflammatory agents, which only partially and temporarily relieve the symptoms of the condition, are currently prescribed. According to 2004 Verispan audits, anal fissures afflict an estimated 765,000 Americans, resulting in over one million physician visits each year. These data for 2004 show about 84,000 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. The Company 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 accelerating the rate of pain reduction associated with 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 ("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. The FDA, after conducting its own analysis and raising other issues not covered in the SPA, issued a Not Approvable letter in December 2004.

The Company submitted an amended NDA containing new analyses of data from its trials to the FDA in April 2005, and the submission has been under review at the FDA since then. In January 2006, the FDA indicated that the company's submission will be reviewed on April 25, 2006 by the Cardiovascular and Renal Drug Products Advisory Committee. The Committee's recommendation for approval or non-approval of Cellegesic is expected to be rendered at the conclusion of its review. While the FDA will consider the findings of the Committee, the final regulatory decision rests with the Agency. The FDA has not indicated when its final decision will be communicated. Cellegesic cannot be marketed in the United States unless and until the FDA grants marketing approval for the product.

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

Cellegy obtained rights to the late-stage product candidate, Savvy, with its October 2004 acquisition of Biosyn. Savvy, a microbicidal gel, is one of the most clinically advanced product candidates in development for the reduction in transmission of HIV and has also shown promising results in the prevention of other STDs, including those caused by herpes simplex virus and Chlamydia. Savvy has also shown activity against gonorrhea and syphilis.

Savvy is currently undergoing a Phase 3 trial for reduction of HIV transmission in Nigeria in populations of women at risk for HIV infection. The primary endpoint of the study is a 50% reduction in the rate of transmission of HIV in the Savvy group compared with the placebo. The current enrollment for the Nigerian trial is approximately 2,000 women.

In November 2005, the company discontinued its Phase 3 trial for reduction of HIV transmission in Ghana which had enrolled approximately 2,100 women. The Data Monitoring Committee reviewing interim data from the Savvy Ghana Phase 3 HIV prevention trial made the recommendation in November 2005 that continuing the trial would not allow the effect of Savvy (C31G vaginal gel) on HIV to be determined because of a lower than expected rate of HIV seroconversion in the trial. The estimated annual rate of HIV seroconversion in the Ghana study population was 3.7% at the time of trial initiation, but the observed annual rate was 1.2% eighteen months into the trial. This lower rate was possibly due in part to procedures designed to ensure ethical trial design, including counseling on HIV prevention and distribution of condoms. There were no safety issues associated with the Ghana trial.

Consideration is being given to expansion of the ongoing Savvy Phase 3 HIV prevention trial in Nigeria and/or the opening of new trial sites in areas with higher HIV incidence as ways to determine the effectiveness of Savvy. Additionally, data from the Ghana trial will be analyzed for effects on other endpoints including pregnancy. If the data warrant, the Ghana results will be submitted as a supplemental data package for the contraception New Drug Application.

A Phase 3 trial for contraception is ongoing in the United States, with about 686 women enrolled out of an expected total enrollment of 1,600 by the end of 2007.

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 its mechanism of action, C31G has a low potential for resistance and is active against drug resistant pathogens.

Certain Phase 3 trial expenses for Savvy, and certain other clinical and preclinical development costs for the Biosyn pipeline, are funded by grant and contract commitments through agencies including: the United States Agency for International Development; the National Institute for Child Health and Development; the National Institute for Allergy and Infectious Disease; CONRAD (formerly the Contraceptive Research and Development Program); and other governmental 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. The company has no current plans to develop the product further and is seeking to either sell or out-license the technology.

Tostrex<sup>®</sup> (testosterone gel), which is the brand name for Fortigel in Europe, was approved in December 2004 by the Medical Products Agency in Sweden for the treatment of male hypogonadism and was launched by ProStrakan in September 2005. ProStrakan is currently seeking additional approvals of Tostrex by other member states of the European Union 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, 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 the proper dosage was determined 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, the Company stopped enrollment in the Phase 2 clinical study. Later in 2004, the Company 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. 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 Cellegy may decide not to pursue the further development of Tostrelle.

**Marketed Products**

*Rectogesic (nitroglycerin ointment for the treatment of anal fissures)*

Rectogesic (nitroglycerin ointment), the brand name for Cellegesic outside of the United States, was approved by the MHRA for sale in the United Kingdom in September 2004 and was launched by ProStrakan in May 2005. Approvals by other member states of the European Union are being sought by ProStrakan through the Mutual Recognition Procedure.

In November 2005, Cellegy renegotiated its marketing agreement with ProStrakan. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase the product directly from the manufacturer rather than from Cellegy. In connection with its revised marketing agreement, Cellegy received a payment of \$2 million and may receive certain future milestone payments of up to \$750,000 upon approval of the product in certain major European countries.

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.

On March 24, 2006 Cellegy announced that its European marketing partner ProStrakan had successfully completed the European Union Mutual Recognition Procedure for Rectogesic. Following the successful conclusion of the MRP process, national licenses will be sought and are expected to be issued in due course in the 19 additional countries included in the MRP submission application. Cellegy is entitled to receive \$250,000 for each marketing regulatory approval obtained in the first of any three countries out of France, Italy, Germany or Spain up to a maximum total amount payable of \$750,000. PDI is entitled to receive one-half of these payments under its previous agreements with Cellegy.

#### *Tostrex (testosterone gel)*

Tostrex was approved in December 2004 by the MPA for the treatment of male hypogonadism and was launched by ProStrakan in September 2005. ProStrakan is currently seeking additional approvals of Tostrex by other member states of the European Union through the Mutual Recognition Procedure.

### **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 specialty pharmaceutical company located in the United Kingdom with European-wide marketing 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 past clinical trials and Rectogesic and Tostrex for European commercial sales. PendoPharm will be the commercial manufacturer of these products in the event of any future regulatory approvals in other markets. In 2005, the Company modified its relationship with PendoPharm concerning the manufacture of Rectogesic, giving control to ProStrakan. Similar control was given to ProStrakan in 2006 regarding the manufacture of Tostrex. 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.
- *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 and peripheral vascular disorders. 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.

*Biosyn.* Biosyn's topical microbicide technology expands our product pipeline in women's health care. In 2004, Biosyn's lead product, Savvy, entered three concurrent Phase 3 clinical studies; a contraception study in the United States and two HIV studies Africa. In Africa, studies were being conducted in Nigeria and in Ghana testing Savvy's effectiveness in preventing HIV transmission in women. In November 2005, the company discontinued its Ghana trial due to a lower than expected rate of HIV seroconversion in the trial. The estimated annual rate of HIV seroconversion in the Ghana study population was 3.7% at the time of trial initiation, but the observed annual rate was 1.2% eighteen months into the trial. This lower rate was possibly due in part to procedures designed to ensure ethical trial design, including counseling on HIV prevention and distribution of condoms. There were no safety issues associated with the Ghana trial.



If the Phase 3 trial for contraception in the United States is successful, Savvy could be the first product among many microbicide products in various stages of development to enter the commercial marketplace. 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, ("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.* 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-spasmodic 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 and selected aspects of female sexual dysfunction.

## **Patents and Trade Secrets**

Our policy is to protect our technology by, among other things, filing patent applications for technology that we consider important to 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. Currently, Cellegy holds a number of issued and pending US and foreign patents pertaining to our principal products.

*Cellegesic and Rectogesic ointment.* Two issued U.S. patents and over 20 issued foreign patents relate to our topical nitroglycerin products, Cellegesic and Rectogesic ointments, for the treatment of anal disorders. While the European patent was challenged and subsequently revoked during opposition proceedings in December 2003, Cellegy has filed an appeal to the decision, and the case stands on appeal.

*Testosterone gel products for males and females.* Three issued U.S. patents, five issued foreign patents and over 5 pending patent applications relate to our topical testosterone products Fortigel, Tostrex and Tostrelle gels.

*Savvy Contraceptive gel.* Two issued U.S. patents and over 20 issued foreign patents relate to Savvy gel for contraception and the reduction in transmission of HIV infection.

In addition, Cellegy also holds issued and pending patents pertaining to our potential back-up products for treatment of anal disorders as well as for our earlier pipeline products for the treatment of female sexual disorders, urogenital disorders, and vascular insufficiency.

## Acquisitions and Divestitures

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 subsequently renamed Cellegy Canada. Its operations were discontinued in the fourth quarter of 2005 and the company's assets liquidated by December 31, 2005. All cancer prevention related patents and in-process technology were returned by action of agreement to Parseq Innovations, from whom Cellegy originally acquired the patents.

In June 2000, Cellegy acquired Quay Pharmaceuticals (subsequently renamed Cellegy Australia), an Australian company marketing Rectogesic, for the treatment of anal fissures. Cellegy continues to self-market Rectogesic through Cellegy Australia.

In December 2005, the Company divested its skin care business.

## License Agreements

### *Cellegy*

In December 2002, Cellegy entered into a license agreement (the "PDI Agreement"), with PDI, Inc. ("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.

On April 11, 2005, Cellegy entered into a settlement agreement with PDI resolving the lawsuits that the companies had filed against each other. Under the terms of the settlement agreement, the license agreement was terminated and all product rights have reverted to Cellegy. Cellegy paid \$2.0 million to PDI upon signing the settlement agreement. Cellegy also issued a \$3.0 million promissory note to PDI and a \$3.5 million non-negotiable senior convertible debenture. The settlement of the Company's lawsuit with PDI resulted in the recognition of the remaining \$6.5 million in deferred revenue from PDI as license revenue during the second quarter of 2005.

In July 2004, Cellegy and ProStrakan entered into to an exclusive license agreement for the future commercialization of Tostrex<sup>®</sup> (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.

In December 2004, Cellegy and ProStrakan entered into an exclusive license agreement for the commercialization of Rectogesic in Europe. Under the terms of the original agreement, Cellegy received a non-refundable upfront payment of \$1.0 million and is entitled to receive additional 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. The agreement covers 38 European territories, including all EU member states. Under the original agreement, Cellegy was responsible for supplying finished product to ProStrakan through its contract manufacturer.

In November 2005, the company renegotiated its marketing agreement with ProStrakan relating to Rectogesic. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase the product directly from the manufacturer rather than from Cellegy. In connection with its revised marketing agreement, Cellegy received a payment of \$2.0 million and may receive certain future milestone payments of up to \$750,000 upon approval of the product in certain major European countries.

In January 2006, Cellegy amended its 2004 agreement with ProStrakan concerning Tostrex. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase Tostrex directly from Cellegy's contract manufacturer rather than purchasing the product from Cellegy under the terms of the original agreement. Cellegy will continue to receive milestones and royalties as set forth in the original agreement.

#### *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 2011 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.

On February 1, 2006 Cellegy announced that it had entered into a non-exclusive, developing world licensing agreement with CONRAD for collaboration on the development of Cellegy's entire microbicide pipeline. The agreement encompasses the licensing of Savvy currently in Phase 3 clinical trials in the United States and Africa; UC-781, currently in expanded Phase 1 trials in the United States and Thailand; and Cyanovirin-N, currently in pre-clinical development.

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 demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various dose and regimens. 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 an SPA, 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 Cellegy, thus rendering its 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 Cellegy.

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 15, 2006, the Company had 18 full-time employees and 1 part-time employee, including 4 full-time employees at our Brisbane, California office, and 14 full-time employees and 1 part-time employee 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](http://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., 1800 Byberry Road, Building 13, Huntingdon Valley, Pa, 19006, Attention: Chief Financial Officer, Cellegy will provide a copy of the 10-K to any stockholder.

## **ITEM 1A: RISK FACTORS**

### ***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 deficit accumulated during the development stage as of December 31, 2005, was approximately \$132.3 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. If we are able to obtain sufficient funding, 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 registered public accounting firm, which may negatively impact our business.***

Our audit opinion from our independent registered public accounting firm regarding the consolidated financial statements for the years ended December 31, 2004 and 2005, included an explanatory paragraph indicating that there is substantial doubt about the Company’s ability to continue as a going concern. We have incurred losses and negative cash flows from operations since inception. 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 are uncertain and failure to obtain needed financing could affect our ability to develop or market products or to continue operations.***

Throughout our history, we have consumed substantial amounts of cash. Our cash needs may increase during 2006 to fund our research, development and clinical trial programs, administrative and litigation expenses, and 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.

As of December 31, 2005, Cellegy had approximately \$2.3 million in cash and cash equivalents. Cellegy has no current source of significant ongoing revenues or capital beyond existing cash, product sales and grant funding.

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 product candidates;
- the commercial success of our products that are approved for marketing;
- the costs of filing, prosecuting, defending and enforcing patent claims, oppositions and appeals, and our other intellectual property rights;
- the cost and outcome of the current litigation with PDI, Inc., 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.



In order to complete the development, manufacturing and other pre-launch marketing activities necessary to commercialize our products, additional financing will be required. 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, sales of technology or assets, 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.

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 will be adequate to satisfy our capital needs through at least April 30, 2006 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. Funds provided from sales of subsidiaries, assets, equity or debt financing, or other arrangements, if obtained, would permit satisfaction of capital needs for a longer period of time. A favorable determination by the FDA Advisory Committee and the FDA following the scheduled April 2006 hearing on our Cellegesic NDA may improve the prospects for one or more such transactions.

***We could be forced into bankruptcy.***

There is a risk that one or more of our creditors could bring lawsuits to collect amounts to which they believe they are entitled. In the event of lawsuits of this type, if we are unable to negotiate settlements or satisfy our obligations, we could voluntarily file bankruptcy proceedings, or we could become the subject of an involuntary bankruptcy proceeding filed by one or more creditors against us.

***The outcome of the lawsuit with PDI is uncertain. An unfavorable outcome will have a material adverse affect on our financial position and stock price.***

As more fully described under Item 3, "Legal Proceedings", the Company is presently engaged in a lawsuit with PDI alleging that Cellegy is in material breach of the April 2005 settlement agreement between Cellegy and PDI and related documents, including two promissory notes given by Cellegy to PDI, as a result of Cellegy's failure to notify PDI of the receipt of certain payments and of Cellegy's failure to pay amounts to which PDI believes it is entitled. The lawsuit seeks immediate payment of the notes along with payments for default interest and damages. An unfavorable outcome to this lawsuit would have a material adverse affect on our business and stock price.

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

The process of developing and obtaining approval for a new pharmaceutical product within this regulatory framework requires a number of years and substantial expenditures. There can be no assurance that necessary approvals will be obtained on a timely basis, if at all. Delays in obtaining regulatory approvals could 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. 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.

The Company submitted an amended NDA containing new analyses of data from its trials to the FDA in April 2005 and has been under review at the FDA since then. In January, 2006 the FDA indicated that the Company's submission will be reviewed April 25, 2006 by the Cardiovascular and Renal Drug Products Advisory Committee. The Committee's recommendation for approval or non-approval of Cellegesic is expected to be rendered at the conclusion of its review. While the FDA will consider the findings of the Committee, the final regulatory decision rests with the Agency. The FDA has not indicated when its final decision will be communicated. Cellegesic cannot be marketed in the United States unless and until the FDA grants marketing approval for the product.

Similarly, since 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 (“NGOs”). Nevertheless, these Phase 3 trials and Cellegy’s other planned clinical trials could require Cellegy to provide substantial funding in 2006. 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.

***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, Savvy 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 instead 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 products. 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 there under 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. Cellegy currently has a limited number of agreements with third parties to commercialize our product candidates. Cellegy may not be able to establish other future 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.

***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 ("GMP") 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 and commercial supply of prescription products in those territories, while the Australian and South Korean product sales are sourced by a pharmaceutical manufacturer in Australia. 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 produce product under GMP as required by the FDA or by 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

***We have limited sales and marketing experience.***

We may market some of our products, if successfully developed and approved and if we obtain sufficient funding, 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 payers.

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.***

Past 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 health risks associated with testosterone replacement therapy ("TRT"). 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 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 or too costly to implement, the Phase 3 program may be significantly delayed or we may decide not to pursue further development of Tostrelle product. 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. These arrangements 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, and impede our ability to raise capital or lead to the de-listing of our stock.

We are evaluating our internal controls over financial reporting to allow management to report on, and our independent registered public accounting firm 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 to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("Section 404"). As a result, we expect to incur significant additional expenses and diversion of management's time. Cellegy is considered a non-accelerated filer, and as such is required to comply with the Section 404 requirements for its fiscal year ending December 31, 2007. 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, 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. 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, including the SEC. 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. 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 clinical trial and product liability lawsuits.***

The testing of human health care product candidates entails an inherent risk of allegations of clinical trial liability, while the marketing and sale of approved products entails an inherent risk of allegations of product liability. We are subject to the risk that substantial liability claims from the testing or marketing of pharmaceutical products could be asserted against us in the future. Cellegy has obtained clinical trials insurance coverage relating to our clinical trials in an aggregate amount of \$3 million. 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 liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. In addition, a product or clinical trial liability action against us would be expensive and time-consuming to defend, even if we ultimately prevailed. If we are required to pay a claim, we may not have sufficient financial resources and our business and results of operations may be harmed.

***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 due to overall market conditions and due to matters or events more specific to Cellegy. Events or announcements that could significantly impact our stock price include:

- Publicity or announcements regarding regulatory developments relating to our products;
- Clinical trial results, particularly the outcome of our more advanced studies; or negative responses from both domestic and foreign 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 revenue levels;
- Negative public 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 existing litigation or other potential legal proceedings; or
- Other potentially negative financial announcements, including delisting from the OTCBB, a 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 Structured Secondary Offering (“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 (“VWAP”) of our common stock, 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.



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 OTCBB, 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 Investments in Public Equity ("PIPE"), shelf offerings, and secondary offerings.

Under the terms of the Kingsbridge SSO, if we fail to issue and sell common stock to Kingsbridge pursuant to draw downs at least equal to \$2.66 million, then we have agreed to pay \$266,000 to Kingsbridge. We have made draw-downs of less than this amount. As a result, unless these provisions are amended or waived, we owe Kingsbridge \$266,000.

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

A substantial portion of our shares is held by a relatively small number of stockholders. Sales of a significant number of 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 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 2006, when we change our accounting policy to record expense for the fair value of stock options granted our net loss may 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 1B: UNRESOLVED STAFF COMMENTS

None.

## ITEM 2: PROPERTIES

In March of 2005, Cellegy relocated its South San Francisco offices to the nearby city of Brisbane where it is subleasing approximately 5,800 square feet of office space with an expiration date of May 31, 2007. The company relocated its headquarters to Biosyn's Huntingdon Valley, Pennsylvania facilities in September 2005 and expects to close the Brisbane office during the second quarter of 2006. Biosyn's facilities consist of approximately 10,000 square feet of leased laboratory and office space with an expiration date of October 31, 2008. The company believes its current facilities to be adequate for its anticipated needs.

## ITEM 3: LEGAL PROCEEDINGS

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

In October 2003, the Company received a communication from PDI invoking mediation procedures under its exclusive license agreement with PDI 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.

On April 11, 2005, Cellegy entered into a settlement agreement with PDI resolving the lawsuits that the companies had filed against each other. Under the terms of the settlement agreement, the license agreement was terminated and all product rights reverted to Cellegy. Under the settlement agreement, the previous license agreement was terminated and all product rights reverted to Cellegy. Cellegy paid \$2 million to PDI upon signing the settlement agreement.

Cellegy also issued a \$3.0 million Secured Promissory Note to PDI, payable in 18 months, with earlier payments of amounts owed under the note required to be made to the extent of 50% of licensing fees, royalties or milestone payments (or, in each case, other payments in the nature thereof) received by Cellegy under Cellegy's agreements or arrangements with respect to Cellegy's Tostrex® (testosterone gel) and Rectogesic® (nitroglycerin ointment) products in territories outside of North America, and 50% of licensing fees, royalties or milestone payments (or, in each case, other payments in the nature thereof) received by Cellegy under Cellegy's agreements or arrangements with respect to Fortigel licensees in North American markets. These payments are required to be made to PDI within two business days after Cellegy receives the payments. These various payments will be made until the amount owed under the note is paid in full. Cellegy's obligations under the note are secured by a security interest in favor of PDI, which is reflected in a security agreement between Cellegy and PDI, in Cellegy's interests in the payments described above and any proceeds there from (and certain related collateral). In addition, Cellegy is required to make payments on the \$3.0 million note with respect to 10% of proceeds received by Cellegy in excess of \$5 million from financing transactions. Payments made in 2005 totaled \$200,000. Amounts owed under the note may be accelerated upon an event of default, which include (but are not limited to) certain kinds of bankruptcy filings or certain related actions or proceedings, an uncured material breach of Cellegy's obligations under the note, the security interest no longer being a valid, perfected, first priority security interest, and a default in indebtedness of Cellegy with an aggregate principal amount in excess of \$2 million that results in the maturity of such indebtedness being accelerated before its stated maturity. Cellegy made a \$100,000 payment to PDI in October 2005 shortly after the due date specified in the secured note and has paid interest to PDI on that amount. Cellegy also issued to PDI a \$3.5 million principal amount Convertible Senior Note due April 11, 2008. Cellegy may redeem the note at any time before the maturity date upon not less than 30 or more than 60 days notice to PDI, at a redemption price equal to the principal amount; if Cellegy delivers such a redemption notice, PDI may convert the note into shares of Cellegy common stock at a price of \$1.65 per share. In addition, after the 18 month anniversary of the debenture, PDI may convert the note into Cellegy common stock at a price of \$1.65 per share. If Cellegy does redeem the note within the first 18 months; then Cellegy has agreed to file a registration statement relating to possible resale of any shares issued to PDI after 18 months. 2,121,212 shares would be issuable upon such conversion. As long as amounts are owed under the note, Cellegy has agreed not to incur or become responsible for any indebtedness that ranks contractually senior or pari passu in right of payment to amounts outstanding under the note. Events of default under the senior note are generally similar to events of default under the secured note.

On December 1, 2005, the Company received a notice from PDI notifying the Company that PDI considers that Cellegy to be in default of the Secured Promissory Note and the Nonnegotiable Convertible Senior Note which were part of the settlement agreement. PDI's notice states that PDI believes that Cellegy is in material breach of the Secured Promissory Note as a result of Cellegy's failure to notify PDI of the receipt of certain payments and of Cellegy's failure to pay amounts to which PDI believes it is entitled. PDI also notified Cellegy that PDI believes that an outstanding principal amount of \$2.8 million, plus default interest, of the Secured Promissory Note and outstanding principal amount of \$3.5 million, plus default interest, of the Nonnegotiable Convertible Senior Note are immediately due and payable in cash pursuant to the "Event of Default" provisions of the settlement agreement. Cellegy had previously made certain payments pursuant to the provisions of the settlement agreement. Among other things, PDI claimed that it was entitled to \$1.0 million of the \$2.0 million payment that Strakan paid to Cellegy in connection with the November 2005 negotiation of the license agreement relating to Rectogesic.

On December 2, 2005, PDI filed suit in United States District Court for the Southern District of New York requesting that the court declare that Cellegy has breached its obligations under the settlement agreement, order Cellegy to specifically perform its obligations under the settlement agreement, and awarded PDI damages in the amount of \$6.4 million plus default interest as well as certain other amounts. Cellegy does not agree that the payments made by Strakan under the renegotiated agreement fall within the definition of "Pledged Collateral" in the settlement documents and does not believe that any amount is owed to PDI as a result of such payments. The proceedings are in the discovery stage and no trial date has been set. The Company intends to vigorously defend itself in the litigation.

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

Not applicable.

## 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 OTC Bulletin Board ("OTCBB") exchange under the symbol "CLGY.OB". Cellegy's common stock was traded on the Nasdaq National Market until September 14, 2005, when its listing was transferred to the Nasdaq Small Cap Market. On December 29, 2005, the common stock was delisted from the Nasdaq Small Cap Market, and shortly thereafter the common stock began trading on the OTCBB. 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 Small Cap Market and OTCBB for the periods indicated below.

	<u>High</u>	<u>Low</u>
<b>2004</b>		
First Quarter	\$6.74	\$3.14
Second Quarter	4.65	3.65
Third Quarter	4.62	3.46
Fourth Quarter	5.14	2.69
<b>2005</b>		
First Quarter	\$3.05	\$1.62
Second Quarter	2.45	1.29
Third Quarter	1.60	1.24
Fourth Quarter	1.40	0.42
<b>2006</b>		
First Quarter through March 15	0.93	0.42

On September 14, 2005 the Company received a determination letter from the Nasdaq Listing Qualifications Panel transferring its stock listing to the Nasdaq Small Cap Market. On December 29, 2005 Cellegy was delisted from the Nasdaq Small Cap Market. The delisting resulted from the Company not satisfying the \$35 million market capitalization requirement under Nasdaq Marketplace Rule 4310(c)(2)(B)(ii). The Company also did not comply with alternative standards for continued listing on the Nasdaq Small Cap Market.

#### Holder

As of March 9, 2006 there were approximately 154 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. 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 2006 annual meeting of stockholders.

#### Recent Sales of Unregistered Securities

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, 2005 and 2004 and for each of the three years in the period ended December 31, 2005 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.

**Statements of Operations Data: (In thousands except per share data)**

	Years ended December 31,				
	2005	2004	2003	2002	2001
Revenues	\$ 12,835	\$ 2,596	\$ 1,620	\$ 1,402	\$ 877
Costs and expenses <sup>1</sup>	18,115	31,370	15,512	17,163	21,847
Operating loss	(5,279)	(28,774)	(13,892)	(15,761)	(20,970)
Other income (expense)	271	620	360	520	1,505
Net loss	\$ (5,008)	\$ (28,154)	\$ (13,532)	\$ (15,241)	\$ (19,465)
Basic and diluted net loss per common share	\$ (0.18)	\$ (1.28)	\$ (0.68)	\$ (0.86)	\$ (1.26)
Dividends per share of Common Stock	—	—	—	—	—
Weighted average common shares used in computing basic and diluted net loss per common share	28,497	22,021	19,964	17,643	15,503

<sup>1</sup> Includes a charge of \$14,982,000 for purchased research and development relating to the Biosyn acquisition in October 2004.

**Balance Sheet Data: (In thousands)**

	December 31,				
	2005	2004	2003	2002	2001
Cash, cash equivalents, restricted cash and investments <sup>1</sup>	\$ 2,251	\$ 8,933	\$ 11,564	\$ 23,858	\$ 17,190
Total assets	6,450	13,863	15,331	28,379	22,367
Long term portion of deferred revenue	3,084	13,865	13,335	14,168	—
Long term payables	212	717	725	717	485
Deficit accumulated during the development stage	(132,311)	(127,303)	(99,149)	(85,617)	(70,377)
Total stockholders' equity (deficit)	(6,477)	(6,743)	(1,580)	10,534	19,845

<sup>1</sup> Includes restricted cash of \$0 in 2005, \$227,500 in 2004, 2003 and 2002, and \$614,000 in 2001.

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

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.

**Major Events**

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. 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 entered into an exclusive license agreement for the future commercialization of Tostrex® (testosterone gel) in Europe and received a \$500,000 non-refundable upfront payment. 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, and Cellegy was responsible for supplying finished product to ProStrakan through Cellegy's contract manufacturer. Cellegy could receive future milestone payments and royalties on net sales of Tostrex. In January 2006, Cellegy amended its 2004 agreement with ProStrakan concerning Tostrex. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase Tostrex directly from Cellegy's contract manufacturer rather than purchasing the product from Cellegy under the terms of the original agreement. Cellegy will continue to be eligible to receive milestones and royalties as set forth in the original agreement.

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 remained 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. In connection therewith, Cellegy received a non-refundable upfront payment of \$1.0 million and was entitled to receive additional milestone payments and payments for products sold to ProStrakan. ProStrakan will be responsible for additional regulatory filings, sales, marketing and distribution of Rectogesic throughout Europe. Under the original agreement, Cellegy was responsible for supplying finished product to ProStrakan through its contract manufacturer.

On April 11, 2005, Cellegy entered into a settlement agreement with PDI resolving the lawsuits that the companies had filed against each other. Under the terms of the settlement agreement, the license agreement was terminated and all product rights have reverted to Cellegy. Cellegy paid \$2.0 million to PDI upon signing the settlement agreement. Cellegy also issued a \$3.0 million promissory note to PDI, due in October 2006, and a \$3.5 million non-negotiable senior convertible debenture. The settlement of the Company's lawsuit with PDI resulted in the recognition of the remaining \$6.5 million in deferred revenue from PDI as license revenue during the quarter ended June 30, 2005.

In November 2005, Cellegy renegotiated its marketing agreement with ProStrakan. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase the product directly from the manufacturer rather than from Cellegy. In connection with its revised marketing agreement, Cellegy received a payment of \$2.0 million and may receive certain future milestone payments of up to \$750,000 upon approval of the product in certain major European countries.

On January 16, 2006, Cellegy entered into an amendment of its Exclusive License and Distribution Agreement dated July 9, 2004, with ProStrakan Group plc, whereby ProStrakan will assume responsibility for all of the manufacturing and other product support functions for Tostrex in Europe. In December 2004, the product was approved by the MPA for sale in Sweden.

On February 1, 2006, Cellegy announced that it had entered into a non-exclusive, developing world licensing agreement with CONRAD for the collaboration on the development of Cellegy's entire microbicide pipeline. The agreement encompasses the licensing of Savvy currently in Phase 3 clinical trials in the United States and Africa; UC-781, currently in expanded Phase 1 trials in the United States and Thailand; and Cyanovirin-N, currently in pre-clinical development.

On March 24, 2006, the Company announced that its European marketing partner, ProStrakan had successfully completed the European Union Mutual Recognition Procedure for Rectogesic. Following the successful conclusion of the MRP process, national licenses will be sought and are expected to be issued in due course in the 19 additional countries (in addition to the United Kingdom where approvals have been previously obtained) included in the MRP submission application. Cellegy is entitled to receive \$250,000 for each marketing regulatory approval obtained in the first of any three countries out of France, Italy, Germany or Spain up to a maximum total amount payable of \$750,000. Under its previous agreement with PDI, Inc, PDI is entitled to receive one-half of these payments.

## **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, 2005, \$759,906 of expenses covered under research and development agreements were earned and recorded as grant revenue but were unbilled.

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 recorded in connection with Cellegy's acquisition of Biosyn. In accordance with SFAS No. 142 "Goodwill and Other Intangible Assets", goodwill and other intangible assets are no longer systematically amortized, but rather Cellegy performs an annual assessment for impairment by applying a fair-value based test. This test is generally performed each year in the fourth quarter. 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. An impairment would require Cellegy to charge to earnings the write-down in value of such assets.

*Impairment of Long Lived Assets.* Cellegy 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.

*Notes Payable.* Notes payable include non-interest bearing notes issued by Cellegy to PDI pursuant to a lawsuit settlement, and a note issued to the Ben Franklin Institute. The notes have been recorded at their net present value at the time of issuance.

*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. Cellegy 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 certain warrants issued in conjunction with its financings as derivative financial instruments. 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**

Biosyn was acquired on October 22, 2004 and its results were included in consolidation from its date of acquisition. Cellegy believes that there is no significant impact from inflation and changing prices on its sales, revenues and net losses for the periods presented.

### ***Years Ended December 31, 2005, 2004 and 2003***

*Revenues.* Cellegy had revenues of \$12,835,000, \$2,596,000 and \$1,620,000 in 2005, 2004 and 2003, respectively. Revenues in each of the three years presented consist of licensing, milestone and product sales revenues. Revenues in 2004 and 2005 include grant revenue generated primarily by Biosyn's operations.

*Licensing revenues.* Licensing revenues were \$7,268,000, \$844,000 and \$833,000 in 2005, 2004 and 2003, respectively. The \$6,424,000 increase in licensing revenue in 2005 as compared to 2004 was primarily attributable to the settlement of Cellegy's lawsuit with PDI in April 2005 which resulted in the recognition of the remaining \$6.5 million of deferred revenues from PDI. In 2004 and 2003, 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. The balance of licensing revenues in each of the three years presented arose from the amortization to income of deferred revenue recorded in connection with agreements relating to Rectogesic and Tostrex. We expect licensing revenues to decline significantly in the future.

In November 2005, we amended our 2004 agreement with ProStrakan concerning Rectogesic. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase Rectogesic directly from Cellegy's contract manufacturer rather than purchasing the product from Cellegy under the terms of the original agreement. In return, Cellegy received a non-refundable payment of \$2.0 million and may receive future milestone payments of up to \$750,000 upon approval of the product in certain major European countries. The \$2.0 million non-refundable payment is being amortized to income over the remaining estimated life of the underlying patent. Approximately \$22,000 was amortized to income in 2005.

*Product sales.* Product sales were \$1,157,000, \$745,000 and \$768,000 in 2005, 2004 and 2003, respectively. Pacific rim sales of Rectogesic through our Australian subsidiary were \$637,000, \$563,000 and \$385,000 in 2005, 2004 and 2003, respectively. The revenue growth in 2004 was due primarily to effective advertising and selling programs for Rectogesic throughout Australia. We expect that the growth in sales revenues through our Australian subsidiary will continue to increase in 2006 but at a lower annual rate and activities concerning the research of new markets and new uses for Rectogesic have been undertaken.



Product sales in 2004 and 2003 included \$181,000 and \$316,000 in skin care product sales. There were no skin care product sales in 2005 and, in December 2005, Cellegy divested this business for approximately \$25,000.

Rectogesic was launched in the United Kingdom in May 2005. Product sales in 2005 included approximately \$471,000 of sales of Rectogesic to ProStrakan in connection with ProStrakan's marketing of Rectogesic in the U.K. Due to the renegotiation of its agreement with ProStrakan mentioned above, Cellegy will no longer record sales of Rectogesic to ProStrakan.

Tostrex was launched in Sweden in September 2005. Tostrex sales were not significant in 2005 and unless additional jurisdictions approve the marketing of Tostrex, Cellegy does not expect a significant level of sales from this product. ProStrakan is presently pursuing additional marketing approvals for Tostrex in mainland Europe through the Mutual Recognition Procedure.

In January 2006, Cellegy amended its 2004 agreement with ProStrakan concerning Tostrex. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase Tostrex directly from Cellegy's contract manufacturer rather than purchasing the product from Cellegy under the terms of the original agreement. Cellegy will continue to be eligible to receive milestones and royalties as set forth in the original agreement.

*Grant revenues.* Grant revenues for 2005 were \$4,410,000 and were \$1,008,000 for the period of October 22 to December 31, 2004. Grant revenue was not significant in 2003.

Grant revenues for 2005 were generated by funding from several agencies in support of the following development programs: \$3,146,000 for Cyanovirin-N, \$451,000 for Savvy, \$424,000 for UC-781 and \$387,000 for a UC-781/C31G combination product. 2004 grant revenues for the period of October 22 to December 31, 2004 were as follows: \$562,000 for Cyanovirin-N, \$273,000 for Savvy, \$76,000 for UC-781 and \$94,000 for a UC-781/C31G combination product. The level of grant funding under the various grant arrangements is generally dependent upon the amount of direct labor (primarily laboratory personnel) and direct expenses such as supplies, testing services and other direct costs expected to be incurred in connection with the given program over its duration. The grant agreements generally provide for an overhead percentage that is applied to the direct labor costs. These amounts, along with the amounts billed to the grantor for direct costs comprise the total amount billed and recorded as grant revenue. Grant agreements undergo periodic renegotiation and it is the prerogative of granting agency or foundation to determine the level and duration of future funding of Cellegy's programs. There can be no assurance that Cellegy will be able to maintain grant funding at current levels or at levels necessary to properly fund its research programs.

In addition to the grants funding above, Biosyn benefits indirectly from agency funding paid to third party contractors in support of its ongoing Phase 3 clinical trials. These payments from the funding agencies are made directly to the service providers, not to Biosyn. 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.

*Cost of Product Sales.* Cost of product sales is comprised primarily of direct labor and raw material manufacturing costs for commercialized products and also includes shipping costs and those costs associated with stability and validation testing of finished goods prior to shipment. The stability and validation testing components of cost of product sales comprise a significant percentage of gross sales since these costs are substantially fixed in nature. Cost of product sales were \$385,000, \$148,000 and \$186,000 in 2005, 2004 and 2003, respectively. The increase of \$237,000 in 2005 as compared to 2004 is due to increased sales volume generated by Pacific Rim sales and due to the launch of Rectogesic and Tostrex in 2005. Due to the renegotiation of our agreements with ProStrakan mentioned above, we expect cost of product sales to decline in 2006.

*Research and Development Expenses.* Research and development expenses were \$8,481,000, \$9,599,000 and \$10,558,000 in 2005, 2004 and 2003, respectively. Research and development expenses, which are primarily related to the costs of clinical trials and regulatory filings, represented 48%, 31% and 68% of our total operating expenses in 2005, 2004 and 2003, respectively.

On a consolidated basis, 2005 research and development expenses decreased approximately \$1.1 million compared to 2004.

Cellegy research and development expenses at the parent level decreased \$4.8 million in 2005 as compared to 2004. \$2.2 million of this decrease was predominantly due to the cessation of clinical testing activities for Cellegesic in the U.S., and a \$1.0 million decrease in clinical material manufacturing costs. The balance of the decrease was comprised primarily of decreases in salary costs of \$800,000 due to the termination of Cellegesic and Fortigel trials and the termination of associated personnel, and reductions in related professional, consulting and CRO fees.

Biosyn research and development expenses are included in our operations for a full year for 2005 and for the period of October 22 to December 31, 2004 in 2004. Biosyn's research expenses increased \$4.7 million in 2005 as compared to the short period in 2004 and offset the 2005 decrease in Cellegy research and development expenses noted above. Savvy Phase 3 trials were being conducted in three major locations in 2005: Ghana and Nigeria for HIV clinical testing and in the United States for contraception clinical trials. In late 2005, Cellegy announced that the first interim analysis had taken place for the Ghana trial and that while the trial's Data Monitoring Committee found no reason to interrupt or stop the trial based on a review of safety, the number of sero-conversions were approximately one-third of the expected rate. As a result of this finding, Cellegy decided to terminate the Ghana trial. At the time of the termination, the Ghana HIV trial reached full enrollment. Spending for major programs in 2005 consisted of \$1.6 million in spending related to Savvy HIV and contraception trial programs, \$3.1 million in spending relating to Cyanovirin-N and \$426,000 on UC-781 programs. Savvy related study costs are comprised primarily of \$1.4 million in clinical material manufacturing of active and placebo compounds and applicators and related shipping costs to African trial sites. Cyanovirin-N program costs are comprised of \$2.5 million in direct expenses and UC-781 programs costs are comprised of \$343,000 in direct expenses.

Total research and development in 2004 as compared with 2003 decreased \$959,000 due primarily to a reduction in clinical and regulatory costs in 2004 of \$2,865,000 primarily relating to Cellegesic Phase 3 clinical trial expenses and various Fortigel clinical costs. These were offset somewhat in 2004 by higher research and development expenses of \$860,000 incurred by Biosyn primarily for the development of Savvy 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 Pharmaceuticals for a milestone achieved during 2004.

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.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$9,249,000 in 2005, \$6,641,000 in 2004, and \$4,768,000 in 2003. Biosyn selling, general and administrative expenses are included in Cellegy's operations for a full year for 2005 and for the period of October 22 to December 31, 2004 in 2004. California personnel previously engaged in research or development are now being reported under selling, general and administrative, as the parent's efforts in the latter part of 2005 have shifted substantially towards the management of its manufacturing activities or towards other administrative functions.

In 2005, selling, general and administrative expenses increased by \$2.7 million in 2005 as compared to 2004. Approximately \$1.6 million of this increase is due to the inclusion of Biosyn for a full year in 2005 operations. The balance of this increase was due to: increase in salary expense at the parent level due to increased severance and retention expenses of \$570,000, increase in professional fees of \$515,000 due to accounting and audit fees related to the 2004 reincorporation, legal fees incurred in connection with the PDI litigation and patent fees. The overall increase in selling, general and administrative expenses was partly offset by income of \$1,090,000 recognized upon the receipt of the sublease termination fee. Cellegy announced in the third quarter of 2005 the relocation of its headquarters to its Biosyn facility in Pennsylvania and it is expected that the Brisbane, California office will be closed during the second quarter of 2006.

Selling, general and administrative expenses in 2004 increased by \$1,873,000, 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.

We expect selling, general and administrative expenses in 2006 to decline somewhat due to the 2005 reductions in staffing and related expenses such as benefits, and due to expected reductions in consulting and accounting fees. These reductions, however, may be partially offset by PDI litigation expenses expected in 2006.

*Acquired-In-Process Technology.* Results for 2004 included an in-process technology charge of \$15.0 million incurred in connection with the acquisition of Biosyn on October 22, 2004. The in-process programs include the Phase 3 development of Savvy microbicide vaginal gel. Other development programs include UC-781 and Cyanovirin-N microbicides which are in much earlier stages of testing.

Based on a risk assessment of the technology, its stage of development and the estimated level of effort required to complete the clinical testing to facilitate regulatory review, management 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 no alternative future use. Accordingly, the amount allocated to purchase research and development of approximately \$15.0 million was charged to income in 2004. Substantial 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 approval.

*Other Income (Expense).* Cellegy recognized net interest and other income of \$208,000 in 2005, \$259,000 for 2004, and \$360,000 for 2003. Net interest and other income for 2005 consisted of \$174,000 in interest income, \$626,000 in interest expense primarily from the PDI notes, \$690,000 derivative revaluation income associated with the Kingsbridge and PIPE warrants and \$93,000 primarily consisting of rental income. Net interest and other income for 2004 was comprised primarily of \$110,000 in interest income, \$149,000 in rental income and derivative revaluation income 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. 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 \$2.3 million, \$8.7 million and \$7.6 million at December 31, 2005, 2004 and 2003, respectively.

Cash and cash equivalents decreased \$6.5 million during 2005 due primarily to the inclusion of a full year of Biosyn operations in Cellegy's 2005 consolidated results, the cash payment of \$2.0 million made in connection with settlement of PDI's lawsuit and its associated legal costs, and severance and retention payments of \$521,000. The settlement with PDI included the issuance of two non-interest bearing long-term notes with an aggregate face value of \$6.5 million which Cellegy recorded at their net present value of approximately \$4.7 million. The use of cash from operating activities during 2005 was partially offset by \$5.7 million in net proceeds provided by financing activities from the May 2005 sale of common stock, \$1.1 million received from Vaxgen as part of the sublease termination agreement, \$2.0 million from ProStrakan in connection with the amendment of the Rectogesic agreement. Restricted cash proceeds of \$227,000 were received as part of the termination of the lease on the Company's South San Francisco facility.

Non cash events during 2005 include the recognition of \$6.5 million in licensing revenue from PDI recorded in conjunction with the litigation settlement, \$1.2 million in fixed asset and leasehold improvement write offs due to the Company's move to the Brisbane facility, additional fixed asset write offs of certain manufacturing equipment and modifications of \$374,000 and interest expense of \$532,000 arising from the accretion of the PDI and Ben Franklin notes payable. Accrued expenses and other current liabilities decreased \$690,000 due to the lower accruals for legal, clinical and consulting fees, offset by increases in retention and severance accruals in 2005.

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 2004 private placement financing and Kingsbridge SSO draw downs of approximately \$11.2 million and \$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.

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 \$750,000 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 \$600,000 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.

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, 2005, we had a deficit accumulated during the development stage of \$132.3 million, negative cash flows from operations of \$96.2 million, and cash and cash equivalents of \$2.3 million. We expect negative cash flow from operations to continue for the foreseeable future, with the need to continue or expand development programs and to commercialize products once regulatory approvals have been obtained. We believe we do not have enough financial resources to continue operations beyond April 2006. 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: sales of assets, seeking partnerships with other pharmaceutical companies or private foundations 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.

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 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.

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.

Cellegy believes that available cash resources will be adequate to satisfy our capital needs through at least April 30, 2006 assuming no material adverse financial impact associated with the PDI litigation and any subsequent legal proceedings. At present, our revenues from existing licensing arrangements, funding agreements and other sources are not sufficient to offset our ongoing operating expenses or to pay in full our current obligations. Funds provided from sales of subsidiaries, assets, equity or debt financing, or other arrangements, if obtained, would permit satisfaction of capital needs for a longer period of time. A favorable determination by the FDA Advisory Committee and the FDA following the scheduled April 2006 hearing on our Cellegesic NDA may improve the prospects for one or more such transactions although there can be no assurances that this will be the case. The existence and extent of our obligations could adversely affect our business, operations and financial condition. Failure to obtain additional funds as described above may affect the timing of development, clinical trials or commercialization activities relating to certain products and could require us to curtail our operations, reduce personnel, sell part or all of our assets or seek protection under bankruptcy laws. There is a risk that one or more of our creditors could bring lawsuits to collect amounts to which they believe they are entitled. In the event of lawsuits of this type, if we are unable to negotiate settlements or satisfy our obligations, we could voluntarily file bankruptcy proceedings, or we could become the subject of an involuntary bankruptcy proceeding filed by one or more creditors against us.

### Contractual Obligations

The table below summarizes certain of our future contractual obligations, which include obligations under our current facilities leases in Brisbane, California and Huntingdon Valley, Pennsylvania along with capital equipment lease obligations at December 31, 2005 (in thousands):

	<u>Total</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>
Operating lease	\$ 756	\$ 332	\$ 264	\$ 160
Capital lease	60	55	5	-
PDI Notes	6,300	2,800	-	3,500
Total	<u>\$ 7,116</u>	<u>\$ 3,187</u>	<u>\$ 269</u>	<u>\$ 3,660</u>

In March 2005, we relocated our principal office from South San Francisco to Brisbane, California. Our sublease for the office in Brisbane has a term that expires February 28, 2006. In March, 2006, Cellegy extended its sublease agreement with Vaxgen. Under the terms of the new agreement, the Company will lease its existing facilities in Brisbane for \$6,000 per month beginning March 1, 2006 through June 30, 2006 and for \$13,000 per month until May 31, 2007.

Other obligations not reflected in the table are comprised primarily of employment agreements, employee retention agreements, and severance payments of \$129,000 to a former executive officer. License agreements and notes payable. The above table also excludes milestone, royalty payments and the repayment obligation, as such amounts are not probable or estimable at this time. License agreements generally provide for payment by us of annual license fees, milestone payments and royalties upon successful commercialization of products.

Under the Kingsbridge SSO, we have not issued and sold common stock pursuant to the draw down provisions equal to at least \$2.66 million during the term of the agreement which expires in January 2006. As a result, unless these provisions are amended or waived we owe \$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.

### Off Balance Sheet Arrangements

As more fully described in Note 8, "Notes Payable", Cellegy issued a \$3.5 million senior convertible debenture to PDI in 2005 in connection with the settlement of its lawsuit with PDI. Cellegy may redeem the note at anytime before the maturity date upon prior notice to PDI, at a redemption price equal to the principal amount. If Cellegy delivers such a redemption notice, PDI may convert the note into shares of Cellegy common stock at a price of \$1.65 per share. In addition, after the 18th month anniversary of the debenture, PDI may convert the note into Cellegy common stock at a price of \$1.65 per share. If Cellegy does not redeem the note within the first 18 months, then Cellegy has agreed to file a registration statement relating to the possible resale of any shares issued to PDI after 18 months. 2,121,212 shares would be issuable upon such conversion.

## Recent Accounting Pronouncements

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 exchange 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 public companies with a fiscal year that begins after June 15, 2005. The cumulative effect of this pronouncement applied on a modified prospective basis will be measured and recognized starting the first quarter of 2006. We anticipate that the impact of Adopting SFAS No. 123R will result in an annual expense of approximately \$292,000 based on known grants. 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.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3". The statement requires retrospective application of changes in accounting principle to prior periods' financial statements, unless it is impracticable to determine either the period specific effects or the cumulative effect of the change. When it is impracticable to determine the period specific effects of an accounting change on one or more individual prior periods presented, this statement requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable, and that a corresponding adjustment be made to the opening balance of the retained earnings for that period rather than being reported in the income statement. The statement also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This pronouncement is effective for accounting changes made in fiscal years beginning after December 15, 2005. The Company does not believe adoption of SFAS 154 will have a material effect on its consolidated financial position, results of operations or cash flows.

### 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, 2005 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. 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 and to the May 2005 investors to purchase approximately 1.4 million 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.

**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-38 of this report.

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Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
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**ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES**

None.

**ITEM 9A: CONTROLS AND PROCEDURES***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 the end of the period covered by this form 10K. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures were effective in timely providing them with material information relating to the Company, as required to be disclosed in the reports the Company files under the Exchange Act.

*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 Officer and Chief Financial Officer that occurred during the Company's last fiscal 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 2005 fiscal year and to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held in June 2006 (the "2006 Proxy Statement"). Such information is incorporated herein by reference. Information required by this Item with respect to executive officers is set forth below:

Richard C. Williams	62	Chairman and Interim Chief Executive Officer, Director
John J. Chandler	64	Vice President, Corporate Development
Robert J. Caso	50	Vice President, Finance and Chief Financial Officer

*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.

*Robert J. Caso.* Mr. Caso became Vice President, Finance and Chief Financial Officer in March 2005. From January 2003 through 2004, he headed a multinational team in connection with the implementation of an SAP application for Johnson & Johnson's Worldwide Pharmaceutical Group. Subsequent to Johnson & Johnson's acquisition of Centocor in 1999, Mr. Caso held the Financial Controller position at Centocor. From 1988 through 1995 he held various finance positions at Centocor and held the Corporate Controller position from 1996 to 1999. Mr. Caso has substantial experience in finance operations, accounting systems, business financing and domestic and international taxation. Mr. Caso is a Certified Public Accountant and holds a BS in Accounting from Villanova University and an MBA in Finance from Lehigh University.

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

### ITEM 11: EXECUTIVE COMPENSATION

Information with respect to this Item may be found in the section captioned "Executive Compensation" appearing in the forthcoming 2006 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 2006 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 2006 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 2006 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibits

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

<b>Exhibit Number</b>	<b>Exhibit Title</b>
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 and to Exhibit 10.6 to the Annual Report on Form 10-K for the year ended December 31, 2004 (the "2004 Form 10-K").) (Incorporated by reference to Exhibit 10.6 to the Annual Report on Form 10-K for the year ended December 31, 2004 (the "2004 Form 10-K").)
10.5	Sublease Agreement, dated as of March 18, 2005, by and between the Company and VaxGen, Inc. (Incorporated by reference to Exhibit 10.6 to the Annual Report on Form 10-K for the year ended December 31, 2004 (the "2004 Form 10-K").)
*10.6	Employment Agreement, effective January 1, 2003, between the Company and K. Michael Forrest.
10.7	Share Purchase Agreement dated as of November 27, 2001, by and among the Company, Vaxis Therapeutics Corporation and certain stockholders of Vaxis. (Incorporated by reference to Exhibit 10.14 to the Company's Form 10-K for the fiscal year ended December 31, 2001.)
10.8	Exclusive License Agreement dated as of December 31, 2002, by and between the Company and PDI, Inc. (Confidential treatment has been requested with respect to portions of this agreement.) (Incorporated herein by reference to Exhibit 10.10 to the Company's Form 10-K for the year ended December 31, 2002.)
10.9	Common Stock Purchase Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited. (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.)
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 Appendix B to the Registrant's definitive proxy statement filed with the Commission on April 28, 2004.)
- 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. (Incorporated by reference to Exhibit 10.18 to the 2004 Form 10-K.)
- 10.19 Exclusive License Agreement for Tostrex dated as of July 9, 2004, by and between ProStrakan 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 ProStrakan International Limited and the Company. (Confidential treatment has been requested for portions of this agreement.) (Incorporated by reference to Exhibit 10.20 to the 2004 Form 10-K.)
- 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.) (Incorporated by reference to Exhibit 10.21 to the 2004 Form 10-K.)
- 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.) (Incorporated by reference to Exhibit 10.22 to the 2004 Form 10-K.)
- 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.) Incorporated by reference to Exhibit 10.23 to the 2004 Form 10-K.)
- 10.24 2005 Equity Incentive Plan.
- 10.25 Forms of Option Agreements under the 2005 Equity Incentive Plan.
- 10.30 First Amended and Restated Exclusive Equity Agreement dated as of November 9, 2005, between Cellegy and ProStrakan International Limited. (Confidential treatment has been requested for portions of this exhibit.)
- 10.31 First Amended and Restated Exclusive License Agreement dated as of January 16, 2006, between Cellegy and ProStrakan International Limited. (Confidential treatment has been requested for portions of this exhibit.)
- 21.1 Subsidiaries of the Registrant.
- 23.1 Consent of PricewaterhouseCoopers 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.

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\* 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 Huntingdon Valley, Commonwealth of Pennsylvania, on March 30, 2006.

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 Robert J. Caso, 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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<b>Principal Executive Officer:</b>		
<u>/s/ RICHARD C. WILLIAMS</u> Richard C. Williams	Chairman, Interim Chief Executive Officer and Director	March 30, 2006
<b>Principal Financial Officer and Principal Accounting Officer:</b>		
<u>/s/ ROBERT J. CASO</u> Robert J. Caso	Vice President, Finance, Chief Financial Officer and Secretary	March 30, 2006
<b>Directors:</b>		
<u>/s/ JOHN Q. ADAMS</u> John Q. Adams, Sr.	Director	March 30, 2006
<u>/s/ TOBI B. KLAR, M.D.</u> Tobi B. Klar, M.D.	Director	March 30, 2006
<u>/s/ ROBERT B. ROTHERMEL</u> Robert B. Rothermel	Director	March 30, 2006
<u>/s/ THOMAS M. STEINBERG</u> Thomas M. Steinberg	Director	March 30, 2006

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statement of operations, stockholders' equity (deficit) and comprehensive loss, and cash flows present fairly, in all material respects, the financial position of Cellegy Pharmaceuticals, Inc. and its subsidiaries (a development stage company) at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, and cumulatively, for the period from January 1, 2003 to December 31, 2005 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 64.7 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.

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.

PricewaterhouseCoopers LLP  
March 30, 2006

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

**Consolidated Balance Sheets**

	December 31,	
	2005	2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,250,989	\$ 8,705,120
Short-term investments	11,189	—
Accounts receivable	1,085,235	885,810
Prepaid expenses and other current assets	1,428,866	282,184
<b>Total current assets</b>	<b>4,776,279</b>	<b>9,873,114</b>
Restricted cash	—	227,500
Property and equipment, net	496,419	1,952,408
Goodwill	981,081	1,031,311
Intangible assets, net	196,204	778,992
<b>Total assets</b>	<b>\$ 6,449,983</b>	<b>\$ 13,863,325</b>
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,756,296	\$ 1,691,952
Accrued expenses and other current liabilities	2,402,237	2,724,808
Current portion of deferred revenue	302,593	1,196,260
Current portion of notes payable	4,975,892	—
<b>Total current liabilities</b>	<b>9,437,018</b>	<b>5,613,020</b>
Notes payable	212,300	717,257
Derivative instrument	192,570	410,800
Deferred revenue	3,084,629	13,865,064
<b>Total liabilities</b>	<b>12,926,517</b>	<b>20,606,141</b>
Commitments and contingencies (Note 12)		
Stockholders' deficit:		
Preferred stock, no par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2005 and 2004	—	—
Common stock, par value \$.0001; 50,000,000 shares authorized; 29,831,625 and 26,120,440 shares issued and outstanding at December 31, 2005 and 2004, respectively	2,983	2,612
Additional paid-in capital	125,547,788	120,253,688
Accumulated other comprehensive income	283,694	304,244
Deficit accumulated during the development stage	(132,310,999)	(127,303,360)
<b>Total stockholders' deficit</b>	<b>(6,476,534)</b>	<b>(6,742,816)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 6,449,983</b>	<b>\$ 13,863,325</b>

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
	2005	2004	2003	June 26, 1989 (inception) to December 31, 2005
<b>Revenues:</b>				
Licensing and contract revenue from affiliates	\$ —	\$ —	\$ —	\$ 1,145,373
Licensing, milestone and development funding	7,268,270	844,044	833,340	10,497,062
Grants	4,410,243	1,007,500	18,833	5,984,709
Product sales	1,156,832	744,833	768,325	7,772,402
<b>Total revenues</b>	<b>12,835,345</b>	<b>2,596,377</b>	<b>1,620,498</b>	<b>25,399,546</b>
<b>Costs and expenses:</b>				
Cost of product sales	384,727	147,849	185,891	2,039,341
Research and development	8,481,105	9,599,310	10,558,174	90,255,973
Selling, general and administrative	9,248,820	6,641,205	4,768,529	47,609,150
Acquired in-process technology	—	14,981,816	—	22,331,918
<b>Total costs and expenses</b>	<b>18,114,652</b>	<b>31,370,180</b>	<b>15,512,594</b>	<b>162,236,382</b>
Operating loss	(5,279,307)	(28,773,803)	(13,892,096)	(136,836,836)
Interest and other income	207,669	258,693	359,948	7,053,024
Interest and other expense	(625,709)	(28,952)	—	(2,158,390)
Derivative revaluation	689,708	390,000	—	1,079,708
Net loss	(5,007,639)	(28,154,062)	(13,532,148)	(130,862,494)
Non-cash preferred dividends		—	—	1,448,505
Net loss applicable to common stockholders	\$ (5,007,639)	\$ (28,154,062)	\$ (13,532,148)	\$ (132,310,999)
Basic and diluted net loss per common share	\$ (0.18)	\$ (1.28)	\$ (0.68)	
Weighted average common shares used in computing basic and diluted net loss per common share	28,497,364	22,020,689	19,963,552	

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



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

**Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss**

	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 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	-	\$ -	-	\$ -	-	\$ -
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 connection with notes payable in financing	-	-	-	-	-	-	-	487,333	-	-	-	487,333
Issuance of common stock in connection with private placement of common stock in July, 1997, net of issuance 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) and Comprehensive Loss (Continued)**

	Series A		Series B Convertible		Series C Convertible		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Convertible Preferred Stock		Preferred Stock		Preferred Stock							
	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 costs	-	-	-	-	-	-	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	-	-	-	-	-	-	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) and Comprehensive Loss (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	-	-	-	-	-	-	571,086	966,479	-	-	-	966,479
Compensation expense related to options and warrants issued to non-employees	-	-	-	-	-	-	-	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
Unrealized gain/(loss) on investments	-	-	-	-	-	-	-	-	-	103,385	-	103,385
Gain/(loss) on foreign currency translation	-	-	-	-	-	-	-	-	-	(19,927)	-	(19,927)
Net loss	-	-	-	-	-	-	-	-	-	-	(68,928,043)	(68,928,043)
<b>Total Comprehensive Loss</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(68,844,585)</b>
Balances at December 31, 2001	-	-	-	-	-	-	17,295,724	90,137,811	-	83,458	(70,376,548)	19,844,721
Exercise of options to purchase common stock	-	-	-	-	-	-	156,632	454,983	-	-	-	454,983
Issuance of common stock in connection with the private placement of common stock in November 2002, net of issuance 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
<b>Components of comprehensive loss:</b>												
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)
<b>Total Comprehensive Loss</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(15,312,229)</b>
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) and Comprehensive Loss (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 costs of \$16,741	-	-	-	-	-	-	3,020,000	302	10,310,402	-	-	10,310,704
Kingsbridge drawdown, net of issuance costs of \$156,928	-	-	-	-	-	-	246,399	25	843,043	-	-	843,068
Derivative instrument in connection with Kingsbridge financing	-	-	-	-	-	-	-	-	(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 Stockholders' Equity (Deficit) and Comprehensive Loss (Continued)**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Deficit Accumulated During the Development	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Stage	Deficit
Exercise of options to purchase common stock	-	-	-	-	-	-	89,366	9	41,511	-	-	41,520
Compensation expense for options related to non employees	-	-	-	-	-	-	-	-	651	-	-	651
Issuance of common stock and warrants in connection with the private placement of common stock in May 2005, net of issuance cost of \$233,000	-	-	-	-	-	-	3,621,819	362	5,720,826	-	-	5,721,188
Derivative instrument issued in connection with the May, 2005 PIPE	-	-	-	-	-	-	-	-	(471,479)	-	-	(471,479)
Components of comprehensive loss												
Gain/(Loss) on foreign currency translation	-	-	-	-	-	-	-	-	-	(29,148)	-	(29,148)
Unrealized Gain on Market Securities	-	-	-	-	-	-	-	-	2,591	8,598	-	11,189
Net loss	-	-	-	-	-	-	-	-	-	-	(5,007,639)	(5,007,639)
Total comprehensive loss	-	-	-	-	-	-	-	-	-	-	-	(5,025,598)
Balances at December 31, 2005	-	\$ -	-	\$ -	-	\$ -	29,831,625	\$ 2,983	\$ 125,547,788	\$ 283,694	\$ (132,310,999)	\$ (6,476,534)

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
	2005	2004	2003	June 26, 1989 (inception) to December 31, 2005
<b>Operating activities</b>				
Net loss.	\$ (5,007,639)	\$ (28,154,062)	\$ (13,532,148)	\$ (130,862,494)
<b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b>				
Acquired in-process technology.	—	14,981,816	—	22,331,918
Depreciation	360,236	415,078	373,507	3,377,937
Bad debt expense and other non-cash items.	199,798	—	—	199,798
Intangible assets amortization	582,788	164,066	193,409	1,923,931
Loss (gain) on sale of fixed assets.	1,000,840	30,710	666,875	1,611,949
Equity compensation expense	651	109,149	578,784	2,300,299
Derivative revaluation	(689,708)	(390,000)	—	(1,079,708)
Interest accretion on notes payable	531,759	—	—	531,759
PDI Settlement	2,000,000	—	—	2,000,000
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
<b>Changes in operating assets and liabilities:</b>				
Prepaid expenses and other current assets.	(602,428)	142,077	(3,566)	(907,832)
Accounts receivable	(265,416)	(398,900)	72,833	(855,880)
Other assets	58,642	—	—	308,642
Accounts payable	83,345	(285,952)	720,061	474,271
Other long term liabilities	(489,658)	(261,807)	—	(34,846)
Deferred revenue	(13,718,802)	476,075	(832,000)	925,273
Accrued expenses and other current liabilities.	(773,375)	(1,179,173)	(1,057,540)	(838,701)
Net cash provided by operating activities	(16,728,967)	(13,600,923)	(12,769,785)	(96,211,002)
<b>Investing activities</b>				
Purchases of property and equipment	(103,497)	(203,988)	(362,335)	(5,507,240)
Purchases of investments	(11,189)	—	(11,019,220)	(98,920,763)
Sale of investments.	—	—	5,334,000	43,509,646
Maturity of investments	—	3,686,919	4,000,000	55,304,678
Proceeds from restricted cash.	227,500	—	—	613,999
Proceeds from sale of property	—	—	50,337	237,674
Acquisition of Vaxis, Quay and Biosyn.	—	(303,966)	—	(815,522)
Net cash provided by (used in) investing activities	112,814	3,178,965)	(1,997,218)	(5,577,528)
<b>Financing activities</b>				
Proceeds from notes payable.	—	—	—	8,047,424
Issuance of notes payable.	4,444,133	—	—	4,444,133
Repayment of notes payable.	—	—	—	(6,610,608)
Net proceeds from issuance of common stock	5,747,037	11,457,601	525,436	86,841,626
Other assets	—	—	—	(614,000)
Issuance of convertible preferred stock, net of issuance cost.	—	—	—	11,757,735
Deferred financing costs.	—	—	—	(80,170)
Net cash provided by (used in) financing activities	10,191,170	11,457,601	525,436	103,786,140
Effect of exchange rate changes on cash.	(29,148)	19,599	262,928	253,379
Net increase (decrease) in cash and cash equivalents.	(6,454,131)	1,055,242	(13,978,639)	2,250,989
Cash and cash equivalents, beginning of period.	8,705,120	7,649,878	21,628,517	—
Cash and cash equivalents, end of period	<u>\$ 2,250,989</u>	<u>\$ 8,705,120</u>	<u>\$ 7,649,878</u>	<u>\$ 2,250,989</u>

The accompanying notes are an integral part of these financial statements

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

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

	Years ended December 31,			Period from
				June 26, 1989
	2005	2004	2003	(inception) to December 31, 2005
<b>Supplemental cash flow information</b>				
Interest paid	\$ 85,958	\$ —	\$ —	\$ 725,945
<b>Supplemental disclosure of non-cash transactions:</b>				
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	5,720,826	—	—	5,998,026
Issuance of warrants in connection with Kingsbridge financing	—	800,800	—	800,800
Issuance of warrants in connection with notes payable financing	471,479	—	—	958,812
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

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

**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. Cellegy Canada, Inc.’s operations ceased in the fourth quarter of 2005 with all of the subsidiary’s assets liquidated. Canada’s 2005 results were included in the consolidation up until the liquidation. 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, engaged in the development and commercialization of 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.

*Liquidity and Capital Resources*

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, 2005, we had a deficit accumulated during the development stage of \$132.3 million, negative cash flows from operations of \$96.2 million, and cash and cash equivalents of \$2.3 million. We expect negative cash flow from operations to continue for the foreseeable future, with the need to continue or expand development programs and to commercialize products once regulatory approvals have been obtained. We believe we do not have enough financial resources to continue operations beyond April 2006. 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: sales of assets, seeking partnerships with other pharmaceutical companies or private foundations 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.

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 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.



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

*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, 2005, \$759,906 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. Unbilled grants at December 31, 2004 were \$833,630.

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.

*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.

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

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, 2005 and 2004. The Company's cash and cash equivalents are maintained at two financial institutions in the United States, and one financial institution in Australia. 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 was classified as restricted cash and was shown separately in the balance sheet as a non-current asset. In 2005 the lease was terminated and the letter of credit cancelled.

*Concentration of Credit Risk*

At December 31, 2005, the Company had its cash in money market funds.

*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.

	<u>Estimated Useful Life</u>
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 represents the difference between the purchase price and the estimated fair value of the net assets acquired when accounted for by the purchase method of accounting. In accordance with FAS 142, "Goodwill and Intangible Assets", we do not amortize goodwill. 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.

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

SFAS No. 142 also requires that intangible assets with definite lives be amortized over their estimated useful lives. The Company amortizes intangible assets on a straight-line basis over their estimated useful lives.

*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 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.

*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:

	<b>December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Gain (loss) on foreign exchange translation	\$ 275,096	\$ 284,199	\$ 254,810
Unrealized gain (loss) on investments	8,598	20,045	20,045
Accumulated other comprehensive income (loss)	\$ 283,694	\$ 304,244	\$ 274,855

*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.

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

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:

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss, as reported	\$ (5,007,639)	\$ (28,154,062)	\$ (13,532,148)
Add: Stock based employee costs included in reported net loss	—	80,860	425,000
Deduct: Stock-based employee compensation costs determined under the fair value based method for all awards	(421,750)	(790,518)	(1,839,447)
Net loss, pro forma	<u>\$ (5,429,389)</u>	<u>\$ (28,863,720)</u>	<u>\$ (14,946,595)</u>
Basic and diluted net loss per common share, as reported	\$ (0.18)	\$ (1.28)	\$ (0.68)
Basic and diluted net loss per common share, pro forma	\$ (0.19)	\$ (1.31)	\$ (0.75)

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

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Risk-free interest rate	4.4%	3.6%	2.9%
Dividend yield	0%	0%	0%
Volatility	0.78	0.86	0.98
Expected life of options in years	5.9	4.3	4.3

The weighted average per share grant date fair value of options granted during the years ended December 31, 2005, 2004, and 2003 was \$1.81, \$4.37 and \$3.28 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.

*Recent Accounting Pronouncements*

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 public companies with a fiscal year that begins after June 15, 2005. The cumulative effect of this pronouncement when adopted by the Company, applied on a modified prospective basis, would be measured and recognized starting the first quarter of 2006. We anticipate that the impact of adopting SFAS No. 123R will result in an annual expense of approximately \$292,000 based on known grants. 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.

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

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3". The statement requires retrospective application of changes in accounting principle to prior periods' financial statements, unless it is impracticable to determine either the period specific effects or the cumulative effect of the change. When it is impracticable to determine the period specific effects of an accounting change on one or more individual prior periods presented, this statement requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable, and that a corresponding adjustment be made to the opening balance of the retained earnings for that period rather than being reported in the income statement. The statement also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. This pronouncement is effective for accounting changes made in fiscal years beginning after December 15, 2005. The Company does not believe adoption of SFAS 154 will have a material effect on its consolidated financial position, results of operations or cash flows.

*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:

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Options	3,658,764	4,345,777	4,198,216
Warrants	2,374,593	945,869	—
Total number of shares excluded	6,033,357	5,291,646	4,198,216

Excluded also are 2,121,212 shares that would be issuable upon conversion of the PDI Notes (see also Note 16).

**2. Accounts Receivable**

Accounts receivable consists of the following:

	<b>Years ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
Unbilled grants receivable	\$ 759,906	\$ 833,630
Trade receivables net of allowances of \$35,000 in 2005	265,031	26,036
Other receivables	60,298	26,144
Total	\$ 1,085,235	\$ 885,810

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

**3. Short-term Investments**

At December 31, 2005, the Company had an investment in Marketable Securities of approximately \$11,000. In January 2006 the investment was liquidated realizing a gain of approximated \$8,500. At December 31, 2004, the Company had no investments.

**4. Prepaid Expenses and Other Current Assets**

At December 31, 2005 and December 31, 2004 this account includes the following:

	<b>Years ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
Prepaid Insurance	\$ 196,000	\$ 186,000
Prepaid Rent	35,000	—
Prepaid Compensation	803,000	—
Inventory	351,000	52,000
Other	44,000	44,000
<b>Total</b>	<b>\$ 1,429,000</b>	<b>\$ 282,000</b>

Inventories are valued at the lower of cost or market. As of December 31, 2005, Cellegy had inventory of \$257,000 located in Canada and \$94,000 in Australia. All of Cellegy's Canadian inventory was sold in January 2006 for \$257,000.

**5. Intangible Assets, net**

The Company's intangible assets and related accumulated amortization at December 31, 2005 and December 31, 2004, respectively, were as follows:

	<b>December 31, 2005</b>			<b>December 31, 2004</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Capitalized non-compete agreement with Vaxis	\$ —	\$ —	\$ —	\$ 463,544	\$ (293,578)	\$ 169,966
Capitalized workforce—Biosyn acquisition	381,558	(185,354)	196,204	635,504	(26,478)	609,026
	<b>\$ 381,558</b>	<b>\$ (185,354)</b>	<b>\$ 196,204</b>	<b>\$ 1,099,048</b>	<b>\$ (320,056)</b>	<b>\$ 778,992</b>

Subsequent to the purchase of Biosyn in 2004, several of its key people left the Company in 2005. Their departure required the reduction in the carrying value of the work force in place intangible asset recorded in 2004. Estimating the fair market value of the key people remaining resulted in an impairment of the asset as of December 31, 2005 of approximately \$254,000. This amount was recognized as impairment expense in the fourth quarter of 2005.

In 2005, Cellegy Canada, Inc. was liquidated and the intangible asset for the Vaxis non-compete agreement was fully amortized. The \$50,000 decrease in goodwill in 2005 is due to changes in foreign currency.

Amortization recorded for the years ended December 31, 2005, 2004 and 2003 were approximately \$324,000, \$111,000 and \$176,000, respectively.

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

Estimated amortization expense for each of the three years ended December 31, 2006 through 2008 is as follows:

*Estimated future amortization expense:*

For the twelve months ended December 31:

2006	\$69,000
2007	\$69,000
2008	\$58,000

**6. Property and Equipment, net**

Property and equipment, net consist of the following:

	<u>Years ended December 31,</u>	
	<u>2005</u>	<u>2004</u>
Furniture and fixtures	\$ 81,247	\$ 199,202
Office equipment	337,247	261,718
Laboratory equipment	517,970	1,296,113
Leasehold improvements	81,599	2,081,313
	<u>1,018,063</u>	<u>3,838,346</u>
Less: accumulated depreciation and amortization	(521,644)	(1,885,938)
<b>Total</b>	<u><u>\$ 496,419</u></u>	<u><u>\$ 1,952,408</u></u>

Depreciation expense for the years ended December 31, 2005, 2004 and 2003 was \$360,000, \$420,000 and 370,000 respectively. In March 2005, the Company relocated its South San Francisco offices to Brisbane, California. At that time all leasehold improvements and some office equipment were left at the facility. The Company received cash from the subsequent tenant for these items which was recognized as a net gain of approximately \$484,000 on disposal of fixed assets. In December 2005, the Company also wrote off assets for production equipment and leasehold improvements for production facilities. The loss on the disposal of these fixed assets for the year 2005 was approximately \$324,000 and \$105,000 respectively.

**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, 2005 and 2004 were as follows:

	<u>Years ended December 31,</u>	
	<u>2005</u>	<u>2004</u>
Accrued clinical expenses	\$ 641,995	\$ 612,937
Accrued legal fees	60,830	453,953
Accrued employee bonuses, retention and severance	1,039,571	507,723
Accrued consulting fees	45,934	339,142
Other	613,909	811,053
<b>Total</b>	<u><u>\$ 2,402,239</u></u>	<u><u>\$ 2,724,808</u></u>

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

**8. Notes Payable**

*Ben Franklin Note*

Included in notes payables is a note issued by Biosyn to Ben Franklin Technology Center of Southeastern Pennsylvania ("Ben Franklin Note") in October 1992 for funds provided by Ben Franklin for the development of a compound to prevent transmission of AIDS.

The note is recorded at its estimated fair value of \$205,000 and was assumed by Cellegy in connection with its acquisition of Biosyn. 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 \$572,902 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.

*PDI Notes*

The notes were issued in April 2005 by Cellegy to PDI, Inc. ("PDI") pursuant to a lawsuit settlement agreement signed by both parties in April 2005. The terms of the notes issued to PDI are as follows:

The \$3.0 million secured promissory note has an outstanding balance of \$2.8 million and a net present value of \$2.5 million at December 31, 2005 and is payable in October 2006. There is no stated interest rate and no periodic payments are required. Cellegy is required to make current payments on the note to the extent of (i) 50% of licensing fees, royalties or milestone payment, (or, in each case, these payments in the nature thereof) received by Cellegy with respect to any of Cellegy's agreements or arrangements with respect to Tostrex or Rectogesic products in territories outside of North America, and (ii) 50% of licensing fees, royalties or milestone payments (or, in each case, other payments in the nature thereof) received by Cellegy with respect to any of Cellegy's agreements or arrangements with respect to Fortigel in North American markets. These payments are required to be made to PDI within two business days after Cellegy receives the payments. Cellegy's obligations under the note are secured by a security interest in favor of PDI, which is reflected in a security agreement between Cellegy and PDI, in Cellegy's interests in the payments described above and any proceeds therefrom (and certain related collateral). In addition, Cellegy is required to make payments on the \$3.0 million note with respect to 10% of proceeds received by Cellegy in excess of \$5.0 million from financing transactions. Payments made in 2005 totaled \$200,000.

Amounts owed under the note may be accelerated upon an event of default, which is defined to include, but not limited to, any of the following: Cellegy's failure to pay any amounts owed under the note when due; certain kinds of bankruptcy filings or certain related actions or proceedings; any breach of any of Cellegy's covenants, conditions or agreements in the note or security agreement following notice from PDI that remains uncured for 30 days; the security interest no longer being a valid, perfected, first priority security interest; and a default in indebtedness of Cellegy with an aggregate principal amount in excess of \$2.0 million that results in the maturity of such indebtedness being accelerated before its stated maturity. The net present value of collateralized \$3.0 million note will be recalculated based on its remaining principal whenever a payment is made by Cellegy. Cellegy made a \$100,000 payment to PDI in October 2005 shortly after the due date specified in the secured note and has paid interest to PDI on that amount.

The \$3.5 million non-negotiable senior convertible debenture was recorded at a net present value of \$2.5 million as of December 31, 2005 and has a maturity date of April 11, 2008, three years from the PDI settlement date of April 11, 2005. There is no stated interest rate and no periodic payments are required. Cellegy may redeem the note at anytime before the maturity date upon prior notice to PDI, at a redemption price equal to the principal amount. If Cellegy delivers such a redemption notice, PDI may convert the note into shares of Cellegy common stock at a price of \$1.65 per share. In addition, after the 18th month anniversary of the debenture, PDI may convert the note into Cellegy common stock at a price of \$1.65 per share. If Cellegy does not redeem the note within the first 18 months, then Cellegy has agreed to file a registration statement relating to the possible resale of any shares issued to PDI after 18 months. 2,121,212 shares would be issuable upon such conversion. As long as amounts are owed under the note, Cellegy has agreed not to incur or become responsible for any indebtedness that ranks contractually senior or pari passu in right of payment to amounts outstanding under the note. Events of default under the senior note are generally similar to events of default under the secured note.



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

Cellegy has classified the notes as current for financial reporting purposes because of the payments expected to be made within the next year and due to other uncertainties noted above. In addition, on December 1, 2005 the company received a notice from PDI, Inc. notifying the company that PDI considers Cellegy in default of the secured promissory note and the non-negotiable convertible senior note which were part of the settlement entered into between Cellegy and PDI on April 11, 2005. PDI's notice states that PDI believes that Cellegy is in material breach of the secured promissory note as a result of Cellegy's failure to notify PDI of the receipt of certain payments and of Cellegy's failure to pay amounts to which PDI believes it is entitled.

In November 2005, Cellegy renegotiated its Exclusive License and Distribution Agreement with ProStrakan Group Limited ("ProStrakan") relating to Rectogesic. Under the renegotiated agreement, ProStrakan assumed all responsibility for manufacturing and product support functions and will purchase the product directly from the manufacturer rather than purchasing from Cellegy under the terms of the original agreement. In return, ProStrakan paid Cellegy \$2.0 million. PDI claims that it is entitled to \$1.0 million of that payment. Cellegy does not agree that the payment made by ProStrakan falls within the definition of "Pledged Collateral" in the settlement agreement and related documents and does not believe that any amount is owed to PDI as a result of such payments. The Company plans to vigorously defend itself against such claims.

The Company accretes interest and principal to the PDI notes using a rate of 15% using the effective interest rate method.

The Ben Franklin note has a face value of \$778,000 and net present value of \$205,000 at December 31, 2005. The note has no scheduled repayment term. Payment is based on 3% of Biosyn's revenues excluding research and development grants.

At December 31, 2005, future minimum payments on the above notes were payable as follows (in thousands):

2006	\$ 2,800
2007	—
2008	3,500
2009 and thereafter	<u>778</u>
Total payments	7,078
Less: Amount representing discount	<u>(1,897)</u>
Net present value of notes at December 31, 2005	<u>\$ 5,181</u>

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

**9. Equity Financing**

On May 12, 2005, Cellegy raised approximately \$5.7 million after offering expenses in a private placement of its common stock and warrants to existing and new institutional and individual investors. The transaction consisted of the sale of approximately 3,621,819 shares of common stock and the issuance of Class A Warrants to purchase approximately 714,362 shares of common stock at an exercise price of \$2.25 per share. The Class A Warrants can be called if the Company's common stock trades for 20 consecutive days over \$5.00. The Company also issued Class B Warrants to purchase approximately 714,362 shares of common stock at an exercise price of \$2.50 per share. Class A and B Warrants can be called by the Company if the Company's closing bid price of a share of Common Stock equals or exceeds \$5.00 or \$5.50, respectively, for any twenty (20) consecutive trading days commencing after the Registration Statement has been declared effective at a redemption price equal to \$0.01 per share of common stock. Three directors of Cellegy purchased a total of 50,000 shares in the offering at the closing market price of the common stock on the date of the transaction for \$2.13 per share. The directors did not receive any warrants. The purchase price for shares purchased by the non-director investors was \$1.65 per share. Pursuant to the transaction agreements, the Company has filed a registration statement on Form S-3 with the Securities and Exchange Commission, which was declared effective on July 8, 2005, covering the possible resale of the shares from time to time in the future.

**10. Derivative Instruments**

The warrants are revalued at the end of each reporting period as long as they remain outstanding. The estimated fair value of all warrants, using the Black-Scholes valuation model, recorded as derivative liability at December 31, 2005 and December 31, 2004 was \$193,000 and \$411,000. The changes in the estimated fair value of the warrants have been recorded as other income and expense in the income statement. For the years ended December 31, 2005 and December 31, 2004, the Company recognized \$689,000 and \$390,000 respectively as other income from derivative revaluation.

**11. Deferred Revenue**

Current and long-term deferred revenue totaling \$3.4 million at December 31, 2005 and \$15.1 million at December 31, 2004 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 include \$6.5 million in income recognition as a result of the PDI settlement in April 2005 with the remaining balances 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.

**12. 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. The sublease was terminated in 2005 and the rental income ceased as of the termination. Future minimum lease payments at December 31, 2005, are as follows:

<u>Years ended December 31,</u>	<u>Future Minimum Lease Commitments</u>
2006	\$ 331,467
2007	264,483
2008	160,167
Total	<u>\$ 756,117</u>

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

Rent expense, net of sublease income, was \$269,000, \$382,000, and \$336,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The Company received \$93,000, \$149,000 and \$148,000 in sublease income, which is reflected in other income (expense), during the year ended December 31, 2005, 2004 and 2003, respectively.

*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 \$53,000 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, 2005 are as follows:

Years ended December 31:	
2006	\$ 55,000
2007	5,000
<b>Total minimum lease payments</b>	<b>60,000</b>
Less amount representing interest	(13,000)
<b>Present value of minimum lease payments</b>	<b>47,000</b>
Less current maturities	(44,000)
<b>Long-term obligation</b>	<b>\$ 3,000</b>

*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, 2005. In 2005, Canadian operations were terminated and its assets were liquidated.

*Legal Proceedings*

In October 2003, the Company received a communication from PDI invoking mediation procedures under its exclusive license agreement with PDI 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.

On April 11, 2005, Cellegy entered into a settlement agreement with PDI resolving the lawsuits that the companies had filed against each other. Under the terms of the settlement agreement, the license agreement was terminated and all product rights reverted to Cellegy. Under the settlement agreement, the previous license agreement was terminated and all product rights reverted to Cellegy. Cellegy paid \$2 million to PDI upon signing the settlement agreement.

Cellegy also issued a \$3.0 million Secured Promissory Note to PDI, payable in 18 months, with earlier payments of amounts owed under the note required to be made to the extent of 50% of licensing fees, royalties or milestone payments (or, in each case, other payments in the nature thereof) received by Cellegy under Cellegy’s agreements or arrangements with respect to Cellegy’s Tostrex® (testosterone gel) and Rectogesic® (nitroglycerin ointment) products in territories outside of North America, and 50% of licensing fees, royalties or milestone payments (or, in each case, other payments in the nature thereof) received by Cellegy under Cellegy’s agreements or arrangements with respect to Fortigel licensees in North American markets. These payments are required to be made to PDI within two business days after Cellegy receives the payments. These various payments will be made until the amount owed under the note is paid in full. Cellegy’s obligations under the note are secured by a security interest in favor of PDI, which is reflected in a security agreement between Cellegy and PDI, in Cellegy’s interests in the payments described above and any proceeds there from (and certain related collateral). In addition, Cellegy is required to make payments on the \$3.0 million note with respect to 10% of proceeds received by Cellegy in excess of \$5 million from financing transactions. Payments made in 2005 totaled \$200,000. Amounts owed under the note may be accelerated upon an event of default, which include (but are not limited to) certain kinds of bankruptcy filings or certain related actions or proceedings, an uncured material breach of Cellegy’s obligations under the note, the security interest no longer being a valid, perfected, first priority security interest, and a default in indebtedness of Cellegy with an aggregate principal amount in excess of \$2 million that results in the maturity of such indebtedness being accelerated before its stated maturity. Cellegy made a \$100,000 payment to PDI in October 2005 shortly after the due date specified in the secured note and has paid interest to PDI on that amount. Cellegy also issued to PDI a \$3.5 million principal amount Convertible Senior Note due April 11, 2008. Cellegy may redeem the note at any time before the maturity date upon not less than 30 or more than 60 days notice to PDI, at a redemption price equal to the principal amount; if Cellegy delivers such a redemption notice, PDI may convert the note into shares of Cellegy common stock at a price of \$1.65 per share. In addition, after the 18 month anniversary of the debenture, PDI may convert the note into Cellegy common stock at a price of \$1.65 per share. If Cellegy does redeem the note within the first 18 months; then Cellegy has agreed to file a registration statement relating to possible resale of any shares issued to PDI after 18 months. 2,121,212 shares would be issuable upon such conversion. As long as amounts are owed under the note, Cellegy has agreed not to incur or become responsible for any indebtedness that ranks contractually senior or pari passu in right of payment to amounts outstanding under the note. Events of default under the senior note are generally similar to events of default under the secured note.

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

**13. 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 the first day of the calendar quarter following three months 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, 2005, 2004 and 2003 were not significant.

**14. 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 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 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. Cellegy also liquidated approximately \$3.5 million of Biosyn's debt at the time of the acquisition.

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	<u>410,000</u>
Total purchase price	<u>\$ 11,856,000</u>

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	<u>(135,000)</u>
Net assets	<u>\$ 11,856,000</u>

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

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 microbacial vaginal gel, which may have the potential to prevent HIV / AIDS and other sexually transmitted diseases in women. This product candidate, called 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 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 being 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 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.

**Notes to Consolidated Financial Statements (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. 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.

	<b>Years Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>
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)

**15. 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 April 2005, pursuant to a settlement with PDI concerning litigation initiated in December of 2003, the companies terminated their agreement and all rights to Fortigel reverted back to Cellegy. See also Note 12.

In July 2004, Cellegy and 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. Under the original agreement, the Company was 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.

In January 2006, Cellegy amended its 2004 agreement with ProStrakan concerning Tostrex. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase Tostrex directly from Cellegy's contract manufacturer rather than purchasing the product from Cellegy under the terms of the original agreement. Cellegy will continue to receive milestones and royalties as set forth in the original agreement.

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 payment of \$1.0 million and is entitled to receive an additional \$4.6 million in milestone payments, along with additional payments based on sales of product to ProStrakan for distribution 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.

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

In November 2005, the Company amended its 2004 agreement with ProStrakan concerning Rectogesic. Under the terms of the amended agreement, ProStrakan will assume responsibility for all manufacturing and other product support functions and will purchase Rectogesic directly from Cellegy's contract manufacturer rather than purchasing the product from Cellegy under the terms of the original agreement. In return, Cellegy received a non-refundable payment of \$2.0 million and may receive future milestone payments of up to \$750,000 upon approval of the product in certain major European countries. The \$2.0 million payment is being amortized to income over the remaining estimated life of the underlying patent considered in connection with the 2004 agreement.

*Biosyn*

In October 1989, Biosyn entered into an agreement whereby it obtained an exclusive license to develop and market products using the C31G Technology.

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 2011 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 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.

On February 1, 2006 Cellegy announced that it had entered into a non-exclusive, developing world licensing agreement with CONRAD for the collaboration on the development of Cellegy's entire microbicide pipeline. The agreement encompasses the licensing in the developing countries (as defined in the agreements) of Savvy clinical trials in the United States and Africa; UC-781, currently in expanded Phase 1 trials in the United States and Thailand; and Cyanovirin-N, currently in pre-clinical development.

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

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

**16. Stockholders' Equity (Deficit)**

*Common Stock Private Placements*

In January 2004, the Company entered into a Structured Secondary Offering facility agreement with Kingsbridge Capital Limited ("Kingsbridge SSO"). The Kingsbridge 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 Kingsbridge 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.

On May 12, 2005, Cellegy raised approximately \$5.7 million after offering expenses, in a private placement of its common stock and warrants, to existing and new institutional and individual investors. The transaction consisted of the sale of approximately 3,621,819 shares of common stock. The Company also issued Class A Warrants to purchase approximately 714,362 shares of common stock at an exercise price of \$2.25 per share. The Class A warrants can be called by the Company if the Company's common stock trades for 20 consecutive days over \$5.00. The Company also issued Class B Warrants to purchase approximately 714,362 shares of common stock at an exercise price of \$2.50 per share. Class A and B Warrants can be called by the Company if the Company's closing bid price of a share of Common Stock equals or exceeds \$5.00 or \$5.50, respectively, for any twenty (20) consecutive trading days commencing after the Registration Statement has been declared effective at a redemption price equal to \$0.01 per share of common stock. Three directors of Cellegy purchased a total of 50,000 shares in the offering at the closing market price of the common stock on the date of the transaction for \$2.13 per share. The directors did not receive any warrants. The purchase price for shares purchased by the non-director investors was \$1.65 per share. Pursuant to the transaction agreements, the Company has filed a registration statement on Form S-3 with the Securities and Exchange Commission, which was declared effective on July 8, 2005, covering the possible resale of the shares from time to time in the future.

*PDI Senior Convertible Debenture*

As more fully described in Note 8, "Notes Payable", Cellegy issued a \$3.5 million senior convertible debenture to PDI in 2005 in connection with the settlement of its lawsuit with PDI. Cellegy may redeem the note at any time before the maturity date upon prior notice to PDI, at a redemption price equal to the principal amount. If Cellegy delivers such a redemption notice, PDI may convert the note into shares of Cellegy common stock at a price of \$1.65 per share. In addition, after the 18th month anniversary of the debenture, PDI may convert the note into Cellegy common stock at a price of \$1.65 per share. If Cellegy does not redeem the note within the first 18 months, then Cellegy has agreed to file a registration statement relating to the possible resale of any shares issued to PDI after 18 months. 2,121,212 shares would be issuable upon such conversion.



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

*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 Restated Certificate of Incorporation provides 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.

*Stock Market Listing*

On September 14, 2005 the Company received a determination letter from the Nasdaq Listing Qualifications Panel transferring its stock listing to the Nasdaq Small Cap Market. On December 29, 2005 Cellegy was delisted from the Nasdaq Small Cap Market. The delisting resulted from the Company not satisfying the \$35 million market capitalization requirement under Nasdaq Marketplace Rule 4310(c)(2)(B)(ii). The Company also does not comply with alternative standards for continued listing on the Nasdaq Small Cap Market. The Company's stock currently trades on the Over the Counter Bulletin Board.

*Stock Option Plans*

*2005 Equity Incentive Plan*

The Company's Stockholders approved a new 2005 Equity Incentive Plan (the "2005 Plan") at the Annual Meeting of Stockholders held September 28, 2005. The 2005 Plan replaces the 1995 Equity Incentive Plan ("Prior Plan") which had expired. The 2005 Plan will be administered by the Board and the Board has delegated administration to the Compensation Committee. The Board of Directors may at any time amend, alter, suspend or discontinue the 2005 Plan without stockholder approval, except as required by applicable law. The 2005 Plan is not subject to the ERISA and is not qualified under Section 401(a) of the Code.

The 2005 Plan provides for the grant of options and other awards to employees, directors and consultants. Options granted under the 2005 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 2005 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 2005 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 2005 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. As of December 31, 2005 there were outstanding options to purchase 49,500 shares under the 2005 Plan and 950,500 shares were available for options or other awards under the 2005 Plan.

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

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

	<b>Shares Under Option</b>	<b>Weighted Average Exercise Price</b>
Beginning Balance	-	\$ -
Granted	49,500	1.34
Canceled	-	-
Exercised	-	-
Balance at December 31, 2005	<u>49,500</u>	1.34

The following table summarizes those stock options outstanding related to the 2005 Plan at December 31, 2005:

<b>Range of Exercise Prices</b>	<b>Options Outstanding</b>		
	<b>Weighted Average Number of Options</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Exercise Price</b>
\$1.34	48,000	9.6 years	\$ 1.34
\$1.35 - \$1.60	1,500	9.7 years	1.39
Total	<u>49,500</u>	9.7 years	1.34

There were no options exercisable under the 2005 plan as of December 31, 2005.

*Prior Plan*

The total number of shares reserved and available for issuance pursuant to the exercise of Awards under the Prior Plan is 4,850,000 shares. The Prior Plan will continue to govern the stock options previously granted under the Prior Plan. However, no further stock options or other awards will be made pursuant to the Prior Plan.

	<b>Shares Under Option</b>	<b>Weighted Average Exercise Price</b>
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
Granted	287,150	1.89
Exercised	(14,920)	2.35
Cancelled	(835,135)	4.54
Balance at December 31, 2005	<u>2,238,737</u>	4.67

The following table summarizes those stock options outstanding and exercisable related to the Prior Plan at December 31, 2005:

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

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

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Weighted Average Number of Options</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Exercise Price</u>	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>
\$1.35 - \$2.30	618,952	5.4 years	\$1.85	361,802	\$1.80
\$2.89 - \$4.00	563,951	2.5 years	3.50	520,119	3.55
\$4.38 - \$6.50	506,000	1.7 years	5.10	489,125	5.12
\$7.00 - \$8.93	496,834	2.0 years	7.97	496,834	7.97
\$15.00	53,000	2.2 years	15.00	53,000	15.00
Total	<u>2,238,737</u>	3.0 years	4.67	<u>1,920,880</u>	5.08

At December 31, 2004 and 2003, options to purchase 2,801,642 shares of common stock with an average price of \$4.90 and 2,173,078 shares of common stock with an average price of \$4.77 were vested and exercisable, respectively. No future options may be granted under the Prior Plan.

*Directors' 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 2005, a total of 350,000 shares were reserved for issuance under the Directors' Plan. The 2005 Plan replaces 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:

	<u>Shares Under Option</u>	<u>Weighted Average Exercise Price</u>
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
Granted	—	—
Exercised	—	—
Balance at December 31, 2005	<u>307,500</u>	4.74

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

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

The following table summarizes those stock options outstanding and exercisable related to the Directors' Plan at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$1.34 - \$3.25	35,000	6.3 years	\$2.62	35,000	\$2.62
\$4.30 - \$5.50	254,500	3.7 years	4.90	218,500	4.98
\$6.50 - \$8.50	18,000	2.6 years	6.72	18,000	6.72
Total	<u>307,500</u>	3.6 years	4.74	<u>271,500</u>	4.79

At December 31, 2004 and 2003, options to purchase 307,500 shares of common stock with a weighted average exercise price of \$4.74 and 251,167 shares of common stock with a weighted average exercise price of \$4.79 were vested and exercisable, respectively. At December 31, 2005, there were no options available for future 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 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, 2005, 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. During 2005, 74,446 options were exercised and 99,162 were cancelled. The following table summarizes information about stock options outstanding and exercisable related to Biosyn option grants at December 31, 2005:

Range of Exercise Prices	Options Outstanding and Exercisable		
	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$0.06	11,872	1.8 years	\$0.06
\$0.29	20,233	7.6 years	0.29
\$1.46 - \$6.83	8,564	8.5 years	1.46
\$8.76	3,855	6.1 years	8.76
\$14.60 - \$21.02	18,503	3.1 years	18.68
Total	<u>63,027</u>	5.2 years	6.30

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

*Shares Reserved*

As of December 31, 2005, the Company has reserved shares of common stock for future issuance as follows:

Biosyn options	63,027
Director's Plan	307,500
Warrants	2,374,593
Non-plan options	1,000,000
Neptune agreement	1,080,082
Kingsbridge SSO	3,493,601
1995 Equity Incentive Plan	2,238,737
2005 Equity Incentive Plan	950,500
<b>Total</b>	<b>11,508,040</b>

*Warrants*

The Company has the following warrants outstanding to purchase common stock as of December 31, 2005:

	<b>Warrant Shares</b>	<b>Exercise Price Per Share</b>	<b>Date Issued</b>	<b>Expiration Date</b>
June 2004 PIPE Financing	604,000	\$ 4.62	July 27, 2004	July 27, 2009
Biosyn warrants	81,869	5.84 - 17.52	Oct. 22, 2004	2006 - 2014
Kingsbridge SSO	260,000	5.27	Jan. 16, 2004	Jan. 16, 2009
May 2005 PIPE Financing				
Series A	714,362	2.25	May 13, 2005	May 13, 2010
Series B	714,362	2.50	May 13, 2005	May 13, 2010
<b>Total</b>	<b>2,374,593</b>			

*Non-Cash Compensation Expense Related to Stock Options*

For the year ended December 31, 2005, 2004 and 2003, The Company recorded \$651, \$109,000 and \$579,000, respectively.

**17. Income Taxes**

At December 31, 2005 the Company had net operating loss carryforwards of approximately \$87.9 million and \$44.2 million for federal and state purposes, respectively. The federal net operating loss carryforwards expire between the years 2006 and 2025. The state net operating loss carryforwards expire between the years 2006 and 2015. At December 31, 2005, the Company also had research and development credit carryforwards of approximately \$2.9 million and \$1.5 million for federal and state purposes, respectively. The federal credits expire between the years 2006 and 2025 and the state credits do not expire. The Tax Reform Act of 1986 (the Act) provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company's ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore the Company may not be able to take full advantage of these carryforwards for Federal income tax purposes. The Company determined that the net operating loss carryforwards relating to Biosyn are limited due to its acquisition in 2004 and has reflected the estimated amount of usable net operating loss carryforwards in its deferred tax assets below.

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. The amount of deferred tax assets in 2005 and 2004 not available to be recorded as a benefit due to the exercise of non-qualified employee stock options is approximately \$643,000 and \$599,000, respectively.

Under the provisions of paragraph 30 of SFAS No. 109, if a valuation allowance is recognized for the deferred tax asset for an acquired entity's deductible temporary differences or operating loss or tax credit carryforwards at the acquisition date, the tax benefits for those items that are first recognized in financial statements after the acquisition date shall be applied (a) first to reduce to zero any goodwill related to the acquisition, (b) second to reduce to zero other noncurrent intangible assets related to the acquisition, and (c) third to reduce income tax expense. The future tax benefit of the Biosyn pre-acquisition net operating losses, tax credits, and other deductible temporary differences, when they are ultimately recognized, will be recorded in accordance with paragraph 30 of SFAS 109.

Significant components of the Company's deferred tax liabilities and assets are as follows (in thousands):

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

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

	December 31,	
	2005	2004
Deferred tax assets:		
Net operating loss carryforwards	\$ 31,400	\$ 35,700
Deferred revenue	3,000	6,000
Credit carryforwards	3,800	3,600
Capitalized research and development	10,100	2,100
Depreciation and amortization	1,400	2,000
Intangible assets	(100)	(300)
Other, net	400	1,100
Total deferred tax assets	50,000	50,200
Valuation allowance	(50,000)	(50,200)
Net deferred tax assets	\$ —	\$ —

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

	2005		2004	
	Net loss	\$ (5,008)		\$ (28,154)
Tax at Federal statutory rate	(1,703)	34.0%	(9,572)	34.0%
Meals and entertainment	8	-0.1%	9	-0.1%
Stock compensation expense	38	-0.8%	(240)	0.1%
Purchased research and development	—	—%	5,349	-19.0%
Research credits	(15)	0.3%	(121)	0.4%
Deferred taxes not benefited	1,672	-33.4%	4,575	-16.2%
Provision for taxes	\$ —	—%	\$ —	—%

The valuation allowance for deferred tax assets for 2005 decreased by approximately \$200,000 and increased in 2004 by approximately \$14.0 million.

**18. Segment Reporting**

Cellegy's revenues consisted of Rectogesic Sales in Europe, Australia, New Zealand, Singapore and South Korea, as well as licensing revenue relating to Fortigel, Rectogesic and Tostrex. Revenues also consist of grant funding from various domestic agencies and foundations. The Company has divested skin care business in December 2005. The Company has not reflected the sale of the skin care business as a discontinued operation due to immateriality.

Management regularly assesses segment operating performance and makes decisions as to how resources are allocated based upon segment performance. The accounting policies of the reportable segments are consistent with those described in the Summary of Significant Accounting Policies (Footnote 1).

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

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

Revenues from external sources by major geographic area are as follows:

<b>Revenues</b>	<b>Years ended December 31,</b>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
North America			
Pharmaceuticals	\$ 11,758,235	\$ 1,840,840	\$ 919,513
Skin care	—	181,386	316,000
Europe			
Pharmaceuticals	440,477	10,704	—
Skin care	—	—	—
Australia & Pacific Rim			
Pharmaceuticals	636,632	563,447	384,985
Skin care	—	—	—
	<u>\$ 12,835,345</u>	<u>\$ 2,596,377</u>	<u>\$ 1,620,498</u>

Revenues from product sales to one customer represented approximately 38%, 7% and 20% of total revenue from 2005, 2004 and 2003 respectively.

Operating income (loss) by geographic region is as follows:

<b>Operating Income (Loss)</b>	<b>Years ended December 31,</b>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
North America			
Pharmaceuticals	\$ (4,912,541)	\$ (25,689,094)	\$ (10,125,038)
Skin care	—	(2,531,258)	(3,479,572)
Europe			
Pharmaceuticals	(184,803)	(149,375)	—
Skin care	—	—	—
Australia & Pacific Rim			
Pharmaceuticals	89,705	215,666	72,462
Skin care	—	—	—
	<u>\$ (5,007,639)</u>	<u>\$ (28,154,061)</u>	<u>\$ (13,532,148)</u>

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

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

Assets by major geographic region are as follows:

Assets	Years ended December 31,		
	2005	2004	2003
North America	\$ 4,957,406	\$ 12,532,030	\$ 15,151,186
Australia & Pacific Rim	1,232,502	1,331,295	179,621
	<u>\$ 6,189,908</u>	<u>\$ 13,863,325</u>	<u>\$ 15,330,807</u>

**19. Related Party Transactions**

The Company pays fees to their board members for their services to the board including the audit, nominating, and compensation committees. The total cash payments to these directors during 2005, 2004 and 2003 were \$75,500, \$180,703, and \$103,000, respectively. In mid 2005, at the request of the directors, the Company deferred the payment of board fees.

There were no consulting fees paid in cash to any board members in 2005, 2004 and 2003. The Company recognized \$131,000 in non-cash compensation expense during 2003 associated with the valuation of vested stock options previously issued under a consulting agreement to a former board member.

Three directors, Messrs. Adams, Rothermel and Williams purchased a total of 50,000 shares in connection with the May 2005 PIPE financing at the closing market price of the common stock on the date of the transaction.

**20. Subsequent Events**

On March 24, 2006 the Company announced that its European marketing partner, ProStrakan had successfully completed the European Union Mutual Recognition Procedure for Rectogesic. Following the successful conclusion of the MRP process, national licenses will be issued in due course in the 19 additional countries (in addition to the United Kingdom, where approvals have previously been obtained) included in the MRP submission application. Cellegy is entitled to receive \$250,000 for each marketing regulatory approval obtained in the first of any three countries out of France, Italy, Germany or Spain up to a maximum total amount payable of \$750,000. Under Cellegy's previous agreements with PDI, Inc., PDI is entitled to receive one-half of these payments.



**21. Quarterly Financial Data (Unaudited)**  
**(Amounts in thousands, except per share data)**

	2005			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	\$ 1,606	\$ 7,749	\$ 1,952	\$ 1,528
Operating income (loss)	(5,210)	4,947	(2,676)	(2,340)
Net Income (loss)	(5,086)	4,835	(2,793)	(1,964)
Basic net income (loss) per common share	(0.19)	0.17	(0.09)	(0.08)
Diluted net income (loss) per common share	(0.19)	0.16	(0.09)	(0.08)

	2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	\$ 338	\$ 430	\$ 483	\$ 1,345
Operating loss <sup>1</sup>	(3,245)	(2,837)	(3,194)	(19,498)
Net loss <sup>1</sup>	(3,058)	(2,708)	(3,143)	(19,245)
Basic and diluted net loss per common share	(0.15)	(0.13)	(0.14)	(0.76)

<sup>1</sup>Includes a charge of \$14,982,000 for acquired in-process technology relating to the Biosyn acquisition in October 2004.

## CELLEGY PHARMACEUTICALS, INC.

## 2005 EQUITY INCENTIVE PLAN

Adopted June 8, 2005

1. **PURPOSE.** The purpose of this Plan is to provide incentives to attract, retain and motivate eligible persons whose present and potential contributions are important to the success of the Company, its Parent, Subsidiaries and Affiliates, by offering them an opportunity to participate in the Company's future performance through awards of Options, Restricted Stock and Stock Bonuses. Capitalized terms not defined in the text are defined in Section 23.

2. **SHARES SUBJECT TO THE PLAN.**

2.1 **Number of Shares Available.** Subject to Sections 2.2 and 18, the total number of Shares reserved and available for grant and issuance pursuant to this Plan will be one million (1,000,000) shares. Subject to Sections 2.2 and 18, Shares that: (a) are subject to issuance upon exercise of an Option but cease to be subject to such Option for any reason other than exercise of such Option; (b) are subject to an Award granted hereunder but are forfeited or are repurchased by the Company; (c) are subject to an Award that otherwise terminates without Shares being issued; (d) are withheld if an Award is exercised through a reduction of shares subject to the Award ("net exercise"); or (e) are withheld in order to satisfy federal, state or local tax liability (to the extent permitted by the Committee), shall not count against the above limit and will again be available for grant and issuance in connection with future Awards under this Plan. If the exercise price of any Option is satisfied by delivering shares of Common Stock to the Company (be either actual delivery or by attestation), only the number of shares of Common Stock delivered to the Participant net of the shares of Common Stock delivered to the Company or attested to shall be deemed delivered for purposes of determining the maximum number of shares of Common Stock available for delivery pursuant to the 2005 Plan. At all times the Company shall reserve and keep available a sufficient number of Shares as shall be required to satisfy the requirements of all outstanding Options granted under this Plan and all other outstanding but unvested Awards granted under this Plan.

2.2 **Adjustment of Shares.** In the event that the number of outstanding Shares is changed by a stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or similar change in the capital structure of the Company without consideration, then (a) the number of Shares reserved for issuance under this Plan, (b) the Exercise Prices of and number of Shares subject to outstanding Options, (c) the share amounts set forth in Section 3 below, and (d) the number of Shares subject to other outstanding Awards will be proportionately adjusted, subject to any required action by the Board or the shareholders of the Company and compliance with applicable securities laws; provided, however, that fractions of a Share will not be issued but will either be replaced by a cash payment equal to the Fair Market Value of such fraction of a Share or will be rounded up to the nearest whole Share, as determined by the Committee.

3. **ELIGIBILITY.** ISOs (as defined in Section 5 below) may be granted only to employees (including officers and directors who are also employees) of the Company or of a Parent or Subsidiary of the Company. All other Awards may be granted to employees, officers, directors, consultants and advisors of the Company or any Parent, Subsidiary or Affiliate of the Company; provided such consultants and advisors render bona fide services not in connection with the offer and sale of securities in a capital-raising transaction. Subject to the provisions of this Plan relating to capitalization adjustment, at any time that the Company may be subject to the applicable provisions of Section 162(m) of the Code, no employee shall be eligible to be granted Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent of the Fair Market Value of the Common Stock on the date the Award is granted covering more than 500,000 Shares in any calendar year under this Plan pursuant to the grant of Awards hereunder, other than new employees of the Company or of a Parent or Subsidiary of the Company (including new employees who are also officers and directors of the Company or any Parent or Subsidiary of the Company), who are eligible to receive up to a maximum of 1,000,000 shares in the calendar year in which they commence their employment. A person may be granted more than one Award under this Plan.

#### 4. ADMINISTRATION.

4.1 Committee Authority. This Plan will be administered by the Committee or by the Board acting as the Committee.

Subject to the general purposes, terms and conditions of this Plan, and to the direction of the Board, the Committee will have full power to implement and carry out this Plan. Without limitation, the Committee will have the authority to:

- (a) construe and interpret this Plan, any Award Agreement and any other agreement or document executed pursuant to this Plan;
- (b) prescribe, amend and rescind rules and regulations relating to this Plan;
- (c) select persons to receive Awards;
- (d) determine the form and terms of Awards (which need not be identical), including but not limited to, the time or times at which Options shall be exercisable and the extension or acceleration of any such provisions or limitations, based in each case on such factors as the Committee shall determine, in its sole discretion;
- (e) determine the number of Shares or other consideration subject to Awards;
- (f) determine whether Awards will be granted singly, in combination with, in tandem with, in replacement of, or as alternatives to, other Awards under this Plan or any other incentive or compensation plan of the Company or any Parent, Subsidiary or Affiliate of the Company;
- (g) grant waivers of Plan or Award conditions;
- (h) determine the vesting, exercisability and payment of Awards;
- (i) correct any defect, supply any omission or reconcile any inconsistency in this Plan, any Award or any Award Agreement;
- (j) determine whether an Award has been earned; and
- (k) make all other determinations necessary or advisable for the administration of this Plan.

In the sole discretion of the Board, the Committee may consist solely of two or more Outside Directors, in accordance with the Section 162(m) of the Code, and/or solely of two or more Non-Employee Directors in accordance with Rule 16b-3. In addition, the Board or the Committee, in its sole discretion, may (1) delegate to a committee of one or more members of the Board who need not be Outside Directors the authority to grant Awards to eligible persons who are either (a) not then Covered Employees and are not expected to be Covered Employees at the time of recognition of income resulting from such Award, or (b) not persons with respect to whom the Company wishes to comply with Section 162(m) of the Code, and/or (2) delegate to a committee of one or more members of the Board who need not be Non-Employee Directors the authority to grant Awards to eligible persons who are not then subject to Section 16 of the Exchange Act. The Board may delegate to one or more officers of the Company the authority to do one or both of the following: (i) designate officers and employees of the Company or any of its Subsidiaries to be recipients of Awards and the terms thereof, and (ii) determine the number of shares of Common Stock to be subject to such Awards granted to such officers and employees of the Company; provided, however, that the Board resolutions regarding such delegation shall specify the total number of shares of Common Stock that may be subject to the Awards granted by such officer and that such officer may not grant an Award to himself or herself. Notwithstanding anything to the contrary in this Section, the Board may not delegate to an officer the authority to determine the Fair Market Value of the Common Stock.

4.2 Committee Discretion. Any determination made by the Committee with respect to any Award will be made in its sole discretion at the time of grant of the Award or, unless in contravention of any express term of this Plan or Award, at any later time, and such determination will be final and binding on the Company and on all persons having an interest in any Award under this Plan. The Committee may delegate to one or more officers of the Company the authority to grant an Award under this Plan to Participants who are not Insiders of the Company.

4.3 Compliance with Code Section 162(m). If two or more members of the Board are Outside Directors, then subject to the provisions of Section 4.1 above, the Committee shall be comprised of at least two members of the Board, all of whom are Outside Directors.

4.4 Liability and Indemnification of the Committee. No member of the group constituting the Committee, or any employee of the Company to whom the Committee delegates certain administrative responsibilities, shall be liable for any act or omission on such member's or employee's own part, including but not limited to the exercise of any power or discretion given to such member, or employee as delegatee, under this Plan, except for those acts or omissions resulting from such member's or employee's own gross negligence or willful misconduct. The Company shall indemnify each present and future member of the group constituting the Committee and each present and future employee delegated administrative responsibilities by such Committee against, and each member of the group constituting the Committee or employee delegated administrative responsibilities by such Committee shall be entitled without further act on his or her part to indemnity from the Company for, all expenses (including the amount of judgments or settlements approved by the Company and made with a view to the curtailment of costs of litigation, other than amounts paid to the Company itself) reasonably incurred by such person in connection with or arising out of any action, suit or proceeding to the full extent permitted by law and by the Articles of Incorporation and Bylaws of the Company.

5. OPTIONS. The Committee may grant Options to eligible persons and will determine whether such Options will be Incentive Stock Options within the meaning of the Code ("**ISOs**") or Nonqualified Stock Options ("**NQSOs**"), the number of Shares subject to the Option, the Exercise Price of the Option, the period during which the Option may be exercised, and all other terms and conditions of the Option, subject to the following:

5.1 Form of Option Grant. Each Option granted under this Plan will be evidenced by an Award Agreement which will expressly identify the Option as an ISO or an NQSO ("**Stock Option Agreement**"), and will be in such form and contain such provisions (which need not be the same for each Participant) as the Committee may from time to time approve, and which will comply with and be subject to the terms and conditions of this Plan.

5.2 Date of Grant. The date of grant of an Option will be the date on which the Committee makes the determination to grant such Option, unless otherwise specified by the Committee. The Stock Option Agreement and a copy of this Plan will be delivered to the Participant within a reasonable time after the granting of the Option.

5.3 Exercise Period and Expiration Date. An Option will vest and become exercisable within the times or upon the occurrence of events determined by the Committee and set forth in the Award Agreement governing such Options, subject to the provisions of Section 5.6, and subject to Company policies established by the Committee from time to time. The Committee may provide for Options to vest and become exercisable at one time or from time to time, periodically or otherwise, in such number of Shares or percentage of Shares subject to the Option as the Committee determines.

No Option will be exercisable after the expiration of ten (10) years from the date the Option is granted; and provided further that no ISO granted to a person who directly or by attribution owns more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or of any Parent or Subsidiary of the Company ("**Ten Percent Shareholder**") will be exercisable after the expiration of five (5) years from the date the ISO is granted.

5.4 Exercise Price. The Exercise Price of an NQSO will be determined by the Committee when the Option is granted; provided, however, that if expressly required by one or more state securities authorities or laws as a condition of issuing Awards and Shares in compliance with the securities laws of such state, the exercise price of an NQSO shall not be less than 85% of the Fair Market Value of the Shares on the date of grant and the Exercise Price of any NQSO granted to a Ten Percent Shareholder shall not be less than 110% of the Fair Market Value of the Shares on the date of grant. Notwithstanding the foregoing, an NQSO may be granted with an exercise price lower than that set forth in the preceding sentence if such Option is granted pursuant to an assumption or a substitution for another Option in a manner consistent with the provisions of Section 424(a) of the Code. The Exercise Price of an ISO will be not less than 100% of the Fair Market Value of the Shares on the date of grant and the Exercise Price of any ISO granted to a Ten Percent Shareholder will not be less than 110% of the Fair Market Value of the Shares on the date of grant. Notwithstanding the foregoing, an ISO may be granted with an exercise price lower than that set forth in the preceding sentence if such Option is granted pursuant to an assumption or a substitution for another Option in a manner consistent with the provisions of Section 424(a) of the Code. Payment for the Shares purchased may be made in accordance with Section 8 of this Plan.

5.5 Method of Exercise. Options may be exercised only by delivery to the Company of a written stock option exercise agreement (the "**Exercise Agreement**") in a form approved by the Committee (which need not be the same for each Participant), stating the number of Shares being purchased, the restrictions imposed on the Shares purchased under such Exercise Agreement, if any, and such representations and agreements regarding Participant's investment intent and access to information and other matters, if any, as may be required or desirable by the Company to comply with applicable securities laws, together with payment in full of the Exercise Price for the number of Shares being purchased.

5.6 Termination. Notwithstanding the exercise periods set forth in the Stock Option Agreement, exercise of an Option will always be subject to the following:

- (a) If the Participant is Terminated for any reason except death or Disability, then the Participant may exercise such Participant's Options only to the extent that such Options would have been exercisable upon the Termination Date no later than three (3) months after the Termination Date (or such shorter or longer time period not exceeding five (5) years as may be determined by the Committee, with any exercise beyond three (3) months after the Termination Date deemed to be an NQSO), but in any event, no later than the expiration date of the Options.
- (b) If the Participant is Terminated because of Participant's death or Disability (or the Participant dies within three (3) months after a Termination other than because of Participant's death or Disability), then Participant's Options may be exercised only to the extent that such Options would have been exercisable by Participant on the Termination Date and must be exercised by Participant (or Participant's legal representative or authorized assignee) no later than twelve (12) months after the Termination Date (or such shorter (but not less than six months) or longer time period not exceeding five (5) years as may be determined by the Committee, with any such exercise beyond (a) three (3) months after the Termination Date when the Termination is for any reason other than the Participant's death or disability as defined in Section 22(e)(3) of the Code, or (b) twelve (12) months after the Termination Date when the Termination is for Participant's death or Disability, deemed to be an NQSO), but in any event no later than the expiration date of the Options.

- (c) Award Agreements and other agreements relating to Awards under this Plan may include a provision that if Participant is terminated for Cause, neither the Participant, the Participant's estate nor such other person who may then hold the Option shall be entitled to exercise any Option with respect to any Shares whatsoever, after termination of service, whether or not after termination of service the Participant may receive payment from the Company or Subsidiary for vacation pay, for services rendered prior to termination, for services rendered for the day on which termination occurs, for salary in lieu of notice, or for any other benefits. For the purpose of this paragraph, termination of service shall be deemed to occur on the date when the Company dispatches notice or advice to the Participant that the Participant's service is terminated.

5.7 Limitations on Exercise. The Committee may specify a reasonable minimum number of Shares that may be purchased on any exercise of an Option, provided that such minimum number will not prevent Participant from exercising the Option for the full number of Shares for which it is then exercisable.

5.8 Limitations on ISOs. The aggregate Fair Market Value (determined as of the date of grant) of Shares with respect to which ISOs are exercisable for the first time by a Participant during any calendar year (under this Plan or under any other incentive stock option plan of the Company or any Affiliate, Parent or Subsidiary of the Company) will not exceed \$100,000. If the Fair Market Value of Shares on the date of grant with respect to which ISOs are exercisable for the first time by a Participant during any calendar year exceeds \$100,000, then the Options for the first \$100,000 worth of Shares to become exercisable in such calendar year will be ISOs and the Options for the amount in excess of \$100,000 that become exercisable in that calendar year will be NQSOs. In the event that the Code or the regulations promulgated thereunder are amended after the Effective Date of this Plan to provide for a different limit on the Fair Market Value of Shares permitted to be subject to ISOs, such different limit will be automatically incorporated herein and will apply to any Options granted after the effective date of such amendment.

5.9 Modification, Extension or Renewal. The Committee may modify, extend or renew outstanding Options and authorize the grant of new Options in substitution therefor, provided that any such action may not, without the written consent of a Participant, impair any of such Participant's rights under any Option previously granted. Any outstanding ISO that is modified, extended, renewed or otherwise altered will be treated in accordance with Section 424(h) of the Code. The Committee may reduce the Exercise Price of outstanding Options without the consent of Participants effected by a written notice to them; provided, however, that the Exercise Price may not be reduced below the minimum Exercise Price that would be permitted under Section 5.4 of this Plan for Options granted on the date the action is taken to reduce the Exercise Price.

5.10 No Disqualification. Notwithstanding any other provision in this Plan, no term of this Plan relating to ISOs will be interpreted, amended or altered, nor will any discretion or authority granted under this Plan be exercised, so as to disqualify this Plan under Section 422 of the Code or, without the consent of the Participant affected, to disqualify any ISO under Section 422 of the Code.

5.11 Automatic Grant Program for Non-Employee Directors. Each Non-employee Director shall be eligible to receive Options under the automatic option grant program described below (the "**Program**").

(a) Initial Grant. Each Non-Employee Director who becomes a member of the Board will automatically be granted an NQSO to purchase 30,000 Shares (the "**Initial Grant**"). Initial Grants shall be made on the first business day after the date such Optionee is first elected to the Board.

(b) Succeeding Annual Grants. On the first business day after each of the Company's annual meeting of shareholders, if the Non-Employee Director is still a member of the Board, has served continuously as a member of the Board for at least one year, and has not received an Initial Grant in the same calendar year, the Optionee will automatically be granted an NQSO for 12,000 Shares (a "**Annual Grant**").

(c) Vesting. Options granted under the Program shall be exercisable as they vest. The date an Optionee receives an Initial Grant or a Annual Grant is referred to as the "**Start Date**" for such Option. Each Initial Grant and Annual Grant will vest as follows, so long as the Optionee continuously remains a director of the Company: (a) on the first anniversary of the Start Date, the grant will vest as to one-third (1/3) of the Shares subject to the Annual Grant or Initial Grant (as the case may be); (b) on the second anniversary of the Start Date, the grant will vest as to a one-third (1/3) of the Shares subject to the Annual Grant or Initial Grant (as the case may be); and (c) on the third anniversary of the Start Date, the grant will vest as to an additional one-third (1/3) of the Shares subject to the Annual Grant or Initial Grant (as the case may be).

(d) Exercise Price. The exercise price of an Option granted under the Program shall be the Fair Market Value of the Shares, at the time that the Option is granted.

(e) Termination of Option. Except as provided below in this Section, each Option shall expire ten (10) years after its Start Date (the "**Expiration Date**"). The Option shall cease to vest if the Optionee ceases to be a member of the Board. The date on which the Optionee ceases to be a member of the Board shall be referred to in this Section as the "**Termination Date**". An Option may be exercised after the Termination Date only as set forth below:

(i) If the Optionee ceases to be a member of the Board for any reason, then each Option then held by such Optionee, to the extent (and only to the extent) that it would have been exercisable by the Optionee on the Termination Date, may be exercised by the Optionee (or the Optionee's legal representative) within twelve (12) months after the Termination Date (or such shorter or longer period as is specified in the Option Agreement), but in no event later than the Expiration Date.

(f) Acceleration of Options. In the event of a corporate transaction of the kind described in Section 18 below, the vesting of all options granted pursuant to this Plan will accelerate and the options will become exercisable in full prior to the consummation of such event at such times and on such conditions as the Committee determines.

**6. RESTRICTED STOCK.** A Restricted Stock Award is an offer by the Company to sell to an eligible person Shares that are subject to restrictions. The Committee will determine to whom an offer will be made, the number of Shares the person may purchase, the price to be paid (the "**Purchase Price**"), the restrictions to which the Shares will be subject, if any, and all other terms and conditions of the Restricted Stock Award, subject to the following:

6.1 Form of Restricted Stock Award. All purchases under a Restricted Stock Award made pursuant to this Plan will be evidenced by an Award Agreement ("**Restricted Stock Purchase Agreement**") that will be in such form (which need not be the same for each Participant) as the Committee will from time to time approve, and will comply with and be subject to the terms and conditions of this Plan. The offer of Restricted Stock will be accepted by the Participant's execution and delivery of the Restricted Stock Purchase Agreement and full payment for the Shares to the Company within thirty (30) days from the date the Restricted Stock Purchase Agreement is delivered to the person. If such person does not execute and deliver the Restricted Stock Purchase Agreement along with full payment for the Shares to the Company within thirty (30) days, then the offer will terminate, unless otherwise determined by the Committee.

6.2 Purchase Price. The Purchase Price of Shares sold pursuant to a Restricted Stock Award will be determined by the Committee; provided, that if expressly required by any state securities authorities as a condition of the offer and sale of Shares subject to Restricted Stock Awards in compliance with the securities laws of such state, the Purchase Price will be at least 85% of the Fair Market Value of the Shares on the date the Restricted Stock Award is granted, except in the case of a sale to a Ten Percent Shareholder, in which case the Purchase Price will be 100% of the Fair Market Value. Payment of the Purchase Price may be made in accordance with Section 8 of this Plan.

6.3 Restrictions. Restricted Stock Awards will be subject to such restrictions (if any) as the Committee may impose. The Committee may provide for the lapse of such restrictions in installments and may accelerate or waive such restrictions, in whole or part, based on length of service, performance or such other factors or criteria as the Committee may determine.

## 7. STOCK BONUSES.

7.1 Awards of Stock Bonuses. A Stock Bonus is an award of Shares (which may consist of Restricted Stock) for services rendered to the Company or any Parent, Subsidiary or Affiliate of the Company. A Stock Bonus may be awarded for past services already rendered to the Company, or any Parent, Subsidiary or Affiliate of the Company (provided that the Participant pays the Company the par value, if any, of the Shares awarded by such Stock Bonus in cash) pursuant to an Award Agreement (the "**Stock Bonus Agreement**") that will be in such form (which need not be the same for each Participant) as the Committee will from time to time approve, and will comply with and be subject to the terms and conditions of this Plan. A Stock Bonus may be awarded upon satisfaction of such performance goals as are set out in advance in the Participant's individual Award Agreement (the "**Performance Stock Bonus Agreement**") that will be in such form (which need not be the same for each Participant) as the Committee will from time to time approve, and will comply with and be subject to the terms and conditions of this Plan. Stock Bonuses may vary from Participant to Participant and between groups of Participants, and may be based upon the achievement of the Company, Parent, Subsidiary or Affiliate and/or individual performance factors or upon such other criteria as the Committee may determine.

7.2 Terms of Stock Bonuses. The Committee will determine the number of Shares to be awarded to the Participant and whether such Shares will be Restricted Stock. If the Stock Bonus is being earned upon the satisfaction of performance goals pursuant to a Performance Stock Bonus Agreement, then the Committee will determine: (a) the nature, length and starting date of any period during which performance is to be measured (the "**Performance Period**") for each Stock Bonus; (b) the performance goals and criteria to be used to measure the performance, if any; (c) the number of Shares that may be awarded to the Participant; and (d) the extent to which such Stock Bonuses have been earned. Performance Periods may overlap and Participants may participate simultaneously with respect to Stock Bonuses that are subject to different Performance Periods and different performance goals and other criteria. The number of Shares may be fixed or may vary in accordance with such performance goals and criteria as may be determined by the Committee. The Committee may adjust the performance goals applicable to the Stock Bonuses to take into account changes in law and accounting or tax rules and to make such adjustments as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events or circumstances to avoid windfalls or hardships.

7.3 Form of Payment. The earned portion of a Stock Bonus may be paid currently or on a deferred basis with such interest or dividend equivalent, if any, as the Committee may determine. Payment may be made in the form of cash, whole Shares, including Restricted Stock, or a combination thereof, either in a lump sum payment or in installments, all as the Committee will determine.

7.4 Termination During Performance Period. If a Participant is Terminated during a Performance Period for any reason, then such Participant will be entitled to payment (whether in Shares, cash or otherwise) with respect to the Stock Bonus only to the extent earned as of the date of Termination in accordance with the Performance Stock Bonus Agreement, unless the Committee determines otherwise.

## 8. PAYMENT FOR SHARE PURCHASES.

8.1 Payment. Payment for Shares purchased pursuant to this Plan may be made in cash (by check) or, where expressly approved for the Participant by the Committee and where permitted by law:



- (a) by cancellation of indebtedness of the Company to the Participant;
- (b) by surrender of shares that either: (1) have been owned by Participant for more than six (6) months and have been paid for within the meaning of SEC Rule 144 (and, if such shares were purchased from the Company by use of a promissory note, such note has been fully paid with respect to such shares); or (2) were obtained by Participant in the public market;
- (c) by waiver of compensation due or accrued to the Participant for services rendered; provided, that the portion of the Purchase Price equal to the par value of the Shares, if any, must be paid in cash;
- (e) with respect only to purchases upon exercise of an Option, and provided that a public market for the Company's stock exists:
  - (1) through a "same day sale" commitment from the Participant and a broker-dealer that is a member of the National Association of Securities Dealers (an "**NASD Dealer**") whereby the Participant irrevocably elects to exercise the Option and to sell a portion of the Shares so purchased to pay for the Exercise Price, and whereby the NASD Dealer irrevocably commits upon receipt of such Shares to forward the Exercise Price directly to the Company; or
  - (2) through a "margin" commitment from the Participant and a NASD Dealer whereby the Participant irrevocably elects to exercise the Option and to pledge the Shares so purchased to the NASD Dealer in a margin account as security for a loan from the NASD Dealer in the amount of the Exercise Price, and whereby the NASD Dealer irrevocably commits upon receipt of such Shares to forward the Exercise Price directly to the Company; or
- (f) by any combination of the foregoing.

**9. WITHHOLDING TAXES.**

9.1 Withholding Generally. Whenever Shares are to be issued in satisfaction of Awards granted under this Plan, the Company may require the Participant to remit to the Company an amount sufficient to satisfy federal, state and local withholding tax requirements prior to the delivery of any certificate or certificates for such Shares. Whenever, under this Plan, payments in satisfaction of Awards are to be made in cash, such payment will be net of an amount sufficient to satisfy federal, state, and local withholding tax requirements.

9.2 Stock Withholding. When, under applicable tax laws, a Participant incurs tax liability in connection with the exercise or vesting of any Award that is subject to tax withholding and the Participant is obligated to pay the Company the amount required to be withheld, the Committee may in its sole discretion allow the Participant to satisfy the minimum withholding tax obligation by electing to have the Company withhold from the Shares to be issued that number of Shares having a Fair Market Value equal to the minimum amount required to be withheld, determined on the date that the amount of tax to be withheld is to be determined. All elections by a Participant to have Shares withheld for this purpose will be made in accordance with the requirements established by the Committee and be in writing in a form acceptable to the Committee.

**10. PRIVILEGES OF STOCK OWNERSHIP.**

10.1 Voting and Dividends. No Participant will have any of the rights of a shareholder with respect to any Shares until the Shares are issued to the Participant. After Shares are issued to the Participant, the Participant will be a shareholder and have all the rights of a shareholder with respect to such Shares, including the right to vote and receive all dividends or other distributions made or paid with respect to such Shares; provided, that if such Shares are Restricted Stock, then any new, additional or different securities the Participant may become entitled to receive with respect to such Shares by virtue of a stock dividend, stock split or any other change in the corporate or capital structure of the Company will be subject to the same restrictions as the Restricted Stock; provided, further, that the Participant will have no right to retain such stock dividends or stock distributions with respect to Shares that are repurchased at the Participant's original Purchase Price pursuant to Section 12.

10.2 Financial Statements. If expressly required by any state securities authorities as a condition of the offer and issuance of Awards in compliance with the securities laws of such state, the Company shall provide to each Participant during the period such Participant holds an outstanding Award a copy of the financial statements of the Company as prepared either by the Company or independent certified public accountants of the Company. Such financial statements shall be delivered as soon as practicable following the end of the Company's fiscal year during the period Awards are outstanding; provided, however, the Company will not be required to provide such financial statements to Participants whose services in connection with the Company assure them access to equivalent information.

**11. TRANSFERABILITY.** Unless determined otherwise by the Committee, Awards granted under this Plan, and any interest therein, will not be transferable or assignable by Participant, and may not be made subject to execution, attachment or similar process, otherwise than by will or by the laws of descent and distribution. During the lifetime of the Participant an Award will be exercisable only by the Participant, and any elections with respect to an Award, may be made only by the Participant. If the Committee in its sole discretion makes an Award or any interest therein transferable, such Award may only be transferred pursuant to such additional terms and conditions as the Committee deems appropriate.

**12. RESTRICTIONS ON SHARES.** At the discretion of the Committee, the Company may reserve to itself and/or its assignee(s) in the Award Agreement a right to repurchase a portion of or all Shares that are not "Vested" (as defined in the Stock Option Agreement) held by a Participant following such Participant's Termination at any time within ninety (90) days after the later of Participant's Termination Date and the date Participant purchases Shares under this Plan, for cash and/or cancellation of purchase money indebtedness, at the Participant's original Purchase Price, provided, that the right to repurchase lapses at the rate of at least 20% per year over five (5) years from the date the Shares were purchased (or from the date of grant of options in the case of Shares obtained pursuant to a Stock Option Agreement and Stock Option Exercise Agreement), and if the right to repurchase is assignable, the assignee must pay the Company, upon assignment of the right to repurchase, cash equal to the excess of the Fair Market Value of the Shares over the original Purchase Price.

**13. CERTIFICATES.** All certificates for Shares or other securities delivered under this Plan will be subject to such stock transfer orders, legends and other restrictions as the Committee may deem necessary or advisable, including restrictions under any applicable federal, state or foreign securities law, or any rules, regulations and other requirements of the SEC or any stock exchange or automated quotation system upon which the Shares may be listed or quoted.

**14. ESCROW.** To enforce any restrictions on a Participant's Shares, the Committee may require the Participant to deposit all certificates representing Shares, together with stock powers or other instruments of transfer approved by the Committee, appropriately endorsed in blank, with the Company or an agent designated by the Company, to hold in escrow until such restrictions have lapsed or terminated, and the Committee may cause a legend or legends referencing such restrictions to be placed on the certificates.

15. **REPRICING, EXCHANGE, BUYOUT OF AWARDS.** The repricing of Options is permitted without prior stockholder approval, provided that the terms of the repricing satisfy the requirements of Section 409A of the Code and any regulations or rulings promulgated by the Internal Revenue Service. The Committee may, at any time or from time to time, authorize the Company, in the case of an Option exchange without stockholder approval, and with the consent of the respective Participants, to issue new Awards in exchange for the surrender and cancellation of any or all outstanding Awards, to reduce the exercise price of any Award to the then current fair market value, or take any other action that is treated as a "repricing" under generally accepted accounting principles. The Committee may at any time buy from a Participant an Option previously granted with payment in cash, Shares or other consideration, based on such terms and conditions as the Committee and the Participant may agree.

16. **SECURITIES LAW AND OTHER REGULATORY COMPLIANCE.** An Award will not be effective unless such Award is in compliance with all applicable federal and state securities laws, rules and regulations of any governmental body, and the requirements of any stock exchange or automated quotation system upon which the Shares may then be listed or quoted, as they are in effect on the date of grant of the Award and also on the date of exercise or other issuance. Notwithstanding any other provision in this Plan, the Company will have no obligation to issue or deliver certificates for Shares under this Plan prior to: (a) obtaining any approvals from governmental agencies that the Company determines are necessary or advisable; and/or (b) completion of any registration or other qualification of such Shares under any state or federal law or ruling of any governmental body that the Company determines to be necessary or advisable. The Company will be under no obligation to register the Shares with the SEC or to effect compliance with the registration, qualification or listing requirements of any state securities laws, stock exchange or automated quotation system, and the Company will have no liability for any inability or failure to do so.

17. **NO OBLIGATION TO EMPLOY.** Nothing in this Plan or any Award granted under this Plan will confer or be deemed to confer on any Participant any right to continue in the employ of, or to continue any other relationship with, the Company or any Parent, Subsidiary or Affiliate of the Company or limit in any way the right of the Company or any Parent, Subsidiary or Affiliate of the Company to terminate Participant's employment or other relationship at any time, with or without cause.

18. **CORPORATE TRANSACTIONS.**

18.1 **Assumption or Replacement of Awards by Successor.** In the event of (a) a dissolution or liquidation of the Company, (b) a merger or consolidation in which the Company is not the surviving corporation (other than a merger or consolidation with a wholly-owned subsidiary, a reincorporation of the Company in a different jurisdiction, or other transaction in which there is no substantial change in the shareholders of the Company or their relative stock holdings and the Awards granted under this Plan are assumed, converted or replaced by the successor corporation, which assumption will be binding on all Participants), (c) a merger in which the Company is the surviving corporation but after which the shareholders of the Company immediately before such merger (other than any shareholder which merges (or which owns or controls another corporation which merges) with the Company in such merger) cease to own their shares or other equity interests in the Company, (d) the sale of substantially all of the assets of the Company, or (e) any other transaction which qualifies as a "corporate transaction" under Section 424(a) of the Code wherein the shareholders of the Company give up all of their equity interest in the Company (except for the acquisition, sale or transfer of all or substantially all of the outstanding shares of the Company from or by the shareholders of the Company), any or all outstanding Awards may be assumed, converted or replaced by the successor corporation (if any), which assumption, conversion or replacement will be binding on all Participants. In the alternative, the successor corporation may substitute equivalent Awards or provide substantially similar consideration to Participants as was provided to shareholders (after taking into account the existing provisions of the Awards). The successor corporation may also issue, in place of outstanding Shares of the Company held by the Participant, substantially similar shares or other property subject to repurchase restrictions no less favorable to the Participant. In the event such successor corporation (if any) refuses to assume or replace such Awards, as provided above, pursuant to a transaction described in this Subsection 18.1, such Awards shall immediately vest as to 100% of the Shares subject thereto immediately prior to the consummation of such transaction. All Awards that are not assumed as part of such transaction shall expire at the closing of such transaction unless otherwise determined by the Board. Notwithstanding the foregoing, the Board may, in its sole discretion, provide that the vesting of any or all other Awards granted pursuant to this Plan will accelerate upon a transaction described in this Section 18.1. If the Board exercises such discretion with respect to Options, such Options will become exercisable in full prior to the consummation of such event at such time and on such conditions as the Board determines, and if such Options are not exercised prior to the consummation of the corporate transaction, they shall terminate at such time as determined by the Board.

18.2 Other Treatment of Awards. Subject to any greater rights granted to Participants under the foregoing provisions of this Section 18, in the event of the occurrence of any transaction described in Section 18.1, any outstanding Awards will be treated as provided in the applicable agreement or plan of merger, consolidation, dissolution, liquidation, sale of assets or other corporate transaction.

18.3 Assumption of Awards by the Company. The Company, from time to time, also may substitute or assume outstanding awards granted by another company, whether in connection with an acquisition of such other company or otherwise, by either; (a) granting an Award under this Plan in substitution of such other company's award; or (b) assuming such award as if it had been granted under this Plan if the terms of such assumed award could be applied to an Award granted under this Plan. Such substitution or assumption will be permissible if the holder of the substituted or assumed award would have been eligible to be granted an Award under this Plan if the other company had applied the rules of this Plan to such grant. In the event the Company assumes an award granted by another company, the terms and conditions of such award will remain unchanged (except that the exercise price and the number and nature of Shares issuable upon exercise of any such option will be adjusted appropriately pursuant to Section 424(a) of the Code). In the event the Company elects to grant a new Option rather than assuming an existing option, such new Option may be granted with a similarly adjusted Exercise Price.

19. ADOPTION AND SHAREHOLDER APPROVAL. This Plan was adopted by the Board on June 8, 2005 (the "*Effective Date*"). This Plan shall be approved by the stockholders of the Company (excluding Shares issued pursuant to this Plan), consistent with applicable laws, within twelve (12) months after the Effective Date. Upon the Effective Date, the Board may grant Awards pursuant to this Plan; provided, however, that: (a) no Option may be exercised prior to initial shareholder approval of this Plan; (b) no Option granted pursuant to an increase in the number of Shares subject to this Plan approved by the Board will be exercised prior to the time such increase has been approved by the stockholders of the Company; and (c) in the event that stockholder approval of such increase is not obtained within the time period provided herein, all Awards granted hereunder will be canceled, any Shares issued pursuant to any Award will be canceled, and any purchase of Shares hereunder will be rescinded.

20. TERM OF PLAN. Unless earlier terminated as provided herein, this Plan will terminate ten (10) years following the Effective Date.

21. AMENDMENT OR TERMINATION OF PLAN. The Board may at any time terminate or amend this Plan in any respect, including without limitation amendment of any form of Award Agreement or instrument to be executed pursuant to this Plan. Notwithstanding the foregoing, neither the Board nor the Committee shall, without the approval of the shareholders of the Company, amend this Plan in any manner that requires such shareholder approval pursuant to the Code or the regulations promulgated thereunder as such provisions apply to ISO plans or (if the Company is subject to the Exchange Act) pursuant to the Exchange Act or any rule promulgated thereunder.

22. NONEXCLUSIVITY OF THE PLAN. Neither the adoption of this Plan by the Board, the submission of this Plan to the shareholders of the Company for approval, nor any provision of this Plan will be construed as creating any limitations on the power of the Board to adopt such additional compensation arrangements as it may deem desirable, including, without limitation, the granting of stock options and bonuses otherwise than under this Plan, and such arrangements may be either generally applicable or applicable only in specific cases.

23. DEFINITIONS. As used in this Plan, the following terms will have the following meanings:

**"Affiliate"** means any corporation that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, another corporation, where "control" (including the terms "controlled by" and "under common control with") means the possession, direct or indirect, of the power to cause the direction of the management and policies of the corporation, whether through the ownership of voting securities, by contract or otherwise.

**"Award"** means any award under this Plan, including any Option, Restricted Stock or Stock Bonus.

**"Award Agreement"** means, with respect to each Award, the signed written agreement between the Company and the Participant setting forth the terms and conditions of the Award.

**"Board"** means the Board of Directors of the Company.

**"Cause"** means termination of the Participant's employment on the basis of the Participant's conviction (or a plea of nolo contendere) of fraud, misappropriation, embezzlement or any other act or acts of dishonesty constituting a felony and resulting or intended to result directly or indirectly in a substantial gain or personal enrichment to the Participant at the expense of the Company or any Subsidiary.

**"Code"** means the Internal Revenue Code of 1986, as amended.

**"Committee"** means the committee appointed by the Board to administer this Plan, or if no such committee is appointed, the Board.

**"Company"** means Cellegy Pharmaceuticals, Inc. a corporation organized under the laws of the State of Delaware, or any successor corporation.

**"Covered Employee"** means the chief executive officer and the four (4) other highest compensated officers of the Company for whom total compensation is required to be reported to stockholders under the Exchange Act, as determined for purposes Section 162(m) of the Code.

**"Disability"** means a disability, whether temporary or permanent, partial or total, as determined by the Committee.

**"Exchange Act"** means the Securities Exchange Act of 1934, as amended.

**"Exercise Price"** means the price at which a holder of an Option may purchase the Shares issuable upon exercise of the Option.

**"Fair Market Value"** means, as of any date, the value of a share of the Company's Common Stock determined by the Board in its sole discretion, exercised in good faith; provided, however, that if the Common Stock of the Company is quoted on the Small Cap Market of the National Association of Securities Dealers Automated Quotation System or is regularly quoted by a recognized securities dealer, and selling prices are reported, the Fair Market Value per share shall be the closing sales price for such stock or the closing bid if no sales were reported, as quoted on such system or by such dealer, for the date the value is to be determined (or if there are not sales for such date, then for the last preceding business day on which there were sales); provided, however, that if the Common Stock of the Company is listed on any established stock exchange or a national market system, including without limitation the National Market System of the National Association of Securities Dealers Automated Quotation System, the Fair Market Value per share shall be the closing sales price for such stock or the closing bid if no sales were reported, as quoted on such system or exchange (or the largest such exchange) for the date the value is to be determined (or if there are not sales for such date, then for the last preceding business day on which there were sales), as reported in the Wall Street Journal or similar publication.

**"Insider"** means an officer or director of the Company or any other person whose transactions in the Company's Common Stock are subject to Section 16 of the Exchange Act.

**"Non-employee Director"** means a director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("**Regulation S-K**")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

**"Option"** means an award of an option to purchase Shares pursuant to Section 5.

**"Outside Directors"** means a director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), in not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation," and does not receive remuneration from the Company or an "affiliated corporation" either directly or indirectly, in any capacity other than as a director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

**"Parent"** means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if at the time of the granting of an Award under this Plan, each of such corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

**"Participant"** means a person who receives an Award under this Plan.

**"Plan"** means this Cellegy Pharmaceutical, Inc. 2005 Equity Incentive Plan, as amended from time to time.

**"Restricted Stock Award"** means an award of Shares pursuant to Section 6.

**"SEC"** means the Securities and Exchange Commission.

**"Securities Act"** means the Securities Act of 1933, as amended.

**"Shares"** means shares of the Company's Common Stock reserved for issuance under this Plan, as adjusted pursuant to Sections 2 and 18, and any successor security.

**"Stock Bonus"** means an award of Shares, or cash in lieu of Shares, pursuant to Section 7.

**"Subsidiary"** means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company if, at the time of granting of the Award, each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

**"Termination"** or **"Terminated"** means, for purposes of this Plan with respect to a Participant, that the Participant has for any reason ceased to provide services as an employee, director, consultant or advisor to the Company or a Parent, Subsidiary or Affiliate of the Company, except in the case of sick leave, military leave, or any other leave of absence approved by the Committee, provided that such leave is for a period of not more than ninety (90) days, or reinstatement upon the expiration of such leave is guaranteed by contract or statute. The Committee will have sole discretion to determine whether a Participant has ceased to provide services and the effective date on which the Participant ceased to provide services (the "**Termination Date**").

**CELLEGY PHARMACEUTICALS, INC.  
2005 EQUITY INCENTIVE PLAN  
STOCK OPTION AGREEMENT**

This Stock Option Agreement (this "**Agreement**") is made and entered into as of the date of grant set forth below (the "**Date of Grant**") by and between Cellegy Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and the participant named below ("**Participant**"). Capitalized terms not defined herein shall have the meaning ascribed to them in the Company's 2005 Equity Incentive Plan, as amended (the "**2005 Plan**").

**Participant:**  
**Social Security Number:**  
**Participant's Address:**

**Total Option Shares:**  
**Exercise Price Per Share:**  
**Date of Grant:**  
**Vesting Start Date:**  
**Expiration Date:**  
**Type of Stock Option**

(Check one):  **Incentive Stock Option**  
 **Nonqualified Stock Option**

1. **Grant of Option.** The Company hereby grants to Participant an option (this "**Option**") to purchase up to the total number of shares of Common Stock of the Company set forth above (collectively, the "**Shares**") at the Exercise Price Per Share set forth above (the "**Exercise Price**"), subject to all of the terms and conditions of this Agreement and the 2005 Plan. If designated as an Incentive Stock Option above, this Option is intended to qualify as an "incentive stock option" ("**ISO**") within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**"). Capitalized terms not defined in this Agreement will have the meanings given to them in the 2005 Plan.

2. **Vesting; Exercise Period.**

2.1 **Vesting of Right to Exercise Option.** This Option shall become exercisable as it vests as to portions of the Shares as follows: (a) this Option shall not be exercisable with respect to any of the Shares until \_\_\_\_\_ (the "**Vesting Start Date**"); (b) On the Vesting Start Date this Option shall become exercisable as to twenty-five percent (25%) of the Shares; and (c) thereafter, on the first anniversary of the Vesting Start Date and on each successive anniversary of the Vesting Start Date, this Option shall become exercisable as to an additional twenty-five percent (25%) of the Shares; provided that this Option shall in no event ever become exercisable with respect to more than 100% of the Shares. Vesting will occur so long as Participant continuously provides services to the Company or any Subsidiary, Parent or Affiliate of the Company and is not terminated.

2.2 **Expiration.** This Option shall expire on the Expiration Date set forth above and must be exercised, if at all, on or before the earlier of the Expiration Date or the date on which this Option is earlier terminated in accordance with the provisions of Section 3.

3. **Termination.**

3.1 **Termination for Cause.** If Participant is Terminated for cause, then this Option, to the extent (and only to the extent) that it would have been exercisable by Participant on the date of Termination, may be exercised by Participant no later than three (3) months after the date of Termination, but in any event no later than the Expiration Date.

3.2 *Termination Because of Death or Disability.* If Participant is Terminated because of death or Disability or Participant, then this Option, to the extent that it is exercisable by Participant on the date of Termination, may be exercised by Participant (or Participant's legal representative) no later than twelve (12) months after the date of Termination, but in any event no later than the Expiration Date.

3.3 *No Obligation to Employ.* Nothing in the Plan or this Agreement shall confer on Participant any right to continue in the employ of, or other relationship with, the Company or any Parent, Subsidiary or Affiliate of the Company, or limit in any way the right of the Company or any Parent, Subsidiary or Affiliate of the Company to terminate Participant's employment or other relationship at any time, with or without cause.

#### 4. *Manner of Exercise.*

4.1 *Stock Option Exercise Agreement.* To exercise this Option, Participant (or in the case of exercise after Participant's death, Participant's executor, administrator, heir or legatee, as the case may be) must deliver to the Company an executed stock option exercise agreement in such form as may be approved by the Company from time to time (the "**Exercise Agreement**"), which shall set forth, *inter alia*, Participant's election to exercise this Option, the number of Shares being purchased, any restrictions imposed on the Shares and any representations, warranties and agreements regarding Participant's investment intent and access to information as may be required by the Company to comply with applicable securities laws. If someone other than Participant exercises this Option, then such person must submit documentation reasonably acceptable to the Company that such person has the right to exercise this Option.

4.2 *Limitations on Exercise.* This Option may not be exercised unless such exercise is in compliance with all applicable federal and state securities laws, as they are in effect on the date of exercise. This Option may not be exercised as to fewer than 100 Shares unless it is exercised as to all Shares as to which this Option is then exercisable.

4.3 *Payment.* The Exercise Agreement shall be accompanied by full payment of the Exercise Price for the Shares being purchased in cash (by check), or, if the Company in its discretion agrees in writing and where permitted by law:

(a) by cancellation of indebtedness of the Company to the Participant;

(b) by waiver of compensation due or accrued to Participant for services rendered;

(c) provided that a public market for the Company's stock exists: (1) through a "same day sale" commitment from Participant and a broker-dealer that is a member of the National Association of Securities Dealers (an "**NASD Dealer**") whereby Participant irrevocably elects to exercise this Option and to sell a portion of the Shares so purchased to pay for the exercise price and whereby the NASD Dealer irrevocably commits upon receipt of such Shares to forward the exercise price directly to the Company; or (2) through a "margin" commitment from Participant and a NASD Dealer whereby Participant irrevocably elects to exercise this Option and to pledge the Shares so purchased to the NASD Dealer in a margin account as security for a loan from the NASD Dealer in the amount of the exercise price, and whereby the NASD Dealer irrevocably commits upon receipt of such Shares to forward the exercise price directly to the Company; or

(d) by any combination of the foregoing.

4.4 *Tax Withholding.* Prior to the issuance of the Shares upon exercise of this Option, Participant must pay or provide for any applicable federal or state withholding obligations of the Company. If the Committee permits, Participant may provide for payment of withholding taxes upon exercise of this Option by requesting that the Company retain Shares with a Fair Market Value equal to the minimum amount of taxes required to be withheld. In such case, the Company shall issue the net number of Shares to the Participant by deducting the Shares retained from the Shares issuable upon exercise.



4.5 *Issuance of Shares.* Provided that the Exercise Agreement and payment are in form and substance satisfactory to counsel for the Company, the Company shall issue the Shares registered in the name of Participant, Participant's authorized assignee, or Participant's legal representative, and shall deliver certificates representing the Shares with the appropriate legends affixed thereto.

5. ***Notice of Disqualifying Disposition of ISO Shares.*** If this Option is an ISO, and if Participant sells or otherwise disposes of any of the Shares acquired pursuant to the ISO on or before the later of (a) the date two (2) years after the Date of Grant, and (b) the date one (1) year after transfer of such Shares to Participant upon exercise of this Option, then Participant shall immediately notify the Company in writing of such disposition. Participant agrees that Participant may be subject to income tax withholding by the Company on the compensation income recognized by Participant from the early disposition by payment in cash or out of the current wages or other compensation payable to Participant.

6 ***Compliance with Laws and Regulations.*** The exercise of this Option and the issuance and transfer of Shares shall be subject to compliance by the Company and Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Common Stock may be listed at the time of such issuance or transfer. Participant understands that the Company is under no obligation to register or qualify the Shares with the Securities and Exchange Commission, any state securities commission or any stock exchange to effect such compliance.

7. ***Non-transferability of Option.*** This Option may not be transferred in any manner other than by will or by the laws of descent and distribution and may be exercised during the lifetime of Participant only by Participant. The terms of this Option shall be binding upon the executors, administrators, successors and assigns of Participant.

8. ***Tax Consequences.*** Set forth below is a brief summary as of the Date of Grant of some of the federal tax consequences of exercise of this Option and disposition of the Shares. THIS SUMMARY IS NECESSARILY INCOMPLETE, AND THE TAX LAWS AND REGULATIONS ARE SUBJECT TO CHANGE. PARTICIPANT SHOULD CONSULT A TAX ADVISOR BEFORE EXERCISING THE OPTION OR DISPOSING OF THE SHARES.

8.1 *Exercise of ISO.* If this Option qualifies as an ISO, there will be no regular federal income tax liability upon the exercise of this Option, although the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price will be treated as a tax preference item for federal income tax purposes and may subject the Participant to the alternative minimum tax in the year of exercise.

8.2 *Exercise of Nonqualified Stock Option.* If this Option does not qualify as an ISO, there may be a regular federal income tax liability upon the exercise of this Option. Participant will be treated as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price. The Company will be required to withhold from Participant's compensation or collect from Participant and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise.

8.3 *Disposition of Shares.* If the Shares are held for more than twelve (12) months after the date of the transfer of the Shares pursuant to the exercise of this Option (and, in the case of an ISO, are disposed of more than two (2) years after the Date of Grant), then any gain realized on disposition of the Shares will be treated as long term capital gain for federal income tax purposes. If Shares purchased under an ISO are disposed of within one (1) year of exercise or within two (2) years after the Date of Grant, then any gain realized on such disposition will be treated as compensation income (taxable at ordinary income rates) to the extent of the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price. The Company will be required to withhold from Participant's compensation or collect from Participant and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise.

9. **Privileges of Stock Ownership.** Participant shall not have any of the rights of a stockholder with respect to any Shares until Participant exercises this Option and pays the Exercise Price.

10. **Interpretation.** Any dispute regarding the interpretation of this Agreement shall be submitted by Participant or the Company to the Committee for review. The resolution of such a dispute by the Committee shall be final and binding on the Company and Participant.

11. **Entire Agreement.** The 2005 Plan is incorporated herein by reference. This Agreement and the 2005 Plan and the Exercise Agreement constitute the entire agreement and understanding of the parties hereto with respect to the subject matter hereof and supersede all prior understandings and agreements with respect to such subject matter.

12. **Notices.** Any notice required to be given or delivered to the Company under the terms of this Agreement shall be in writing and addressed to the Corporate Secretary of the Company at its principal corporate offices. Any notice required to be given or delivered to Participant shall be in writing and addressed to Participant at the address indicated above or to such other address as such party may designate in writing from time to time to the Company. All notices shall be deemed to have been given or delivered upon: personal delivery; three (3) days after deposit in the United States mail by certified or registered mail (return receipt requested); one (1) business day after deposit with any return receipt express courier (prepaid); or one (1) business day after transmission by telecopier with confirmation of successful transmission.

13. **Successors and Assigns.** The Company may assign any of its rights under this Agreement. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement shall be binding upon Participant and Participant's heirs, executors, administrators, legal representatives, successors and assigns.

14. **Governing Law.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to that body of law pertaining to choice of law or conflict of law.

15. **Acceptance.** Participant hereby acknowledges receipt of a copy of the 2005 Plan and this Agreement. Participant has read and understands the terms and provisions thereof, and accepts this Option subject to all the terms and conditions of the 2005 Plan and this Agreement. Participant acknowledges that there may be adverse tax consequences upon exercise of this Option or disposition of the Shares and that the Company has advised Participant to consult a tax advisor prior to such exercise or disposition.

**[Remainder of page intentionally left blank]**

**IN WITNESS WHEREOF**, the Company has caused this Agreement to be executed by its duly authorized representative and Participant has executed this Agreement as of the Date of Grant.

**CELLEGY PHARMACEUTICALS, INC.**

**PARTICIPANT**

By:

\_\_\_\_\_

\_\_\_\_\_

(Signature)

\_\_\_\_\_  
(Please print title)

\_\_\_\_\_  
(Please print name)

\_\_\_\_\_  
(Please print title)

CELLEGY PHARMACEUTICALS, INC.  
2005 EQUITY INCENTIVE PLAN  
DIRECTOR STOCK OPTION AGREEMENT

This Director Stock Option Agreement (this "**Agreement**") is made and entered into as of the date of grant set forth below (the "**Date of Grant**") by and between Cellegy Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and the participant named below ("**Participant**"). Capitalized terms not defined herein shall have the meaning ascribed to them in the Company's 2005 Equity Incentive Plan, as amended (the "**2005 Plan**").

**Participant:**  
**Social Security Number:**  
**Participant's Address:**

**Total Option Shares:**  
**Exercise Price Per Share:**  
**Date of Grant:**  
**Vesting Start Date:**  
**Expiration Date:**  
**Type of Stock Option**

(Check one):     **Incentive Stock Option**  
    **Nonqualified Stock Option**

1.            **Grant of Option.** The Company hereby grants to Participant an option (this "**Option**") to purchase up to the total number of shares of Common Stock of the Company set forth above (collectively, the "**Shares**") at the Exercise Price Per Share set forth above (the "**Exercise Price**"), subject to all of the terms and conditions of this Agreement and the 2005 Plan, including without limitation Section 5.11 of the 2005 Plan. This Option is granted pursuant to Section 5.11 of the 2005 Plan and is not intended to qualify as an "incentive stock option" ("**ISO**") within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**"). Capitalized terms not defined in this Agreement will have the meanings given to them in the 2005 Plan.

2.            **Vesting; Exercise Period.**

2.1 *Vesting of Right to Exercise Option.* Subject to the terms and conditions of the 2005 Plan and this Grant, this Option shall vest and become exercisable as to one-third ( $\frac{1}{3}$ ) of the Shares on the first anniversary of the Date of Grant. Thereafter, this Option shall vest as one-third ( $\frac{1}{3}$ ) of the total Shares upon each of the next two (2) successive anniversaries of the Date of Grant, so long as the Optionee continuously remains a member of the Board of Directors of the Company (a "**Board Member**").

2.2 *Expiration.* This Option shall expire on the Expiration Date set forth above and must be exercised, if at all, on or before the earlier of the Expiration Date or the date on which this Option is earlier terminated in accordance with the provisions of Section 3.

3.            **Termination.**

3.1 *Termination.* The Option shall cease to vest if the Participant ceases to be a Board Member (the "**Termination Date**"). If Participant is Terminated for cause, then this Option, to the extent (and only to the extent) that it would have been exercisable by Participant on the date of Termination, may be exercised by Participant (or the Participant's legal representative) no later than twelve (12) months after the Termination Date, but in no event later than the Expiration Date.

3.2 *Acceleration of Options.* In the event of a corporate transaction of the kind described in Section 18 of the 2005 Plan, the vesting of the Option will accelerate and the Option will become exercisable in full prior to the consummation of such event at such times and on such conditions as the Committee determines.

3.3 *No Right to Remain a Director.* Nothing in the 2005 Plan or this Agreement shall confer on Participant any right to remain a Board Member or limit in any way the right of the Company to terminate Participant's relationship with the Company at any time.

#### 4. ***Manner of Exercise.***

4.1 *Stock Option Exercise Agreement.* To exercise this Option, Participant (or in the case of exercise after Participant's death, Participant's executor, administrator, heir or legatee, as the case may be) must deliver to the Company an executed stock option exercise agreement in such form as may be approved by the Company from time to time (the "***Exercise Agreement***"), which shall set forth, *inter alia*, Participant's election to exercise this Option, the number of Shares being purchased, any restrictions imposed on the Shares and any representations, warranties and agreements regarding Participant's investment intent and access to information as may be required by the Company to comply with applicable securities laws. If someone other than Participant exercises this Option, then such person must submit documentation reasonably acceptable to the Company that such person has the right to exercise this Option.

4.2 *Limitations on Exercise.* This Option may not be exercised unless such exercise is in compliance with all applicable federal and state securities laws, as they are in effect on the date of exercise. This Option may not be exercised as to fewer than 100 Shares unless it is exercised as to all Shares as to which this Option is then exercisable.

4.3 *Payment.* The Exercise Agreement shall be accompanied by full payment of the Exercise Price for the Shares being purchased in cash (by check), or, if the Company in its discretion agrees in writing and where permitted by law:

(a) by cancellation of indebtedness of the Company to the Participant;

(b) by waiver of compensation due or accrued to Participant for services rendered;

(c) provided that a public market for the Company's stock exists: (1) through a "same day sale" commitment from Participant and a broker-dealer that is a member of the National Association of Securities Dealers (an "***NASD Dealer***") whereby Participant irrevocably elects to exercise this Option and to sell a portion of the Shares so purchased to pay for the exercise price and whereby the NASD Dealer irrevocably commits upon receipt of such Shares to forward the exercise price directly to the Company; or (2) through a "margin" commitment from Participant and a NASD Dealer whereby Participant irrevocably elects to exercise this Option and to pledge the Shares so purchased to the NASD Dealer in a margin account as security for a loan from the NASD Dealer in the amount of the exercise price, and whereby the NASD Dealer irrevocably commits upon receipt of such Shares to forward the exercise price directly to the Company; or

(d) by any combination of the foregoing.

4.4 *Tax Withholding.* Prior to the issuance of the Shares upon exercise of this Option, Participant must pay or provide for any applicable federal or state withholding obligations of the Company. If the Committee permits, Participant may provide for payment of withholding taxes upon exercise of this Option by requesting that the Company retain Shares with a Fair Market Value equal to the minimum amount of taxes required to be withheld. In such case, the Company shall issue the net number of Shares to the Participant by deducting the Shares retained from the Shares issuable upon exercise.

4.5 *Issuance of Shares.* Provided that the Exercise Agreement and payment are in form and substance satisfactory to counsel for the Company, the Company shall issue the Shares registered in the name of Participant, Participant's authorized assignee, or Participant's legal representative, and shall deliver certificates representing the Shares with the appropriate legends affixed thereto.

5. ***Compliance with Laws and Regulations.*** The exercise of this Option and the issuance and transfer of Shares shall be subject to compliance by the Company and Participant with all applicable requirements of federal and state securities laws and with all applicable requirements of any stock exchange on which the Company's Common Stock may be listed at the time of such issuance or transfer. Participant understands that the Company is under no obligation to register or qualify the Shares with the Securities and Exchange Commission, any state securities commission or any stock exchange to effect such compliance.

6. **Non-transferability of Option.** This Option may not be transferred in any manner other than by will or by the laws of descent and distribution and may be exercised during the lifetime of Participant only by Participant. The terms of this Option shall be binding upon the executors, administrators, successors and assigns of Participant.

7. **Tax Consequences.** Set forth below is a brief summary as of the Date of Grant of some of the federal tax consequences of exercise of this Option and disposition of the Shares. THIS SUMMARY IS NECESSARILY INCOMPLETE, AND THE TAX LAWS AND REGULATIONS ARE SUBJECT TO CHANGE. PARTICIPANT SHOULD CONSULT A TAX ADVISOR BEFORE EXERCISING THE OPTION OR DISPOSING OF THE SHARES.

7.1. **Exercise of Nonqualified Stock Option.** There may be a regular federal income tax liability upon the exercise of this Option. Participant will be treated as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price. The Company may be required to withhold from Participant's compensation or collect from Participant and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise.

8. **Privileges of Stock Ownership.** Participant shall not have any of the rights of a stockholder with respect to any Shares until Participant exercises this Option and pays the Exercise Price.

9. **Interpretation.** Any dispute regarding the interpretation of this Agreement shall be submitted by Participant or the Company to the Committee for review. The resolution of such a dispute by the Committee shall be final and binding on the Company and Participant.

10. **Entire Agreement.** The 2005 Plan is incorporated herein by reference. This Agreement and the 2005 Plan and the Exercise Agreement constitute the entire agreement and understanding of the parties hereto with respect to the subject matter hereof and supersede all prior understandings and agreements with respect to such subject matter.

11. **Notices.** Any notice required to be given or delivered to the Company under the terms of this Agreement shall be in writing and addressed to the Corporate Secretary of the Company at its principal corporate offices. Any notice required to be given or delivered to Participant shall be in writing and addressed to Participant at the address indicated above or to such other address as such party may designate in writing from time to time to the Company. All notices shall be deemed to have been given or delivered upon: personal delivery; three (3) days after deposit in the United States mail by certified or registered mail (return receipt requested); one (1) business day after deposit with any return receipt express courier (prepaid); or one (1) business day after transmission by telecopier with confirmation of successful transmission.

12. **Successors and Assigns.** The Company may assign any of its rights under this Agreement. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein, this Agreement shall be binding upon Participant and Participant's heirs, executors, administrators, legal representatives, successors and assigns.

13. **Governing Law.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to that body of law pertaining to choice of law or conflict of law.

14. **Acceptance.** Participant hereby acknowledges receipt of a copy of the 2005 Plan and this Agreement. Participant has read and understands the terms and provisions thereof, and accepts this Option subject to all the terms and conditions of the 2005 Plan and this Agreement. Participant acknowledges that there may be adverse tax consequences upon exercise of this Option or disposition of the Shares and that the Company has advised Participant to consult a tax advisor prior to such exercise or disposition.

**[Remainder of page intentionally left blank]**

**IN WITNESS WHEREOF**, the Company has caused this Agreement to be executed by its duly authorized representative and Participant has executed this Agreement as of the Date of Grant.

**CELLEGY PHARMACEUTICALS, INC.**

**PARTICIPANT**

By:

\_\_\_\_\_

\_\_\_\_\_

(Signature)

\_\_\_\_\_

(Please print title)

\_\_\_\_\_

(Please print name)

\_\_\_\_\_

(Please print title)

**FIRST AMENDED AND RESTATED EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT FOR RECTOGESIC®**

**Between**

**STRAKAN INTERNATIONAL LIMITED**

**And**

**Cellegy Pharmaceuticals, Inc.**

**Confidential**

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



**FIRST AMENDED AND RESTATED  
EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT**

THIS FIRST AMENDED AND RESTATED EXCLUSIVE LICENSE AND DISTRIBUTION LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of November 9, 2005 (the "**Agreement Date**"), by and between Cellegy Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 1800 Byberry Road, Building 13, Huntingdon Valley, PA, 19006-3525 USA ("**Cellegy**"), and Strakan International Limited, a company organized and existing under the laws of Bermuda with a branch office at Buckholm Mill, Galashiels, TD1 2HB, UK ("**Licensee**").

**BACKGROUND**

A. Cellegy owns or possesses certain intellectual property rights with respect to the Licensed Product (as hereinafter defined) and certain rights pertaining to Cellegy's Marks (as hereinafter defined).

B. The Parties previously entered into an Exclusive License and Distribution Agreement ("**Prior Agreement**") dated as of July 9, 2004 (the "**Prior Agreement Date**"), pursuant to which Licensee obtained an exclusive license to certain rights to the Licensed Product under such intellectual property rights, and to Cellegy's Marks within the Territory (as hereinafter defined).

C. The Parties desire to amend the Prior Agreement in various respects, as reflected in this Agreement.

**AGREEMENT**

Commencing with the Agreement Date, this Agreement shall amend, restate and supersede in its entirety the Prior Agreement. In consideration of the foregoing and of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the Parties (as hereinafter defined) mutually agree as follows:

ARTICLE 1  
**DEFINITIONS**

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

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

- (i) exercise or control the right to vote attached to 50% or more of the issued shares in the party;
- (ii) dispose of or exercise a right of disposal in respect of 50% or more of the issued voting shares in the party;
- (iii) appoint one half or more of the number of directors to the board of the party; or
- (iv) determine substantially the conduct of the party's business activities.

**"Agreement"** means this First Amended and Restated Exclusive License and Distribution Agreement.

**"Approvals"** are registration approvals, registrations or authorizations provided by the Relevant Regulatory Authority in the Territory for the importation, storage, Development, promotion, marketing, distribution or sale of the Licensed Product, but excluding any pricing approvals that may be required by any Relevant Regulatory Authority of a country within the Territory.

**"Cellegy Information"** means the technical and clinical information concerning the Licensed Product that is developed by Cellegy and that is included in the new drug application filed with the Relevant Regulatory Authority in the United Kingdom, and Cellegy's European common technical document format, and which may include, without limitation, data in support of indications, bioequivalency data and information, clinical data, pharmacotoxicological data, analytical methods, stability and pharmaceutical data concerning the Licensed Product, and any other of Cellegy's related supporting documentation or other information or materials of Cellegy in Cellegy's possession from time to time that Cellegy may in its discretion from time to time develop before the date that all required Approvals are obtained and that may be necessary for, or useful in connection with obtaining and maintaining Approvals for the Licensed Product in the Territory.

**"Cellegy Marks"** means the trademarks, service marks and/or trade names owned by Cellegy or that Cellegy has the right to use in connection with the Licensed Product as set forth on Exhibit C hereto and as further described in Section 13.1, that are used by Licensee, its Affiliates or Sublicensees in connection with the importation, storage, Development, promotion, marketing, distribution and sale of the Licensed Product.

**"Cellegy Patents"** means the patents identified on Exhibit B hereto.

**"Cellegy Supply Agreement"** means the supply agreement between Cellegy and Manufacturer governing the supply of the Licensed Product to Cellegy or Cellegy's nominees or licensees outside the Territory and incorporating the terms and conditions of a relevant Technical Agreement.

**“Commercially Reasonable and Diligent Efforts”** shall mean with respect to Development and commercialization of the Licensed Product, a Party’s reasonable efforts no less than those efforts used by the Party in its other development, commercialization or marketing projects with other technologies and products having comparable commercial potential.

**“Competing Licensed Products”** has the meaning set forth in Section 2.4.

**“Development”** (including variations such as “Develop” and the like) shall mean all appropriate measures, steps and the like that are necessary to prepare and compile dossiers appropriate for obtaining Approvals for the Licensed Product in the Territory and conducting clinical trials in the Territory (if required). As it relates to Cellegy, “Development” shall mean that Cellegy shall provide Licensee a copy of the dossier concerning the Licensed Product filed by Cellegy with the Relevant Regulatory Authority in the United Kingdom, and such other materials relating thereto or to obtaining other Approvals for the Licensed Product in the Territory as Cellegy may in its discretion from time to time develop before the date that all required Approvals are obtained.

**“Dollars”** or **“\$”** means United States dollars.

**“Prior Agreement Date”** means the date set forth at the beginning of the Prior Agreement.

**“Euros”** or **“€”** shall mean currency denominated in Euros.

**“Field”** shall mean the use of the Licensed Product for the treatment of the pain associated with chronic anal fissure, for the treatment of one (1) or more of the symptoms associated with or related to hemorrhoids, and for any other additional therapeutic and medicinal uses of the Licensed Product within the Territory.

**“GMP”** means good manufacturing practices in conformity with the regulations and regulatory interpretations of the Relevant Regulatory Authorities in each country in the Territory, including without limitation EU cGMP such regulations covering good manufacturing practices set forth in the relevant legislation or guidelines and applicable to the Territory, as such regulations may be amended and interpreted by the Relevant Regulatory Authorities from time to time.

**“Initial Indication”** means the treatment of the pain associated with chronic anal fissure.

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

**“Know-How”** means all data, information, methods, procedures, processes and materials, which is or comes to be possessed, acquired, licensed or owned by Cellegy as of the Prior Agreement Date and from time to time thereafter, to the extent that such data, information, methods, procedures, processes and materials specifically relate to the manufacture, development, testing or use of the Licensed Product, including but not limited to, biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data (other than such Know-How which is the subject of a patent or of a provisional or filed patent application), and for which Cellegy has the right to license, disclose or provide to Licensee.

**“Launch Date”** means following Approval the date upon which the Licensed Product is first commercially offered for sale in a country in the Territory, determined on a country by country basis.

**“Licensed Product”** means the pharmaceutical product known as Rectogesic® ointment,— a nitroglycerin ointment in any formulations or presentations for the treatment of pain associated with chronic anal fissure and, if Approvals are obtained, for the treatment of one or more additional indications.

**“Licensee Supply Agreement”** means the supply agreement between Licensee and Manufacturer governing the supply of the Licensed Product to Licensee by Manufacturer for the Territory and incorporating the terms and conditions of a relevant Technical Agreement.

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

**“Major European Countries”** shall mean France, Germany, Italy, Spain and the United Kingdom.

**“Manufacturer”** means the existing Third Party manufacturer of the Licensed Product or any other manufacturer that may in the future enter into a Cellegy Supply Agreement or a Licensee Supply Agreement.

**“Marketing Authorization”** means any approval (including any applicable pricing and governmental reimbursement approvals) in Licensee’s name required to Develop, market and sell the Licensed Product in a particular country in the Territory.

**“M.R.P”** means the mutual recognition procedure as defined in Article 28 of European Directive 2001/83/EC.

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

- (i) reasonable credited allowances actually granted to such Third Party customers for spoiled, damaged, rejected, recalled, outdated or returned Licensed Product,
- (ii) the amounts of reasonable trade and cash discounts actually allowed, to the extent such trade and cash discounts are specifically allowed on account of the purchase of such Licensed Product,
- (iii) sales taxes, excise taxes, use taxes and import/export duties and any other government charges (other than taxes on income) actually due or incurred or paid by Licensee, or its Affiliates or Sublicensees, in connection with the sales of the Licensed Product to any Third Party, and
- (iv) reasonable allowances, adjustments, reimbursements, discounts, chargebacks and rebates actually granted to Third Parties, including, but not limited to, rebates given to health care organizations or other Third Parties, and any bona fide payment made in respect of any sales of Licensed Product to any governmental or quasi-governmental body or agency, whether during the actual Sales Period or not.

**“Party”** means Cellegy or Licensee, and Parties shall mean both Cellegy and Licensee.

**“Patent Rights”** means (i) the patents and patent applications listed in Exhibit B hereto and any patents and patent applications existing as of the Prior Agreement Date; (ii) any patent or patent application hereafter which is acquired by Cellegy or under which Cellegy becomes licensed and with the right to sublicense to Licensee, during the term of this Agreement, in each case of (i) and (ii) above relating to the Licensed Product, its manufacture, use or sale, including methods of use and screening or processes that use the Licensed Product; (iii) any divisionals, continuations and continuations-in-part defined in (i) or (ii); (iv) any extension, renewal or reissue or patent identified in any reissue or re-examination of any patent or patent application identified in (i) through (iv), in each case, to the extent that such items relate to the Licensed Product. Such items set forth in sub-items (i) through (iv) will be identified and added by the Parties to Exhibit B from time to time during the term of this Agreement.

**“Relevant Regulatory Authority”**, in relation to a country or region in the Territory, means the governmental authority, regulating the use, importation, storage, Development, promotion, marketing, distribution or sale of therapeutic substances and the grant of Approvals in such country or region.

**“Retained Information”** means any and all books and records prepared and maintained by Cellegy now or in the future in connection with the Licensed Product, including, without limitation, in relation to any and all additional formulations, therapeutic and medicinal uses and further including, without limitation, all regulatory files (including correspondence with regulatory authorities), assays, test methods, batch records, analytical methods including validation protocol and the drug master file and stability studies in relation thereto in each case to the extent that Cellegy is permitted by law and under its agreements to provide such information to Licensee.

“**Sublicensee**” means any person to whom Licensee sublicenses the rights, or any portion thereof, granted by Cellegy to Licensee pursuant to Section 2.1 hereof.

“**Technical Agreements**” mean the agreements between Cellegy and Manufacturer for Product supplied outside the Territory, and between Strakan and Manufacturer for Licensed Product supplied within the Territory, defining the roles and responsibilities for the parties in relation to, inter alia, (i) manufacture and supply of the Licensed Product pursuant to GMP; and (ii) regarding regulatory, safety and pharmacovigilance issues, the terms and conditions of which are incorporated into any supply agreement for the Licensed Product.

“**Territory**” means the countries listed on Exhibit A hereto.

“**Third Party**” means any party other than Cellegy or Licensee, or Licensee’s Affiliates or Sublicensees.

ARTICLE 2  
GRANT OF LICENSE

2.1 Grant. Cellegy grants to Licensee an exclusive fully paid up license, with a right to sublicense as set forth herein, under all of Cellegy’s Intellectual Property Rights to manufacture or have manufactured anywhere in the world, import, store, Develop, have Developed (through agreements with contract research organizations or similar Third Parties, performing work on behalf of and for the benefit of Licensee), promote, market, distribute, offer for sale, and sell the Licensed Product in the Field within the Territory, and to use Cellegy’s Intellectual Property Rights and the Retained Information in connection with the manufacturing, importation, storage, Development, promotion, marketing, distribution and sale of Licensed Product in the Field within the Territory and obtaining any Approvals hereunder. Licensee’s rights to the Licensed Product and the Intellectual Property Rights are limited to those expressly granted, and all others are reserved to Cellegy.

2.2 Right to sub-license. Licensee may freely sub-license any of its rights or obligations under this Agreement, directly or indirectly, in whole or in part. Any such sublicense shall not relieve Licensee of any of its obligations hereunder, and Licensee shall remain responsible and liable for compliance by any such Third Party, Affiliate or Sublicensee with this Agreement, all relevant laws, regulations and requirements relating to the manufacturing, importation, distribution, marketing, promotion and sale of the Licensed Product in the Territory, and any acts or omissions by any such Third Party, Affiliate or Sublicensee that would constitute a breach of this Agreement if such sublicense had not been entered into and the actions or omissions were those of Licensee rather than the Third Party, Affiliate or Sublicensee. Any sublicense agreement shall contain terms and conditions that are not inconsistent with those of this Agreement.

2.3 Acceptance of Appointment; Sales Outside Territory.

(a) Licensee hereby accepts appointment as Cellegy’s exclusive licensee of Licensed Product in the Territory, as provided in Section 2.1 above.

(b) Licensee shall not, and Licensee shall use all Commercially Reasonable and Diligent Efforts to ensure that its officers, directors, employees, Affiliates, agents or representatives (collectively, "**Agents**") shall not, without the prior written consent of Cellegy, directly or indirectly promote, sell, distribute or otherwise make available (for remuneration or gratuitously) Licensed Product outside the Territory or sell, distribute or otherwise make available (for remuneration or gratuitously) Licensed Product to persons outside the Territory for the purpose of resale or distribution (whether for remuneration or gratuitously) outside the Territory. Without limiting the foregoing, Licensee agrees to use all Commercially Reasonable and Diligent Efforts to ensure compliance with the preceding sentence, including without limitation placing appropriate notices on the labels of Licensed Products; provided, however, that Licensee shall not be obligated to include any notices in a particular country in the Territory that would conflict with any relevant requirements of the Relevant Regulatory Authority for such country, and Licensee's failure or refusal to include any such notices in such circumstances shall not constitute a breach of any provision of this Agreement.

2.4 Competing Products. Until June 30, 2007, or, if earlier, the maximum period of time permitted by applicable European Union regulations, Licensee shall not, and shall use all Commercially Reasonable and Diligent Efforts to ensure that its officers, directors, employees, Affiliates, Sublicensees, agents or representatives (collectively, "**Agents**") shall not, directly or indirectly, promote, sell or distribute products within the Major European Countries that are directly competitive in the treatment of anal fissures (the "**Competing Licensed Products**"). If applicable law or applicable European Union regulations provide that the foregoing covenant is unenforceable or require that the duration of the foregoing covenant be shorter than the term of this Agreement, then such provision shall be deemed automatically conformed in order to comply with applicable law or regulations.

### ARTICLE 3 REPRESENTATIONS AND WARRANTIES

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

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

(b) Except as disclosed by Cellegy to Licensee in a writing prior to the Agreement Date specifically referencing this Section 3.1(b), Cellegy is not subject to, or bound by, any provision of: (i) its certificate of incorporation or by-laws, (ii) any mortgage, deed of trust, lease, note, shareholders' agreement, bond, indenture, license, permit, trust, custodianship, or other instrument, agreement or restriction, or (iii) any judgment, order, writ, injunction or decree of any court, governmental body, administrative agency or arbitrator, that would prevent, or be violated by, or under which there would be a default as a result of, nor is the consent of any person required for, the execution, delivery and performance by Cellegy of this Agreement and the obligations contained herein, including without limitation, the grant to Licensee of the license described in Section 2.1 hereof.

(c) Subject to the final sentence of this Section 3.1(c): (i) Cellegy is the exclusive owner of all right, title and interest in the Patent Rights in the applicable countries in the Territory; (ii) the patent applications included in the Patent Rights have been duly filed and contain no material errors; and (iii) Cellegy shall maintain all Patent Rights for the full duration of this Agreement or such earlier time, if any, as Licensee forecloses on the Patent Rights pursuant to Article 9. Attached hereto as Exhibit B is a complete and accurate list of all patents and patent applications included in the Patent Rights. Notwithstanding the foregoing, as Cellegy has disclosed in its filings with the Securities and Exchange Commission, the Board of Opposition of the European Patent Office rendered a verbal decision revoking Cellegy's European patent relating to the Licensed Product; and although Cellegy has appealed this decision, Cellegy makes no representation or warranty regarding the outcome of the opposition and appeal process, the Cellegy Patent Rights may be held to be invalid or revoked, and any representation or warranty of Cellegy made herein regarding Cellegy Patent Rights is qualified in its entirety by the foregoing matters.

(d) Cellegy is the exclusive owner of all right, title and interest in the Cellegy Marks in the Territory. Cellegy shall maintain at its sole expense where applicable all Cellegy Marks for the full duration of this Agreement or such earlier time, if any, as Licensee forecloses on the Cellegy Marks pursuant to Article 9. Attached hereto as Exhibit C is a complete and accurate list of all trade marks and trade mark applications included in the Cellegy Marks.

(e) To the best of Cellegy's knowledge, neither the development, use or sale of the Licensed Product or the practice of any of the inventions included in the Patent Rights or the use of the Cellegy Marks or the use of the Know-How by Licensee as contemplated by this Agreement infringes upon any Third Party's know-how, patent, trade mark or other intellectual property rights in the Territory.

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

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

(h) CELLEGY MAKES NO REPRESENTATION OR WARRANTY OTHER THAN THOSE EXPRESSLY PROVIDED HEREUNDER, AND CELLEGY HEREBY DISCLAIMS ALL SUCH OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, OR THE FITNESS FOR A PARTICULAR PURPOSE, OF THE LICENSED PRODUCT OR THE KNOW-HOW. EXCEPT AS MAY BE EXPRESSLY PROVIDED ELSEWHERE HEREIN, CELLEGY MAKES NO REPRESENTATION OR WARRANTY THAT THE LICENSED PRODUCT IS OR WILL BE SHOWN TO BE SAFE OR EFFECTIVE FOR ANY INDICATION. THE FOREGOING SHALL NOT REDUCE THE SCOPE OF ANY REPRESENTATION OR WARRANTY OF CELLEGY EXPRESSLY MADE TO LICENSEE HEREIN.



(i) Cellegy will use all Commercially Reasonable and Diligent Efforts to ensure that Cellegy will provide reasonable notice to Licensee of any significant changes to the Cellegy Information supplied to Licensee or the materials or processes described in that information in relation to any Licensed Product.

3.2 Representations and Warranties of Licensee. Licensee hereby represents and warrants to Cellegy as follows:

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

(b) Licensee's Affiliates shall not conduct themselves in such a way that Licensee will be in breach of any term or condition of this Agreement.

(c) To the best of Licensee's knowledge, Licensee currently is in compliance in all material respects with all applicable laws and has received, or will receive where relevant, all applicable pharmaceutical product certifications and registrations from appropriate governmental entities that are necessary to perform its obligations under this Agreement. Licensee agrees that during the term of this Agreement it will comply in all material respects with all applicable laws and regulations regarding the export, sale and distribution of the Licensed Product in the Territory.

ARTICLE 4  
APPROVAL AND MARKETING PLANS

4.1 Approval Plan; Marketing Plan. The overall timetable to obtain Approvals for the Licensed Product in the Major European Countries has been set forth in a written plan by Licensee which Cellegy has approved (the "**Approval Plan**"). In addition, Licensee has prepared and Cellegy has approved a marketing plan in connection with the promotion, marketing and distribution of the Licensed Product in the Major European Countries (the "**Marketing Plan**").

ARTICLE 5  
REGULATORY MATTERS; APPROVALS

5.1 Regulatory Matters; Approvals.

(a) Licensee shall use Commercially Reasonable and Diligent Efforts, subject to this Agreement, to obtain at its sole expense all Approvals that are necessary for the sale of the Licensed Product within the Territory for the Initial Indication only, including without limitation any additional clinical trials, studies or data in addition to the Cellegy Information that may be required in order to obtain or maintain Approvals for the Licensed Product in each country in the Territory for the Initial Indication, and comply with any and all applicable statutory, administrative or regulatory requirements of the Territory or any governmental or political subdivisions thereof (collectively, "**Laws**") in relation to the manufacture, importation, storage, Development, promotion, marketing, distribution or sale of the Licensed Product in the Territory under this Agreement, including, without limitation, Licensed Product documentation such as Licensed Product tracking, samples, Licensed Product complaints, adverse event reporting requirements, post-marketing surveillance activities, and documentation of recalls, which documentation shall be maintained by the Licensee for the period required by the Relevant Regulatory Authorities in the Territory notwithstanding termination or expiration of this Agreement, any Licensed Product registrations with any government agency or health authority, or any registration, approvals, or filing of this Agreement. Licensee shall inform Cellegy on at least a semi-annual basis (and more frequently if Cellegy so reasonably requests) about the progress of such registration work, and will promptly provide Cellegy with a copy of all presentations and documents submitted by Licensee to any Relevant Regulatory Authority with respect to the Licensed Product. Cellegy shall, upon Licensee's written request, provide reasonable assistance to Licensee, at Licensee's sole cost, regarding obtaining such Approvals in the Territory, including allowing Licensee reasonable access to relevant experts in relation to the Cellegy Information for the purpose of obtaining Approvals.

(b) With respect to indications other than the Initial Indication, Licensee shall be responsible for the conduct of such clinical trials or studies as Licensee may in its discretion undertake.

(c) Utilizing the United Kingdom Marketing Authorization for the Licensed Product Licensee will make filings that are required to seek and obtain Approvals for the Licensed Product in each other Major European Country through the M.R.P provided that the dossier used in the United Kingdom is acceptable for use in an MRP application. If the Relevant Regulatory Authority in a country other than the United Kingdom determines that such dossier is not complete or acceptable for the initiation of an M.R.P. application in such country, then the parties shall meet and attempt to agree on an appropriate course of action. If Licensee desires to not seek Approvals in one or more Major European Countries because Licensee concludes in good faith that for regulatory or marketing reasons it would not be in the parties' best interests to pursue Approvals in such countries, it shall notify Cellegy and if Cellegy disagrees, the parties shall meet in good faith to attempt to agree whether Approvals will be sought in such country or countries. If alteration by Cellegy of the Cellegy Information after the date of this Agreement requires additional time to submit or revise regulatory filings relating to Approvals, then the time periods set forth above for making filings and obtaining Approvals shall be extended by the additional period of time required to submit or revise such filings. Licensee shall have no liability nor shall it be deemed to be in breach of this Agreement in the event that Approvals are not obtained in any or all other Major European Countries or in any other country in the Territory.

(d) With the exception of the assignment of the Approval that Cellegy has obtained in the United Kingdom and such other materials as Cellegy in its discretion may provide to Licensee pursuant to this Agreement, Licensee shall pay all costs in connection with the filing, prosecution, meetings, communications, and review by Relevant Regulatory Authorities of Approval applications and Approvals relating to the Licensed Product in the Territory and complying with applicable laws and regulations.

5.2 Cooperation Regarding Material Events. Each Party will immediately notify the other Party of any material events relating to the Development of the Licensed Product in the Territory, including, without limitation, any material comments or concerns raised by any Relevant Regulatory Authority. To the extent either Party receives written or material oral communication from any Relevant Regulatory Authority relating to the Licensed Product in the Territory, the party receiving such communication shall notify the other parties and provide a copy of any written communication as soon as reasonably practicable.

5.3 Copies of Documents. Each Party agrees to provide to the other Party a copy of (i) any documents or reports relating to the Licensed Product that are filed with any Relevant Regulatory Authority in the Territory under this Agreement, including any Approval applications; and (ii) all data, database information and safety reports from clinical trials conducted by or on behalf of Licensee. In particular, Licensee acknowledges that Cellegy has provided to Licensee a copy of the dossier concerning the Licensed Product filed in the United Kingdom. All such documents and reports shall be centralized and held at Licensee or by a Third Party selected by Licensee and agreed to by Cellegy, provided however, that Cellegy shall be entitled to obtain and keep copies of any such documents and records but only for the uses specifically set forth in this Agreement.

5.4 Meetings With Regulatory Authorities. Licensee shall be responsible for conducting all meetings and discussions and routine telephone communications with any Relevant Regulatory Authority, related to clinical studies, Approval applications and Approvals for the Licensed Product in the Territory. Licensee will keep Cellegy apprised of all material communications with such Relevant Regulatory Authorities.

5.5 Clinical Trials. Licensee shall at its own cost be responsible for the conduct of all studies and clinical trials that may be necessary or appropriate to obtain all required Approvals (with the exception of the Approval for the United Kingdom that has been obtained) and any post-Approval Clinical Trials and for the grant of all necessary approvals and maintaining in effect all appropriate policies of insurance for clinical trials for the use of the Licensed Product in the Territory. Licensee agrees to provide such data and materials regarding any such studies or trials as Cellegy may reasonably request, and Cellegy may use such materials for its own business purposes in connection with obtaining or maintaining Approvals for the Licensed Product in other jurisdictions outside the Territory. Licensee may enter into one or more manufacturing and supply agreement(s) (or similar arrangements) with Third Party contract manufacturer(s) for such clinical supplies.

5.6 Cellegy Obligations. Promptly following entering into this Agreement Cellegy shall, to the extent it has not already done so pursuant to the Prior Agreement:

(a) provide Licensee with a complete copy of the Cellegy Information as well as copies of clinical data, analysis and reports of Cellegy or its other licensees of the Licensed Product in other countries (to the extent in Cellegy's possession and that Cellegy is permitted to provide such information under the terms of its agreements with such licensees, with Cellegy agreeing to use commercially reasonable efforts after the date of this Agreement to include provisions in agreements with other licensees of the Licensed Product to permit the sharing of such data, analysis and reports from licensees);

(b) provide Licensee with any information in its possession that is reasonably likely to jeopardize or otherwise have a material adverse impact on the application, or any grant, maintenance, variation or renewal of the Approvals;

(c) use commercially reasonable efforts to assist Licensee to enter into Licensee Supply Agreement and Technical Agreement with the Manufacturer; and

(d) notify Licensee and promptly provide all relevant assistance and supporting documentation to Licensee and Manufacturer, where relevant, should Cellegy make any alteration to the Licensed Product, or the manufacture, or packing of the Licensed Product that requires notification to a Relevant Regulatory Authority.

5.7 Approvals.

(a) All Approvals by any Relevant Regulatory Authority which are necessary to sell the Licensed Product within the Territory shall be issued to, owned by and held in the name of Licensee.

(b) Licensee shall promptly provide to Cellegy, upon Cellegy's request, such evidence that Cellegy shall reasonably require, confirming that all Approvals necessary to import, store, Develop, promote, market, distribute and sell the Licensed Product in the Territory have been obtained.

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

ARTICLE 6  
POST- APPROVAL RESPONSIBILITIES

6.1 Responsibility. Each Party acknowledges that Licensee or the Affiliate or Sublicensee named by Licensee as the holder of the Approvals bears the ultimate responsibility *vis-à-vis* the Relevant Regulatory Authorities for complying with the regulatory requirements applicable to the manufacture, importation, storage, Development, promotion, marketing, distribution and sale of the Licensed Product in the Territory.

6.2 Collaboration. The Parties shall collaborate with each other and each Party agrees to provide the other Party with any reasonable assistance it may require to ensure compliance with the Approvals.

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

ARTICLE 7  
INFORMATION; DATA; PHARMACOVIGILANCE

7.1 Clinical Data. (a) All clinical data and reports related to clinical trials for the Licensed Product in the Territory shall be owned by the Party funding such clinical trial(s). Other than to a Sublicensee in connection with the transactions contemplated by this Agreement, Licensee shall not sell, disclose to or share with any Third Party, or grant any Third Party right to use, any clinical data arising owned by Licensee as a result of the preceding sentence. Each Party shall have access to, and copies of, all such data and reports related to clinical trials for the Licensed Product in the Territory, and each Party may use such data without any additional payments to the other Party. Each Party shall treat such data and reports as Confidential Information of the other Party, and neither Party shall disclose or use such data or reports for any purpose other than performing its obligations under this Agreement or as otherwise expressly authorized in writing by the other party except to the extent that data or reports are required by the voluntary or compulsory prior registration of a clinical trial, and except for such disclosures as a Party reasonably believes is required by securities or regulatory laws or regulations. If a Party itself obtains data from a clinical trial hereunder, it shall promptly transfer all of the clean, final data for such trial to Licensee or to Cellegy, as the case may be. The parties shall coordinate the transfers of any such data.

7.2 Safety Data Base. The Parties will, as soon as practical, organize a serious adverse event data base (the "**SAE Data Base**"). Cellegy and Licensee shall jointly own the SAE Data Base and all data contained therein, and the data from the SAE Data Base shall be made available to both Parties. Licensee shall be responsible for, and bear the costs of, data for the SAE Data Base related to the Territory. Cellegy shall be responsible for, and bear the costs of, data for the SAE Data Base related to territories outside the Territory. The provisions governing the management of such SAE Data Base shall be agreed separately by the Parties.

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

7.3 Adverse Events. The Parties recognize that as the holder of the Approvals, Licensee will be required to submit information and file reports to various governmental agencies on compounds under clinical investigation, compounds proposed for marketing, or marketed drugs. The process and responsibilities for such reports will be governed by the Adverse Event Reporting Addendum separately agreed to by the Parties.

7.4 Product Complaints. Each Party will maintain a record of all non-medical and medical Licensed Product-related complaints and will notify the other Party of any complaint in a sufficient time to allow the other Party to comply with any regulatory requirements it may have with respect to such complaint. The details and responsibilities governing the management of such Licensed Product-related complaints shall be agreed separately by the Parties.

7.5 Further Development. For the avoidance of doubt, Licensee shall be free and clear to conduct further development (including conducting clinical trials), formulation work for any and all additional therapeutic and medicinal uses of the Licensed Product within the Territory and to sub-license its rights obtained hereunder within the Territory without the need for consent or any further payment or compensation due to Cellegy whatsoever. Licensee shall provide information relating to such development, work and uses as provided above.

7.6 Access and Use of Retained Information, Future Information and Personnel. At any time on or after the Agreement Date at no cost to Licensee: (i) Cellegy shall cooperate with Licensee in making Retained Information available; (ii) Cellegy shall use reasonable efforts to make available to Licensee for a minimum period of [\*] certain Cellegy personnel identified separately in writing, to assist, inter alia, Licensee in relation to the MRP; and (iii) Cellegy shall furnish copies of such Retained Information for review by Licensee, to the extent practicable, at the reasonable request of Licensee. At any time on or after the Agreement Date at no cost to Cellegy, Licensee shall cooperate with Cellegy in making any information developed by or on behalf of Licensee or its licensees relating to any further development (including conducting clinical trials and any related technical or clinical data, analysis and reports), formulation work and clinical trials for any and all additional therapeutic and medicinal uses of the Licensed Product within the Territory.

## ARTICLE 8 MILESTONE PAYMENTS

8.1 Milestone Payments. After the Agreement Date, Licensee shall pay Cellegy milestone payments in the particular amounts specified below (with all payments to be made in U.S. Dollars): Licensee shall pay to Cellegy three (3) milestone payments, each milestone being

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

the amount of [\*] for each Approval obtained in the first of [\*] up to a maximum total amount payable of [\*]. Such payments shall be due no later than [\*] after achievement of the milestone.

8.2 Sales Milestones. In addition, Licensee shall pay Cellegy the following amounts, within [\*] after the end of the month in which the relevant milestone is achieved:

(a) [\*]

(b) [\*]

(c) Licensee shall provide to Cellegy sufficient information from time to time regarding Licensed Product sales to enable Cellegy to determine whether one or more of the above milestones have been satisfied.

(d) Licensee's obligations to pay sales milestones under this Section shall terminate and be of no further force or effect on June 30, 2007 and Licensee shall not be deemed to be in breach of this Article 8.2 if it fails to achieve such Net Sales referred to above prior to June 30, 2007.

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

ARTICLE 9  
SECURITY INTEREST IN CELLEGY PATENTS AND CELLEGY MARKS

9.1 Definitions. For purposes of this Article, the following terms shall have the following meanings:

“Obligations” means the performance in all material respects of Cellegy's obligations to Licensee under this Agreement.

“Collateral” means the Cellegy Patents and the Cellegy Marks.

“UCC” means the Uniform Commercial Code as in effect from time to time in the State of California or any other state (including without limitation Delaware) the laws of which are required to be applied in connection with the perfection of security interests.

9.2 Security Interest. In consideration of and as security for the full and complete performance of the Obligations, Cellegy hereby grants to Licensee a security interest in the Collateral, subject to the rights of any Third Party separately identified in writing by Cellegy to Licensee before the date of this Agreement expressly referencing this Section.

9.3 Default.

(a) If Licensee terminates this Agreement pursuant to Section 16.2 (an “**Event of Default**”), then Licensee shall have the rights and remedies of a secured party under the UCC. In addition to exercising any other rights or remedies that Licensee may have at law or in equity, Licensee may, at its option, and without demand first made, exercise any one or all of the following rights and remedies: (i) collect the Collateral and its proceeds; (ii) take possession of the Collateral wherever it may be found, using all reasonable means to do so, or require Cellegy to assemble the Collateral and make it available to Licensee at a place designated by Licensee which is reasonably convenient to Cellegy; (iii) proceed with the foreclosure of the security interest in the Collateral granted herein and the sale or endorsement and collection of the proceeds of the Collateral in any manner permitted by law or provided for herein; and (iv) sell, lease or otherwise dispose of the Collateral at public or private sale, with or without having the Collateral at the place of sale, subject to the notice requirement below.

(b) No Election of Remedies. The election by Licensee of any right or remedy will not prevent Licensee from exercising any other right or remedy against Cellegy.

(c) Sales of Collateral. Any item of Collateral may be sold for cash or other value at public or private sale or other disposition and the proceeds thereof collected by or for Licensee. Cellegy agrees to promptly execute and deliver, or promptly cause to be executed and delivered, such instruments, documents, assignments, waivers, certificates and affidavits and supply or cause to be supplied such further information and take such further action as Licensee may require in connection with any such sale or disposition. Licensee will have the right upon any such public sale or sales, and, to the extent permitted by law, upon any such private sale or sales, to purchase the whole or any part of the Collateral so sold, free of any right or equity of redemption in Cellegy, which right or equity is hereby waived or released. If any notice of a proposed sale, lease, license or other disposition of Collateral shall be required by law, such notice shall be deemed reasonable and proper if given at least ten (10) days before such sale, lease, license or other disposition. Licensee agrees to give Cellegy thirty (30) days prior written notice of any sale, lease, license or other disposition of Collateral (or any part thereof) by Licensee.

(d) Application of Proceeds. The proceeds of all sales and collections in respect of the Collateral, the application of which is not otherwise specifically herein provided for, will be applied as follows: (i) first, to the payment of the costs and expenses of such sale or sales and collections and the attorneys' fees and out-of-pocket expenses incurred by Licensee relating to costs of collection; (ii) second, to satisfaction of the Obligations; and (iii) third, any surplus then remaining will be paid to Cellegy.

(e) Cooperation. Upon the occurrence of an Event of Default and foreclosure on the Collateral by Licensee, Cellegy will cooperate with Licensee and execute such instruments of assignment and transfer as Licensee may reasonably request in order to vest Licensee with ownership of the Collateral.



ARTICLE 10  
MARKETING

10.1 General Promotional Duties. Licensee shall: (i) not make false or misleading representations to customers or other persons with regard to the Licensed Product, and (ii) subject to sub-clause (i), shall not make any representations with respect to the specifications, features or capabilities of the Licensed Product which are not consistent with the relevant Approvals.

10.2 Marketing Effort; Minimum Expenditures for Commercialization. At all times prior to June 30, 2007, Licensee agrees to exert its Commercially Reasonable and Diligent Efforts to introduce, promote and, sell the Licensed Product within the Major European Countries following receipt of Marketing Authorization in such Major European Countries and minimum satisfactory (in Licensee's sole opinion) reimbursement price.

10.3 Minimum Sales. At all times prior to June 30, 2007, Licensee shall use Commercially Reasonable and Diligent Efforts to achieve agreed annual minimum unit sales of Licensed Product in each Major European Country and commencing in each such country upon the [\*] from launch and representing [\*] of the sales forecasts of the Licensed Product in each Major European Country as set forth in the Marketing Plan ("**Minimum Sales**").

ARTICLE 11  
MANUFACTURING; SUPPLY OF LICENSED PRODUCT

11.1 Production and Supply of Product.

(a) During the term of this Agreement or thereafter, Cellegy reserves the right, without obligation or liability to Licensee, to manufacture, have manufactured, produce, assemble, warehouse or source the Licensed Product for sale outside of the Territory at any worldwide location, including Canada or the United States of America and locations within or outside the Territory.

(b) Cellegy agrees to use all Commercially Reasonable and Diligent Efforts to (i) maintain its existing Cellegy Supply Agreement with the existing Manufacturer until at least March 31, 2006, (ii) cooperate with Licensee with the goal that, prior to the establishment of the Licensee Supply Agreement, Licensee may purchase Licensed Product directly from the Manufacturer, and (iii) until Licensee enters into a Licensee Supply Agreement, cooperate with Licensee to involve Licensee in discussions between Cellegy and Manufacturer concerning product pricing or other material terms of the Cellegy Supply Agreement.-

11.2 Forecasts. Until such time as Licensee enters into a Licensee Supply Agreement, Licensee shall be responsible for combining (if practicable in Licensee's sole opinion) its forecast for Licensed Product in the Territory and Cellegy's forecast for Licensed Product outside the Territory and for delivering all combined forecasts for the Parties to the Manufacturer providing that both Cellegy and Licensee are utilizing the same Manufacturer. Should the Parties decide to utilize separate manufacturers, each Party will be responsible for providing their Manufacturer with its own forecasts. Additional details concerning relating to orders from the Manufacturer shall be mutually agreed upon and set forth on Exhibit E.

11.3 Additional Manufacturing Location. Either Cellegy or Licensee may initiate activities relating to the establishment of a Manufacturer within the Territory.

11.4 Payment. In consideration of the amendments to the Prior Agreement and the execution of this Agreement concerning the purchase by Licensee of Licensed Products, at the Agreement Date Licensee shall deliver to Cellegy the amount of [\*\*] by electronic funds transfer to the bank account designated by Cellegy in writing. Cellegy agrees that after the Agreement Date, Licensee shall have no further obligation to pay Cellegy any amounts with respect to the purchase of Licensed Products from the Manufacturer or other manufacturers, including with respect to purchase order no. 05-1180 dated October 31, 2005.

11.5 Warranty Limitation, Disclaimer. Except as expressly set forth in this Agreement, the sole warranty, if any, given by Cellegy regarding any Licensed Product shall be that written limited warranty, if any, which shall accompany such Licensed Product or which shall otherwise be designated in writing by Cellegy as applicable to such Licensed Product, as the same may be revised by Cellegy from time to time. After the initial commercial launch of the Licensed Product, subsequent changes to the written limited warranty must be approved by Licensee, which approval shall not be unreasonably withheld. THE WRITTEN LIMITED WARRANTY, IF ANY, APPLICABLE TO ANY PARTICULAR PRODUCT SHALL STATE THE FULL EXTENT OF CELLEGY'S LIABILITY WHETHER DIRECT OR INDIRECT, SPECIAL OR CONSEQUENTIAL, RESULTING FROM ANY BREACH OF SUCH WARRANTY. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT WITH RESPECT TO WARRANTIES MADE TO LICENSEE, CELLEGY FURTHER DISCLAIMS ALL EXPRESS, STATUTORY AND IMPLIED WARRANTIES APPLICABLE TO THE LICENSED PRODUCT.

11.6 Recalls.

- (a) Licensee may recall any quantity of Licensed Product at any time, and Licensee will administer any such recall in the Territory.
- (b) If the Relevant Regulatory Authority requires or otherwise initiates a recall of the Licensed Product for any reason whatsoever, Licensee will immediately administer the recall.

ARTICLE 12  
PATENT RIGHTS

12.1 No Ownership By Licensee. Except as provided in Article 9, Licensee shall not be deemed by anything contained in this Agreement or done pursuant to it to acquire any right, title or interest in or to the Cellegy Patent Rights or any patent owned by or licensed to Cellegy now or hereafter covering or applicable to any Licensed Product, nor in or to any invention or improvement, owned by Cellegy, now or hereafter embodied in the Licensed Product, whether or not such invention or improvement is patentable under the laws of any country.

12.2 New Cellegy Inventions/Improvements to the Licensed Product. If Cellegy develops and commercially offers:

- (a) any improvements in terms of dosage, route of administration or formulation of the Licensed Product for the same indication; or
- (b) any improvement in terms of dosage, route of administration or formulation of any product derived from the Licensed Product for the same indication; then

such improvements shall be included within the definition of Licensed Product herein at no additional costs to Licensee.

12.3 Improvements by Licensee. If, during the term of this Agreement other than where Cellegy is in material breach or if Article 9 applies in which case this article 12.3 shall not apply, Licensee or any Sublicensee invents or designs any improved Licensed Product or any associated method, apparatus, equipment or process related to or having application to the Licensed Product, or makes an improvement thereon, whether or not patented or patentable in any jurisdiction, Licensee shall make or cause a prompt and full disclosure to Cellegy of such invention, design or improvement ("**Licensee Improvement**"), and hereby irrevocably transfers, conveys and assigns to Cellegy all of its right, title and interest therein. Licensee shall execute such documents, render such assistance, and take such other action as Cellegy may reasonably request, at Cellegy's expense, to apply for, register, perfect, confirm, and protect Cellegy's rights therein. Cellegy shall have the exclusive right to apply for or register any patents or other proprietary protections with respect thereto. Such Licensee Improvements shall be licensed back from Cellegy to Licensee as, and shall be deemed part of, the Licensed Product, at no additional cost to Licensee.

ARTICLE 13  
CELLEGY MARKS

13.1 Use of Cellegy Marks by Licensee. Licensee, its Affiliates and Sublicensees will have the exclusive right to use Cellegy's Mark Rectogesic™ in the Territory in connection with the importation, storage, Development, promotion, marketing, distribution and sale of Licensed Product. In such event, Licensee and its Affiliates (and Sublicensees) shall use Cellegy's Marks only in the form and manner prescribed by Cellegy. In no event shall Licensee use any of Cellegy's Marks or any similar mark or term as part of its business name. Should Rectogesic™ not be registered or registerable by Cellegy in all countries of the Territory, then Cellegy may notify Licensee that another Cellegy trademark will be used; and if no such marks are registered or registerable by Cellegy in all countries of the Territory, then Licensee may propose an alternative trade mark/s for Cellegy's approval, such approval not to be unreasonably withheld or delayed. Cellegy shall apply for and maintain such alternative trade mark at Cellegy's sole expense and such alternate trade mark shall become a Cellegy Mark under the terms of this Agreement. For the avoidance of doubt the Licensee shall be free to choose, use and own a different trademark to the Cellegy Marks in relation to the Licensed Product.

13.2 Acknowledgment of Ownership. Except as provided in Article 9 Licensee acknowledges that

- (a) Cellegy owns Cellegy's Marks and all goodwill associated with or symbolized by Cellegy's Marks;
- (b) Licensee has no ownership right in or to any of Cellegy's Marks; and

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

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

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

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

ARTICLE 14  
INFRINGEMENT; INDEMNIFICATION AND OTHER CLAIMS

14.1 Infringement of Intellectual Property Rights. In the event Cellegy or Licensee have reason to believe that a Third Party may be infringing or diluting, as the case may be, Intellectual Property Rights or misappropriating the Licensed Product, such Party shall promptly notify the other Party. Cellegy may, in its discretion, elect to enforce the Intellectual Property Rights through legal action or otherwise, and Licensee agrees to reasonably cooperate with Cellegy in such enforcement subject to reimbursement of its reasonable out-of-pocket expenses together with any reasonable attorneys fees incurred in connection therewith. In the event Cellegy elects not to enforce the Patent Rights relating to the Licensed Product within sixty (60) days after notice of the possible infringement or dilution, and Licensee can demonstrate that the potential infringement or dilution is reasonably likely to result in material lost sales of the Licensed Product within the applicable country, then Licensee may institute a lawsuit or other such actions at its expense to prevent continuation of such potential infringement or dilution, and then Licensee will retain all award, damages or compensation obtained by Licensee in such suit. Cellegy will provide reasonable cooperation with respect to any lawsuit which Licensee may bring pursuant to this Article, subject to reimbursement of its reasonable out-of-pocket expenses and reasonable attorneys fees in connection therewith. Licensee shall not enter into any settlement or compromise of any such claim without the prior written consent of Cellegy, which shall not be unreasonably delayed or withheld.

14.2 Alleged Infringement of Third Party Intellectual Property Rights.

(a) If a claim or lawsuit is brought against Licensee alleging infringement of any patent or infringement or dilution of any trademark owned by a Third Party arising from Licensee's importation, storage, Development, promotion, marketing, distribution and sale of the Licensed Product or use of proprietary rights, Licensee shall provide to Cellegy all information in Licensee's possession regarding such claim or lawsuit. Within a reasonable time after receiving notice of such claim or lawsuit, but in any event within sixty (60) days after receiving such notice, Cellegy shall advise Licensee of Cellegy's decision as what action it plans to take to dispose of such claim or defend such lawsuit.

(b) If Cellegy elects not to dispose of such claim or defend such lawsuit, Licensee may defend the claim or lawsuit. Licensee shall not enter into any settlement or compromise of any such claim or lawsuit without the prior written consent of Cellegy, which shall not be unreasonably delayed or withheld. For the purpose of Licensee's conduct of the claim or defense, Cellegy shall furnish to Licensee such reasonable assistance as Licensee may need and from time to time reasonably request.

14.3 Notice from Licensee. Licensee shall promptly notify Cellegy of any potential or actual litigation or governmental activity in the Territory relating to the Licensed Product or the business operations of Licensee or Cellegy. Licensee shall provide such notice within ten (10) days from the time that Licensee learns of such litigation or activity.

14.4 Indemnification.

(a) Cellegy assumes all risk of loss and indemnifies and holds harmless Licensee, its Affiliates, Sublicensees and their respective directors, officers and employees from and against any and all Loss arising from or incidental to or relating to any claim, demand, lawsuit, action or proceeding (a "**Claim**") arising from or relating to:

(i) any claim or lawsuit which relates to or arises out of the alleged infringement by Licensee of any patent or trademark owned by a Third Party to the extent that the alleged infringement relates to actions covered by the Exclusive License granted to Licensee under Section 2.1 of this Agreement;

(ii) the importation, storage, Development, promotion, marketing, distribution or sale of the Licensed Product based on action or inaction of Cellegy;

(iii) a Product Liability Claim based on action or inaction of Cellegy; or

(iv) any negligence or willful default of Cellegy relating to the Licensed Product or this Agreement; or any material breach by Cellegy of any representation or warranty given in this Agreement; or

(v) any claim by a Third Party against Cellegy or Licensee that entering into this Agreement is a material breach of, or is prohibited by, any agreement between Cellegy and such Third Party.

(b) Any indemnification by, Cellegy pursuant to a claim made under this Section shall be subject to the following limitations:

(i) no indemnification shall be payable unless the aggregate of all Losses for which Cellegy would be liable exceeds on a cumulative basis an amount equal to \$50,000, and then in such circumstances Licensee shall be entitled to demand an indemnity for the total aggregate of all Losses;

(ii) no indemnification shall be payable for any individual items (or series of related individual items) where the Loss relating thereto is less than \$10,000, in which case such items shall not be aggregated;

(iii) no indemnification shall be payable in excess of an aggregate amount equal to the sum of \$2,000,000 and any additional payments made under Section 8.2; and

(iv) no indemnification shall be payable to the extent the liability or obligation is directly caused by any action taken or omitted to be taken by Licensee or any of its Affiliates or Sublicensees.

(c) Licensee assumes all risk of loss and indemnifies and holds harmless Cellegy from all Loss arising from or incidental to or relating to any claim, action or proceeding arising from or relating to:

(i) the importation, storage, Development, promotion, marketing, distribution, or sale, of the Licensed Product based on action or inaction of Licensee, Affiliates, Sublicensees or their respective directors, officers and employees (Licensee and such other Persons sometimes referred to as "**Licensee Indemnified Persons**");

(ii) any Product Liability claim based on action or inaction of any Licensee Indemnified Person;

(iii) any breach by any Licensee Indemnified Person of any representation or warranty given in this Agreement; any negligence or willful default of any Licensee Indemnified Person relating to the Licensed Product or this Agreement; or

(iv) any material breach by Licensee of any representation or warranty given in this Agreement.

(d) In order for a party (the "**Indemnified Party**") to be entitled to any indemnification provided for under this Agreement in respect of, arising out of or involving a claim made by any Person against the Indemnified Party (a "**Third Party Claim**"), such Indemnified Party must notify the indemnifying party (the "**Indemnifying Party**") in writing (and in reasonable detail) of the Third Party Claim within 15 days after receipt by such Indemnified Party of notice of the Third Party Claim; provided, however, that failure to give such notification shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been actually prejudiced as a result of such failure (except that the Indemnifying Party shall not be liable for any expenses incurred during the period in which the Indemnified Party failed to give such notice). Thereafter, the Indemnified Party shall deliver to the Indemnifying Party, within ten days after the Indemnified Party's receipt thereof, copies of all notices and documents (including court papers) received by the Indemnified Party relating to the Third Party Claim.

(e) Subject to the provisions of Section 14.1 and 14.2, if a Third Party Claim is made against an Indemnified Party, the Indemnifying Party shall be entitled to participate in the defense thereof and, if it so chooses, to assume the defense thereof with counsel selected by the Indemnifying Party. Should the Indemnifying Party so elect to assume the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. If the Indemnifying Party assumes such defense, the Indemnified Party shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party shall control such defense. The Indemnifying Party shall be liable for the fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof (other than during any period in which the Indemnified Party shall have failed to give notice of the Third Party Claim as provided above). If the Indemnifying Party chooses to defend or prosecute a Third Party Claim, all the indemnified parties shall cooperate in the defense or prosecution thereof. Such cooperation shall include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. Whether or not the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnifying Party's prior written consent (which consent shall not be unreasonably withheld). If the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall agree to any settlement, compromise or discharge of a Third Party Claim that the Indemnifying Party may recommend and that by its terms obligates the Indemnifying Party to pay the full amount of the liability in connection with such Third Party Claim, which releases the Indemnified Party completely in connection with such Third Party Claim and that would not otherwise materially adversely affect the Indemnified Party.



(f) Other Claims. In the event any Indemnified Party should have a claim against any Indemnifying Party that does not involve a Third Party Claim being asserted against or sought to be collected from such Indemnified Party, the Indemnified Party shall deliver notice of such claim with reasonable promptness to the Indemnifying Party. The failure by any Indemnified Party so to notify the Indemnifying Party shall not relieve the Indemnifying Party from any liability that it may have to such Indemnified Party hereunder, except to the extent that the Indemnifying Party demonstrates that it has been materially prejudiced by such failure. If the Indemnifying Party disputes its liability with respect to such claim, the Indemnifying Party and the Indemnified Party shall proceed in good faith to negotiate a resolution of such dispute and, if not resolved through negotiations, such dispute shall be resolved as provided in Section 18.14.

## ARTICLE 15 CONFIDENTIALITY

15.1 Treatment of Confidential Information. Except as otherwise provided in this Article 15, during the term of this Agreement and for a period of five (5) years thereafter, Licensee and its Affiliates will retain in confidence and use only for purposes of this Agreement any information, data, and materials supplied by Cellegy or on behalf of Cellegy to Licensee and its Affiliates under this Agreement, and Cellegy will retain in confidence and use only for purposes of this Agreement any information, data, and materials supplied by Licensee or on behalf of Licensee to Cellegy under this Agreement. For purposes of this Agreement, all such information and data which a party is obligated to retain in confidence shall be called “**Confidential Information.**” For the avoidance of doubt, Cellegy Information shall constitute Confidential Information of Cellegy.

15.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, Licensee may disclose Confidential Information to its Affiliates, Sublicensees, consultants, outside contractors, clinical investigators or other Third Parties on condition that such entities or persons agree in writing (a) to keep the Confidential Information confidential for the same time periods and to the same extent as Licensee is required to keep the Confidential Information confidential and (b) to use the Confidential Information only for such purposes as Licensee is entitled to use the Confidential Information. Each Party or its Affiliates or sublicensees may disclose such Confidential Information to government or other regulatory authorities to the extent that such disclosure (i) is reasonably necessary to obtain Approvals; or (ii) is otherwise legally required.

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

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

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

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

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

15.4 Confidentiality of Agreement. Except as otherwise required by law or the terms of this Agreement or mutually agreed upon by the Parties, each Party shall treat as confidential the terms, conditions and existence of this Agreement, except that each Party may disclose such terms and conditions and the existence of this Agreement to its Affiliates, sublicensees, and shareholders to the extent required by the any corporate laws, and provided, that each Party shall seek confidential treatment of the key business terms contained in this Agreement, including but not limited to all payments owed hereunder. Notwithstanding the foregoing, the Parties may make such public announcements as they determine including any required by law or applicable stock exchange requirements.

15.5 Return of Confidential Information. Upon termination of this Agreement with respect to the entire Territory, the Parties and Affiliates and sublicensees shall return all Confidential Information of the other Party, in their possession along with a certification that they no longer possess any such Confidential Information.

15.6 Previous Confidentiality Agreements. Confidential information disclosed by either Party to the other Party or its Affiliates prior to the Prior Agreement Date under any written agreement executed by Cellegy and Licensee shall be treated as Confidential Information under Section 15.1 notwithstanding expiration of such prior Confidentiality Agreement.

ARTICLE 16  
TERM; TERMINATION

16.1 Term. Unless terminated sooner pursuant to this Article 16, this Agreement shall become effective as of the Agreement Date and shall continue in full force and effect without term; provided, however, that the license to the Cellegy Patent Rights shall expire with respect to a particular country upon the later of (i) the date of expiration of the last to expire of the Cellegy Patent Rights in the particular country, or (ii) if earlier, the latest date permitted by applicable law, determined on a country-by-country basis.

16.2 Termination Rights.

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

16.2.1 Licensee may terminate this Agreement in whole or in part upon the occurrence of any of the following:

- (a) Cellegy becomes the subject of voluntary bankruptcy or insolvency case; or
- (b) Cellegy becomes the subject of an involuntary bankruptcy or insolvency case that is not dismissed within ninety (90) days; or
- (c) Upon or after the material breach of any provision of this Agreement by Cellegy, if such material breach is not cured (if such default is capable of cure) within thirty (30) days after written notice thereof.

16.2.2 Cellegy may terminate this Agreement:

- (a) If Licensee becomes the subject of a voluntary bankruptcy or insolvency case up until June 30, 2007; or
- (b) If Licensee becomes the subject of an involuntary bankruptcy or insolvency case that is not dismissed within ninety (90) days up until June 30, 2007 ;or
- (c) If Licensee is in breach of its payment obligations under Sections 8.1 or 11.4 and in no other circumstance and only if payment is not then made within thirty (30) days of receiving notice of such breach.

16.3 Licensee's Right to Terminate. Licensee may terminate this Agreement; (i) immediately on written notice on health or safety grounds in relation to the Licensed Product; (ii) immediately on written notice if Approvals is not obtained, through no fault of Licensee, in all Major European Countries [\*] of MRP being initiated; (iii) on [\*] written notice to Cellegy should it no longer be economically viable to market the Licensed Product, based on Licensee's reasonable opinion and determined on a country by country basis; or (iv) [\*] if a claim by any Third Party that the Intellectual Property Rights infringe such Third Party's patent, trade mark, protected know-how or other intellectual property right is made against Licensee and which either (A) prevents use of the Licensed Product in any country of the Territory for a period of [\*], or (B) is not being challenged by either Party pursuant to Article 14 in relation to such country.

16.4 Cellegy's Rights Upon Termination under Section 16.2.2 . Termination of this Agreement shall not extinguish debts and other obligations created or arising between the Parties by virtue of contracts or arrangements entered into hereunder before the effective date of termination of this Agreement (the "**Termination Date**"). Without limiting the generality of the foregoing, in the circumstance where Cellegy terminates in the circumstances set out in Section 16.2.2 upon and following the Termination Date:

(a) Licensee shall be permitted to store, promote, sell and distribute such Licensed Product as well as any Licensed Product in Licensee's inventory within the Territory, subject to the provisions of paragraph (h) below and provided that Licensee shall not sell or otherwise dispose any of the Licensed Product in bulk, in any non-customary manner or otherwise circumvent its regular customers.

(b) Licensee shall cooperate with Cellegy to allow for the orderly transfer of Approvals within the Territory to Cellegy or its designee upon request and without expense to Cellegy. Licensee shall provide Cellegy with (i) full and immediate access to and copies of all marketing and sales information and other materials pertaining to the Licensed Product, including, without limitation, customer lists, past sales history and Licensed Product pricing information, and (ii) any inventions or other materials or rights required to be assigned to Cellegy pursuant to this Agreement. Notwithstanding any other term or provision of this Agreement, effective upon the Termination Date, Licensee shall execute any documents that are necessary to transfer to Cellegy, or Cellegy's designee, all Approvals or intellectual property which are then in the name of and/or held by Licensee and which relate to the marketing or sale of the Licensed Product (the "**Relevant Documents**"). In the event that full Approvals for any Licensed Product in the Territory are not completed before any transfer of operations pursuant to this Article, Licensee shall also transfer to Cellegy or Cellegy's designee, free of any charge, the Cellegy Information and all the data submitted to the Relevant Regulatory Authorities therefor. At Cellegy's request, Licensee shall authorize Cellegy's nominee, without any delay, to perform all the required activities in order to obtain the transfer of such permits and registration rights. If Licensee fails to execute the Relevant Documents, it hereby appoints Cellegy as its agent and authorizes Cellegy to act on its behalf, in order to execute all Relevant Documents. Licensee, its Affiliates and Sublicensees shall terminate any use of the Cellegy Marks and shall, at Cellegy's option, either destroy or return to Cellegy at Licensee's cost all literature, labels, or other materials, incorporation or bearing same.

(c) Each party shall cease to use any of the other party's Confidential Information relating to or in connection with its continued business operations and shall promptly return or assign to the other party any and all physical, written and descriptive matter (including all reproductions and copies thereof) containing that party's Confidential Information, provided that each party may:

(i) provide one copy of the other party's Confidential Information to its legal advisers to be held by them solely for the purpose of determining the scope of that party's obligations under this clause;

(ii) retain one copy of such of the other party's Confidential Information that is required by the Relevant Regulatory Authorities in the Territory, to be retained by that party; and

(iii) retain any documents confidential to it (including board papers, strategic plans and operational reviews) in which the other party's Confidential Information is incorporated, provided that such confidential information shall continue to be treated as Confidential Information hereunder.

(d) Upon expiration or termination for any reason, the obligations of confidentiality and use of Confidential Information under Article 15 shall survive for the period provided therein;

(e) Upon expiration or termination for any reason, Articles 14 and 16 of this Agreement shall survive for the maximum duration permitted by law; and

(f) Articles 5, 8 and 9 shall survive until all outstanding payment obligations and reporting obligations of Licensee and its Affiliates and Sublicensees have been fulfilled, and Sections 9.3 and 9.4 shall survive for two years following the year in which such or expiration became effective.

16.5 Licensee's Rights upon Termination. Where Licensee terminates this Agreement in accordance with the terms hereof Licensee shall have an irrevocable fully paid up exclusive license under the Intellectual Property Rights and Retained Information and, where Licensee terminates this Agreement pursuant to the provisions of Section 16.2.1(c) above, Licensee shall have no obligation to Cellegy to make any further milestone under Section 8.1 or sales milestones under Section 8.2 or other payments or compensation of any kind that may have fallen due after the Termination Date.

ARTICLE 17  
REGISTRATION OF LICENSE; LIMITATION OF LIABILITY

17.1 Registration. Licensee may, at its expense, register the exclusive license granted under this Agreement in any country of the Territory where the government of such country would require one for use, sale or distribution of the Licensed Product in such country and Cellegy shall reasonably cooperate in such registration at Licensee's expense. Upon request by Licensee, Cellegy agrees promptly to execute any "short form" licenses developed in a form reasonably acceptable to both Licensee and Cellegy and reasonably submitted to it by Licensee from time to time in order to effect the foregoing registration in such country at no cost to Licensee.

17.2 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. NOTWITHSTANDING ANYTHING TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY AMOUNTS IN EXCESS OF THE AMOUNTS RECEIVED BY CELLEGY FROM LICENSEE HEREUNDER. THIS LIMITATION WILL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.

ARTICLE 18  
GENERAL PROVISIONS

18.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, other than an obligation to make payments hereunder, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts, acts of God or any other cause beyond the reasonable control of the affected party to anticipate, prevent, avoid or mitigate (a "**Force Majeure Event**"); provided, however, that any failure or delay in fulfilling a term of this Agreement shall not be considered a result of a Force Majeure Event if it arises from a failure of Licensee or Cellegy to comply with applicable laws and regulations. In the event of force majeure lasting more than sixty days (60) days, the Parties agree to meet and discuss how this Agreement can be justly and fairly implemented under the circumstances prevailing in such Country or Countries and if the Parties are unable to agree upon how the Agreement can be implemented then either Party may terminate the Agreement in relation to such country or countries upon sixty (60) days written notice.

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

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

18.4 Notices. Any notice required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or by an internationally recognized overnight courier, or by facsimile (and promptly confirmed by overnight courier), to the addresses given below or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. Any notice sent by overnight courier as aforesaid shall be deemed to have been given two (2) working days after sending.

**In the case of Cellegy:**

Cellegy Pharmaceuticals, Inc.  
1000 Marina Boulevard, Ste. 300  
Brisbane, California 94080  
Attention: John Chandler  
Telephone No.: (650) 616-2200  
Facsimile No.: (650)616-2222, and

With a required copy to:

Weintraub Genshlea Chediak  
400 Capitol Mall, 11<sup>th</sup> floor  
Sacramento, CA 95814  
Attention: Kevin Kelso, Esq.  
Telephone No.: (916) 558-6110  
Facsimile No.: (916) 446-1611

Cellegy Pharmaceuticals, Inc.  
1800 Byberry Road, Building 13  
Huntingdon Valley, PA 19006-3525  
Attention: Chief Financial Officer  
Telephone No.: (215) 914-0900  
Facsimile No.: (215) 914-0914

**In the case of Licensee:**

Strakan International Limited  
Buckholm Mill  
Galashiels  
TD 1 2HB, UK  
Attention: Mr. Andrew McLean,  
Corporate Director  
Telephone No.: 44-1896-668060  
Facsimile No.: 44-1896-668061

18.5 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the written consent of the other Party such consent not to be unreasonably withheld or delayed; provided, however, that either Party may, without such consent, assign this Agreement (i) in connection with the transfer or sale of all or substantially all of its business related to this Agreement; or (ii) in the event of the merger or consolidation of such Party with another corporation; or (iii) to an Affiliate. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

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

18.7 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof and supersedes and replaces all previous negotiations, understandings and representations whether written or oral including, but not limited to, the Heads of Agreement dated November 12, 2004 between the Parties and the Prior Agreement. This Agreement shall not be modified, altered or amended except by a written document signed on behalf of and delivered by both Parties.

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

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

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

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

18.12 No Third Party Beneficiaries. All rights, benefits and remedies under this Agreement are solely intended for the benefit of Cellegy and Licensee or permitted assignees, and no Third Party shall have any rights whatsoever to (i) enforce any obligation contained in this Agreement (ii) seek a benefit or remedy for any breach of this Agreement, or (iii) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the parties.

18.13 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, exclusive of its choice-of-law rules.

18.14 Resolution of Disputes. All disputes arising out of or related to the terms and conditions of this Agreement, or the breach thereof, will be settled as follows.

(a) If a dispute arises under this Agreement, a representative of each party must, following whatever investigation each considers appropriate, promptly discuss the dispute.

(b) If the dispute is not resolved as a result of the discussions in paragraph (a), either party may give written notice to the other party requesting the commencement of negotiations in good faith. The notice shall:



(i) set out the issues in dispute and any other relevant circumstances; and

(ii) designate a senior representative with the appropriate authority to negotiate the dispute.

(c) Within ten (10) business days of receipt of the notice referred to in paragraph (b) the recipient shall notify the other party of a senior representative with similar authority to negotiate the dispute and specify a reasonable time and place to meet within the following fourteen business days.

(d) The representatives must meet in accordance with the notice referred to in paragraph (b) and, using all reasonable endeavors, commence negotiations in good faith to resolve the dispute.

(e) If the dispute is not resolved within thirty (30) days of notification under paragraph (b), then the dispute shall be settled by binding arbitration in Philadelphia, Pennsylvania, in accordance with the then existing rules of International Chamber of Commerce. In any arbitration pursuant to this Section the award shall be rendered by a single arbiter if the Parties agree to one or a majority of three (3) arbiters, one (1) of whom shall be appointed by each Party and the third of whom shall be appointed by mutual agreement of the two Party-appointed arbitrators. Either Party may initiate such an arbitration by giving written notice to the other Party of such arbitration, specifying, in reasonable detail, the dispute to be resolved thereby. The determination of the arbitrators with respect to any dispute will be conclusive and binding on the Parties, and the arbitrators will have right to award attorneys' fees and costs, including but not limited to the costs of the arbitration, to the prevailing Party. Judgment upon the award rendered in any arbitration may be entered in any court of competent jurisdiction in any country. The Parties agree to the exclusive jurisdiction and venue of any state or federal court located in Philadelphia, Pennsylvania for purposes of any action arising out of or relating to this Agreement that is not subject to mandatory arbitration, and agree that service of process in any such action may be made in the manner provided for in this Agreement for the delivery of notices.

(f) Neither Party shall be prevented from applying to a court at any stage for urgent injunctive or other relief.

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

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

18.17 Late Payment. If Licensee fails to pay to Cellegy any amount when due, Licensee agrees to pay interest on the overdue balance at the rate of the LIBOR rate (as quoted in the

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

London edition of the Financial Times and in effect from time to time) plus [\*] or, if such rate exceeds the maximum rate permitted by law, the maximum rate permitted by law. Payments received from Licensee when any overdue balance exists shall be applied first against accrued interest. Licensee shall pay all collection charges and expenses, and including, but not limited to, attorneys' fees, which are incurred by Cellegy in connection with Cellegy's collection of any amounts under or relating to this Agreement, or otherwise in connection with the enforcement of this Agreement.

18.18 ProStrakan Group plc Guarantee. ProStrakan Group plc, of which Licensee is a wholly-owned subsidiary, hereby guarantees the performance of Licensee under this Agreement to the extent, and pursuant to the terms of, the Guarantee attached hereto as Exhibit D.

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

STRAKAN INTERNATIONAL LIMITED

CELLEGY PHARMACEUTICALS, INC.

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

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

Its: \_\_\_\_\_

Its: \_\_\_\_\_

PROSTRAKAN GROUP plc, only as to  
Section 18.18 and the Guarantee

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

Its: \_\_\_\_\_

EXHIBIT A

COUNTRIES IN THE TERRITORY

TERRITORIES

1. Europe  
Andorra  
Albania  
Austria  
Belgium  
Bosnia-Herzegovina  
Bulgaria  
Croatia  
Cyprus  
Czech Republic  
Denmark  
Estonia  
Finland  
France  
Germany  
Gibraltar  
Greece  
Hungary  
Ireland  
Italy  
Latvia  
Liechtenstein  
Lithuania  
Luxembourg  
Republic of Macedonia  
Malta  
Monaco  
Netherlands  
Norway  
Poland  
Portugal  
Romania

1. Europe (continued)  
Slovak Republic  
Slovenia  
Spain  
Sweden  
Switzerland  
United Kingdom  
Republic of Yugoslavia

**EXHIBIT B**  
**PATENTS**

*“Cellegy Patents”*

<b>Cellegy Ref No</b>	<b>Description or Title</b>	<b>Country</b>	<b>Application No.</b>	<b>Filing Date</b>	<b>Patent or Publication No.</b>	<b>Issue/Pub Date</b>	<b>Status</b>	<b>Summary</b>
C045-4510-AT	Nitric oxide donor composition for treatment of anal disorders	Austria	95916264.5	04/10/95	AT 0719145-	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-BE	Nitric oxide donor composition for treatment of anal disorders	Belgium	95916264.5	04/10/95	BE 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-CH	Nitric oxide donor composition for treatment of anal disorders	Switzerland	95916264.5	04/10/95	CH 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-DE	Nitric oxide donor composition for treatment of anal disorders	Germany	95916264.5	04/10/95	DE 0719145	9/6/00	On Appeal	German translation filed 11/9/00. National Phase of European application 95916264.5
C045-4510-DK	Nitric oxide donor composition for treatment of anal disorders	Denmark	95916264.5	04/10/95	DK 0719145	9/6/00	On Appeal	Danish translation filed 11/00. National Phase of European application 95916264.5
C045-4510-EP	Nitric oxide donor composition and method for treatment of anal disorders	Europe	95916264.5	04/10/95	0719145	9/6/00	On Appeal	On Appeal
C045-4510-ES	Nitric oxide donor composition for treatment of anal disorders	Spain	95916264.5	04/10/95	ES 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5

C045-4510-	FR	Nitric oxide donor composition for treatment of anal disorders	France	95916264.5	04/10/95	FR 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	GB	Nitric oxide donor composition for treatment of anal disorders	United Kingdom	95916264.5	04/10/95	GB 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5.
C045-4510-	GR	Nitric oxide donor composition for treatment of anal disorders	Greece	95916264.5	04/10/95	GR 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	IE	Nitric oxide donor composition for treatment of anal disorders	Ireland	95916264.5	04/10/95	IE 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	IT	Nitric oxide donor composition for treatment of anal disorders	Italy	95916264.5	04/10/95	51262BE/2000	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	LU	Nitric oxide donor composition for treatment of anal disorders	Luxembourg	95916264.5	04/10/95	LU 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	MC	Nitric oxide donor composition for treatment of anal disorders	Monaco	95916264.5	04/10/95	MC 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	NL	Nitric oxide donor composition for treatment of anal disorders	Netherlands	95916264.5	04/10/95	NL 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5
C045-4510-	PT	Nitric oxide donor composition for treatment of anal disorders	Portugal	95916264.5	04/10/95	PT 0719145	9/6/00	On Appeal	Portuguese translation filed 10/27/00. National Phase of European application 95916264.5
C045-4510-	SE	Nitric oxide donor composition for treatment of anal disorders	Sweden	95916264.5	04/10/95	SE 0719145	9/6/00	On Appeal	National Phase of European application 95916264.5

Microdose Cases										
V003-310	PC	Microdose Therapy	PCT	PCT/CA98/00603	06/22/98	WO 98/58633	12/30/98	National Phase	PCT claiming priority from first and second provisionals.	
V003-310	EP	Microdose Therapy	Europe	98 930577.6	06/22/98			Pending	National Phase of PCT/CA98/00603.	Allowable Claim 1 on file: The use of NO or a NO-donor selected from glyceryl trinitrate (GTN) and sodium nitroprusside in the manufacture of a medicament for the treatment of female sexual dysfunction associated with a vascular condition, wherein the medicament does not appreciably alter normal systemic vascular tone, said medicament providing a dose of NO or NO-donor that is 1/2 to about 1/20 of that required to induce vasodilation in an anatomical site lacking said vascular condition.
V003-311	EP	Microdose Therapy	Europe	04 029432.4	12/13/04	Pub. No. 1535611	Pub. 6/1/05	Pending	DIV of the 310 EP case.	
Remodeling Cases										
V004-410	PC	Methods for Remodelling Neuronal and Cardiovascular Pathways	PCT	PCT/CA99/00787	08/25/99	WO 00/12110	3/9/00	National Phase	PCT claiming priority to provisional application.	
V004-410	EP	Methods for Remodelling Neuronal and Cardiovascular Pathways	Europe	99 939874.6	08/25/99			Pending	National Phase of PCT/CA99/00787.	Pending Claim 1: The use of one or more phosphodiesterase inhibitors which lower blood pressure for the manufacture of a medicament for chronic administration in the management of sexual dysfunction by remodeling an ilio-hypogastric-pudendal arterial bed and genitalia, the medicament being adapted for administration at a dose that is from about one twentieth to about one half the dose required to evoke vasodilation in a human patient exhibiting normal circulation.
Urogenital Disorders Cases										
C081-8120	PC	Use of Nitric Oxide donors and other agents for the	PCT	PCT/US02/07026	03/06/02	WO 02/069906	9/12/02	National Phase	PCT claiming priority to	

		treatment of urogenital disorders						provisional application.	
C081-8120	EP	Use of Nitric Oxide donors and other agents for the treatment of urogenital disorders	Europe	2723359.2	03/06/02			Pending National Phase of PCT/US02/07026.	Allowed Claim 1 from equivalent US case: A method for relieving the vulvar pain of vulvodynia in a patient, the method comprising topically administering to the affected vulvar area of the patient a NO donor in a therapeutically effective amount, wherein the vulvar pain which is not caused by dyspareunia is relieved.

**EXHIBIT C**  
**CELLEGY MARKS**

Name	Status	Country	Registration Date	Renewal
Rectogesic	Registered	European Union	10/25/02	9/13/10
Rectogesic	Registered	Switzerland	3/8/01	9/8/10
Rectogesic	no filing	Andorra		
Rectogesic	no filing	Albania		
Rectogesic	no filing	Bosnia-Herzegovina		
Rectogesic	no filing	Bulgaria		
Rectogesic	no filing	Croatia		
Rectogesic	no filing	Gibraltar		
Rectogesic	no filing	Republic of Yugoslavia		
Rectogesic	no filing	Republic of Macedonia		
Rectogesic	no filing	Monaco		

C

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**EXHIBIT D**  
**PROSTRAKAN GROUP plc GUARANTEE**

ProStrakan Group plc (“**Group**”) hereby unconditionally guarantees and undertakes to Cellegy that Licensee will duly and punctually observe and perform all the undertakings, covenants and obligations of Licensee under this Agreement (including the payment of any damages becoming due to Cellegy as a result of any breach by Licensee of such undertakings, covenants and obligations) and under any agreements between the Parties (or any of them) which are expressly supplemental to this Agreement or which this Agreement requires to be executed (the “**Obligations**”) to the intent that if Licensee shall fail for whatever reason so to observe and perform any Obligations, Group shall be liable to perform the same in all respects as if Group was the party principally bound thereby in place of Licensee on demand from Cellegy.

D

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**EXHIBIT E**

**FLOW DIAGRAM SHOWING**

**ORDERING AND COMMUNICATION PATHWAYS**

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**First Amended and Restated Exclusive License Agreement For Tostrex®**

**Between**

**STRAKAN INTERNATIONAL LIMITED**

**And**

**Cellegy Pharmaceuticals, Inc.**

**Confidential**

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

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## FIRST AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT

THIS FIRST AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of January 16, 2006 (the "**Agreement Date**"), by and between Cellegy Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 1800 Byberry Road, Building 13, Huntingdon Valley, PA, 19006-3525 USA ("**Cellegy**"), and Strakan International Limited, a company organized and existing under the laws of Bermuda with a branch office at Buckholm Mill, Galashiels, TD1 2HB, UK ("**Licensee**").

### **BACKGROUND**

A. Cellegy owns or possesses certain intellectual property rights with respect to the Licensed Product (as hereinafter defined) and certain rights pertaining to Cellegy's Marks (as hereinafter defined)

B. The Parties previously entered into an Exclusive License and Distribution Agreement ("**Prior Agreement**") dated as of July 9, 2004 (the "**Effective Date**"), pursuant to which Licensee obtained an exclusive license to certain rights to the Licensed Product under such intellectual property rights, and to Cellegy's Marks within the Territory (as hereinafter defined).

C. The Parties desire to amend the Prior Agreement in various respects, as reflected in this Agreement.

### **AGREEMENT**

Commencing with the Agreement Date, this Agreement shall amend, restate and supersede in its entirety the Prior Agreement. In consideration of the foregoing and of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the Parties (as hereinafter defined) mutually agree as follows:

#### **ARTICLE 1** **DEFINITIONS**

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

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

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



- (ii) dispose of or exercise a right of disposal in respect of 50% or more of the issued voting shares in the party;
- (iii) appoint one half or more of the number of directors to the board of the party; or
- (iv) determine substantially the conduct of the party's business activities.

**"Agreement"** means this First Amended and Restated Exclusive License Agreement.

**"Approvals"** are registration approvals, registrations or authorizations provided by the Relevant Regulatory Authority in the Territory for the [manufacture,]importation, storage, Development, promotion, marketing, distribution or sale of the Licensed Product, but excluding any pricing approvals that may be required by any Relevant Regulatory Authority of a country within the Territory.

**"Cellegy Information"** means the technical and clinical information concerning the Licensed Product that is developed by Cellegy and that is included in the new drug application filed with the Relevant Regulatory Authority in Sweden, and Cellegy's European common technical document format, and which may include, without limitation, data in support of indications, bioequivalency data and information, clinical data, pharmaco-toxicological data, analytical methods, stability and pharmaceutical data concerning the Licensed Product, and any other related supporting documentation or other information or materials in Cellegy's possession from time to time that Cellegy may in its discretion from time to time develop before the date that all required Approvals are obtained and that may be necessary for, or useful in connection with obtaining and maintaining Approvals for the Licensed Product in the Territory.

**"Cellegy Marks"** means the trademarks, service marks and/or trade names owned by Cellegy or that Cellegy has the right to use in connection with the Licensed Product as set forth on Exhibit E hereto and as further described in Section 13.1, that are used by Licensee, its Affiliates or Sublicensees in connection with the importation, storage, Development, promotion, marketing, distribution and sale of the Licensed Product.

**"Cellegy Patents"** means the patents identified on Exhibit D hereto.

**"Cellegy Supply Agreement"** means the supply agreement between Cellegy and Manufacturer to Licensee governing the supply of the Licensed Product to Cellegy or Cellegy's nominees or licensees outside the Territory and incorporating the terms and conditions of a relevant Technical Agreement.

**"Cellegy Surcharge"** means 10% of the per unit cost.

**“Commercially Reasonable and Diligent Efforts”** shall mean with respect to Development and commercialization of the Licensed Product, a Party’s reasonable efforts no less than those efforts used by the Party in its other development, commercialization or marketing projects with other technologies and products having comparable commercial potential.

**“Competing Licensed Products”** has the meaning set forth in Section 2.4.

**“Current SmPC”** has the meaning set forth in Section 11.4.

**“Development”** (including variations such as “Develop” and the like) shall mean all appropriate measures, steps and the like that are necessary to prepare and compile dossiers appropriate for obtaining Approvals for the Licensed Product in the Territory and conducting clinical trials in the Territory (if required). As it relates to Cellegy, “Development” shall mean that Cellegy shall provide Licensee a copy of the dossier concerning the Licensed Product filed by Cellegy with the Relevant Regulatory Authority in Sweden, and such other materials relating thereto or to obtaining other Approvals for the Licensed Product in the Territory as Cellegy may in its discretion from time to time develop before the date that all required Approvals are obtained.

**“Dollars”** or **“\$”** means United States dollars.

**“Effective Date”** means the date set forth at the beginning of the Prior Agreement.

**“Euros”** or **“€”** shall mean currency denominated in Euros.

**“GMP”** means good manufacturing practices in conformity with the regulations and regulatory interpretations of the Relevant Regulatory Authorities in each country in the Territory, including without limitation EU cGMP such regulations covering good manufacturing practices set forth in the relevant legislation or guidelines and applicable to the Territory, as such regulations may be amended and interpreted by the Relevant Regulatory Authorities from time to time.

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

**“Know-How”** means all data, information, methods, procedures, processes and materials, which is or comes to be possessed, acquired, licensed or owned by Cellegy as of the Effective Date and from time to time thereafter of this Agreement, to the extent that such data, information, methods, procedures, processes and materials specifically relate to the manufacture, development, testing or use of the Licensed Product, including but not limited to, biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data (other than such Know-How which is the subject of a patent or of a provisional or filed patent application), and for which Cellegy has the right to license, disclose or provide to Licensee.

**“Launch Date”** means following Approval the date upon which the Licensed Product is first commercially offered for sale in a country in the Territory, determined on a country by country basis.

**“Licensed Product”** means the pharmaceutical product known as Tostrex® (testosterone) 2% topical testosterone gel for the treatment of male hypogonadism, in the pharmaceutical presentation described in Exhibit A.

**“Licensee Product”** has the meaning set forth in Section 2.4.

**“Licensee Supply Agreement”** means the supply agreement between Licensee and Manufacturer governing the supply of the Licensed Product to Licensee by Manufacturer for the Territory and incorporating the terms and conditions of a relevant Technical Agreement.

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

**“Major European Countries”** shall mean France, Germany, Italy, Spain and United Kingdom.

**“Manufacturer”** means Cellegy’s nominated Third Party manufacturer of the Licensed Product or any other manufacturer nominated by Cellegy or by Licensee.

**“Minimum Sales”** means agreed targets for unit sales of Licensed Product in the Territory, as set forth on Exhibit C hereto.

**“M.R.P”** means the mutual recognition procedure as defined in Article 28 of European Directive 2001/83/EC.

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

(i) reasonable credited allowances actually granted to such Third Party customers,

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

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

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

**“Party”** means Cellegy or Licensee, and Parties shall mean both Cellegy and Licensee.

**“Patent Rights”** means (i) the patents and patent applications listed in Exhibit D hereto and any patents and patent applications existing as of the Effective Date; (ii) any patent or patent application hereafter which is acquired by Cellegy or under which Cellegy becomes licensed and with the right to sublicense to Licensee, during the term of this Agreement, in each case of (i) and (ii) above relating to the Licensed Product, its manufacture, use or sale, including methods of use and screening or processes that use the Licensed Product; (iii) any divisionals, continuations and continuations-in-part defined in (i) or (ii); (iv) any extension, renewal or reissue or patent identified in any reissue or re-examination of any patent or patent application identified in (i) through (iv), in each case, to the extent that such items relate to the Licensed Product. Such items set forth in sub-items (i) through (iv) will be identified and added by the Parties to Exhibit D from time to time during the term of this Agreement.

**“Relevant Regulatory Authority”**, in relation to a country or region in the Territory, means the governmental authority, regulating the use, importation, storage, Development, promotion, marketing, distribution or sale of therapeutic substances and the grant of Approvals in such country or region.

**“Steering Committee”** means the Steering Committee, as described in Article 4 of this Agreement.

**“Sublicensee”** means any person to whom Licensee sublicenses the rights, or any portion thereof, granted by Cellegy to Licensee pursuant to Section 2.1 hereof.

**“Technical Agreement”** means the agreements between Cellegy and Manufacturer for Licensed Product supplied outside the Territory, and between Licensee and Manufacturer for Licensed Product supplied within the Territory, defining the roles and responsibilities for the parties to the Technical Agreements in relation to, inter alia, (i) manufacture and supply of the Licensed Product pursuant to GMP; and (ii) regarding regulatory, safety and pharmacovigilance issues, the terms and conditions of which are incorporated into any supply agreement for the Licensed Product.

**“Territory”** means the countries listed on Exhibit B hereto.

**“Third Party”** means any party other than Cellegy or Licensee, or Licensee’s Affiliates or Sublicensees.

ARTICLE 2  
GRANT OF LICENSE

2.1 Grant. Cellegy hereby grants to Licensee an exclusive, royalty-bearing, license, with a right to sublicense as set forth herein, under all of Cellegy's Intellectual Property Rights to manufacture or have manufactured anywhere in the world, import, store, Develop, have Developed (through agreements with contract research organizations or similar Third Parties, performing work on behalf of and for the benefit of Licensee), promote, market, distribute, offer for sale, and sell the Licensed Product within the Territory, and to use Cellegy's Intellectual Property Rights in connection with the importation, storage, Development, promotion, marketing, distribution and sale of Licensed Product and obtaining any Approvals hereunder, in each of the above cases only in relation to promotion, marketing, distribution, offer for sale and sale of the Licensed Product within the Territory. Licensee's rights to the Licensed Product and the Intellectual Property Rights are limited to those expressly granted, and all others are reserved to Cellegy.

2.2 Right to sub-license. Subject to Section 2.5 below, Licensee may sub-license any of its rights or obligations under this Agreement, directly or indirectly, in whole or in part:

(a) to Third Parties approved by Cellegy in writing, which approval will not be unreasonably withheld or delayed; and

(b) to a Cellegy approved Third Party Manufacturer in the case of Licensee sub-licensing the rights to manufacture the Licensed Product and subject to appropriate confidential disclosure by Cellegy of the Cellegy Information and Know-How which Cellegy shall disclose to allow the manufacture of the Licensed Product by such Manufacturer; and

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

(c) to any of its Affiliates that are engaged primarily in the business of manufacture, importation, storage, Development, promotion, marketing, distribution and sale of pharmaceutical products, as Licensee sees fit.

Any such sublicense shall not relieve Licensee of any of its obligations hereunder, and Licensee shall remain responsible and liable for compliance by any such Third Party, Affiliate or Sublicensee with this Agreement, all relevant laws, regulations and requirements relating to the importation, distribution, marketing, promotion and sale of the Licensed Product in the Territory, and any acts or omissions by any such Third Party, Affiliate or Sublicensee that would constitute a breach of this Agreement if such sublicense had not been entered into and the actions or omissions were those of Licensee rather than the Third Party, Affiliate or Sublicensee. Any sublicense agreement shall contain terms and conditions that are not inconsistent with those of this Agreement.

2.3 Acceptance of Appointment; Sales Outside Territory.

(a) Licensee hereby accepts appointment as Cellegy's exclusive licensee of Licensed Product in the Territory, as provided in Section 2.1 above.

(b) Licensee shall not, and Licensee shall use all Commercially Reasonable and Diligent Efforts to ensure that its officers, directors, employees, Affiliates, agents or representatives (collectively, "**Agents**") shall not, without the prior written consent of Cellegy, directly or indirectly promote, sell, distribute or otherwise make available (for remuneration or gratuitously) Licensed Product outside the Territory or sell, distribute or otherwise make available (for remuneration or gratuitously) Licensed Product to persons outside the Territory for the purpose of resale or distribution (whether for remuneration or gratuitously) outside the Territory. Without limiting the foregoing, Licensee agrees to use all Commercially Reasonable and Diligent Efforts to ensure compliance with the preceding sentence, including without limitation placing appropriate notices on the labels of Licensed Products; provided, however, that Licensee shall not be obligated to include any notices in a particular country in the Territory that would conflict with any relevant requirements of the Relevant Regulatory Authority for such country, and Licensee's failure or refusal to include any such notices in such circumstances shall not constitute a breach of any provision of this Agreement.

2.4 Competing Products. During the term of this Agreement, or, if earlier, the maximum period of time permitted by applicable European Union regulations, Licensee shall not, and shall use all Commercially Reasonable and Diligent Efforts to ensure that its officers, directors, employees, Affiliates, Sublicensees, agents or representatives (collectively, "**Agents**") shall not, directly or indirectly, promote, sell or distribute products within the Territory that are directly competitive in the treatment of male hypogonadism or such other indications for the Licensed Product as may be added to this Agreement (the "**Competing Licensed Products**"), excluding Licensee's [\*] (the "**Licensee Product**"). For the avoidance of doubt, this shall not preclude Licensee from conducting research and development in relation to projects or products

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that may be associated with the treatment of male hypogonadism or such other indication for the Licensed Product added to this Agreement. If applicable law or applicable European Union regulations provide that the foregoing covenant is unenforceable or require that the duration of the foregoing covenant be shorter than the term of this Agreement, then if at any time during the term of this Agreement when such covenant is not effective Licensee or its Agents directly or indirectly promote, sell or distribute Competing Licensed Products, Cellegy may terminate this Agreement with respect to any country where such Competing Licensed Products are being promoted, sold or distributed by delivery of written notice to Licensee.

2.5 Right of First Negotiation Regarding Licensee Product in North America. Before Licensee enters into any agreement with any Third Party which includes the right to develop, promote, distribute or sell the Licensee Product for use in males in territories that include the United States of America or Canada ("**North America**"), or any agreement with any Third Party which includes worldwide rights to develop, promote, distribute or sell the Licensee Product, Licensee shall first offer to Cellegy in writing (the "**Negotiation Notice**") a one-time right of exclusive first negotiation to negotiate with Licensee concerning exclusive development, marketing and/or distribution rights in North America (or worldwide, as the case may be) for such Licensee Product, for a negotiation period not to exceed [\*] (the "**Negotiation Period**"). Cellegy shall exercise the Right of First Negotiation granted herein by providing written notice of its election (the "**Exercise Notice**") to Licensee within [\*] after the date of delivery of the Negotiation Notice to Cellegy. The Negotiation Period shall commence upon delivery to Licensee of the Exercise Notice. During the Negotiation Period, Licensee shall not enter into any agreement with any person other than Cellegy with respect to the development, promotion, distribution or sale of the Licensee Product within any country in North America (or worldwide, as the case may be). During the Negotiation Period, the Parties shall negotiate in good faith; provided, however, that nothing in this Article shall be deemed to create a legal obligation on the part of Licensee to enter into any such agreement. This Right of First Negotiation shall terminate upon the first to occur of (i) Cellegy's failure to timely deliver its Exercise Notice following receipt of the Negotiation Notice; (ii) the expiration of the Negotiation Period; (iii) the mutual termination of negotiations by the Parties conducted under this Article; or (iv) the effective date of termination of this Agreement by either Party as provided elsewhere in this Agreement.

ARTICLE 3  
REPRESENTATIONS AND WARRANTIES

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

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

(b) Cellegy is not subject to, or bound by, any provision of: (i) its articles of incorporation or by-laws, (ii) any mortgage, deed of trust, lease, note, shareholders' agreement, bond, indenture, license, permit, trust, custodianship, or other instrument, agreement or restriction, or (iii) any judgment, order, writ, injunction or decree of any court, governmental body, administrative agency or arbitrator, that would prevent, or be violated by, or under which there would be a default as a result of, nor is the consent of any person required for, the execution, delivery and performance by Cellegy of this Agreement and the obligations contained herein, including without limitation, the grant to Licensee of the license described in Section 2.1 hereof.

(c) Cellegy is the exclusive owner of all right, title and interest in the Patent Rights in the applicable countries in the Territory, and the patent applications included in the Patent Rights have been duly filed and contain no material errors. Cellegy shall maintain all Patent Rights for the full duration of this Agreement. Attached hereto as Exhibit D is a complete and accurate list of all patents and patent applications included in the Patent Rights.

(d) Cellegy is the exclusive owner of all right, title and interest in the Cellegy Marks in the Territory. Cellegy shall maintain at its sole expense where applicable all Cellegy Marks for the full duration of this Agreement. Attached hereto as Exhibit E is a complete and accurate list of all trade marks and trade mark applications included in the Cellegy Marks.

(e) To the best of Cellegy's knowledge, neither the development, use or sale of the Licensed Product or the practice of any of the inventions included in the Patent Rights or the use of the Cellegy Marks or the use of the Know-How by Licensee as contemplated by this Agreement infringes upon any Third Party's know-how, patent, trade mark or other intellectual property rights in the Territory.

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

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

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

(i) CELLEGY MAKES NO REPRESENTATION OR WARRANTY OTHER THAN THOSE EXPRESSLY PROVIDED HEREUNDER, AND CELLEGY HEREBY DISCLAIMS ALL SUCH OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, OR THE FITNESS FOR A PARTICULAR PURPOSE, OF THE LICENSED PRODUCT OR THE KNOW-HOW. EXCEPT AS MAY BE EXPRESSLY PROVIDED ELSEWHERE HEREIN, CELLEGY MAKES NO REPRESENTATION OR WARRANTY THAT THE LICENSED PRODUCT IS OR WILL BE SHOWN TO BE SAFE OR EFFECTIVE FOR ANY INDICATION. THE FOREGOING SHALL NOT REDUCE THE SCOPE OF ANY REPRESENTATION OR WARRANTY OF CELLEGY EXPRESSLY MADE TO LICENSEE HEREIN.

(j) Cellegy will use all Commercially Reasonable and Diligent Efforts to ensure that Cellegy will not alter the Cellegy Information supplied to Licensee or the materials or processes described in that information in relation to any of the Licensed Product without the prior written notification to Licensee.



3.2 Representations and Warranties of Licensee. Licensee hereby represents and warrants to Cellegy as follows:

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

(b) Licensee's Affiliates shall not conduct themselves in such a way that Licensee will be in breach of any term or condition of this Agreement.

(c) Licensee currently is in compliance in all material respects with all applicable laws and has received, or will receive where relevant, all applicable pharmaceutical product certifications and registrations from appropriate governmental entities that are necessary to perform its obligations under this Agreement.

ARTICLE 4  
MANAGEMENT OF THE COLLABORATION

4.1 Steering Committee.

(a) Upon execution of the Prior Agreement, Cellegy and Licensee established a Steering Committee (the "***Steering Committee***") which shall have the responsibilities described in this Article 4. The Steering Committee shall be initially comprised of a total of six (6) members, of which three (3) members shall be appointed by Licensee and three (3) members

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

shall be appointed by Cellegy. The total number of Steering Committee members may be changed by the Steering Committee from time to time as appropriate, but in all cases it will be comprised of an equal number of members designated by each of Cellegy and Licensee, and in no event shall the Steering Committee be comprised of an aggregate of less than six (6) members. Each of Cellegy and Licensee may substitute its representatives from time to time and the substitution shall be effective upon notice to the other Party. The Steering Committee shall meet once every quarter during the first year of the term of this Agreement and thereafter at such other times as the Steering Committee may agree (but at least one time each year), on such dates and at such places as to be agreed upon between the Parties. Each representative on the Steering Committee will have one vote in decisions submitted to the Steering Committee. The meetings of the Steering Committee may be held in person or in any other reasonable manner, including, without limitation, by telephone, video conference or e-mail.

(b) [\*] shall designate a Chairperson who will serve as such. The Chairperson shall send notices (not less than 15 business days in advance of such meetings) and agendas for all regular Steering Committee meetings to all Steering Committee members. The location of regularly scheduled Steering Committee meetings shall alternate among the offices of the Parties, unless otherwise agreed. Meetings may be held telephonically or by video conference, but each member shall attend at least one meeting in person each year. The Party hosting any Steering Committee meeting shall appoint one person (who need not be a member of the Steering Committee) to attend the meeting and record the minutes of the meeting. Such minutes shall be circulated to the Parties promptly following the meeting for review, comment and approval.

4.2 Responsibilities of the Steering Committee. The Steering Committee will be primarily responsible for activities relating to implementation of the activities contemplated by this Agreement. The Steering Committee shall, subject to the provisions set forth in this Agreement (including the dispute resolution procedures hereof), be the primary vehicle for interaction between the Parties with respect to the Development and commercialization of the Licensed Product in the Territory. In particular, the Steering Committee shall perform the following functions:

(a) exchange of information and facilitation of cooperation and coordination between the Parties as they exercise their respective rights and meet their respective obligations under this Agreement;

(b) perform such other functions as appropriate to further the purposes of this Agreement, as determined by the mutual agreement of the Parties;

(c) with the exception of the Approval application that Cellegy has already submitted in Sweden, prior to submitting any Approval application, the Steering Committee shall discuss the scope and content of such Approval application. The Steering Committee may

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review and comment on all Approval applications, and such comments will be considered by the Parties as long as such comments are provided in a timely manner. In the event of a dispute within the Steering Committee or between the Parties directly or indirectly relating to the choice of countries within the Territory where Approval applications shall be filed and Approvals shall be obtained then clause 4.3 shall not apply. Licensee shall have final decision-making authority with respect to such Approval application issues; however, any such decisions shall be based on Licensee's good faith belief that such decision is consistent with commercialization requirements of the Territory; and

(d) In the event that the Current SmPC requires substantial and significant changes as described in Section 11.4(b), then the Steering Committee shall review the timetable and the Approval Plan, and if it so determines to revise and modify such timetable and Approval Plan, then the time periods for obtaining Approvals (as set out in Section 5.1(b)) and consequently commercializing the Licensed Product (as set out in Sections 10.3(i) and (ii)) shall be extended by the amount of time determined by the Steering Committee.

(e) at the end of [\*] review and attempt to agree on the Minimum Sales for [\*].

4.3 Voting; Deadlocks. Each member of the Steering Committee shall have one vote, and all the decisions of the Steering Committee shall be made by a simple majority of the members of such committee; provided, however, that in the event the members of the Steering Committee are deadlocked and cannot reach a decision within three (3) days after notice of a deadlock with regard to any decision required to be made by such committee (each, a “*Dispute*”), then the Dispute shall be referred to the Chief Executive Officer of each Party.. If such Dispute is not resolved by the Chief Executive Officers within five (5) working days of such referral, then (i) Cellegy’s Chief Executive Officer (or such other officer as Cellegy determines) will have the authority to cast the tie-breaking vote with regard to such Dispute if, and only if, the Dispute relates to clinical studies or trials where, in Cellegy’s good faith opinion, the conduct or results of the studies or activities could have a detrimental effect on the commercial viability of the Licensed Product outside of the Territory, and (ii) for other kinds of Disputes, if the Chief Executive Officers cannot agree within such time period, then the Dispute shall be resolved by means of the dispute resolution procedures set forth in Section 18.14 of this Agreement.

4.4 Approval Plan; Marketing Plan. The overall timetable to obtain Approvals for the Licensed Product in the Territory shall be set forth in a written plan (the “Approval Plan”). In addition, Licensee shall prepare a marketing plan, including details of promotional effort, size of sales force, associated budget in connection with the promotion, marketing and distribution of the Licensed Product in the Major European Countries (the “Marketing Plan”). The initial Marketing Plan for Sweden shall be submitted no later than six (6) weeks after the Effective Date of this Agreement. The initial Marketing Plans for the Major European Countries shall be

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submitted no later than three (3) months after the Effective Date, and the initial Marketing Plans for the other countries in the Territory shall be submitted no later than one (1) year after the Effective Date. Such initial Marketing Plans shall be subject to review and approval by Cellegy, such approval not to be unreasonably withheld or delayed. The Marketing Plans shall be consistent in all material respects with the provisions of this Agreement. Subsequent revisions and updates to the Marketing Plan shall be delivered annually and no later than the end of the first week in January (or, if Licensee makes interim revisions or updates, then as soon as reasonably practicable after Licensee prepares such revisions or updates).

ARTICLE 5  
REGULATORY MATTERS; APPROVALS

5.1 Regulatory Matters; Approvals.

(a) Licensee shall use Commercially Reasonable and Diligent Efforts, subject to this Agreement, and with the exception of the Approval application that Cellegy has already submitted in Sweden, to obtain at its sole expense obtain all Approvals that are necessary for the sale of the Licensed Product within the Territory including without limitation: any additional clinical trials, studies or data in addition to the Cellegy Information that may be required in order to obtain or maintain Approvals for Licensed Product in each country in the Territory, and comply with any and all applicable statutory, administrative or regulatory requirements of the Territory or any governmental or political subdivisions thereof (collectively, "**Laws**") in relation to the manufacture, importation, storage, Development promotion, marketing, distribution or sale of the Licensed Product in the Territory under this Agreement, including, without limitation, Licensed Product documentation such as Licensed Product tracking, samples, Licensed Product complaints, adverse event reporting requirements, post-marketing surveillance activities, and documentation of recalls, which documentation shall be maintained by the Licensee for the period required by the Relevant Regulatory Authorities in the Territory notwithstanding termination or expiration of this Agreement, any Licensed Product registrations with any government agency or health authority, or any registration, approvals, or filing of this Agreement. Licensee shall inform Cellegy on at least a semi-annual basis (and more frequently if Cellegy so reasonably requests) about the progress of such registration work, and will promptly provide Cellegy with a copy of all presentations and documents submitted by Licensee to any Relevant Regulatory Authority with respect to the Licensed Product. Cellegy shall do all that is necessary to assign the Approval in Sweden to Licensee, including notifying the Swedish Relevant Regulatory Authority of such a change. Cellegy shall, upon Licensee's written request, provide reasonable assistance to Licensee, at Licensee's sole cost, regarding obtaining such Approvals in the Territory, including allowing Licensee reasonable access to relevant experts in relation to the Cellegy Information for the purpose of obtaining Approvals.

(b) Licensee agrees that it will make all filings that are required to seek and obtain Approvals for the Licensed Product in each Major European Country by initiating the M.R.P. no later than [\*] after the date of Approval of the variation dealing with impurities in the

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Licensed Product which variation was filed 18 May 2005 with the Relevant Regulatory Authority in Sweden, provided that the dossier used in Sweden is acceptable for use in an M.R.P. application. If the Relevant Regulatory Authority in a country other than Sweden determines that such dossier is not complete or acceptable for the initiation of an M.R.P. application in such country, then the Steering Committee shall promptly meet and attempt to agree on an appropriate course of action, and recommend an appropriate modification to the above deadline as applied to such country. Licensee agrees that it will make all filings that are required to seek and obtain Approvals for the Licensed Product in other countries in the Territory no later than [\*] after the completion of the M.R.P. and to use Commercially Reasonable and Diligent Efforts to take such actions as may be required to promptly obtain Approvals in all of the foregoing countries. If Licensee desires to not seek Approvals in one or more countries in the Territory because Licensee concludes in good faith that for regulatory or marketing reasons it would not be in the parties' best interests to pursue Approvals in such countries, it shall notify the Steering Committee and the Steering Committee shall decide whether Approvals will be sought in such country or countries. If alteration by Cellegy of the Cellegy Information after the date of this Agreement requires additional time to submit or revise regulatory filings relating to Approvals, then the time periods set forth above for making filings and obtaining Approvals shall be extended by the additional period of time required to submit or revise such filings.

(c) With the exception of the Approval application that Cellegy has already submitted in Sweden and such other materials as Cellegy in its discretion may provide to Licensee pursuant to this Agreement, Licensee shall pay all costs in connection with the filing, prosecution, meetings, communications, and review by Relevant Regulatory Authorities of Approval applications and Approvals relating to the Licensed Product in the Territory and complying with applicable laws and regulations.

5.2 Reversion of Product Rights in Certain Circumstances. If further clinical development is required for Approval in a given country (or countries) within the Territory and Licensee elects not to conduct any required clinical studies within twenty-four (24) months after the need for further clinical studies is identified, then the rights in the Licensed Product in any such country shall revert to Cellegy at no further cost to Licensee.

5.3 Cooperation Regarding Material Events. Each Party will immediately notify the other Party of any material events relating to the Development of the Licensed Product in the Territory, including, without limitation, any material comments or concerns raised by any Relevant Regulatory Authority.

5.4 Copies of Documents. Each Party agrees to provide to the other Party a copy of (i) any documents or reports relating to the Licensed Product that are filed with any Relevant Regulatory Authority in the Territory under this Agreement, including any Approval applications; and (ii) all data, database information and safety reports from clinical trials conducted by or on behalf of Licensee. In particular, Licensee acknowledges that Cellegy has provided to Licensee a copy of the dossier concerning the Licensed Product filed in Sweden. All such documents and reports shall be centralized and held at Licensee or by a Third Party selected by Licensee and agreed to by Cellegy, provided however, that Cellegy shall be entitled to obtain and keep copies of any such documents and records but only for the uses specifically set forth in this Agreement.

5.5 Approval Application in Sweden. Cellegy agrees to continue the ongoing Approval process in Sweden; provided, however, that the foregoing shall not obligate Cellegy to conduct any additional studies or trials. Cellegy shall provide Licensee with a copy of such other reports, analysis and clinical data relating to the Licensed Product in a timely manner as Cellegy may from time to time develop before the date that all required Approvals are obtained.

5.6 Meetings With Regulatory Authorities. Licensee shall be responsible for conducting all meetings and discussions and routine telephone communications with any Relevant Regulatory Authority, related to clinical studies, Approval applications and Approvals for the Licensed Product in the Territory; provided that Licensee shall use Commercially Reasonable and Diligent Efforts to conduct such meetings and discussions to facilitate the Approval of the Licensed Product in the Territory. Licensee will inform Cellegy and the Steering Committee early in advance of all meetings with such Relevant Regulatory Authorities and will keep Cellegy and the Steering Committee apprised of all material communications with such Relevant Regulatory Authorities. Cellegy or its designee shall be entitled to attend all meetings with Relevant Regulatory Authorities. If appropriate Cellegy, or Cellegy's designee, will provide reasonable assistance and technical support for the preparation of and attendance at any relevant meeting with a Relevant Regulatory Authority.

5.7 Inspection. Licensee and Cellegy shall use all Commercially Reasonable and Diligent efforts to procure that Manufacturer, shall cooperate in good faith with respect to the conduct of any inspections by any Relevant Regulatory Authority of Licensee's or Manufacturer's site and facilities related to the manufacture of the Licensed Product for the Territory, and each Party shall be given the opportunity to attend such site inspection and the summary, or wrap up, meeting related to the Licensed Product with such Relevant Regulatory Authority at the conclusion of such site inspection. To the extent either Party receives written or material oral communication from any Relevant Regulatory Authority relating to the Licensed Product in the Territory, the party receiving such communication shall notify the other parties and provide a copy of any written communication as soon as reasonably practicable.

5.8 Clinical Trials. Licensee shall at its own cost be responsible for the conduct of all studies and clinical trials that may be necessary or appropriate to obtain all required Approvals (excluding Sweden) and any post-Approval Clinical Trials and for the grant of all necessary approvals and maintaining in effect all appropriate policies of insurance for clinical trials for the Licensed Product in the Territory. All clinical trials for the Licensed Product in the Territory that are initiated after the date of this Agreement shall be performed in compliance with and in conformity to ICH and E.U. good clinical practice guidelines. Licensee shall provide Cellegy with the study plans and/or protocols relating to any such clinical trial before the trial is started, and Cellegy shall have the right to review and comment on such trial plans or protocols. It will be the responsibility of the Party conducting the trial to register such trial, unless by law Cellegy as the originator of the Licensed Product is required to register it in which circumstance if Licensee is conducting the trial it shall supply Cellegy with the appropriate information to enable the trial to be registered. At the completion of each clinical trial initiated after the Effective Date, Licensee shall prepare a written report, in compliance with the relevant ICH guidelines summarizing the results of such clinical trial, and containing an analysis of the clinical significance of such results, which reports shall be submitted to Cellegy as soon as is reasonably practicable after completion of the relevant clinical trial. Licensee may enter into one or more manufacturing and supply agreement(s) (or similar arrangements) with Third Party contract manufacturer(s) for such clinical supplies, providing that use of the Third Party contract manufacturer(s) has been approved by Cellegy .

5.9 Cellegy Obligations. Promptly following entering into this Agreement Cellegy shall, to the extent it has not already done so pursuant to the Prior Agreement:

- (a) provide Licensee with a complete copy of the Cellegy Information;

(b) provide Licensee with any information in its possession that is reasonably likely to jeopardize or otherwise have a material adverse impact on the application, or any grant, maintenance, variation or renewal of the Approvals;

(c) except as provided in Section 5.8 above, at its cost promptly provide to Licensee a sufficient quantity of the Licensed Product reasonably necessary for Licensee to prepare and submit the application, and the grant, maintenance, variation or renewal of Approvals;

(d) use Commercially Reasonable and Diligent Efforts to assist Licensee and Manufacturer to procure the assistance of any Third Party supplier of raw materials, in meeting the demands of the Relevant Regulatory Authority relating to any application and any grant, maintenance, variation or renewal of Approvals;

(e) use commercially reasonable efforts to assist Licensee to enter into Licensee Supply Agreement and Technical Agreement with the Manufacturer; and

(f) notify Licensee and promptly provide all relevant assistance and supporting documentation to Licensee and Manufacturer, where relevant, should Cellegy make any alteration to the Licensed Product, or the manufacture, or packing of the Licensed Product that requires notification to a Relevant Regulatory Authority.

#### 5.10 Approvals.

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

(b) Licensee shall promptly provide to Cellegy, upon Cellegy's request, such evidence that Cellegy shall reasonably require, confirming that all Approvals necessary to import, store, Develop, promote, market, distribute and sell the Licensed Product in the Territory have been obtained.

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

### ARTICLE 6 POST- APPROVAL RESPONSIBILITIES

6.1 Responsibility. Each Party acknowledges that Licensee or the Affiliate or Sublicensee named by Licensee as the holder of the Approvals bears the ultimate responsibility *vis-à-vis* the Relevant Regulatory Authorities for complying with the regulatory requirements applicable to the manufacture, importation, storage, Development, promotion, marketing, distribution and sale of the Licensed Product in the Territory.

6.2 Collaboration. The Parties shall collaborate with each other and each Party agrees to provide the other Party with any reasonable assistance it may require to ensure compliance with the Approvals.

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

ARTICLE 7  
INFORMATION; DATA; PHARMACOVIGILANCE

7.1 Clinical Data. All clinical data and reports related to clinical trials for the Licensed Product in the Territory shall be owned by the Party funding such clinical trial(s). Other than to a Sublicensee in connection with the transactions contemplated by this Agreement, Licensee shall not sell, disclose to or share with any Third Party, or grant any Third Party right to use, any clinical data arising owned by Licensee as a result of the preceding sentence. Each Party shall have access to, and copies of, all such data and reports related to clinical trials for the Licensed Product in the Territory, and each Party may use such data without any additional payments to the other Party. Each Party shall treat such data and reports as Confidential Information of the other Party, and neither Party shall disclose or use such data or reports for any purpose other than performing its obligations under this Agreement or as otherwise expressly authorized in writing by the Steering Committee except to the extent that data or reports are required by the voluntary or compulsory prior registration of a clinical trial, and except for such disclosures as a Party reasonably believes is required by securities or regulatory laws or

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

regulations. If a Party itself obtains data from a clinical trial hereunder, it shall promptly transfer all of the clean, final data for such trial to Licensee or to Cellegy, as the case may be. The Steering Committee shall coordinate the transfers of any such data.

7.2 Safety Data Base. The Parties will, as soon as practical, organize a serious adverse event data base (the "*SAE Data Base*"). Cellegy and Licensee shall jointly own the SAE Data Base and all data contained therein, and the data from the SAE Data Base shall be made available to both Parties. Licensee shall be responsible for, and bear the costs of, data for the SAE Data Base related to the Territory. Cellegy shall be responsible for, and bear the costs of, data for the SAE Data Base related to territories outside the Territory. As soon as practicable, the Parties shall attach a policy governing the formation and administration of the SAE Data Base to this Agreement as part of Exhibit G.



7.3 Adverse Events. The Parties recognize that as the holder of the Approvals, Licensee will be required to submit information and file reports to various governmental agencies on compounds under clinical investigation, compounds proposed for marketing, or marketed drugs. The process and responsibilities for such reports will be governed by the Adverse Event Reporting Addendum separately agreed to by the Parties.

7.4 Product Complaints. Each Party will maintain a record of all non-medical and medical Licensed Product-related complaints and will notify the other Party of any complaint in a sufficient time to allow the other Party to comply with any regulatory requirements it may have with respect to such complaint. The details and responsibilities governing the management of such Licensed Product-related complaints shall be detailed in Exhibit G.

ARTICLE 8  
MILESTONE PAYMENTS; ROYALTIES AND RELATED PAYMENTS

8.1 Milestone Payments. Licensee shall pay Cellegy a milestone payment in the particular amounts specified below:

(a) Five Hundred Thousand Dollars (\$500,000), within five (5) business days after the date the Prior Agreement was executed and delivered by both parties hereto, receipt of which amount is hereby acknowledged by Cellegy.

(b) With respect to [\*], the amounts set forth below, payable on the earlier to occur of (i) [\*], or (ii) [\*]:

[\*]

8.2 [\*]

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

(a) [\*]

(b) [\*]

(c) [\*]

(d) [\*]

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

8.4 Royalties in General. In consideration of the exclusive license granted to Licensee hereunder, Licensee shall pay or cause to be paid to Cellegy the Royalty set forth herein. The “**Royalty**” shall be equal to the following amounts:

(a) For aggregate, annual Net Sales of the Product in the Territory up to [\*] Million Euros [\*], the Royalty shall be equal to [\*] Percent [\*] of Net Sales.

(b) For aggregate, annual Net Sales of the Licensed Product in the Territory in excess of [\*] Million Euros [\*], the Royalty shall be equal to [\*] Percent [\*] of Net Sales. (For example, Net Sales of [\*] would accrue Royalties equal to [\*] of [\*] and [\*] of [\*], which is equal to [\*].)

8.5 Period for Royalty Payments; Residual Payments. Royalty payments will continue as set forth above, on a country by country basis, until the later of (i) ten years from the Launch Date for the Licensed Product in such country, or (ii) expiration, lapse or invalidation by a final, non appealable order or judgment of a court or other governmental authority of competent jurisdiction, of the last valid claim included within any of the Cellegy Patents covering such country in the Territory relating to the Licensed Product. Thereafter, following the period of time described in the preceding sentence, Licensee will pay Cellegy a [\*] royalty with respect to Net Sales in such country for ongoing use of Cellegy’s trademark Tostrex® and know-how relating to the Licensed Product.

ARTICLE 9  
ROYALTY REPORTS AND ACCOUNTING

9.1 Quarterly Royalty Reports; Records. During the term of this Agreement after the first Launch Date, Licensee shall furnish or cause to be furnished to Cellegy a written report within sixty (60) days following the end of each preceding calendar quarter (the “**Royalty Report**”) covering such preceding calendar quarter (the “**Royalty Period**”) showing:

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

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

(c) the exchange rates used in determining the amount of Dollars, using the exchange rates normally used by Licensee in its management and financial reporting, provided, however, that the exchange rates used by Licensee in preparation of the Royalty Report shall not be materially different from the exchange rates posted in the London edition of the *Financial Times* published on the last day of such Royalty Period.

With respect to sales of Licensed Product invoiced in Dollars, the Net Sales and royalty payable shall be expressed in Dollars. With respect to sales of Licensed Product invoiced in a currency other than Dollars, the Net Sales and royalty payable shall be expressed in the domestic currency of the country where such sale was made together with the Dollar equivalent of the royalty payable, calculated using the exchange rates as described in clause (c) above. Licensee, and its Affiliates and Sublicensees shall keep contemporaneous, legible, verifiable and accurate records in sufficient detail to enable the royalties payable hereunder to be determined and substantiated. A final Royalty Report shall be due upon the expiration or termination of this Agreement. Any income or other tax which Licensee is requested to pay or withhold on behalf of Cellegy with respect to any upfront or milestone payment and Royalties shall be deducted from the amount of such upfront and milestone payments and Royalties due, provided, however, that in regard to any such deduction Licensee shall give Cellegy such assistance as may reasonably be necessary to enable or assist Cellegy to claim appropriate tax credits or exemptions therefrom and shall upon request give Cellegy proper evidence from time to time as to the withholding and payment of the tax. If Cellegy is unable to claim such an exemption or recover such amounts that have been deducted or withheld, or if any restrictions are imposed by a governmental entity in a particular country in the Territory regarding the payment of milestones or Royalties to companies outside of such countries, then the Steering Committee shall promptly meet to agree upon a suitable response. If the Steering Committee is unable to agree on a suitable response, then Cellegy may, in its discretion, discontinue the supply of the Licensed Product to Licensee for sale in such country.

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

9.3 Right to Audit Licensee.

(a) Upon the written request of Cellegy, at Cellegy's expense and not more than once in each year, Licensee and its Affiliates shall permit an independent public accountant and auditor bound to strict secrecy (the "**Auditor**"), selected by Cellegy to have access during normal business hours to those records of Licensee and its Affiliates as may be reasonably

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

necessary to verify the accuracy of the Royalty Reports furnished by Licensee hereunder in respect of any year ending not more than twenty four (24) months prior to the date of such request. Cellegy acknowledges that the Auditor shall conduct its audit in such a manner so as to not unreasonably interfere with Licensee's, its Affiliates', or Sublicensees' business.

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

(c) If the Auditor's report shows any underpayment of royalties, Licensee shall remit, or shall cause its Affiliates or Sublicensees to remit, to Cellegy the amount of such underpayment within thirty (30) days after Licensee's receipt of the Auditor's report assuming there is no disagreement as to the Auditor's calculation; if there is such a disagreement, the result shall be resolved under Section 18.14 of this Agreement. In the event that the amount of any underpayment of royalties is in excess of [\*] percent [\*] of the total royalties due to Cellegy with respect to the period covered by the Auditor's report, Licensee shall reimburse Cellegy for the reasonable cost of the audit in which the underpayment was discovered. In addition, in the event that the amount of any underpayment of royalties is in excess of [\*] percent [\*] of the total royalties due to Cellegy with respect to the period covered by the Auditor's report, Licensee shall reimburse Cellegy for the reasonable cost of the next subsequent audit.

ARTICLE 10  
MARKETING

10.1 General Promotional Duties.

(a) Licensee shall: (i) at all times display, demonstrate and otherwise represent the Licensed Product fairly in comparison with other competitive products or therapies, (ii) shall not make false or misleading representations to customers or other persons with regard to the Licensed Product or Cellegy, and (iii) subject to sub-clause (ii), shall not make any representations with respect to the specifications, features or capabilities of the Licensed Product which are not consistent with the relevant Approvals. Licensee, its Affiliates and Sublicensees shall promote, market and sell the Licensed Product only for the therapeutic indications for which Approvals are granted in the Territory.

10.2 Marketing Effort; Minimum Expenditures for Commercialization.

(a) Licensee agrees to exert its Commercially Reasonable and Diligent Efforts to introduce, promote and, sell the Licensed Product within the Territory, including, without limitation, the attainment of the Minimum Sales, and to commence sales of the Licensed Product in all Major European Countries within [\*] months following Approval in such countries, subject to Section 10.3 below.

(b) Licensee shall detail commercialization expenditures relating to the Development and marketing of the Licensed Product in the Territory in the Marketing Report as described at Section 4.4 of this Agreement.

10.3 Licensee's Failure to Commercialize in the Territory.

(a) If Licensee fails to make commercial sales of the Product in a particular country within the Territory within (i) [\*] in Major European Countries, and (ii) [\*] for other countries in the Territory, after Approval has been obtained (including price reimbursement approval where applicable) for commercial sale in such country, other than failures caused by (i) the Relevant Regulatory Authority approving a minimum reimbursement price for sale of the Product in such country that does not permit the Licensed Product to be economically sold in such country; or (ii) Cellegy's inability to supply Licensed Product in a timely manner, or (iii) Cellegy's material breach of any relevant obligation under this Agreement; (iv) health or safety reasons relating to the Licensed Product, or (v) the assertion of a proceeding or lawsuit brought against Licensee by any Third Party that the Intellectual Property Rights infringe such Third Party's patent, trade mark, protected know-how or other intellectual property right that prevents sales of the Licensed Product in a particular country of the Territory, then Cellegy may, upon notice to Licensee, terminate all of Licensee's rights under this Agreement with respect to the Licensed Product in such country and recapture all rights granted to Licensee with respect to the

Licensed Product in such country hereunder. In the event that rights to the Licensed Product are returned to Cellegy due to a failure to launch within a particular country within the time frames specified above, a minimum royalty for [\*] will be due with respect to the Major European Countries, and a minimum royalty for [\*] will be due in any other country in the Territory. Should price reimbursement approval for the Licensed Product not be achieved in any country of the Territory the Parties shall meet to discuss how to proceed.

(b) If Licensee decides in good faith for commercial reasons not to file an application for Approval in a particular country within the Territory or to pursue commercial launch in that country following Approval, it shall notify Cellegy and the Parties shall discuss in good faith the termination of the license granted in Section 2.1 and the return of all rights to the Licensed Product to Cellegy within such country.

10.4 Minimum Sales.

(a) Exhibit C hereto sets forth certain targets for the agreed minimum unit sales of Licensed Product in the Territory (“**Minimum Sales**”) for a period of [\*]. It is acknowledged by the Parties that all Approvals pursuant to the MRP will not be obtained within [\*] following the Launch Date in the first country of the Territory through no fault of Licensee and the Parties have agreed to vary the Minimum Sales accordingly.

(b) If Licensee fails to achieve the Minimum Sales in a given year then Licensee shall pay to Cellegy the Royalties that would have been due to Cellegy had the Minimum Sales for that particular year been achieved, such shortfall in the Royalties to be paid within sixty (60) days following the end of the relevant year. For the avoidance of doubt this shall be Cellegy’s sole remedy for Licensee’s failure to achieve the Minimum Sales in any year, except as provided in paragraph (d) below. However in the event Licensee fails to pay the relevant shortfall within sixty (60) days following the end of the relevant year this shall constitute material breach and Cellegy shall be entitled to terminate this Agreement in accordance with Section 16.2(c).

(c) The Minimum Sales amounts set forth on Exhibit C are subject to review and revision as described in Section 11.4 below.

(d) At any time commencing with “Year 3” Minimum Sales as set forth on Exhibit C, if Licensee fails to achieve, in any particular country, the annual Minimum Sales amounts for such country as set forth on Exhibit C for any [\*] consecutive years, and if the Relevant Regulatory Authority for such country has not required any substantial and significant changes to the Current SmPC that can reasonably be expected to materially and adversely affect Licensee’s competitive position and ability to market and sell the Licensed Product in such country, then if the Steering Committee cannot agree (without the occurrence of a deadlock) on mutually satisfactory modifications to the Minimum Sales amounts for such country, then Cellegy may, at its option, make the exclusive license granted pursuant to Sections 2.1 and 2.2

herein a nonexclusive license for the remainder of the term of this Agreement as it relates to such country in the Territory, except for the right to use Cellegy Marks granted to Licensee hereunder, which shall continue to be exclusive for Cellegy's Mark actually being used in connection with the Licensed Product, and without limiting the above may import, store, Develop, have Developed, promote, market, distribute, offer for sale, and sell the Licensed Product in such country on its own or through a Third Party licensee.

ARTICLE 11  
MANUFACTURING; SUPPLY OF LICENSED PRODUCT

11.1 Production and Supply of Product.

(a) Without limitation on Cellegy's other rights, during the term of this Agreement and thereafter, Cellegy may, without obligation or liability to Licensee, manufacture, have manufactured, produce, assemble, warehouse or source the Licensed Product for sale outside of the Territory at any worldwide location, including Canada or the United States of America and locations within or outside the Territory.

(b) Cellegy agrees to use all Commercially Reasonable and Diligent Efforts to (i) maintain its existing Cellegy Supply Agreement with the existing Manufacturer until at least March 31, 2006, (ii) cooperate with Licensee with the goal that, prior to the establishment of the Licensee Supply Agreement, Licensee may purchase Licensed Product directly from the Manufacturer, and (iii) until Licensee enters into a Licensee Supply Agreement, cooperate with Licensee to involve Licensee in discussions between Cellegy and Manufacturer concerning product pricing or other material terms of the Cellegy Supply Agreement.

11.2 Forecasts. Until such time as Licensee enters into a Licensee Supply Agreement, Licensee shall be responsible for combining (if practicable in Licensee's sole opinion) its forecast for Licensed Product in the Territory and Cellegy's forecast for Licensed Product outside the Territory and for delivering all combined forecasts for the Parties to the Manufacturer providing that both Cellegy and Licensee are utilizing the same Manufacturer. Should the Parties decide to utilize separate manufacturers, each Party will be responsible for providing their Manufacturer with its own forecasts.

11.3 [\*]

11.4Pricing. For each order of Licensed Product delivered to Licensee by Manufacturer, Licensee will pay Cellegy the Cellegy Surcharge (plus, if applicable, the additional percentage of total Licensed Product cost and Cellegy Surcharge as set forth below) within forty-five (45) days of the receipt of the invoice for such order from Manufacturer. Licensee will pay Cellegy the Cellegy Surcharge multiplied by the number of Licensed Product units on the relevant Manufacturer invoice for supply of the Licensed Product to Licensee.

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

(a) If the royalty paid to Cellegy for each unit of Licensed Product sold is equal to or greater than [\*], Licensee shall pay Cellegy the Cellegy Surcharge multiplied by the number of Licensed Product units.

(b) If the royalty paid to Cellegy for each unit of Licensed Product sold is between [\*], Licensee shall pay Cellegy the Cellegy Surcharge multiplied by the number of Licensed Product units, plus [\*] of the total of the invoiced purchase price from the Manufacturer and the Cellegy Surcharge.

(c) If the royalty paid to Cellegy for each unit of Licensed Product sold is less than [\*], Licensee shall pay Cellegy the Cellegy Surcharge multiplied by the number of Licensed Product units, plus [\*] of the total of the invoiced purchase price from the Manufacturer and the Cellegy Surcharge..

(d) Both Parties agree to work in mutual cooperation and in collaboration with Manufacturer to manage the purchase price, production, packaging, delivery and availability of the Licensed Product for sale in the Territory. The Parties agree to explore arrangements for Cellegy to contract with a secondary Manufacturer as a back-up manufacturer of Licensed Product as soon as reasonably possible. Cellegy agrees to inform Licensee of any amendments to any Manufacturer contract that may have any material effect on the purchase price of the Licensed Product.

**11.5 Warranty Limitation; Disclaimer. Except as expressly set forth in this Agreement, the sole warranty, if any, given by Cellegy regarding any Licensed Product shall be that written limited warranty, if any, which shall accompany such Licensed Product or which shall otherwise be designated in writing by Cellegy as applicable to such Licensed Product, as the same may be revised by Cellegy from time to time. After the initial commercial launch of the Licensed Product, subsequent changes to the written limited warranty must be approved by Licensee, which approval shall not be unreasonably withheld. THE WRITTEN LIMITED WARRANTY, IF ANY, APPLICABLE TO ANY PARTICULAR PRODUCT SHALL STATE THE FULL EXTENT OF CELLEGY'S LIABILITY, WHETHER DIRECT OR INDIRECT, SPECIAL OR CONSEQUENTIAL, RESULTING FROM ANY BREACH OF SUCH WARRANTY. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT WITH RESPECT TO WARRANTIES MADE TO LICENSEE, CELLEGY FURTHER DISCLAIMS ALL EXPRESS, STATUTORY AND IMPLIED WARRANTIES APPLICABLE TO THE LICENSED PRODUCT.**

11.6 Recalls.

(a) Licensee may recall any quantity of Licensed Product at any time, and Licensee will administer any such recall in the Territory.



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

ARTICLE 12  
PATENT RIGHTS

12.1 No Ownership By Licensee. Licensee shall not be deemed by anything contained in this Agreement or done pursuant to it to acquire any right, title or interest in or to the Cellegy Patent Rights or any patent owned by or licensed to Cellegy now or hereafter covering or applicable to any Licensed Product, nor in or to any invention or improvement, owned by Cellegy, now or hereafter embodied in the Licensed Product, whether or not such invention or improvement is patentable under the laws of any country.

12.2 New Cellegy Inventions/Improvements to the Licensed Product. If Cellegy develops and commercially offers:

(a) any improvements in terms of dosage, route of administration or formulation of the Licensed Product for the same indication; or

(b) any improvement in terms of dosage, route of administration or formulation of any product derived from the Licensed Product for the same indication; then

such improvements shall be included within the definition of Licensed Product herein at no additional costs to Licensee.

12.3 Improvements by Licensee. If, during the term of the Prior Agreement or this Agreement or within one (1) year after the date of its termination, Licensee or any Sublicensee invents or designs any improved Licensed Product or any associated method, apparatus, equipment or process related to or having application to the Licensed Product, or makes an improvement thereon, whether or not patented or patentable in any jurisdiction, Licensee shall make or cause a prompt and full disclosure to Cellegy of such invention, design or improvement ("**Licensee Improvement**"), and hereby irrevocably transfers, conveys and assigns to Cellegy all of its right, title and interest therein. Licensee shall execute such documents, render such assistance, and take such other action as Cellegy may reasonably request, at Cellegy's expense, to apply for, register, perfect, confirm, and protect Cellegy's rights therein. Cellegy shall have the exclusive right to apply for or register any patents or other proprietary protections with respect thereto. Such Licensee Improvements shall be licensed back from Cellegy to Licensee as, and shall be deemed part of, the Licensed Product, at no additional cost to Licensee.

ARTICLE 13  
CELLEGY MARKS

13.1 Use of Cellegy Marks by Licensee. Licensee, its Affiliates and Sublicensees will have the exclusive right to use Cellegy's Mark Tostrex in the Territory in connection with the importation, storage, Development, promotion, marketing, distribution and sale of Licensed Product. In such event, Licensee and its Affiliates (and Sublicensees) shall use Cellegy's Marks only in the form and manner prescribed by Cellegy. In no event shall Licensee use any of Cellegy's Marks or any similar mark or term as part of its business name. Should Tostrex not be registered or registerable by Cellegy in all countries of the Territory, then Cellegy may notify Licensee that one of the other "Cellegy's Marks" will be used; and if no such marks are registered or registerable by Cellegy in all countries of the Territory, then Licensee may propose an alternative trade mark/s for Cellegy's approval, such approval not to be unreasonably withheld or delayed Cellegy shall apply for and maintain such alternative trade mark at Cellegy's sole expense and such alternate trade mark shall become a Cellegy Mark under the terms of this Agreement.

13.2 Acknowledgment of Ownership. Licensee acknowledges that

- (a) Cellegy owns Cellegy's Marks and all goodwill associated with or symbolized by Cellegy's Marks;
- (b) Licensee has no ownership right in or to any of Cellegy's Marks; and

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

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

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

13.5 Termination of Use. Upon expiration or earlier termination of this Agreement, Licensee shall cease using Cellegy's Marks in any manner, either similar or dissimilar to the use enumerated above.

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

ARTICLE 14  
INFRINGEMENT; INDEMNIFICATION AND OTHER CLAIMS

14.1 Infringement of Intellectual Property Rights. In the event Cellegy or Licensee have reason to believe that a Third Party may be infringing or diluting, as the case may be, Intellectual Property Rights or misappropriating the Licensed Product, such Party shall promptly notify the other Party. Cellegy may, in its discretion, elect to enforce the Intellectual Property Rights through legal action or otherwise, and Licensee agrees to reasonably cooperate with Cellegy in such enforcement subject to reimbursement of its reasonable out-of-pocket expenses together with any reasonable attorneys fees incurred in connection therewith. In the event Cellegy elects not to enforce the Patent Rights relating to the Licensed Product within sixty (60) days after notice of the possible infringement or dilution, and Licensee can demonstrate that the potential infringement or dilution is reasonably likely to result in material lost sales of the Licensed Product within the applicable country, then Licensee may institute a lawsuit or other such actions at its expense to prevent continuation of such potential infringement or dilution, and then (i) during the pendency of such action, Licensee shall be entitled to defer the payment of 50% of the royalties due to Cellegy on Net Sales under Section 8.4 in the relevant country or countries, with such deferred amount being paid to Cellegy at the successful conclusion of such action, and (ii) Licensee will retain all award, damages or compensation obtained by Licensee in such suit, except that Cellegy shall receive a portion equivalent to the royalties it would have received in accordance with the terms of this Agreement as if such amount were Net Sales of Licensee. Cellegy will provide reasonable cooperation with respect to any lawsuit which Licensee may bring pursuant to this Article, subject to reimbursement of its reasonable out-of-pocket expenses and reasonable attorneys fees in connection therewith. Licensee shall not enter into any settlement or compromise of any such claim without the prior written consent of Cellegy, which shall not be unreasonably delayed or withheld.

#### 14.2 Alleged Infringement of Third Party Intellectual Property Rights.

(a) If a claim or lawsuit is brought against Licensee alleging infringement of any patent or infringement or dilution of any trademark owned by a Third Party arising from Licensee's importation, storage, Development, promotion, marketing, distribution and sale of the Licensed Product or use of proprietary rights, Licensee shall provide to Cellegy all information in Licensee's possession regarding such claim or lawsuit. Within a reasonable time after receiving notice of such claim or lawsuit, but in any event within sixty (60) days after receiving such notice, Cellegy shall advise Licensee of Cellegy's decision as what action it plans to take to dispose of such claim or defend such lawsuit.

(b) If Cellegy elects not to dispose of such claim or defend such lawsuit, Licensee may defend the claim or lawsuit. Licensee shall not enter into any settlement or compromise of any such claim or lawsuit without the prior written consent of Cellegy, which shall not be unreasonably delayed or withheld. For the purpose of Licensee's conduct of the claim or defense, Cellegy shall furnish to Licensee such reasonable assistance as Licensee may need and from time to time reasonably request.

14.3 Product Liability Claims. Licensee shall immediately notify Cellegy in writing of any product liability claim or product liability action brought against Licensee with respect to the Licensed Product based on any reason other than (i) alleged defects in the manufacture or supply of the Licensed Product or (ii) any action or inaction in relation to the manufacture or supply of the Licensed Product on the part of Licensee or any of its employees, affiliates or sublicensees (a "**Product Liability Claim**"). Upon receiving such written notice, Cellegy shall assume and have sole control of the defense of any such claim or action, including the power to conduct and conclude any and all negotiations, compromises or settlements. Licensee may participate in (but not control) the defense of any such Product Liability Claim, but at its own expense. Licensee shall comply with all reasonable requests from Cellegy for information, materials or assistance, with respect to the conduct of such defense at Cellegy's expense. Cellegy shall be responsible for payment of all Product Liability Claims. Nothing in this Article shall be construed as requiring Cellegy to conduct and/or assume Licensee's independent defense against any claim or action, if such claim or action involves the independent conduct, acts or omissions of Licensee for Product Liability Claims or actions brought with respect to the manufacture or supply of the Licensed Product.

14.4 Notice from Licensee. Licensee shall promptly notify Cellegy of any potential or actual litigation or governmental activity in the Territory relating to the Licensed Product or the business operations of Licensee or Cellegy. Licensee shall provide such notice within ten (10) days from the time that Licensee learns of such litigation or activity.

14.5 Indemnification.

(a) Cellegy assumes all risk of loss and indemnifies and holds harmless Licensee, its Affiliates, Sublicensees and their respective directors, officers and employees from and against any and all Loss arising from or incidental to or relating to any claim, demand, lawsuit, action or proceeding (a "**Claim**") arising from or relating to:

(i) any claim or lawsuit which relates to or arises out of the alleged infringement by Licensee of any patent or trademark owned by a Third Party to the extent that the alleged infringement relates to actions covered by the Exclusive License granted to Licensee under Section 2.1 of this Agreement;

(ii) the manufacture, importation, storage, Development, promotion, marketing, distribution or sale of the Licensed Product based on action or inaction of Cellegy;

(iii) a Product Liability Claim based on action or inaction of Cellegy; or

(iv) any negligence or willful default of Cellegy relating to the Licensed Product or this Agreement; or any breach by Cellegy of any representation or warranty given in this Agreement.

(b) Licensee assumes all risk of loss and indemnifies and holds harmless Cellegy from all Loss arising from or incidental to or relating to any claim, action or proceeding arising from or relating to:

(i) the manufacture, importation, storage, Development, promotion, marketing, distribution, or sale, of the Licensed Product based on action or inaction of Licensee, Affiliates, Sublicensees or their respective directors, officers and employees (Licensee and such other Persons sometimes referred to as "**Licensee Indemnified Persons**");

(ii) any Product Liability claim based on action or inaction of any Licensee Indemnified Person;

(iii) any breach by any Licensee Indemnified Person of any representation or warranty given in this Agreement; any negligence or willful default of any Licensee Indemnified Person relating to the Licensed Product or this Agreement; or

(iv) any breach by Licensee of any representation or warranty given in this Agreement.

(c) Licensee shall give Cellegy written notice (a “**Notice of Claim**”) promptly after Licensee becomes aware of the assertion, whether orally or in writing, of a Claim brought by a Third Party (in each such case, a “**Third-Party Claim**”) that may require indemnification pursuant to this Agreement. Each Notice of Claim by a party hereunder will contain the following information:

(i) that the Person has incurred, paid or accrued or, in good faith, believes it will have to incur, pay or accrue, Losses and, if reasonably determinable at the time, a good faith estimate of the aggregate amount of Losses arising from such Claim (which amount may be the amount of damages claimed by a third party in the Claim); and

(ii) A BRIEF DESCRIPTION, IN REASONABLE DETAIL (TO THE EXTENT REASONABLY AVAILABLE TO THE PARTY), OF THE FACTS, CIRCUMSTANCES OR EVENTS GIVING RISE TO THE ALLEGED LOSSES BASED ON THE PARTY’S GOOD FAITH BELIEF THEREOF, INCLUDING THE IDENTITY AND ADDRESS OF ANY THIRD-PARTY CLAIMANT AND COPIES OF ANY FORMAL DEMAND OR COMPLAINT, THE AMOUNT OF LOSSES, THE DATE EACH SUCH ITEM WAS INCURRED, PAID OR ACCRUED, OR THE BASIS FOR SUCH ANTICIPATED LIABILITY, AND THE SPECIFIC NATURE OF THE BREACH TO WHICH SUCH ITEM IS RELATED.

## ARTICLE 15 CONFIDENTIALITY

15.1 Treatment of Confidential Information. Except as otherwise provided in this Article 15, during the term of this Agreement and for a period of five (5) years thereafter, Licensee and its Affiliates will retain in confidence and use only for purposes of this Agreement any information, data, and materials supplied by Cellegy or on behalf of Cellegy to Licensee and its Affiliates under this Agreement, and Cellegy will retain in confidence and use only for purposes of this Agreement any information, data, and materials supplied by Licensee or on behalf of Licensee to Cellegy under this Agreement. For purposes of this Agreement, all such information and data which a party is obligated to retain in confidence shall be called “**Confidential Information.**” For the avoidance of doubt, Cellegy Information shall constitute Confidential Information of Cellegy.

15.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, Licensee may disclose Confidential Information to its Affiliates, Sublicensees, consultants, outside contractors, clinical investigators or other Third Parties on condition that such entities or persons agree in writing (a) to keep the Confidential Information confidential for the same time periods and to the same extent as Licensee is required to keep the Confidential Information confidential and (b) to use the Confidential Information only for such purposes as Licensee is entitled to use the Confidential Information. Each Party or its Affiliates or sublicensees may disclose such Confidential Information to government or other regulatory authorities to the extent that such disclosure (i) is reasonably necessary to obtain Approvals; or (ii) is otherwise legally required.

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

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

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

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

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

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

15.5 Return of Confidential Information. Upon termination of this Agreement with respect to the entire Territory, the Parties and Affiliates and sublicensees shall return all Confidential Information of the other Party, in their possession along with a certification that they no longer possess any such Confidential Information.

15.6 Previous Confidentiality Agreements. Confidential information disclosed by either Party to the other Party or its Affiliates prior to the Effective Date of this Agreement under any written agreement executed by Cellegy and Licensee shall be treated as Confidential Information under Section 15.1 notwithstanding expiration of such prior Confidentiality Agreement.

ARTICLE 16  
TERM; TERMINATION

16.1 Term. Unless terminated sooner pursuant to this Article 16, this Agreement shall become effective as of the Effective Date and shall continue in full force and effect in each country until the later of (i) the date of expiration of the last to expire of Licensee's obligation to make royalty payments in a particular country, or (ii) ten years from the Launch Date. For countries in which none of Cellegy's Patents are filed, the Agreement shall terminate upon the date of the last to expire of Cellegy's Patents in the last applicable country. Such termination may be made with respect to one or more countries of the Territory without affecting the rest of this Agreement or the Exclusive License granted hereunder in any other country of the Territory.

16.2 Bilateral Termination Rights. Either Party may terminate this Agreement in whole or in part upon the occurrence of any of the following:

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

(b) The other Party becomes the subject of an involuntary bankruptcy or insolvency case that is not dismissed within ninety (90) days; or

(c) Upon or after the material breach of any provision of this Agreement by the other Party, if such material breach is not cured (if such default is capable of cure) within thirty (30) days after written notice thereof to the Party in default.

16.3 Cellegy's Right to Terminate. Cellegy may terminate this Agreement with immediate effect upon written notice to Licensee if a Change in Control of Licensee shall occur, PROVIDED THAT this shall not apply in the case whereby Licensee or its Affiliates undergoes an initial public offering of its stock on a recognized stock exchange. Subject to the aforesaid provision, for purposes of this Article, a "**Change in Control**" means (i) any reorganization, consolidation, merger, tender offer, purchase of stock or similar transaction or series of related transactions (each, a "**combination transaction**") in which Licensee (or any direct or indirect parent entity of Licensee (a "**Parent**")) is a constituent corporation or is a party if, as a result of such combination transaction, the voting securities of Licensee (or any Parent) that are outstanding immediately before the consummation of such combination transaction (other than any such securities that are held by an "Acquiring Stockholder", as defined below) do not represent, or are not converted into, securities of the surviving corporation of such combination transaction (or such surviving corporation's parent or other Affiliate) that, immediately after the consummation of such combination transaction, together possess at least a majority of the total voting power of all outstanding securities of such surviving corporation (or its parent or other Affiliate, if applicable) that are outstanding immediately after the consummation of such combination transaction, including securities of such surviving corporation (or its parent or other Affiliate, if applicable) that are held by the Acquiring Stockholder; or (ii) a sale of all or substantially all of the assets or the business of the Licensee (or any Parent), if, and only if, in each of the above cases, the acquiring entity (or its parent or other Affiliate) engages in the



development, distribution, or sale of Competing Licensed Products. For purposes of this Article, an "**Acquiring Stockholder**" means a stockholder or stockholders of the Licensee (or any Parent) that (i) merges or combines with the Licensee (or any Parent) in such combination transaction or (ii) owns or controls a majority of another corporation that merges or combines with the Licensee (or Parent) in such combination transaction. Licensee agrees to use its Commercially Reasonable and Diligent Efforts to notify Cellegy at least thirty (30) days before any such Change in Control.

16.4 Licensee's Right to Terminate. Licensee may terminate this Agreement; (i) immediately on written notice on health or safety grounds in relation to the Licensed Product; (ii) immediately on written notice if Approval is not obtained by Cellegy in Sweden; (iii) immediately on written notice if Approvals is not obtained, through no fault of Licensee, in all Major European Countries within [\*] of MRP being initiated; (iv) on one (1) year's written notice to Cellegy should it no longer be economically viable to market the Licensed Product, based on Licensee's reasonable opinion and determined on a country by country basis; or (v) immediately upon written notice if a claim by any Third Party that the Intellectual Property Rights infringe such Third Party's patent, trade mark, protected know-how or other intellectual property right is made against Licensee and which either (A) prevents use of the Licensed Product in any country of the Territory for a period of sixty (60) consecutive days, or (B) is not being challenged by either Party pursuant to Article 14 in relation to such country.

16.5 Rights Upon Termination or Expiration. Termination of this Agreement shall not extinguish debts and other obligations created or arising between the Parties by virtue of contracts or arrangements entered into hereunder before the effective date of termination of this Agreement (the "**Termination Date**"). Without limiting the generality of the foregoing, upon and following the Termination Date:

(a) Licensee shall not be relieved of its obligation to (i) pay for Licensed Product delivered by Cellegy prior to the Termination Date, or (ii) accept and pay for all Licensed Product covered by orders received and accepted by Cellegy prior to the Termination Date. Cellegy shall be obligated to complete all orders received and accepted prior to the Termination Date, provided that Cellegy receives reasonable assurance of payment. In each such case, Licensee shall be permitted to store, promote, sell and distribute such Licensed Product as well as any Licensed Product in Licensee's inventory within the Territory, subject to the provisions of paragraph (h) below and provided that Licensee shall not sell or otherwise dispose any of the Licensed Product in bulk, in any non-customary manner or otherwise circumvent its regular customers.

(b) Licensee shall cooperate with Cellegy to allow for the orderly transfer of Approvals within the Territory to Cellegy or its designee upon request and without expense to Cellegy. Licensee shall provide Cellegy with (i) full and immediate access to and copies of all marketing and sales information and other materials pertaining to the Licensed Product, including, without limitation, customer lists, past sales history and Licensed Product pricing information, and (ii) any inventions or other materials or rights required to be assigned to Cellegy pursuant to this Agreement. Notwithstanding any other term or provision of this Agreement, effective upon the Termination Date, Licensee shall execute any documents that are necessary to transfer to Cellegy, or Cellegy's designee, all Approvals or intellectual property which are then in the name of and/or held by Licensee and which relate to the marketing or sale of the Licensed Product (the "**Relevant Documents**"). In the event that full Approvals for any Licensed Product in the Territory are not completed before any transfer of operations pursuant to this Article, Licensee shall also transfer to Cellegy or Cellegy's designee, free of any charge, the Cellegy Information and all the data submitted to the Relevant Regulatory Authorities therefor. At Cellegy's request, Licensee shall authorize Cellegy's nominee, without any delay, to perform all the required activities in order to obtain the transfer of such permits and registration rights. If Licensee fails to execute the Relevant Documents, it hereby appoints Cellegy as its agent and authorizes Cellegy to act on its behalf, in order to execute all Relevant Documents. Licensee, its Affiliates and Sublicensees shall terminate any use of the Cellegy Marks and shall, at Cellegy's option, either destroy or return to Cellegy at Licensee's cost all literature, labels, or other materials, incorporation or bearing same.

(c) Each party shall cease to use any of the other party's Confidential Information relating to or in connection with its continued business operations and shall promptly return or assign to the other party any and all physical, written and descriptive matter (including all reproductions and copies thereof) containing that party's Confidential Information, provided that each party may:

(i) provide one copy of the other party's Confidential Information to its legal advisers to be held by them solely for the purpose of determining the scope of that party's obligations under this clause;

(ii) retain one copy of such of the other party's Confidential Information that is required by the Relevant Regulatory Authorities in the Territory, to be retained by that party; and

(iii) retain any documents confidential to it (including board papers, strategic plans and operational reviews) in which the other party's Confidential Information is incorporated, provided that such confidential information shall continue to be treated as Confidential Information hereunder.

(d) Upon expiration or termination for any reason, the obligations of confidentiality and use of Confidential Information under Article 15 shall survive for the period provided therein;

(e) Upon expiration or termination for any reason, Articles 14 and 16 of this Agreement shall survive for the maximum duration permitted by law;

(f) Articles 5, 8 and 9 shall survive until all outstanding payment obligations and reporting obligations of Licensee and its Affiliates and Sublicensees have been fulfilled, and Sections 9.3 and 9.4 shall survive for two years following the year in which such or expiration became effective; and

(g) Cellegy shall have the right to repurchase all then-current inventory of the Licensed Product then in Licensee's possession, at the landed cost paid by Licensee for such inventory (including delivery, insurance and any applicable import/export taxes paid thereon).

#### ARTICLE 17

##### REGISTRATION OF LICENSE; LIMITATION OF LIABILITY

17.1 Registration. Licensee may, at its expense, register the exclusive license granted under this Agreement in any country of the Territory where the government of such country would require one for use, sale or distribution of the Licensed Product in such country and Cellegy shall reasonably cooperate in such registration at Licensee's expense. Upon request by Licensee, Cellegy agrees promptly to execute any "short form" licenses developed in a form reasonably acceptable to both Licensee and Cellegy and reasonably submitted to it by Licensee from time to time in order to effect the foregoing registration in such country at no cost to Licensee.

17.2 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. NOTWITHSTANDING ANYTHING TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY AMOUNTS IN EXCESS OF THE AMOUNTS RECEIVED BY CELLEGY FROM LICENSEE HEREUNDER. THIS LIMITATION WILL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.

#### ARTICLE 18

##### GENERAL PROVISIONS

18.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, other than an obligation to make payments hereunder, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts, acts of God or any other cause beyond the reasonable control of the affected party to anticipate, prevent, avoid or mitigate (a "**Force Majeure Event**"); provided, however, that any failure or delay in fulfilling a term of this Agreement shall not be considered a result of a Force Majeure Event if it arises from a failure of Licensee or Cellegy to comply with applicable laws and regulations. In the event of force majeure lasting more than sixty days (60) days, the Parties agree to meet and discuss how this Agreement can be justly and fairly implemented under the circumstances prevailing in such Country or Countries and if the Parties are unable to agree upon how the Agreement can be implemented then either Party may terminate the Agreement in relation to such country or countries upon sixty (60) days written notice.

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

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

18.4 Notices. Any notice required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or by an internationally recognized overnight courier, or by facsimile (and promptly confirmed by overnight courier), to the addresses given below or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. Any notice sent by overnight courier as aforesaid shall be deemed to have been given two (2) working days after sending.

In the case of Cellegy:

Cellegy Pharmaceuticals, Inc.  
1000 Marina Boulevard, Ste. 300  
Brisbane, California 94005  
Attention: John Chandler  
Telephone No.: (650) 616-2200  
Facsimile No.: (650)616-2222; and,

With a required copy to:

Weintraub Genshlea Chediak  
400 Capitol Mall, 11<sup>th</sup> floor  
Sacramento, CA 95814  
Attention: Kevin Kelso, Esq.  
Telephone No.: (916) 558-6110  
Facsimile No.: (916) 446-1611

Cellegy Pharmaceuticals, Inc.  
1800 Byberry Road, Building 13  
Huntingdon Valley, PA, 19006-3523  
Attention: Chief Financial Officer  
Telephone No.: (215) 914-0900  
Facsimile No.: (215) 914-0914

**In the case of Licensee:**

Strakan International Limited  
Buckholm Mill  
Galashiels  
TD 1 2HB, UK  
Attention: Mr. Andrew McLean,  
Corporate Director  
Telephone No.: 44-1896-668060  
Facsimile No.: 44-1896-667061

18.5 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the written consent of the other Party; provided, however, that either Party may, without such consent, assign this Agreement (i) in connection with the transfer or sale of all or substantially all of its business related to this Agreement; or (ii) in the event of the merger or consolidation of such Party with another corporation; or (iii) to an Affiliate. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

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

18.7 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof and supersedes and replaces all previous negotiations, understandings and representations whether written or oral including, but not limited to, the Heads of Agreement dated [\*], the Agreement dated [\*], and the Addendum dated [\*] between the Parties and the Confidentiality Agreement described at Section 15.6. This Agreement shall not be modified, altered or amended except by a written document signed on behalf of and delivered by both Parties.

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

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

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

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

18.12 No Third Party Beneficiaries. All rights, benefits and remedies under this Agreement are solely intended for the benefit of Cellegy and Licensee, and no Third Party shall have any rights whatsoever to (i) enforce any obligation contained in this Agreement (ii) seek a benefit or remedy for any breach of this Agreement, or (iii) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the parties.

18.13 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Pennsylvania, exclusive of its choice-of-law rules.

18.14 Resolution of Disputes. All disputes arising out of or related to the terms and conditions of this Agreement, or the breach thereof, will be settled as follows.

(a) If a dispute arises under this Agreement, a representative of each party must, following whatever investigation each considers appropriate, promptly discuss the dispute.

(b) If the dispute is not resolved as a result of the discussions in paragraph (a), either party may give written notice to the other party requesting the commencement of negotiations in good faith. The notice shall:

- (i) set out the issues in dispute and any other relevant circumstances; and
- (ii) designate a senior representative with the appropriate authority to negotiate the dispute.

(c) Within ten (10) business days of receipt of the notice referred to in paragraph (b) the recipient shall notify the other party of a senior representative with similar authority to negotiate the dispute and specify a reasonable time and place to meet within the following fourteen business days.

(d) The representatives must meet in accordance with the notice referred to in paragraph (b) and, using all reasonable endeavors, commence negotiations in good faith to resolve the dispute.

(e) If the dispute is not resolved within thirty (30) days of notification under paragraph (b), then the dispute shall be settled by binding arbitration in Philadelphia, Pennsylvania, in accordance with the then existing rules of International Chamber of Commerce. In any arbitration pursuant to this Section the award shall be rendered by a single arbiter if the Parties agree to one or a majority of three (3) arbiters, one (1) of whom shall be appointed by each Party and the third of whom shall be appointed by mutual agreement of the two Party-appointed arbitrators. Either Party may initiate such an arbitration by giving written notice to the other Party of such arbitration, specifying, in reasonable detail, the dispute to be resolved thereby. The determination of the arbitrators with respect to any dispute will be conclusive and binding on the Parties, and the arbitrators will have right to award attorneys' fees and costs, including but not limited to the costs of the arbitration, to the prevailing Party. Judgment upon the award rendered in any arbitration may be entered in any court of competent jurisdiction in any country. The Parties agree to the exclusive jurisdiction and venue of any state or federal court located in Philadelphia, Pennsylvania for purposes of any action arising out of or relating to this Agreement that is not subject to mandatory arbitration, and agree that service of process in any such action may be made in the manner provided for in this Agreement for the delivery of notices.

(f) Neither Party shall be prevented from applying to a court at any stage for urgent injunctive or other relief.

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

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

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

18.17 Late Payment. If Licensee fails to pay to Cellegy any amount when due, Licensee agrees to pay interest on the overdue balance at the rate of the LIBOR rate (as quoted in the London edition of the Financial Times and in effect from time to time) plus [\*] or, if such rate exceeds the maximum rate permitted by law, the maximum rate permitted by law. Payments received from Licensee when any overdue balance exists shall be applied first against accrued interest. Licensee shall pay all collection charges and expenses, and including, but not limited to, attorneys' fees, which are incurred by Cellegy in connection with Cellegy's collection of any amounts under or relating to this Agreement, or otherwise in connection with the enforcement of this Agreement.

18.18 ProStrakan Group plc Limited Guarantee. ProStrakan Group plc, of which Licensee is a wholly-owned subsidiary, hereby guarantees the performance of Licensee under this Agreement to the extent, and pursuant to the terms of, the Guarantee attached hereto as Exhibit F.

**[Remainder of this page intentionally left blank]**



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

STRAKAN INTERNATIONAL LIMITED

By:

Its: \_\_\_\_\_

ProStrakan Group plc, only as to  
Section 18.18 and the Guarantee

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

Its: \_\_\_\_\_

CELLEGY PHARMACEUTICALS, INC.

By:

Its: \_\_\_\_\_

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

**EXHIBIT A**  
**LICENSED PRODUCT**

[\*] gram metered dosing canister.

[\*] gram metered dosing canister.

**EXHIBIT B**  
**COUNTRIES IN THE TERRITORY**

TERRITORIES

1. Europe

Andorra  
Albania  
Austria  
Belgium  
Bosnia-Herzegovina  
Bulgaria  
Croatia  
Cyprus  
Czech Republic  
Denmark  
Estonia  
Finland  
France  
Germany  
Gibraltar  
Greece  
Hungary  
Ireland  
Italy  
Latvia  
Liechtenstein  
Lithuania  
Luxembourg  
Republic of Macedonia  
Malta  
Monaco  
Netherlands  
Norway  
Poland  
Portugal  
Romania

1. Europe (continued)

Slovak Republic  
Slovenia  
Spain  
Sweden  
Switzerland  
Turkey  
United Kingdom  
Republic of Yugoslavia

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

**EXHIBIT C  
MINIMUM SALES REQUIREMENTS**

[\*]

C

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**EXHIBIT D**  
**PATENTS RIGHTS**

**“Cellegy Patents”**

WO 99/24041 - Entitled ‘Penetration enhancing and irritation reducing systems, including improvements thereto, relating to the Licensed Product in the Field and Territory.

<b>Country</b>	<b>Application No.</b>	<b>Filing Date</b>	<b>Patent or Publication No.</b>	<b>Issue/Pub Date</b>	<b>Status</b>
Europe: AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE*	98956663.3	11/09/98	Pub. No. EP 1030668A1	Pub. 8/30/00	Pending
Norway	20002422	11/09/98	TBD	TBD	Pending
PCT	PCT/US98/23750	11/09/98	WO 99/24041	5/20/99	National Phase

**EXHIBIT E**  
**CELLEGY MARKS**

<b>Name</b>	<b>Status</b>	<b>Country</b>	<b>Registration Date</b>	<b>Renewal</b>
Tostrex	Registered as EU community mark	Austria	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Belgium	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Cyprus	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Czech Republic	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Denmark	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Estonia	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Finland	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	France	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Germany	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Greece	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Hungary	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Ireland	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Italy	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Latvia	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Liechtenstein	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Lithuania	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Luxemburg	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Malta	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Netherlands	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Norway	6/20/2003	1/21/2012

Name	Status	Country	Registration Date	Renewal
Tostrex	Registered as EU community mark	Poland	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Portugal	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Romania	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Slovak Republic	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Slovenia	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Spain	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	Sweden	6/20/2003	1/21/2012
Tostrex	Registered as EU community mark	United Kingdom	6/20/2003	1/21/2012
Tostrex	Registered	Switzerland	1/22/2002	1/22/2012
Tostrex	No application pending	Andorra	-	-
Tostrex	No application pending	Albania	-	-
Tostrex	No application pending	Bosnia-Herzegovina	-	-
Tostrex	No application pending	Bulgaria	-	-
Tostrex	No application pending	Croatia	-	-
Tostrex	No application pending	Gibraltar	-	-
Tostrex	No application pending	Republic of Yugoslavia	-	-
Tostrex	No application pending	Republic of Macedonia	-	-
Tostrex	No application pending	Monaco	-	-

Name	Status	Country	Registration Date	Renewal
Tostran	Registered as EU community mark	Austria	2/4/2004	5/102012
Tostran	Registered as EU community mark	Belgium	2/4/2004	5/102012

Name	Status	Country	Registration Date	Renewal
Tostran	Registered as EU community mark	Cyprus	2/4/2004	5/102012
Tostran	Registered as EU community mark	Czech Republic	2/4/2004	5/102012
Tostran	Registered as EU community mark	Denmark	2/4/2004	5/102012
Tostran	Registered as EU community mark	Estonia	2/4/2004	5/102012
Tostran	Registered as EU community mark	Finland	2/4/2004	5/102012
Tostran	Registered as EU community mark	France	2/4/2004	5/102012
Tostran	Registered as EU community mark	Germany	2/4/2004	5/102012
Tostran	Registered as EU community mark	Greece	2/4/2004	5/102012
Tostran	Registered as EU community mark	Hungary	2/4/2004	5/102012
Tostran	Registered as EU community mark	Ireland	2/4/2004	5/102012
Tostran	Registered as EU community mark	Italy	2/4/2004	5/102012
Tostran	Registered as EU community mark	Latvia	2/4/2004	5/102012
Tostran	Registered as EU community mark	Liechtenstein	2/4/2004	5/102012
Tostran	Registered as EU community mark	Lithuania	2/4/2004	5/102012
Tostran	Registered as EU community mark	Luxemburg	2/4/2004	5/102012
Tostran	Registered as EU community mark	Malta	2/4/2004	5/102012
Tostran	Registered as EU community mark	Netherlands	2/4/2004	5/102012
Tostran	Registered as EU community mark	Norway	2/4/2004	5/102012
Tostran	Registered as EU community mark	Poland	2/4/2004	5/102012
Tostran	Registered as EU community mark	Portugal	2/4/2004	5/102012
Tostran	Registered as EU community mark	Romania	2/4/2004	5/102012
Tostran	Registered as EU community mark	Slovak Republic	2/4/2004	5/102012
Tostran	Registered as EU community mark	Slovenia	2/4/2004	5/102012



Name	Status	Country	Registration Date	Renewal
Tostran	Registered as EU community mark	Spain	2/4/2004	5/102012
Tostran	Registered as EU community mark	Sweden	2/4/2004	5/102012
Tostran	Registered as EU community mark	United Kingdom	2/4/2004	5/102012
Tostran	Registered	Switzerland	9/3/2002	5/3/2012
Tostran	No application pending	Andorra	-	-
Tostran	No application pending	Albania	-	-
Tostran	No application pending	Bosnia-Herzegovina	-	-
Tostran	No application pending	Bulgaria	-	-
Tostran	No application pending	Croatia	-	-
Tostran	No application pending	Gibraltar	-	-
Tostran	No application pending	Republic of Yugoslavia	-	-
Tostran	No application pending	Republic of Macedonia	-	-
Tostran	No application pending	Monaco	-	-

Name	Status	Country	Registration Date	Renewal
Fortigel	Pending approval	Austria	4/28/2003	Unknown
Fortigel	Pending approval	Belgium	4/28/2003	Unknown
Fortigel	Pending approval	Cyprus	4/28/2003	Unknown
Fortigel	Pending approval	Czech Republic	4/28/2003	Unknown
Fortigel	Pending approval	Denmark	4/28/2003	Unknown
Fortigel	Pending approval	Estonia	4/28/2003	Unknown
Fortigel	Pending approval	Finland	4/28/2003	Unknown
Fortigel	Pending approval	France	4/28/2003	Unknown
Fortigel	Pending approval	Germany	4/28/2003	Unknown

Name	Status	Country	Registration Date	Renewal
Fortigel	Pending approval	Greece	4/28/2003	Unknown
Fortigel	Pending approval	Hungary	4/28/2003	Unknown
Fortigel	Pending approval	Ireland	4/28/2003	Unknown
Fortigel	Pending approval	Italy	4/28/2003	Unknown
Fortigel	Pending approval	Latvia	4/28/2003	Unknown
Fortigel	Pending approval	Liechtenstein	4/28/2003	Unknown
Fortigel	Pending approval	Lithuania	4/28/2003	Unknown
Fortigel	Pending approval	Luxemburg	4/28/2003	Unknown
Fortigel	Pending approval	Malta	4/28/2003	Unknown
Fortigel	Pending approval	Netherlands	4/28/2003	Unknown
Fortigel	Pending approval	Norway	4/28/2003	Unknown
Fortigel	Pending approval	Poland	4/28/2003	Unknown
Fortigel	Pending approval	Portugal	4/28/2003	Unknown
Fortigel	Pending approval	Romania	4/28/2003	Unknown
Fortigel	Pending approval	Slovak Republic	4/28/2003	Unknown
Fortigel	Pending approval	Slovenia	4/28/2003	Unknown
Fortigel	Pending approval	Spain	4/28/2003	Unknown
Fortigel	Pending approval	Sweden	4/28/2003	Unknown
Fortigel	Pending approval	United Kingdom	4/28/2003	Unknown
Fortigel	No application pending	Switzerland	-	-
Fortigel	No application pending	Andorra	-	-
Fortigel	No application pending	Albania	-	-
Fortigel	No application pending	Bosnia-Herzegovina	-	-
Fortigel	No application pending	Bulgaria	-	-

<b>Name</b>	<b>Status</b>	<b>Country</b>	<b>Registration Date</b>	<b>Renewal</b>
Fortigel	No application pending	Croatia	-	-
Fortigel	No application pending	Gibraltar	-	-
Fortigel	No application pending	Republic of Yugoslavia	-	-
Fortigel	No application pending	Republic of Macedonia	-	-
Fortigel	No application pending	Monaco	-	-

**EXHIBIT F**  
**STRAKAN GROUP LIMITED GUARANTEE**

ProStrakan Group plc (“**Group**”) hereby unconditionally guarantees and undertakes to Cellegy that Licensee will duly and punctually observe and perform all the undertakings, covenants and obligations of Licensee under this Agreement (including the payment of any damages becoming due to Cellegy as a result of any breach by Licensee of such undertakings, covenants and obligations) and under any agreements between the Parties (or any of them) which are expressly supplemental to this Agreement or which this Agreement requires to be executed (the “**Obligations**”) to the intent that if Licensee shall fail for whatever reason so to observe and perform any Obligations, Group shall be liable to perform the same in all respects as if Group was the party principally bound thereby in place of Licensee on demand from Cellegy.

**EXHIBIT G**

**ADVERSE EVENT REPORTING**

G

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**EXHIBIT 21**

**SUBSIDIARIES OF CELLEGY PHARMACEUTICALS, INC.**

Cellegy Australia Pty Ltd  
Australia

Cellegy Canada Inc.  
Canada

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 33-96384, 333-06065, 333-32301, 333-60343, 333-42840, 333-91588, 333-114229 and 333-121838), Form S-3 (Nos. 333-11457, 333-36057, 333-46087, 333-86193, 333-49466, 333-64864, 333-102485, 333-118841, 333-125787, 333-121836) and Form S-2 (No. 333-114247) of Cellegy Pharmaceuticals, Inc. of our report dated March 30, 2006 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

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Philadelphia, Pennsylvania

March 30, 2006

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**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 fiscal 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, 2006

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

## CERTIFICATION PURSUANT TO SECTION 302 OF THE

## SARBANES-OXLEY ACT OF 2002

I, Robert J. Caso, 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 fiscal quarter in the case of an annual report) that has materially effected, 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, 2006

By: /s/ Robert J. Caso  
Vice President, Finance and Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT**

The undersigned, Richard C. Williams, the Interim Chief Executive Officer of Cellegy Pharmaceuticals, Inc. (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2005 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) 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

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Richard C. Williams  
*Interim Chief Executive Officer*

Dated: March 30, 2006

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT**

The undersigned, Robert J. Caso, as Vice President, Finance and Chief Financial Officer of Cellegy Pharmaceuticals, Inc. (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2005 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ ROBERT J. CASO

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Robert J. Caso  
*Vice President and Chief Financial Officer*

Dated: March 30, 2006

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.

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