

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark one)

**Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the Fiscal Year Ended December 31, 2004**

OR

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Commission File Number 000-26372**

CELLEGY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

1000 Marina Boulevard, Suite 300, Brisbane, California 94005

(Address of Principal Executive Offices) (zip code)

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

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

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

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

Common Stock, \$0.0001 par value

(Title of class)

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

YES

NO

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

YES

NO

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

YES

NO

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

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

Documents Incorporated By Reference:

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

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

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

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

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

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

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

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

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

Products Under Development

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

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

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

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

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

Fortigel (testosterone replacement therapy for male hypogonadism)

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

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

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

Tostrelle (testosterone gel for female hormone replacement therapy)

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

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

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

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

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

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

There are currently no FDA approved drug therapies for anal fissures, although topical anesthetics and anti-inflammatory agents, which only partially relieve the symptoms of the condition, are currently prescribed. According to Verispan audits, anal fissures afflict an estimated 750,000 Americans, resulting in

over one million physician visits each year. The audit data for 2004 show about 75,000 annual uses of pharmacy-compounded nitroglycerin for the treatment of anal fissures.

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

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

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

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

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

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

Marketed Products

Rectogesic (nitroglycerin ointment for the treatment of anal fissures)

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

Skin Care

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

Marketing and Commercialization Strategy

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

- *Self-Marketing to Specialty Physicians in the United States.* If economically viable, we plan to self-market our products to a targeted audience of key physician specialists, including Gastroenterologists and Obstetrician-Gynecologists, through the establishment of our own sales force.
- *Outside the United States.* In most cases, we plan to out-license the overseas rights for the products we develop. During 2004 in two separate transactions, we out-licensed commercial rights to our Tostrex and Rectogesic products in Europe to ProStrakan Group Limited, a privately held specialty pharmaceutical company located in the United Kingdom with European-wide marketing capability.

- *Acquisition of Complementary Products and Companies.* We have successfully completed and integrated several acquisitions including: Biosyn, Inc. in October 2004; Vaxis Therapeutics Corporation in Canada in November 2001; Quay Pharmaceuticals Pty, Ltd. in Australia in June 2000; Neptune Pharmaceuticals in the United States in December 1997. We may selectively acquire other products, technologies or companies with products and distribution operations consistent with our commercial objectives and financial capability.
- *Manufacturing.* Cellegy has manufacturing arrangements with PendoPharm Inc., an FDA approved contract-manufacturing company based in Canada. PendoPharm, an affiliate of Pharmasciences, has successfully manufactured Cellegesic, Fortigel and Tostrelle for our clinical trials and will be the commercial manufacturer for these products. We are planning to validate a domestic contract manufacturer to serve as a second manufacturing source for our product candidates. Our products sold in Australia, New Zealand, Singapore and South Korea are currently supplied by a pharmaceutical manufacturer in Australia, and our skin care products are currently manufactured by a contractor in the United States.

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

Research Programs

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

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

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

Expanded expertise in nitric oxide pharmacology has led to an understanding of the role of nitric oxide as a signaling molecule, operating at lower concentrations than is normally required for vasodilators, especially in tissue under an abnormally vaso-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, male erectile dysfunction and selected aspects of female sexual dysfunction.

Patents and Trade Secrets

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

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

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

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

have been filed in countries of importance to us located in major world markets, including certain countries in Europe, Australia, South Korea, Japan, Mexico and Canada.

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

Product and Company Acquisitions

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

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

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

License Agreements

Cellegy

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

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

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

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

Biosyn

In October 1996, Biosyn acquired the C31G Technology from the entity that originally licensed the technology to Biosyn. As part of the agreement, Biosyn is required to make annual royalty payments equal to the sum of 1% of net product sales of up to \$100 million, 0.5% of the net product sales over \$100

million and 1% of any royalty payments received by Biosyn under license agreement. The term of the agreement lasts until December 31, 2011 or upon the expiration of the C31G Technology's patent protection, whichever is later. Biosyn's current C31G patents expire between 2006 and 2018.

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

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

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

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

Government Regulation

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

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

The results of preclinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA before commencement of human clinical trials. Clinical trials may begin 30 days after the IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. In some instances, the IND application process can result in substantial delay and expense. Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are concerned primarily with the safety and pharmacokinetics of the product. Phase 2 trials are designed primarily to demonstrative effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various dose and 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 a Special Protocol Assessment, can also provide specific written guidance on the acceptability of protocol designs for selected clinical trials.

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

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

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

regulatory approvals could have a material adverse effect on us. If we fail to comply with applicable regulatory requirements for marketing drugs, we could be subject to administrative or judicially imposed sanctions such as warning letters, fines, product recalls or seizures, injunctions against production, distribution, sales, or marketing, delays in obtaining marketing authorizations or the refusal of the government to grant such approvals, suspensions and withdrawals of previously granted approvals, civil penalties and criminal prosecution of Cellegy, our officers or our employees.

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

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

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

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

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

Competition

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

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

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

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

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

Employees

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

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

Available Information

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

ITEM 2: PROPERTIES

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

ITEM 3: LEGAL PROCEEDINGS

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

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

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

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

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

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

ITEM 4A: EXECUTIVE OFFICERS OF THE REGISTRANT

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

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

John J. Chandler. Mr. Chandler became Vice President, Corporate Development in May 1998. From January 1995 to March 1998, he served as Vice President, Europe for the Medical Device Division of American Home Products, now Wyeth. During 1994, he was Area Director, Europe/Latin America for

Wyeth. From 1968 to 1993, he held a series of management and senior management positions with American Cyanamid Company. Mr. Chandler holds an M.B.A. in Marketing from Seton Hall University and a B.S. in Biology from the Queens College of the City University of New York.

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

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

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

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

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

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PART II

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

Price Range of Common Stock

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

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

Holders

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

Dividend Policy

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

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

Recent Sales of Unregistered Securities

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

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

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

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

ITEM 6: SELECTED FINANCIAL DATA

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

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

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

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

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

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

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

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

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

General

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

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

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

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

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

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

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

Critical Accounting Policies and Estimates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Results of Operations

Years Ended December 31, 2004, 2003 and 2002

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

seek to commercialize internally or to reduce resources devoted to product development. In addition, if we do not receive all, or a portion, of the planned Biosyn grant funding, or if such funding is delayed, this could impact our ability to complete our Biosyn development programs on a timely basis, if at all. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect 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.

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

Contractual Obligations

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

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

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

Other obligations not reflected in the table are comprised primarily of employment agreements, license agreements and the fair value of an obligation to a non-profit economic development corporation pursuant to the acquisition of Biosyn. Severance payments of \$597,000 and other healthcare cost reimbursements will be made to Cellegy's former Chief Executive Officer over an 18-month period ending in June 2006. License agreements generally provide for payment by us of annual license fees, milestones payments and royalties upon successful commercialization of products. The note repayment obligation is a non-interest bearing obligation with terms to remit an annual fixed percentage of 3% applied to future revenues of Biosyn if any, until the

principle balance of \$777,902 is satisfied. Under the terms of the obligation, “revenues” are defined to exclude the value of unrestricted research and development funding received by Biosyn from non-profit sources. There is no obligation to make payments in the absence of

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

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

Recent Accounting Pronouncements

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

Factors That May Affect Future Operating Results

Risks Relating to Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- have staffing difficulties;

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

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

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

We have incurred losses since our inception and negative cash flows from operations that raise substantial doubt about our ability to continue as a going concern. Our accumulated deficit as of December 31, 2004, was approximately \$127.3 million. We have never operated profitably and, given our planned level of operating expenses, we expect to continue to incur losses through at least 2006. We plan to devote significant resources to pre-clinical studies, clinical trials, administrative, marketing, sales and patent activities. Accordingly, without substantial revenues from new corporate collaborations, royalties on product

sales or other revenue sources, we expect to incur substantial operating losses in the foreseeable future as our potential products move through development and as we continue to invest in research and clinical trials. As a result of our continuing losses, we may exhaust our resources and may be unable to complete the development of our products, and our accumulated deficit will continue to increase as we continue to incur losses. Our losses may increase in the future, and even if we achieve our revenue targets, we may not be able to sustain or increase profitability on a quarterly or annual basis. The amount of future net losses, and the time required to reach profitability, are both highly uncertain. To achieve sustained profitable operations, we must, among other things, successfully discover, develop, and obtain regulatory approvals for and market pharmaceutical products. We cannot assure you that we will ever be able to achieve or sustain profitability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product sales strategy involving corporate partners is highly uncertain.

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

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

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

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

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

assurance that we will be able to enter into acceptable agreements with them or validate facilities successfully on a timely basis. This is an expensive and time-consuming process and there may be delays and additional costs relating to the technical transfer and validation of alternate suppliers. In the future, we may

not be able to obtain contract manufacturing on commercially acceptable terms for compounds or product formulations in the quantities we need. Manufacturing or quality control problems, lack of financial resources or qualified personnel could occur with our contract manufacturers causing product shipment delays, inadequate supply, or causing the contractor not to be able to maintain compliance with the FDA's current good manufacturing practice requirements necessary to continue manufacturing. Such problems could limit our ability to produce clinical or commercial product, cause us to be in breach of contract obligations with our distributors to supply product to them, reduce our revenues from product sales, and otherwise adversely affect our business and stock price.

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

We have limited sales and marketing experience.

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

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

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

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

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

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

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

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

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

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

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

Our success is dependent upon the efforts of a small management team and staff. We have compensation or employment arrangements and a severance/retention plan in place with all of our executive officers, but none of our executive officers is legally bound to remain employed for any specific

term. Our key personnel include Richard C. Williams, our Chairman and Interim Chief Executive Officer, and Anne-Marie Corner, Senior Vice President, Women's Preventive Health. Mr. Williams has a written arrangement describing his compensation and we have a written employment agreement with Ms. Corner.

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

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

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

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

Risks Relating to Our Industry

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

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

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

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

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

We are subject to the risk of product liability lawsuits.

The testing, marketing and sale of human health care products entails an inherent risk of allegations of product liability. We are subject to the risk that substantial product liability claims could be asserted against us in the future. Cellegy has obtained insurance coverage relating to our clinical trials in an aggregate amount of \$5 million and an aggregate amount of \$7 million relating to the clinical trials relating to products acquired from Biosyn. If any of our product candidates are approved for marketing, we may seek additional coverage. There can be no assurance that Cellegy will be able to obtain or maintain insurance on acceptable terms, particularly in overseas locations, for clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities. Moreover, our current and future coverages may not be adequate to protect us from all of the liabilities that we may

incur. If losses from product liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. In addition, a product liability action against us would be expensive and time-consuming to defend, even if we ultimately prevailed. If we are required to pay a product liability claim, we may not have sufficient financial resources and our business and results of operations may be harmed.

Risks Relating to Our Stock

Our stock price could be volatile.

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

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

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

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

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

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

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

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

Cellegy's common stock is currently listed on the Nasdaq National Market. There are several requirements for the continued listing of our common stock on the Nasdaq National Market, including requirements relating to stock price, stockholders' equity and compliance with certain financial standards. If we fail

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

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

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

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

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

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

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

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

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A: CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

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

(b) Changes in Internal Controls

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

ITEM 9B: OTHER INFORMATION

None.

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PART III

ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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

ITEM 11: EXECUTIVE COMPENSATION

Information with respect to this Item may be found in the section captioned "Executive Compensation" appearing in the forthcoming 2005 Proxy Statement and is incorporated herein by reference.

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

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

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

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PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibits

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

<u>Exhibit Number</u>	<u>Exhibit Title</u>
2.1	Asset Purchase Agreement dated December 31, 1997 between the Company and Neptune Pharmaceutical Corporation. (Confidential treatment has been granted with respect to portions of this agreement.) (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-3, file no. 333-46087, filed on February 11, 1998, as amended.)
2.2	Agreement and Plan of Share Exchange dated as of October 7, 2004, by and between the Company and Biosyn, Inc. (Incorporated by reference to Exhibit 2.1 to the Form 8-K filed October 26, 2004.)
3.1	Amended and Restated Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 8-K filed with the Commission on September 3, 2004 (the "September 2004 8-K").)
3.2	Bylaws of the Company. (Incorporated by reference to Exhibit 3.2 to the September 2004 8-K.)
4.1	Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.1 to the September 2004 8-K.)
*10.1	1995 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.03 to the Company's Registration Statement on Form S-8, file no. 333-91588, filed on June 28, 2002.)
*10.2	Form of Option Agreement under the 1995 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.05 to the Company's Post-effective Amendment No. 1 to Registration Statement on Form S-8,

- file no. 333-91588, filed on September 7, 2004 (the "2004 Form S-8").)
- *10.3 1995 Directors' Stock Option Plan. (Incorporated by reference to Exhibit 10.8 to the Company's Form 10-Q for the fiscal quarter ended filed June 30, 2002.)
 - *10.4 Form of option agreement under the 1995 Directors' Stock Option Plan. (Incorporated by reference to Exhibit 4.07 to the 2004 Form S-8.)
 - 10.5 Sublease Agreement, dated as of March 18, 2005, by and between the Company and VaxGen, Inc.
 - *10.6 Employment Agreement, effective January 1, 2003, between the Company and K. Michael Forrest. (Incorporated by reference to Exhibit 10.6 to the Annual Report on Form 10-K for the year ended December 31, 2003 (the "2003 Form 10-K".))
 - 10.7 Share Purchase Agreement dated as of November 27, 2001, by and among the Company, Vaxis Therapeutics Corporation and certain stockholders of Vaxis. (Incorporated by reference to Exhibit 10.14 to the Company's Form 10-K for the fiscal year ended December 31, 2001.)
 - 10.8 Exclusive License Agreement dated as of December 31, 2002, by and between the Company and PDI, Inc. (Confidential treatment has been requested with respect to portions of this agreement.) (Incorporated herein by reference to Exhibit 10.10 to the Company's Form 10-K for the year ended December 31, 2002.)
 - 10.9 Common Stock Purchase Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited. (Incorporated by reference to Exhibit 10.9 to the 2003 Form 10-K.)
 - 10.10 Registration Rights Agreement dated January 16, 2004 between Cellegy Pharmaceuticals, Inc. and Kingsbridge Capital Limited. (Incorporated by reference to Exhibit 10.10 to the 2003 Form 10-K.)
 - 10.11 Warrant dated January 16, 2004 issued to Kingsbridge Capital Limited. (Incorporated by reference to Exhibit 10.11 to the 2003 Form 10-K.)

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

* Represents a management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Brisbane, State of California, on the 30 of March, 2005.

CELLEGY PHARMACEUTICALS, INC.

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

Power of Attorney

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

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

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

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Report of Independent Registered Public Accounting Firm

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

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

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

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

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
 Cellegy Pharmaceuticals, Inc.

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

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

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

/s/ Ernst & Young LLP

Palo Alto, California
 February 13, 2003

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

	December 31,	
	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,705,120	\$ 7,649,878
Short-term investments	—	3,686,919
Accounts receivable	885,810	158,476
Prepaid expenses and other current assets	282,184	349,647
Total current assets	9,873,114	11,844,920
Restricted cash	227,500	227,500
Property and equipment, net	1,952,408	1,891,726
Goodwill	1,031,311	1,009,973
Intangible assets	778,992	256,688
Other assets	—	100,000
Total assets	<u>\$ 13,863,325</u>	<u>\$ 15,330,807</u>

Liabilities and Stockholders' Deficit

Current liabilities:		
Accounts payable	\$ 1,691,952	\$ 779,796
Accrued expenses and other current liabilities	2,724,808	1,240,250
Current portion of deferred revenue	1,196,260	832,000
Total current liabilities	5,613,020	2,852,046
Long-term payables	717,257	724,560
Derivative instrument	410,800	—
Deferred revenue	13,865,064	13,334,660
Total liabilities	20,606,141	16,911,266
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock, no par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2004 and 2003	—	—
Common stock, par value \$.0001; 50,000,000 shares authorized; 26,120,440 shares issued and outstanding at December 31, 2004; 20,045,000 shares issued and outstanding at December 31, 2003	2,612	97,293,984
Additional paid-in capital	120,253,688	—
Accumulated other comprehensive income	304,244	274,855
Deficit accumulated during the development stage	(127,303,360)	(99,149,298)
Total stockholders' deficit	(6,742,816)	(1,580,459)
Total liabilities and stockholders' deficit	\$ 13,863,325	\$ 15,330,807

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)
Consolidated Statements of Operations

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

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)
Consolidated Statements of Stockholders' Equity (Deficit)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Issuance of convertible preferred stock, net of issuance cost through December 31, 2001	27,649	\$ 6,801,730	—	\$ —	477,081	\$ 4,978,505	—	\$ —	—	\$ —	\$ —	\$ 11,780,235
Issuance of Series A convertible preferred stock and warrants to purchase 14,191 shares of Series A convertible preferred stock in exchange for convertible promissory notes and accrued interest through December 31, 2001	625,845	1,199,536	—	—	—	—	—	—	—	—	—	1,199,536
Issuance of convertible preferred stock for services rendered, and license agreement through December 31, 2001.	50,110	173,198	—	—	—	—	—	—	—	—	—	173,198
Issuance of Series B convertible preferred stock in exchange for convertible promissory notes	—	—	12,750	114,000	—	—	—	—	—	—	—	114,000
Non-cash preferred dividends	—	1,448,505	—	—	—	—	—	—	—	—	(1,448,505)	—
Conversion of preferred stock including dividends to common stock through December 31, 2001	(703,604)	(9,622,969)	(12,750)	(114,000)	(477,081)	(4,978,505)	3,014,644	14,715,474	—	—	—	—
Issuance of warrants in 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.
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Cellegy Pharmaceuticals, Inc.
(a development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)

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

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)

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

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)

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

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

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

Net increase (decrease) in cash and cash equivalents.	1,055,242	(13,978,639)	15,833,139	8,705,120
Cash and cash equivalents, beginning of period.	7,649,878	21,628,517	5,795,378	—
Cash and cash equivalents, end of period	\$ 8,705,120	\$ 7,649,878	\$ 21,628,517	\$ 8,705,120

The accompanying notes are an integral part of these financial statements

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Cellegy Pharmaceuticals, Inc.
(a development stage company)
Consolidated Statements of Cash Flows (Continued)

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

The accompanying notes are an integral part of these financial statements

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Cellegy Pharmaceuticals, Inc.
(a development stage company)
Notes to Consolidated Financial Statements

1. Accounting Policies

Description of Business and Principles of Consolidation

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

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

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

Liquidity and Capital Resources

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

1. Accounting Policies (Continued)

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

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

Use of Estimates

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

Revenue Recognition

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

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

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

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

1. Accounting Policies (Continued)

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

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

Research and Development

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

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

Cash and Cash Equivalents

Cash and cash equivalents consist of demand deposits and highly liquid financial instruments with original maturities of three months or less. The carrying value of cash and cash equivalents approximates fair value at December 31, 2004 and 2003. The Company's cash and cash equivalents are maintained at three financial institutions in the United States, one financial institution in Australia and one financial institution in Canada. Deposits in these financial institutions may, from time to time, exceed federally insured limits.

Short Term Investments

The Company considers all of its investments as available-for-sale securities and reports these investments at their estimated fair market value using available market information. Unrealized gains or losses on available-for-sale securities are included in stockholders' deficit as other comprehensive income

(loss) until their disposition. The cost of securities sold is based on the specific identification method.

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

Restricted Cash

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

Concentration of Credit Risk

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

1. Accounting Policies (Continued)

Property and Equipment

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

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

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

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

Impairment of Long Lived Assets

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

1. Accounting Policies (Continued)

Derivative Instruments

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

response to changes in the Company's stock price. Significant increases in the fair value of the Company's stock could give rise to significant expense in the period of the change. Likewise, a reduction in the Company's stock price could give rise to significant income in the period of the change (see Note 8).

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

Reclassification

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

Foreign Currency Translation

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

Comprehensive Income (Loss)

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

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

1. Accounting Policies (Continued)

Stock-Based Compensation

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

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

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

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

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

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

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling,

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

1. Accounting Policies (Continued)

Recent Accounting Pronouncement

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

Basic and Diluted Net Loss per Common Share

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

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

2. Accounts Receivable

Accounts receivable consists of the following:

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

3. Short-term Investments

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

	2003		
	Cost	Gross Unrealized Gains	Fair Value
Corporate notes	<u>\$ 3,686,800</u>	<u>\$ 119</u>	<u>\$ 3,686,919</u>

4. Intangible Assets, net

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

	December 31, 2004			December 31, 2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Capitalized non-compete	\$ 463,544	\$(293,578)	\$ 169,966	\$ 400,280	\$(143,592)	\$ 256,688

agreement with Vaxis						
Capitalized workforce—						
Biosyn acquisition	635,504	(26,478)	609,026	—	—	—
	<u>\$1,099,048</u>	<u>\$(320,056)</u>	<u>\$ 778,992</u>	<u>\$ 400,280</u>	<u>\$(143,592)</u>	<u>\$ 256,688</u>

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

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

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

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

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

5. Property and Equipment, net

Property and equipment, net consist of the following:

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

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

6. Long-Term Payables

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

7. Accrued Expenses and Other Current Liabilities

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

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

8. Derivative Instrument

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

9. Deferred Revenue

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

10. Commitments and Contingencies

Operating Leases

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

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

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

10. Commitments and Contingencies (Continued)

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

Capital Leases

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

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

Other Agreements

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

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

Legal Proceedings

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

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

10. Commitments and Contingencies (Continued)

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

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

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

11. 401(k) Plan

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

12. Acquisitions

Biosyn Acquisition

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

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

12. Acquisitions (Continued)

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

The purchase price is as follows:

Issuance of Cellegy common stock	\$ 10,478,000
Value of replacement options and warrants to acquire Cellegy common stock	968,000
Transaction costs	410,000
Total purchase price	<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	(135,000)
Net assets	<u>\$ 11,856,000</u>

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

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

12. Acquisitions (Continued)

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

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

Under the income approach, value is based on the calculation of the present value of future economic benefits to be derived from the ownership of the assets, analyzing the earnings potential of the in-process development programs while factoring in the underlying risk associated with obtaining those earnings. Value indications were developed by discounting future net cash flows to their present value using market-based rates of return. For C31G, discount rates ranging from 34% - 37% were applied to cash flows with an additional approximate 52% probability applied to the cash flows representing, for purposes of this valuation, the estimated probability of the C31G Phase 3 trials 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.

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

12. Acquisitions (Continued)

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

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

13. License and Other Agreements

Cellegy

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

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

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

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

13. License and Other Agreements (Continued)

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

Biosyn

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

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

In May 2001, Biosyn entered into an exclusive license agreement with Crompton Corporation under which Biosyn obtained the rights to develop and commercialize UC-781, a non-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.

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

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

13. License and Other Agreements (Continued)

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

14. Stockholders' Equity (Deficit)

Common Stock Private Placements

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

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

Delaware Reincorporation

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

Preferred Stock

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

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

14. Stockholders' Equity (Deficit) (Continued)

Stock Option Plans

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

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

Equity Incentive Plan

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

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

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

14. Stockholders' Equity (Deficit) (Continued)

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

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

Director's Stock Option Plan

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

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

Activity under the Directors' Plan is summarized as follows:

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

14. Stockholders' Equity (Deficit) (Continued)

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

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
\$2.56 - \$3.25	35,000	4.5 years	\$ 2.62	32,334	\$ 2.62
\$4.30 - \$5.50	254,500	4.8 years	\$ 4.90	198,500	\$ 5.04
\$6.50 - \$8.50	18,000	3.6 years	\$ 6.72	18,000	\$ 6.72
Total	<u>307,500</u>	4.7 years	\$ 4.74	<u>248,834</u>	\$ 4.85

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

Non-Plan Options

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

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

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

14. Stockholders' Equity (Deficit) (Continued)

Shares reserved

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

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

Warrants

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

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

Non-cash Compensation Expense Related to Stock Options

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

15. Income Taxes

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

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Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

15. Income Taxes (Continued)

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

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

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

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

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

16. Segment Reporting

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

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16. Segment Reporting (Continued)

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

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

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

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

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

Total assets were minimal for the skin care segment.

Revenue from Major Customer

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

Geographic data

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

Cellegy Pharmaceuticals, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)**17. Related Party Transactions**

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

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

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

18. Subsequent Events

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

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

19. Quarterly Financial Data**(Unaudited)**

	2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(Amounts in thousands, except per share data)			
Revenues	\$ 338	\$ 430	\$ 483	\$ 1,345
Operating loss	(3,245)	(2,837)	(3,194)	(19,498)
Net loss.	(3,058)	(2,708)	(3,143)	(19,245)

Basic and diluted net loss per common share \$ (0.15) \$ (0.13) \$ (0.14) \$ (0.76)

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

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

SUBLEASE

Sublessor: VAXGEN, INC.,
a Delaware corporation

Sublessee: CELLEGY PHARMACEUTICALS, INC.,
a Delaware corporation

Premises
Located at: 1000 Marina Blvd., Ste. 300
Brisbane, California

SUBLEASE AGREEMENT

THIS SUBLEASE AGREEMENT ("Sublease") is entered into effective as of this 18th day of March, 2005, by and between VAXGEN, INC., a Delaware corporation ("Sublessor") and CELLEGY PHARMACEUTICALS, INC., a Delaware corporation ("Sublessee").

RECITALS

- A. Sublessor is presently the lessee of the Master Premises pursuant to the Master Lease. Sublessee has received a copy of the Master Lease.
- B. Sublessor desires to sublease a portion of the Master Premises to Sublessee and Sublessee desires to sublease such portion of the Master Premises from Sublessor pursuant to the terms, covenants and conditions set forth below.
- C. Except as expressly set forth below, all capitalized terms used below without definition shall be as defined in the Basic Sublease Information section.

AGREEMENT

NOW, THEREFORE, FOR GOOD AND VALUABLE CONSIDERATION, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1 **Basic Sublease Information.** The information set forth in this Section (the "Basic Sublease Information") is intended to supplement and/or summarize the provisions set forth in the balance of this Sublease. Each reference in this Sublease to any of the terms set forth below shall mean the respective information set forth next to such term as amplified, construed or supplemented by the particular section(s) of the Sublease pertaining to such information. In the event of a conflict between the provisions of this Section and the balance of the Sublease, the balance of the Sublease shall control.

Sublessor: VAXGEN, INC., a Delaware corporation

Sublessee: CELLEGY PHARMACEUTICALS, INC., a Delaware corporation

Sublessee's
Tax ID No.: 82-0429727

Sublessor's
Address: VaxGen, Inc.
1000 Marina Blvd.
Suite 200
Brisbane, California 94005
Attn: Joseph D. Robinson
Associate Director, Administration
Tel: (650) 624-1000

Sublessee's
Address: 1000 Marina Blvd.
Suite 300
Brisbane, California 94005
Attn: Phyllis Kimmel
Tel: (650) 616-2208

Master Lease: That certain Lease dated May 20, 1998, by and between Master Lessor and Sublessor, as the same has been amended from time to time prior to the date hereof.

Master Lessor: Equity Office Properties

Land: The land upon which the Building and all Common Areas are situated.

Building: That certain building located on the Land, generally known as 1000 Marina Blvd., Brisbane, California, together with related improvements.

Project: The Building and the Land and all Common Areas, known as Sierra Point 1000 Marina.

Master Premises: The premises leased by Sublessor under the Master Lease, together with all appurtenances thereto.

Premises: Suite 300, consisting of approximately 5,751 rentable square feet on the third (3rd) floor of the Building, as more particularly described on Exhibit A hereto.

Parking Rights: Eighteen (18) surface parking spaces. Parking privileges are appurtenant to the Sublease and may not be assigned or sublet.

Common Areas: All areas of the Building and the Land reserved for the joint use of all tenants and occupants of the Building pursuant to the Master Lease, including surface parking areas.

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Permitted Uses: General office purposes.

Monthly Base Rent: One Dollar (\$1.00) per month, increasing to the amount of the Holdover Rent (below) on March 1, 2006.

Security Deposit: \$10,000.00, due on execution of this Sublease.

Holdover Rent: \$17,253.00 per month [\$3.00/RSF].

Term: Term Commencement Date to Expiration Date.

Term Commencement Date: March 10, 2005.

Delivery Date: The date on which Master Lessor's consent to this Sublease has been obtained in accordance with Section 2.3.

Expiration Date: February 28, 2006, subject to Section 4.2 below.

Rent Commencement Date: Delivery Date.

Option to Extend: None.

Brokers: None.

Legal Requirements: All applicable federal, state and local laws, statutes, codes, acts, ordinances, directions, rules, regulations and requirements, including, without limitation, local and state building, electrical, mechanical, seismic, and fire and safety codes, which apply to the Premises or the use or occupancy thereof. Legal Requirements shall include the Americans with Disabilities Act of 1990, 42 U.S.C. §12101 et seq. and Title 24 of the California Department of Rehabilitation Access Code (and related statutes and regulations), and all Environmental Requirements.

Environmental Requirements: All applicable present and future statutes, regulations, rules, ordinances, codes and orders of all governmental agencies, departments, commissions, boards, bureaus or instrumentalities of the United States, the State of California and political subdivisions thereof, and all applicable judicial and administrative and regulatory decrees, judgments and orders, relating to hazardous materials

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(including the reporting, licensing, permitting, investigation and remediation of emissions, discharges, releases or threatened releases of hazardous materials, whether into the air, surface water, groundwater or land, and including the manufacture, processing, distribution, use, treatment, storage, disposal, transport and handling of hazardous materials) or the protection of human health or the environment.

2 Sublease.

2.1 Premises. Sublessor hereby subleases the Premises to Sublessee, and Sublessee hereby subleases the Premises from Sublessor, upon all of the terms, covenants and conditions in this Sublease. On the Delivery Date: (i) the Premises shall be delivered to Sublessee in broom clean condition; and (ii) subject to Sections 2.2 and 2.6 below, the Premises shall be accepted by Sublessee in its "as is" condition. Notwithstanding that the square footage of the Premises is approximate, Base Rent shall not be subject to adjustment by reason of subsequent recalculations of the area of the Premises.

2.2 Sublessor's Work. As soon as practicable following the Delivery Date, and with due regard to causing the least interference with Sublessee's use and occupancy of the Premises, Sublessor shall commence, and complete as expeditiously as practicable, the work within the Premises generally described in Exhibit B, attached hereto (hereinafter, "Sublessor's Work"). Sublessee hereby acknowledges and agrees that neither the commencement nor completion of Sublessor's Work shall have any bearing on the Term nor the Delivery Date.

2.3 Condition Precedent — Master Lessor's Consent. This Sublease is conditioned upon Master Lessor's written approval of this Sublease, if required under the terms of the Master Lease. If such consent is required and for any reason Master Lessor does not consent to this Sublease within the thirty (30) days after the full execution of this Sublease, then this Sublease shall terminate. In the event of any such termination, Sublessor shall return to Sublessee any prepaid rentals and the Security Deposit, and thereupon all rights and obligations of the parties under this Sublease shall cease and terminate, other than Sublessee's indemnity obligations under Section 17. Sublessee shall not occupy or take possession of the Premises, or commence any construction of improvements or alterations therein, until Master Lessor's consent to this Sublease has been obtained in accordance with this Section 2.3.

2.4 Sublease Subject to Master Lease. This Sublease is and shall be at all times subject to all of the terms, covenants and conditions of the Master Lease and shall in all respects be limited and construed in a fashion consistent with the estate granted to Sublessor by Master Lessor pursuant to the Master Lease. Without limiting the generality of the foregoing, Sublessee acknowledges that Master Lessor has reserved rights of entry and inspection that may be greater than those reserved to Sublessor hereunder; that all improvements and alterations made to the Premises may become the property of Master Lessor on surrender of the Premises by Sublessee; that Master Lessor's consent may be required for any assignment of this Sublease or any

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subletting of the Premises by Sublessee; that Master Lessor has reserved the right to discharge liens against the Premises caused by Sublessee or persons acting on Sublessee's behalf and to thereafter sue to collect the same; that Master Lessor's consent may be required under various circumstances in addition to or in lieu of any consent required from Sublessor; that Sublessee's subleasehold estate may be subordinate to liens or encumbrances of Master Lessor; that use of the Premises may be restricted by the Master Lease to a greater degree than by this Sublease; and that Master Lessor may have the option of terminating this Sublease or assuming Sublessor's rights and obligations hereunder upon a cancellation of the Master Lease. Sublessee shall not commit or permit to be committed any act or omission within the Premises, the Building, the Land or Common Areas which shall violate any terms, covenants or conditions of the Master Lease. Each party agrees that it shall promptly forward to the other party any and all notices or other communications received with regard to the Premises by the first party from the Master Lessor under the Master Lease. In the event that the Master Lease shall terminate for any reason, this Sublease shall also terminate and, unless the termination was the fault of Sublessor, the parties hereunder shall have no further obligations or liabilities to each other; provided that any such termination shall not impair the rights of Sublessor under Section 17 hereof. Where any approval or consent of Master Lessor under the Master Lease shall be required for any act of Sublessee hereunder, obtaining the approval or consent of the Master Lessor shall be a condition to the right of Sublessee to undertake such act hereunder. Sublessee acknowledges that it shall have no rights to purchase the Premises, to cancel the Master Lease or to extend the term of the Master Lease pursuant to any such provisions contained in the Master Lease.

2.5 Sublessor's Responsibilities Regarding Master Lease. The parties understand and acknowledge that because Sublessee is not in privity of contract with Master Lessor, Sublessee is dependent upon Sublessor's exercise of its rights and remedies against Master Lessor in order to ensure that Sublessee will obtain the services, utilities and other amenities contemplated under this Sublease and for full use and enjoyment of the Premises. Sublessor hereby covenants and agrees that: (a) it shall not amend the Master Lease in any manner as to adversely affect Sublessee's use or occupancy of the Premises, or its obligations hereunder, without Sublessee's prior written consent; (b) Sublessor shall not agree to any termination of the Master Lease without the prior consent of Sublessee (except as otherwise provided in Sections 14.1 and 15.1); (c) Sublessor shall observe and perform all its obligations as tenant under the Master Lease, subject to Sublessee's performance of its obligations under this Sublease; and (d) Sublessor shall act reasonably and diligently to enforce Master Lessor's compliance with all terms and conditions of the Master Lease as they affect the Premises, and shall cooperate with Sublessee in connection with its obtaining, for the benefit of the Premises and Sublessee, all services, utilities and amenities to be provided by the Master Lessor under the Master Lease; provided, that the foregoing shall not require Sublessor to commence any legal proceedings (including arbitration) against Master Lessor unless all costs associated therewith are paid or reimbursed by Sublessee (but such costs shall be reimbursed to Sublessee from any damages obtained from Master Lessor).

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2.6 Other Improvements. Sublessee acknowledges and agrees that, apart from Sublessor's Work described above in Section 2.2, Sublessee shall be solely responsible for the design and construction (and the payment therefor) of any and all improvements and alterations desired by or required of Sublessee ("Leasehold Improvements"). In connection with any Leasehold Improvements not a part of Sublessor's Work, Sublessee agrees that it shall construct all such Leasehold Improvements in accordance with the further terms of this Sublease and with adherence in all material respects to the plans and specifications therefor, which plans and specifications shall be prepared by Sublessee at its sole cost and expense and shall be subject to (i) Master Lessor's prior written approval, if and to the extent so required under the Master Lease, and (ii) Sublessor's prior written approval, which approval of Sublessor shall not be unreasonably withheld, conditioned or delayed (it being understood and agreed, however, that whether or not Sublessor's approval is required, Sublessee shall nevertheless submit its plans and specifications (and evidence of Master Lessor's consent thereto) to Sublessor prior to commencing any work of improvement to the Premises, and that: (i) Sublessor may, promptly after it receives the foregoing, impose the requirement that Sublessee remove all or specifically-identified portions of Leasehold Improvements upon the expiration or earlier termination of this Sublease; and (ii) even where Sublessor's consent is not required, Sublessor may nevertheless disapprove any specific work contemplated by Sublessee's plans that would interfere with or damage Sublessor's existing cabling and related equipment located in the Premises).

3 Condition of Premises.

3.1 Sublessee's Inspection of Premises. As of the date of this Sublease, Sublessee acknowledges that Sublessee has conducted or has had the opportunity to conduct a comprehensive investigation ("Due Diligence Investigation") of the Premises and all other matters which in Sublessee's judgment may affect the value or suitability of the Premises for Sublessee's purposes or which may influence Sublessee's willingness to enter this Sublease, including, without limitation, (i) the size and configuration of the Premises, the Building, the Common Areas and the Land, including without limitation, access, parking, location or accessibility of utilities, (ii) the condition of the Premises, the Building, the Land and the Common Areas (and all improvements located in or upon the Common Areas), (iii) the existence of any hazardous materials, (iv) soil or topographical conditions and earthquake preparedness; (v) the Master Lease; (vi) title matters; (vii) taxes, (viii) expense data, (ix) insurance costs, (x) permissible uses and zoning or development entitlements; (xi) any applicable covenants, conditions and restrictions; and (xii) compliance with any federal, state or local law, statute, rule or regulation now or hereafter in effect

(including without limitation the Americans With Disabilities Act of 1990, 42 U.S.C. §12101 et seq. and Title 24 of the California Department of Rehabilitation Access Code and related statutes and regulations).

3.2 No Representations and Warranties. Sublessee acknowledges that Sublessor would not sublease the Premises except on an “as is” basis (apart from Sublessor’s Work), and agrees that: (i) subject to Sections 2.2 and 2.6 above, Sublessee accepts the Premises “as is” and with all faults; (ii) neither Sublessor nor any

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of its officers, agents, employees or representatives has made any representations or warranties of any kind or nature, whether express or implied, with respect to the Premises or the balance of the Project, or any of the matters relating thereto (including without limitation the matters referred to in Section 3.1 above), except as otherwise expressly provided in this Sublease; (iii) Sublessor has no duty to make any disclosures concerning the condition of the Premises or the balance of the Project and/or the fitness of the Premises for Sublessee’s intended use, and Sublessee expressly waives any duty which Sublessor might have to make any such disclosures, except as otherwise expressly provided in this Sublease; (iv) Sublessee is relying on Sublessee’s own familiarity with the Premises, the Building, the Common Areas and the Land as described in Section 3.1, together with such further investigations as Sublessee has deemed appropriate, in Sublessee’s sole discretion; (v) except as otherwise provided in Section 2.2 above, neither Sublessor nor Master Lessor (except as expressly provided in the Master Lease) shall be required to perform any work of construction, alteration, repair or maintenance of or to the Premises or the balance of the Project; and (vi) in the event Sublessee subleases all or any portion of the Premises or assigns its interest in this Sublease, Sublessee shall indemnify and defend Sublessor (in accordance with Section 17 below) for, from and against any matters which arise as a result of Sublessee’s failure to disclose any relevant information about the Premises to any subtenant or assignee of Sublessee. If Sublessor obtains or has obtained or provides to Sublessee any services, opinions, or work product of surveyors, architects, soil engineers, environmental auditors, engineers, title insurance companies, governmental authorities or any other person or entity with respect to the Premises or the balance of the Project, Sublessee and Sublessor agree that Sublessor does so only for the convenience of the parties, Sublessor does not vouch for the accuracy or completeness of any such items and the reliance of Sublessee upon any such items shall not create or give rise to any liability of or against Sublessor; provided, however, that Sublessor does hereby represent that, to its current actual knowledge without independent investigation, none of the foregoing documents, materials or reports provided by Sublessor to Sublessee concerning the Premises or the Building contains any material inaccuracy that has not been disclosed to Sublessee.

3.3 Release. Except for the obligations arising under this Sublease and arising by law in connection with this Sublease, Sublessee hereby fully releases and discharges Sublessor, and its officers, directors, employees and agents, from and relinquishes all rights, claims and actions that Sublessee may have against Sublessor, or its officers, directors, employees or agents, which arise out of or are in any way connected with the Premises or the balance of the Project, or any matters related thereto, including but not limited to the matters referred to in Section 3.1 above. This release applies to all described rights, claims, and actions, whether known or unknown, foreseen or unforeseen, present or future. Sublessee specifically waives application of California Civil Code §1542, which provides as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor.

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4 Term.

4.1 Term. The Term of this Sublease shall commence on the Commencement Date specified in the Basic Sublease Information, and subject to Section 4.2 below, shall expire on the Expiration Date specified in the Basic Sublease Information. All obligations of Sublessee hereunder shall commence on the Term Commencement Date. It is expressly understood and agreed that the Base Rent specified in the Basic Sublease Information has been agreed upon based upon a nominal Term of twelve (12) full calendar months, and that such Base Rent shall not be affected, nor subject to adjustment, based on the Delivery Date occurring after the Term Commencement Date (nor by reason of Sublessee’s possession of the Premises being less than twelve (12) full calendar months).

4.2 Notwithstanding Section 4.1, at any time after April 1, 2005, Sublessee may terminate this Lease upon giving not less than ten (10) days advance written notice to Sublessor, provided that any such early termination by Sublessee shall not entitle it to a refund of any rents already due and/or collected.

4.3 Surrender. Upon the expiration or earlier termination of the Term of this Sublease, Sublessee shall surrender the Premises, together with any Leasehold Improvements to the Premises installed by Sublessee in accordance with Section 2.6 (except to the extent that Sublessor (or Master Lessor) has conditioned its consent to such improvements on their being removed on the expiration or earlier termination of the Sublease), and any Alterations (as defined in Section 11 hereof) made thereto (other than any such Alterations which Sublessee is required to remove as set forth in Section 11 hereof), broom clean and free of debris, and in good working order, repair and condition, except for reasonable wear and tear and damage by casualty. All furniture, trade fixtures and other personal property of Sublessee, together with all improvements and Alterations that are designated for removal, shall be removed from the Premises on or before such expiration or earlier termination, if such removal can be undertaken without material damage to the Premises, and Sublessee shall immediately repair any damage resulting from such removal. In no event shall HVAC equipment, plumbing or sprinkler system components, air lines, power panels, electrical distribution systems, lighting fixtures, fencing or any other component from any major building system be removed from the Premises.

4.4 Holding Over. Subject to the terms of the Master Lease, if Sublessee shall, with Sublessor’s written consent, remain in possession of the Premises or any part thereof after the expiration of the Term hereof, such occupancy shall constitute a tenancy from month to month, terminable upon thirty (30) days notice by either party, upon all of the terms, covenants and conditions of this Sublease, except that the monthly Base Rent shall be increased to the amount of the Holdover Rent specified in the Basic Sublease Information (Sublessee hereby acknowledging the magnitude of the increase in Base Rent that will be caused by such holding over). Otherwise, any such occupancy shall constitute a tenancy at sufferance, and Sublessee shall be liable to Sublessor for any and all claims, damages, liabilities, costs and expenses (including attorneys’ fees and expenses) incurred by Sublessor and arising

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out of Sublessee's failure to timely surrender the Premises in accordance with the requirements of this Sublease.

5 Rent.

5.1 Definition. As used in this Sublease, the term "Rent" shall include: (i) the Base Rent; and (ii) all other amounts which Sublessee is obligated to pay under the terms of this Sublease.

5.2 Payment. Base Rent for the entire Term shall be due and payable in advance on the date that this Sublease is executed and delivered by the last of the parties to have executed and delivered the same. In addition to the Base Rent reserved above, Sublessee shall pay to the parties respectively entitled thereto all charges, costs and expenses which arise or may be contemplated under any provisions of this Sublease during the term hereof. All such charges, costs and expenses shall constitute additional Rent, and upon the failure of Sublessee to pay any of such costs, charges or expenses, Sublessor shall have the same rights and remedies as otherwise provided in this Sublease for the failure of Sublessee to pay Base Rent. It is the intention of the parties hereto that, except as expressly provided herein, this Sublease shall not be terminable for any reason by Sublessee, and Sublessee shall in no event be entitled to any abatement of or reduction in rent payable under this Sublease. All Rent payable hereunder shall be paid in lawful money of the United States and without prior notice or demand, deduction or offset for any cause whatsoever. Any delay or failure of Sublessor in computing or billing for any of the rental adjustments or additional Rent as provided in this Sublease shall not constitute a waiver of or in any way impair the continuing obligation of Sublessee to pay any and all Rent.

5.3 Late Charge and Interest. Sublessee acknowledges that its late payment of Rent will cause Sublessor to incur certain costs and expenses not contemplated by this Sublease, including without limitation administrative and collection costs and processing and accounting expenses, the exact amount of which is extremely difficult or impractical to fix. Accordingly, if any installment of Rent is not paid within five (5) days after the date such Rent is due, Sublessee shall pay to Sublessor, in addition to the installment of Rent then owing, a late payment charge equal to Five Hundred and No/00 Dollars (\$500.00), regardless of whether a notice of default or notice of termination has been given by Sublessor. The parties agree that this late charge represents a reasonable estimate of the costs and expenses incurred by Sublessor from, and is fair compensation to Sublessor for its loss suffered by, such nonpayment by Sublessee. In addition to Five Hundred Dollar (\$500.00) late charge, any Rent or other amounts owing under this Sublease which are not paid within five (5) days after the date they are due shall thereafter bear interest at the rate which is the lesser of ten percent (10%) per annum or the maximum rate permitted by law ("Interest Rate"). Nothing in this Section shall relieve Sublessee of its obligation to pay any Rent at the time and in the manner provided by this Sublease or constitute a waiver of any default of Sublessee with regard to any nonpayment of Rent.

6 Security Deposit. Upon the execution and delivery of this Sublease by Sublessee, Sublessee shall deposit the Security Deposit with Sublessor in the form of

Sublessee's check payable to Sublessor. The Security Deposit shall secure Sublessee's obligations under this Sublease to pay Rent and any other monetary amounts, to maintain the Premises and repair damages thereto, to surrender the Premises to Sublessor in the condition required by Section 4.3 above and to discharge Sublessee's other obligations hereunder. Notwithstanding the above, Sublessee acknowledges and agrees that the amount of the Security Deposit shall not in any way be deemed to be a limitation of Sublessee's liability under this Sublease. Sublessor may use and commingle the Security Deposit with other funds of Sublessor. If Sublessee fails to perform Sublessee's obligations hereunder, Sublessor may, but without any obligation to do so, apply all or any portion of the Security Deposit towards fulfillment of Sublessee's unperformed obligations. If Sublessor does so apply any portion of the Security Deposit, Sublessee shall immediately remit to Sublessor cash in an amount to restore the Security Deposit to its original amount. If Sublessee fails to restore the Security Deposit to its original amount within five (5) days after receipt of Sublessor's written demand to do so, Sublessee shall be in default of this Sublease. Upon termination of this Sublease, if Sublessee has then performed all of Sublessee's obligations under this Sublease, Sublessor shall return the Security Deposit, or whatever amount remains of the Security Deposit after Sublessor applied all or a portion of the Security Deposit to perform Sublessee's obligations hereunder, to Sublessee without payment of interest.

7 Utilities and Services.

7.1 Master Lessor to Provide Utilities and Services. Master Lessor is required to provide to the Premises the services and utilities so provided in the Master Lease. As to services and utilities not Master Lessor's responsibility under the Master Lease, Sublessee shall arrange for, and procure all facilities necessary for the provision to the Premises of, all other services and utilities desired by Sublessee, including without limitation, telephone services for the Premises. Sublessee shall make payment for any utilities and services obtained by it directly to the person or entity supplying such services. The parties acknowledge and agree that to the extent that Sublessee is required to pay for any utilities, services or amenities provided to the Premises (including special or excess services or utilities, as provided below), it is their intention that Sublessee be required to pay, or to reimburse Sublessor for, only costs actually payable to the Master Lessor (or the supplying utility) for such utilities, services or other amenities. Sublessee shall not be obligated to pay any surcharge, overhead or administrative expense to Sublessor in connection with any such utilities, services or other amenities.

7.2 Special or Excess Usage. Pursuant to the Master Lease, the tenant may request services and utilities in excess of those that are the Master Lessor's responsibility thereunder. If Sublessee orders any such excess services or utilities from Master Lessor, Sublessee shall advise Sublessor of the amount and times of such additional services and utilities so that Sublessor may apportion to Sublessee invoiced amounts periodically received from Master Lessor relating to the Master Premises, or alternatively, Sublessee shall arrange with Master Lessor for the direct billing to Sublessee of the charges relating to Sublessee's excess usage.

7.3 Nonliability. Sublessor shall not be liable for any inconvenience or loss resulting to Sublessee or its business at the Premises from any failure of Master Lessor to furnish the utilities and services described herein if (a) Master Lessor is excused from liability to Sublessor by reason of the terms and conditions set forth in the Master Lease, or (ii) such failure is the result of accidents, breakage or repairs resulting from Master Lessor's negligence.

8. Operating Expenses; Personal Property Taxes.

8.1 Full Service Lease. Pursuant to the Master Lease, Sublessor is obligated to pay a share of all "Operating Expenses" of the Building and the Project. It is understood and agreed by Sublessor and Sublessee that such Operating Expenses shall be the sole responsibility of Sublessor, that Sublessee shall have no liability to Master Lessor nor Sublessor on account thereof, and that as between Sublessor and Sublessee, this Sublease is intended to be full service to Sublessee.

8.2 Personal Property Taxes. Sublessee shall pay prior to delinquency any and all taxes and assessments against and levied upon trade fixtures, furnishings, equipment, and personal property contained in the Premises. Whenever possible, Sublessee shall cause such items to be assessed and billed separately from the real property portion of the Premises. Sublessee shall be responsible for any taxes and assessments attributable to any such items assessed against the real property portion of the Premises.

9 Use; Compliance with Laws; Permits.

9.1 Use. The Premises are to be used for general office purposes, and for no other purpose or business.

9.2 Compliance with Law; Prohibited Activities. Sublessee shall observe and comply with the requirements of all covenants, conditions and restrictions of record regarding the Premises and Legal Requirements now or hereafter in effect which apply to the Premises or the use or occupancy thereof by Sublessee, including but not limited to the obligation to alter, maintain, repair, improve or restore the Premises, and all parts thereof, in compliance and conformity with all such Legal Requirements. The foregoing notwithstanding, Sublessee shall not be obligated (i) to make any structural improvements or alterations to the Building (unless required by reason of Alterations undertaken or proposed by Sublessee), or (ii) to take any action to observe or comply with any covenants, conditions, restrictions or Legal Requirements that are not required to be observed or complied with by the tenant under the Master Lease. In addition, nothing herein shall limit or impair Sublessee's right to challenge in good faith (and at its own expense) any Legal Requirements or the application thereof to the Premises, and to delay any action in observance or compliance with such Legal Requirements being challenged in good faith to the extent such delay does not result in a default under the Master Lease or risk penalties or fines being assessed against Sublessor or Master Lessor. Sublessee shall not (i) commit, or suffer to be committed or exist, on the Premises any waste, or any nuisance, or other act or thing which may disturb the quiet enjoyment of any other tenant in the Building; or (ii) do or permit to be

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done in or about the Premises, or bring or keep anything therein, which will in any way increase the existing rate, or cause the cancellation, of the all risk fire insurance on the Building. Sublessee shall not use, store, generate, transit or dispose of any hazardous substances upon, in about, or under the Premises, except any use or storage of any such hazardous substances customarily used in Sublessee's business, provided that such use or storage complies with all applicable Legal Requirements. As used herein, hazardous substances means any and all hazardous, ultra-hazardous, or toxic substances, wastes or materials regulated under any laws or regulations applicable to the environment or the protection of human health.

9.3 Permits and Licenses. Sublessee shall apply for and obtain, at its sole expense, all permits, licenses, consents, permissions or other approvals of any governmental or quasi-governmental authorities which may be required in order that Sublessee may construct any improvements or Alterations proposed by Sublessee or as required to operate Sublessee's business. Sublessor agrees that in all such cases, whenever reasonably requested by Sublessee, Sublessor shall cooperate with Sublessee in obtaining such permits, licenses, consents, permissions and other approvals, provided that Sublessor shall not be required to incur any direct or indirect cost or expense as a result of such cooperation.

10 Assignment and Subletting.

10.1 Sublessor's Consent. Subject to Section 10.2, Sublessee shall not transfer or assign this Sublease, or any right or interest hereunder, nor sublet the Premises or any part thereof. No transfer or assignment, whether voluntary or involuntary, by operation of law or under legal process or proceedings, shall be valid or effective. Should Sublessee attempt to make or suffer to be made any transfer or assignment of this Sublease or any subletting of the Premises, or should any of Sublessee's rights under this Sublease be sold or otherwise transferred by or under court order or legal process or otherwise, or should Sublessee be adjudged insolvent or bankrupt, then and in any of the foregoing events Sublessor may, at its sole option, terminate this Sublease upon written notice thereof to Sublessee. Under no circumstances shall any sublease of all or a part of the Premises, or assignment of this Sublease, by Sublessee in any way modify, affect or limit the liability of Sublessee under this Sublease.

10.2 Permitted Transfers. An assignment of this Sublease, or a subletting of the Premises, to any of the following persons shall not be treated as a transfer prohibited by Section 10.1: (a) the parent of CELLEGY PHARMACEUTICALS, INC. or any wholly-owned subsidiary of CELLEGY PHARMACEUTICALS, INC., (b) a corporation into which or with which CELLEGY PHARMACEUTICALS, INC. may be merged or consolidated, provided that the tangible net worth of the resulting corporation is at least equal to the greater of (i) the tangible net worth of CELLEGY PHARMACEUTICALS, INC. on the date of this Sublease, or (ii) the tangible net worth of CELLEGY PHARMACEUTICALS, INC. immediately prior to such merger or consolidation, or (c) any entity to which CELLEGY PHARMACEUTICALS, INC. sells all or substantially all of its assets, provided in each case that such entity expressly assumes all of Sublessee's obligations under this Sublease. In addition, the following

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transfers shall not be deemed an assignment of this Sublease: (x) transfers of Tenant's stock to its owners' immediate family members or to trusts for the benefit of any such family members, provided that the current owners maintain a controlling interest, and (y) if Tenant conducts a public offering of stock, sales of stock made pursuant to such public offering and any subsequent transfers of the offered stock. Further, Sublessee shall not be treated as having violated Section 10.1 by reason of the use or occupancy of the Premises by employees of affiliated companies that are controlled by CELLEGY PHARMACEUTICALS, INC., or which control CELLEGY PHARMACEUTICALS, INC., or which are under common control with CELLEGY PHARMACEUTICALS, INC..

11 Alterations. Sublessee shall not make or suffer to be made any alterations, additions or improvements (collectively "Alterations") in, on, or to the Premises or the Building without the prior written consent of Sublessor, which consent shall not be unreasonably withheld, conditioned or delayed so long as (i) such Alterations are permitted under the Master Lease, or Master Lessor has given its informed consent thereto, and (ii) such proposed Alterations will not interfere with or damage Sublessor's existing cabling and related equipment located in the Premises, and (iii) Sublessee agrees to remove any Alterations that Sublessor identifies for removal (at the expiration or earlier termination of this Sublease) as a condition of Sublessor's giving its consent

thereto. The foregoing notwithstanding, Sublessee shall have the right from time to time to construct and install Alterations costing not more than Five Thousand Dollars (\$5,000.00) without the prior consent of Sublessor (but with prior written notice to Sublessor), subject to (i) all conditions limiting or governing such Alterations set forth in the Master Lease, and (ii) all other terms and conditions of this Sublease. It is understood and agreed that Sublessee shall be solely responsible for removing, at Sublessee's own expense, all Alterations for which Master Lessor's consent was required and given on condition of such removal. Any Alterations in, on or to the Premises that Sublessee desires to undertake, which require the consent of Sublessor hereunder, shall be presented to Sublessor in written form, with proposed conceptual plans. Where Sublessor's consent is required, Sublessor shall to notify Sublessee in writing whether it approves or disapproves said plans. If Sublessor disapproves Sublessee's plans, it shall set forth with specificity and detail the objections it has to the same, and the changes that are needed to make such work acceptable to Sublessor. If Sublessor's consent is not required as provided above, Sublessee shall demonstrate its compliance with the conditions which excuse the need for Sublessor's consent. Whether or not Sublessor's consent is required, Sublessor may require that Sublessee, at Sublessee's sole cost and expense, obtain builder's risk insurance with regard to such Alteration, and/or provide to Sublessor a lien and completion bond in an amount equal to one and one-half times the estimated cost of such Alterations. Sublessee shall reimburse Sublessor for all costs incurred by Sublessor in reviewing Sublessee's plans for any proposed Alteration. Sublessee shall pay promptly for all work related to any Alteration, whether done by Sublessee, upon Sublessee's order or otherwise. Any Alterations Sublessee may be required or permitted to make shall be made by Sublessee at Sublessee's sole cost and expense (including, without limitation, all costs of complying with the Americans with Disabilities Act, whether or not such compliance requires structural improvements), and Sublessee shall notify Sublessor in advance of the same so that Sublessor may, at Sublessor's sole option, post appropriate notices of nonresponsibility. All Alterations shall be made under the

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supervision of a competent architect or licensed structural engineer, in a good and workmanlike manner and in accordance with any plans approved by Sublessor and all applicable laws. Before commencement of any Alteration, Sublessee shall provide to Sublessor a copy of the building permit for such work (if a building permit is legally required) and a list of all contractors or subcontractors to be used. Upon completion of such Alteration, Sublessee shall timely and properly record a Notice of Completion in the county recorder's office for the county in which the Premises are located. Upon the expiration or sooner termination of this Sublease, Sublessee shall, at Sublessee's sole cost and expense, immediately and with all due diligence: (i) remove any Alterations made or paid for by Sublessee that Sublessor (or Master Lessor) has designated for removal; (ii) repair any damage to the Premises resulting from such removal; and (iii) repair and restore the Premises to its original condition, reasonable wear and tear excepted. Leasehold Improvements installed by Sublessee under Section 2.6 that are not designated for removal, and all Alteration not designated for removal by Master Lessor, shall become a part of the Premises and the property of Sublessor upon expiration or sooner termination of this Sublease and shall remain on and be surrendered with the Premises.

12 Repairs and Maintenance. Except to the extent that Master Lessor shall be obligated to maintain, repair or replace the same under the Master Lease, Sublessee shall, at Sublessee's sole expense, keep, maintain, repair and replace all of the Premises to the same extent as the tenant under the Master Lease is so obligated (which shall include, without limitation, the maintenance, repair and replacement of all doors, windows, plate glass, floor coverings, interior walls and ceilings). In addition, Sublessee shall, at Sublessee's sole expense, immediately repair any Common Areas or elements or systems of the Building damaged by Sublessee or Sublessee's agents, employees, licensees, invitees and visitors to the extent required of the tenant under the Master Lease. All maintenance, repairs and replacement by Sublessee hereunder shall be undertaken in accordance with, and shall be governed by, the requirements of Section 11 above. Sublessee acknowledges that Sublessor is under no duty to make any repairs or improvements to the Premises; Sublessee hereby waives the benefit of any statute or principal of law or equity, now or hereinafter in effect, which would afford Sublessee the right to make repairs at Sublessor's expense or to terminate this Sublease because of Sublessor's failure to keep the Premises in good order, condition and repair.

13 Insurance Policies. Prior to occupying the Premises and for the duration of the Term, Sublessee shall procure and maintain in full force and effect and at Sublessee's sole cost and expense the following policies of insurance. Each policy of insurance required to be maintained by Sublessee hereunder shall be issued by an insurance company authorized to do business in the State of California, with a rating classification of at least an A, Class VIII status as rated from time to time in the most current edition of Best's Insurance Reports and shall provide for only such deductibles as are reasonably acceptable to Sublessor. Such policies shall be primary and non-contributing and shall name Sublessor and Master Lessor as additional named insureds. If the Master Lease requires greater or additional insurance coverage, Sublessee shall also carry such insurance.

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13.1 Property. A policy or policies of "special form" property, fire, and extended coverage insurance, including without limitation, coverage of vandalism and malicious mischief, in an amount equal to one hundred percent (100%) of the full insurance replacement value of the Sublessee's improvements, alterations and betterments in the Premises (to the extent such improvements, alterations and betterments were constructed by or at the request of Sublessee).

13.2 Liability. A policy or policies of comprehensive general liability insurance, in the form customary to the locality in which the Premises are located, insuring Sublessee's activities and those of Sublessee's officers, employees, agents, servants, licensees, subtenants, concessionaires and invitees with respect to the Premises against loss, damage or liability for injury or death of any person or loss or damage to property occurring on the Premises or as a result of occupancy or use of the Premises and contractual liability coverage for liability obligations assumed under this Sublease (including without limitation the indemnity provisions of Section 17 below), with a limit of not less than Two Million Dollars (\$2,000,000) for injury to any number of persons and/or property damage in any one occurrence. The adequacy of the coverage afforded by such insurance shall be subject to review by Sublessor from time to time, and, if it reasonably appears in such review that a prudent business person in the area operating a similar business to that operated by the Sublessee on the Premises would increase the limits of such insurance, Sublessee shall effect such increases within thirty (30) days of receipt of notice from Sublessor requesting such increase.

13.3 Other Insurance. Sublessee shall also keep in full force and effect during the Term, (a) insurance payable to Sublessor against loss of Rent in case of fire or other casualty, in an amount at least equal to the amount of Rent payable by Sublessee during the one (1) year next ensuing, as reasonably determined by Sublessor, and (b) workers' compensation insurance in amounts required by applicable law and employer's liability insurance in an amount equal to One Million Dollars (\$1,000,000) per injury or illness.

13.4 Waiver of Subrogation. Any policy or policies of insurance, which either party obtains in connection with the Premises, shall, to the extent the same can be obtained without undue expense, include a clause or endorsement denying the insurer any rights of subrogation against the other party to the extent rights have been waived by the insured prior to the occurrence of injury or loss. Sublessee and Sublessor waive any rights of recovery

against the other for injury or loss due to hazards covered by insurance containing such a waiver of subrogation clause or endorsement to the extent of the injury or loss covered thereby.

13.5 Insurance Certificates. Prior to occupying the Premises (and from time to time, no later than thirty (30) days prior to the expiration of each insurance policy) Sublessee shall furnish to Sublessor a certificate of insurance issued by the insurance carrier of each policy of insurance carried by Sublessee pursuant hereto. Such certificates of insurance shall reflect that Sublessor and Master Lessor are additional named insureds; and (ii) that such insurance policies shall not be cancelable, subject to reduction of coverage or any other material amendment without a minimum of

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thirty (30) days prior written notice to Sublessor and any other additional named insureds.

14 Damage and Destruction.

14.1 Termination of Master Lease. If as the result of any damage or destruction, Master Lessor or Sublessor exercises any option either may have to terminate the Master Lease as to all of the Master Premises, this Sublease shall terminate to the same extent, effective as of the date of such termination of the Master Lease. In addition, if the Sublease is not terminated as hereinbefore provided, Sublessor shall send Sublessee a written notice estimating the time needed to complete repairs or restoration, and Sublessee may, by giving written notice to Sublessor within thirty (30) days after receiving such notice from Sublessor, terminate this Sublease if the Premises cannot be repaired and/or restored within one hundred and eighty (180) days following such damage or destruction.

14.2 Continuation of Sublease. If this Sublease is not terminated following any damage or destruction as provided above, this Sublease shall remain in full force and effect and the responsible party under the Master Lease shall diligently repair, restore or rebuild the Premises or the Building as required by the terms of the Master Lease. The "responsible party under the Master Lease" shall be Master Lessor if the Master Lease so provides, or Sublessor if the Master Lease requires such repairs, restoration or rebuilding to be undertaken by the tenant thereunder. Sublessee waives the provisions of any statute or other principal of law or equity which relate to the right to terminate a lease when the thing leased is destroyed and agrees that such event shall be governed by the terms hereof. Unless this Sublease shall terminate as provided in Section 14.1 above, there shall be no abatement of Rent payable by Sublessee hereunder by reason of any damage or destruction of the Premises, except to the extent of any abatement of rent payable under the Master Lease with regard to the Premises as a result of such damage or destruction. If this Sublease is terminated as a result of any damage or destruction as provided in Section 14.1 above, all proceeds of insurance resulting from such damage or destruction shall be paid to Sublessor (or Master Lessor), and Sublessee hereby assigns such proceeds to Sublessor (and Master Lessor) in any such event (provided that if proceeds of insurance carried separately by Sublessee are intended to compensate Sublessee for moving and relocation costs, equipment, personal property, trade fixtures, furnishing, alterations and improvements that Sublessee is entitled or required to remove on expiration of this Sublease, then such sums may be retained by Sublessee after collection from its insurance carrier). Payment and assignment to Sublessor of any such insurance proceeds shall not be construed as a waiver of any right or remedy Sublessor may have against Sublessee arising from any breach of this Section.

15 Eminent Domain.

15.1 Termination of Master Lease. If as the result of any condemnation by eminent domain, inverse condemnation or sale in lieu of condemnation, for any public or a quasi-public use or purpose ("Condemned" or "Condemnation"), the Master Lease shall terminate or Master Lessor or Sublessor either mutually agree or exercise

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any option either may have to terminate the Master Lease as to all or any portion of the Premises, this Sublease shall terminate to the same extent, effective as of the date of such termination of the Master Lease.

15.2 Partial Condemnation. If this Sublease is not terminated following any such Condemnation as set forth above, this Sublease shall remain in full force and effect and the responsible party under the Master Lease shall diligently repair, restore or rebuild the Premises or the Building as required by the terms of the Master Lease. The "responsible party under the Master Lease" shall be Master Lessor if the Master Lease so provides, or Sublessor if the Master Lease requires such repairs, restoration or rebuilding to be undertaken by the tenant thereunder. Sublessee hereby waives the provisions of California Code of Civil Procedure Section 1265.130 and any other statute or principal of law or equity permitting termination this Sublease upon Condemnation. Unless this Sublease shall terminate as a result of any Condemnation, there shall be no abatement of Rent payable by Sublessee hereunder as a result of any Condemnation, except to the extent of any abatement of rent payable under the Master Lease with regard to the Premises as a result of such Condemnation.

15.3 Sublessee's Award. The entire Condemnation award shall belong solely to Sublessor or Master Lessor, as the case may be. Notwithstanding the foregoing, Sublessee shall have the right to recover from the condemning authority, but not from Sublessor or Master Lessor, such compensation as may be separately awarded to Sublessee (as opposed to any award to Sublessor or Master Lessor) in connection with: its loss of business; personal property, fixtures and leasehold improvements owned by Sublessee (as opposed to the improvements owned by Sublessor or Master Lessor); and the costs of moving Sublessee's personal property, fixtures, and leasehold improvements to a new location.

16 Default.

16.1 Events of Default. The occurrence of any one or more of the following events shall constitute an "Event of Default" on the part of Sublessee with or without notice from Sublessor (except as required by Section 16.1.3 below):

16.1.1 Vacation or Abandonment. Sublessee's vacation (which is defined as the failure to remain open for business at any time during the Term after Sublessee has taken possession of the Premises for a period of thirty (30) continuous days) or abandonment of the Premises;

16.1.2 Payment. Sublessee's failure to pay any installment of Rent on or before five (5) days after said payment is due;

16.1.3 Performance. Sublessee's failure to perform any of Sublessee's covenants, agreements or obligations hereunder (other than the nonpayment of Rent which shall be governed by Section 16.1.2 above) on or before thirty (30) days after written notice thereof from Sublessor, provided that if such failure to perform cannot reasonably be remedied within a 30-day period, Sublessee shall not

be in default if it commences the cure of such failure to perform within said thirty (30) days and diligently prosecutes such cure to completion;

16.1.4 Assignment. A general assignment by Sublessee for the benefit of creditors;

16.1.5 Bankruptcy. The filing of a voluntary petition by Sublessee seeking the rehabilitation, liquidation or reorganization of Sublessee under any law relating to bankruptcy, insolvency or other relief of debtors; or the filing of an involuntary petition by any of Sublessee's creditors seeking substantially the same relief if not dismissed within sixty (60) days;

16.1.6 Receivership. The appointment of a receiver or other custodian to take possession of substantially all of Sublessee's assets or of this leasehold, if not dismissed within sixty (60) days;

16.1.7 Insolvency, Dissolution, Etc. Any court shall enter a decree or order directing the winding up or liquidation of Sublessee or of substantially all of its assets; or Sublessee shall take any action toward the dissolution or winding up of its affairs or the cessation or suspension of its use of the Premises; or

16.1.8 Attachment. Attachment, execution or other judicial seizure of substantially all of Sublessee's assets or this leasehold, if not dismissed or released within sixty (60) days.

16.2 Sublessor's Remedies.

16.2.1 Abandonment. If Sublessee vacates or abandons the Premises, this Sublease shall continue in effect unless and until terminated by Sublessor in writing, and Sublessor shall have all of the rights and remedies provided by Section 1951.4 of the California Civil Code (i.e. Sublessor may continue this Sublease in effect after Sublessee's breach and abandonment and recover Rent as it becomes due, if Sublessee has the right to sublet or assign subject only to reasonable limitations).

16.2.2 Termination. Following the occurrence of any Event of Default (giving due regard to any grace period afforded Sublessee under Section 16.1 above), Sublessor shall have the right, so long as the default continues, to terminate this Sublease by written notice to Sublessee setting forth: (i) the default; (ii) the requirements to cure it; and (iii) a demand for possession, which shall be effective three (3) days after it is given. Sublessor shall not be deemed to have terminated this Sublease other than by delivering written notice of termination to Sublessee.

16.2.3 Possession. Following termination of the Sublease, without prejudice to any other remedies Sublessor may have by reason of Sublessee's default or of such termination, Sublessor may then or at any time thereafter (i) peaceably reenter the Premises, or any part thereof, upon voluntary surrender by Sublessee, or, expel or remove Sublessee and any other persons occupying the Premises, using such legal proceedings as may be available; (ii) repossess and enjoy the Premises, or relet

the Premises or any part thereof for such term or terms (which may be for a term extending beyond the Term), at such rental or rentals and upon such other terms and conditions as Sublessor in Sublessor's sole discretion shall determine, with the right to make reasonable alterations and repairs to the Premises; and (iii) remove all personal property from the Premises.

16.2.4 Recovery. Following termination of the Sublease, Sublessor shall have all the rights and remedies of a Sublessor provided by Section 1951.2 of the California Civil Code which provides that Sublessor may recover from Sublessee the following: (i) the worth at the time of the award of the unpaid rent which had been earned at the time of termination; (ii) the worth at the time of the award of the amount by which the unpaid rent which would have been earned after termination until the time of the award exceeds the amount of such rental loss that Sublessee proves could have been reasonably avoided; (iii) the worth at the time of the award of the amount by which the unpaid rent for the balance of the Term after the time of award exceeds the amount of such rental loss that Sublessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Sublessor for all detriment proximately caused by Sublessee's failure to perform Sublessee's obligations under the Sublease or which in the ordinary course of things would be likely to result therefrom. The "worth at the time of award" of the amounts referred to in (i) and (ii) of this subsection, shall be computed by allowing interest at the Interest Rate set forth in Section 5.3 above. The "worth at the time of the award" of the amount referred to in (iii) above shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%).

16.2.5 Other. If Sublessee causes or threatens to cause a breach of any of the covenants, terms or conditions contained in this Sublease, Sublessor shall be entitled to retain all sums held by Sublessor, any trustee or in any account provided for herein, to enjoin such breach or threatened breach, and to invoke any remedy allowed at law, in equity, by statute or otherwise as though reentry, summary proceedings and other remedies were not provided for in this Sublease.

16.2.6 Cumulative. Each right and remedy of Sublessor provided for in this Sublease shall be cumulative and shall be in addition to every other right or remedy provided for now or hereafter existing at law, in equity, by statute or otherwise. The exercise or beginning of the exercise by Sublessor of any one or more of the rights or remedies provided for in this Sublease, or now or hereafter existing at law, in equity, by statute, or otherwise, shall not preclude the simultaneous or later exercise by Sublessor of any or all other rights or remedies provided for in this Sublease or now or hereafter existing at law, in equity, by statute, or otherwise.

16.2.7 No Waiver. No failure by Sublessor to insist upon the strict performance of any term hereof or to exercise any right or remedy consequent upon a breach thereof, and no acceptance of full or partial payment of rent during the continuance of any such breach shall constitute a waiver of

any such breach or of any such term. Efforts by Sublessor to mitigate the damages caused by Sublessee's breach of this Sublease shall not be construed to be a waiver of Sublessor's right to recover damages under this Section.

16.2.8 **Sublessor's Right to Perform.** Upon Sublessee's failure to perform any obligation of Sublessee hereunder, including, without limitation, payment of Sublessee's insurance premiums and charges of contractors who have supplied materials or labor to the Premises, Sublessor shall have the right, but not the obligation, at any time after giving five (5) days prior written notice to Sublessee, to perform such obligations of Sublessee on behalf of Sublessee and/or to make payment on behalf of Sublessee to such parties. Upon demand, Sublessee shall reimburse Sublessor for the cost of Sublessor's performing such obligations on Sublessee's behalf, plus interest at the Interest Rate set forth in Section 5.3 above, from the date of any such expenditure until the same is repaid.

16.2.9 **Additional Remedies.** In addition to the foregoing remedies and so long as this Sublease is not terminated, Sublessor shall have the right to maintain or improve the Premises without terminating this Sublease, to incur expenses on behalf of Sublessee in seeking a subtenant or assignee, including, without limitation, brokers' commissions, expenses of remodeling the Premises, and any other inducements which Sublessor determines, in Sublessor's sole discretion, are necessary, to cause a receiver to be appointed to administer the Premises and new or existing subleases and to add to the Rent payable hereunder all of Sublessor's costs in so doing, including reasonable attorneys' fees, with interest at the Interest Rate set forth in Section 5.3 above from the date of such expenditure until the same is repaid.

16.2.10 **Additional Rent.** For purposes of any unlawful detainer action by Sublessor against Sublessee pursuant to California Code of Civil Procedure Sections 1161 through 1179, or any similar or successor statutes, Sublessor shall be entitled to recover as Rent not only such sums specified as the Base Rent which may then be overdue, but also any and all additional sums of money as may then be overdue.

16.2.11 **Indemnification.** Sublessor's exercise of any one or more of the remedies set forth in this Section shall not affect the rights of Sublessor or the obligations of Sublessee under the indemnification set forth in Section 17 hereof.

16.2.12 **After Default.** Sublessor shall be under no obligation to observe or perform any covenant of this Sublease on its part to be observed or performed which accrues after the date of any Event of Default, and for so long as the Event of Default continues.

17 **Indemnification of Sublessor.** Sublessee shall indemnify, protect, defend with counsel reasonably acceptable to Sublessor, and hold Sublessor, and its officers, directors, employees and agents, harmless from and against any and all liabilities, penalties, losses, damages, costs and expenses, demands, causes of action, claims or judgments (including, without limitation, attorneys' fees and expenses) (collectively, "Claims") arising, claimed or incurred against or by Sublessor, or its officers, directors, employees or agents, from any matter or thing arising from (i) the use or occupancy of the Premises or the balance of the Project by Sublessee or any sublessee or assignee of Sublessee, or any of their respective officers, directors, employees, agents, licensees and invitees, the conduct of Sublessee's business, or from any activity, work or other

thing done, permitted or suffered by Sublessee in or about the Premises or the balance of the Project; (ii) any accident, injury to or death of Sublessee and/or its officers, directors, employees, agents, invitees or licensees, or loss of or damage to property of the foregoing persons occurring on or about the Premises or any part thereof during the term hereof; (iii) any breach or default in the performance of any obligation on Sublessee's part or to be performed under the terms of this Sublease; or (iv) the performance of any labor or services or the furnishing of any materials or other property in respect of the Premises or any part thereof at the request of Sublessee, or its officers, directors, agents and employees; provided that Sublessee shall have no obligation to indemnify, defend and hold Sublessor harmless from and against any Claims to the extent resulting from the negligence or willful misconduct of Sublessor or from Sublessor's breach of this Sublease or its breach of the Master Lease. Notwithstanding any provision hereof to the contrary, the indemnification provided in this Section shall survive any termination of this Sublease or expiration of the Term hereof. Sublessee shall give prompt notice to Sublessor in case of casualty or accidents of a material nature known to Sublessee on or about the Premises.

18 **Brokerage Commission.** Sublessee represents and warrants to Sublessor that no broker or finder, can properly claim a right to a commission or a finder's fee based upon contacts between the claimant and Sublessee with respect to Sublessor, this Sublease or the Premises. Sublessee shall indemnify, defend (with counsel acceptable to Sublessor) and hold Sublessor harmless from and against any loss, cost or expense, including, but not limited to, attorneys' fees and court costs, resulting from any claim for a fee or commission by any broker or finder in connection with the Premises and this Sublease.

19 **General Provisions.**

19.1 **Notices.** All notices or demands of any kind required or desired to be given hereunder shall be in writing and mailed postage prepaid by certified or registered mail, return receipt requested, or by personal delivery, to the appropriate address indicated in the Basic Sublease Information, or at such other place or places as either Sublessor or Sublessee may, from time to time, designate in a written notice given to the other. Notices shall be deemed to be delivered four (4) days after the date of mailing thereof, or upon earlier receipt.

19.2 **Entry by Sublessor.** Sublessor and its authorized representatives shall have the right to enter the Premises at all reasonable times (including all normal business hours) and upon reasonable oral or written notice (provided that in the event of an emergency, notice need not be given) for the purposes of: inspecting the same; for servicing, altering or repairing Sublessor's existing cabling and related equipment located in the Premises; or taking any action or doing any work permitted hereunder (but nothing herein contained in this Lease shall create or imply any duty on the part of Sublessor to make any such inspection or to take any such action or do any such work). No such entry shall constitute an eviction of Sublessee. In connection with any such entry, Sublessor will use reasonable efforts not to disrupt or interfere with the normal operation of Sublessee's business.

19.3 Estoppel Certificates. Each party shall, from time to time upon not less than thirty (30) days prior written notice from the other execute, acknowledge and deliver to the other a statement in writing (a) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification), and the date to which the Rent and other charges are paid in advance, if any, and (b) acknowledging that there are not, to such party's knowledge, any uncured defaults on the part of the other hereunder, or specifying such defaults if any are claimed, and (c) setting forth the date of expiration of the term hereof.

19.4 Liens. Sublessee covenants that it will not, during the Term hereof, suffer or permit any lien to be attached to or upon the Premises or the balance of the Project, or any portion thereof, by reason of any act or omission on the part of Sublessee, and hereby agrees to save and hold harmless Sublessor from or against any such lien or claim of lien. In the event any such lien does attach or any claim of lien is made against the Premises or the balance of the Project, which is occasioned by any act or omission upon the part of Sublessee, and shall not be released within thirty (30) days after notice from Sublessor to Sublessee so to do, Sublessor in its sole discretion, except as provided below, may pay and discharge the same and remove any such lien from the Premises or the balance of the Project. Sublessee agrees to repay and reimburse Sublessor, upon demand, for any amount which may have been paid by Sublessor in discharging such lien, together with interest at the Interest Rate set forth in Section 5.3 above from the date of the expenditure by Sublessor to the date of repayment by Sublessee.

19.5 Time. Time is of the essence of this Sublease. If any date set forth for the performance of any obligation or for the delivery of any instrument or notice should be on a Saturday, Sunday or legal holiday, compliance with such obligations or delivery shall be deemed acceptable on the next business day following such Saturday, Sunday or legal holiday. As used herein, the term "legal holiday" means any state or federal holiday for which financial institutions and post offices are generally closed in the State of California for observance thereof. Except as expressly provided to the contrary in this Sublease, all references to days shall mean calendar days.

19.6 Entire Agreement. This Sublease contains all of the covenants, conditions and agreements between the parties concerning the Premises, and shall supersede all prior correspondence, agreements and understandings concerning the Premises, both oral and written. No addition or modification of any term or provision of this Sublease shall be effective unless set forth in writing and signed by both Sublessor and Sublessee.

19.7 Successors and Assigns. Subject to the provisions of this Sublease relating to assignment, mortgaging and subletting, this Sublease is intended to and does bind the heirs, executors, administrators, successors and assigns of any and all of the parties hereto.

19.8 Authority. Each individual executing this Sublease on behalf of Sublessee represents and warrants that he or she is duly authorized to execute and deliver this Sublease on behalf of Sublessee, and that this Sublease is binding upon

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Sublessee in accordance with its terms. As a condition precedent to the legal effectiveness of this Sublease, Sublessor may, at Sublessor's option, require corporate or partnership resolutions as are reasonably necessary to establish the authority of Sublessee to execute this Sublease.

19.9 Exhibits. The exhibits attached hereto are made a part of this Sublease by this reference.

19.10 Attorneys' Fees; Waiver of Jury Trial. If any party commences an action against the other party arising out of or in connection with this Sublease, (a) the prevailing party shall be entitled to recover from the losing party the cost and expenses of such action, including reasonable collection fees, attorneys' fees (including without limitation the allocated cost of in-house counsel) and court costs; and (b) the parties agree that the matter shall be tried by the court without a jury, and each party specifically waives the right to a jury trial in any such action.

19.11 Governing Law. This Sublease shall be governed by and construed in accordance with the laws of the State of California applicable to contracts to be performed in such State.

19.12 Captions. All captions and headings in this Sublease are for the purposes of reference and convenience and shall not limit or expand the provisions of this Sublease.

19.13 Definition of Sublessor. As used in this Sublease, the term "Sublessor" means only the current owner of the leasehold interest of the lessee under the Master Lease at the time in question. Each Sublessor is obligated to perform the obligations of the Sublessor hereunder only during the time such Sublessor owns such leasehold interest. Any Sublessor who transfers title to its leasehold interest in the Premises is relieved of all liabilities of Sublessor under this Sublease to be performed on or after the date of such transfer.

19.14 Joint and Several Liability. If more than one person and/or entity is Sublessee, the obligations imposed under this Sublease shall be joint and several.

19.15 Waivers. No provision of this Sublease shall be deemed to have been waived by Sublessor unless such waiver is in writing signed by Sublessor and addressed to Sublessee, nor shall any custom or practice which may evolve between the parties in the administration of the terms hereof be construed to waive Sublessor's right to require the obligations of Sublessee be performed in strict accordance with the terms of this Sublease.

19.16 Signs. Sublessee shall be entitled to have such signs, advertisements or notices upon the Premises or the Building as may be permitted under the Master Lease, and Sublessor shall cooperate with Sublessee, provided such cooperation is without cost to Sublessor, to obtain Master Lessor's consent to such signs, advertisements and notices (to the extent such consent is required under the Master Lease). Any signs, advertisements, or notices placed upon the Premises or the

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balance of the Project shall be removed by the Sublessee at the expiration or sooner termination of the Term of this Sublease, and any damage caused thereby shall be repaired by Sublessee, all at the sole expense of Sublessee.

19.17 Rules and Regulations. Sublessee agrees to observe and to be bound and to cause its employees, visitors and invitees to observe and be bound by all reasonable rules and regulations adopted or to be adopted by Master Lessor relative to the Premises or the Building.

IN WITNESS WHEREOF, the parties shall be deemed to have executed this Sublease as of the date first set forth above.

SUBLESSEE

CELLEGY PHARMACEUTICALS, INC., a
Delaware corporation

By /s/ Richard C. Williams
Name: Richard C. Williams
Title: Chief Executive Officer

By /s/ Richard Juelis
Name: Richard Juelis
Title: Chief Financial Officer

Date: _____, 2005

SUBLESSOR

VAXGEN, INC.,
a Delaware corporation

By /s/ James M. Cunha
Name: James M. Cunha
Title: Chief Financial Officer

By _____
Name: _____
Title: _____

Date: _____, 2005

EXHIBIT A

DESCRIPTION OF SUBLET PREMISES

[floor plan to be attached]

EXHIBIT B

DESCRIPTION OF SUBLESSOR'S WORK

[general description of work related to making the space ready for occupancy
- to be attached]

October 7, 2004

Anne-Marie Corner
586 West Mermaid Lane
Philadelphia, PA 19118

Dear Anne-Marie:

By means of this letter agreement (the "**Agreement**"), we are pleased to confirm the terms of your employment, effective as of the Effective Date (as defined below) and subject to the other terms and conditions herein, with Cellegy Pharmaceuticals, Inc. ("**Cellegy**" or the "**Company**").

1. Effective Date.

This Agreement is entered into in connection with that certain Agreement and Plan of Share Exchange dated as of October 7, 2004 by and between Biosyn, Inc. ("**Biosyn**") and Cellegy (the "**Exchange Agreement**"). The terms of this Agreement shall become effective (the "**Effective Date**") only upon the completion of the "Closing" and the "Effective Time," as those terms are defined in the Exchange Agreement. If the Closing of the transactions contemplated by the Exchange Agreement does not occur, then this Agreement shall have no force or effect and shall terminate in its entirety.

2. Impact on Previous Agreements.

Upon and after the Effective Date and the payment to you at the Closing of the amounts specified pursuant to the Exchange Agreement, this Agreement shall replace and supersede all prior employment agreements or employment arrangements, whether written or oral, between you and Biosyn, including, but not limited to, that certain agreement of employment between Biosyn and you dated June 4, 1999 (as the same may be amended, the "**Prior Employment Agreement**"), that certain Agreement to Defer Salary between Biosyn and you dated as of March 26, 2003, as amended, that certain Amended Agreement for Deferral of Compensation between you and Biosyn dated as of February 17, 2004 and that certain Change of Control Agreement between Biosyn and you dated as of February 18, 2004 (collectively, the "**Prior Employment Arrangements**"), and upon the Effective Date, all Prior Employment Arrangements shall be terminated in their entirety and shall be of no further force or effect. Notwithstanding the foregoing, Subsection 7(d) of the Prior Employment Agreement that relates to the assignment by you to Biosyn of inventions or other intellectual property rights, shall survive and remain effective.

3. Duties.

You will serve as Senior Vice President, Women's Preventive Health and as an Officer of Cellegy Pharmaceuticals, Inc. Your responsibilities will include those described in Exhibit A hereto, subject to the overall directives of the Chief Executive Officer and the Board of Directors of Cellegy. You will initially report to the Chief Executive Officer. You agree to devote your full time, effort and attention to the affairs of Cellegy and shall not, during the term of this Agreement, actively engage in any other business activity, whether or not for profit. The foregoing shall not be construed as preventing you from (a) making investments in other businesses or enterprises, (b) participating in the activities of professional trade organizations related to the business of the Company, as approved by your manager, (c) engaging in civic, charitable or fraternal activities, in each of the above cases whose businesses are not competitive with the Company provided that your ownership does not exceed 1% of each such business or enterprise and (d) serving on the boards of directors of not more than one other entity (and up to one additional nonprofit organization) that is reasonably satisfactory to the Company and whose business is not competitive with the Company. The principal location of your employment will be at the Company's principal executive office located in Huntingdon Valley, Pennsylvania, although you understand and agree that you may be required to travel from time to time for business reasons.

4. Annual Salary.

Subject to the immediately following sentence, during your first year of employment, Cellegy agrees to pay you a monthly salary at an annual rate of \$250,000 per annum (the "**Base Salary**"), payable in conformity with Cellegy's normal payroll periods and subject to all applicable withholdings and deductions. Your salary shall be reviewed by Cellegy's Board of Directors or Compensation Committee on an annual basis and may be increased in the discretion of the Board or such Committee. Your first salary review will occur in approximately December 2005 with respect to your Base Salary for the 2006 year.

5. Bonus.

Promptly after the Effective Date you will be paid a cash bonus of \$25,000 in recognition of your performance during the course of 2004. Effective January 1, 2005, you will be eligible to participate in Cellegy's bonus programs in a manner and percentage similar to similarly situated Cellegy employees, with Company and individual performance targets for the relevant calendar year to be established by Cellegy's Board of Directors or the Compensation Committee thereof (and amounts, if any, paid after completion of the year to which such performance targets relate). As part of this program, you will be eligible to receive an annual cash bonus up to a target amount of 25% of Base Salary based on Company and individual performance.

6. Equity Incentive Programs.

You shall be eligible to participate in future equity incentive programs established by the Company to provide restricted stock, stock options and other equity-based incentives to officers and key employees of the Company.

7. Business Expenses.

You shall be entitled to reimbursement of travel and entertainment expenses incurred in connection with your services hereunder consistent with the policies of Cellegy, upon receipt of reasonable supporting documentation.

8. Benefits; Vacation/PTO.

You shall be entitled to participate in Cellegy's benefit plans to the same extent as other similarly situated Cellegy employees, including plans that provide vacation, medical and dental insurance benefits described in Cellegy's employee handbook, which previously was provided to you. In general, you will be entitled to the number vacation/paid-time-off ("PTO") days that are specified in Cellegy's standard vacation policies for similarly situated employees. Notwithstanding the foregoing, you will be entitled to carry over to Cellegy the same number of accrued but unused PTO days that you had with Biosyn immediately before the Effective Date, and unused PTO days will carry-over at year-end into the succeeding year. However, no additional PTO days shall accrue after the Effective Date until such time as you have used a number of your then accrued PTO days such that the number of your then accrued PTO days is less than the maximum number of PTO days that you would be entitled to under Cellegy's standard policy regarding PTO days, and at that time, the number of PTO days that you shall be entitled to will be governed by Cellegy's standard PTO policies. To the maximum extent permitted under Cellegy's plans, you will be given credit for the time during which you were employed by Biosyn. You will also receive such other benefits as are generally made available from time to time to other similarly situated employees of Cellegy. By signing this Agreement, you agree and acknowledge that in consideration of Cellegy's assumption of your PTO days accrued while you were employed with Biosyn, neither Cellegy nor Biosyn will have any financial obligation to you with respect to such PTO days in connection with any termination of your employment with Biosyn that may be deemed to occur with respect to the transactions contemplated by the Exchange Agreement and your employment by Cellegy (including without limitation any obligation to make any cash payment to you with respect to such accrued unused PTO days).

9. 401(k) Savings Plan.

You will be eligible to participate in Cellegy's 401(k) plan on the same terms and conditions as other Cellegy employees.

10. Termination.

(a) Termination of Employment. Notwithstanding anything contained in this Agreement, this Agreement and your employment hereunder may be terminated at any time (a) voluntarily by you upon prior written notice to Cellegy and (b) by Cellegy immediately upon notice to you. Cellegy may terminate your employment:

(i) for Cause;

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(ii) by reason of your death;

(iii) by reason of your disability, where such disability has continued for a period of ninety (90) days, whether or not consecutive, in any 365 day period ("disability" shall mean your inability to perform the services contemplated by this Agreement for such period, as determined by a physician reasonably satisfactory to both you and Cellegy; provided, that if you and Cellegy do not agree on a physician, you and Cellegy shall each select one, and these two together will select a third physician, whose determination as to disability shall be binding on all parties); and

(iv) without Cause, for any reason or no reason (with employment terminations by reason of death or disability, or your termination of your employment by reason of your non-renewal of the term of this Agreement, not constituting terminations without Cause).

(b) Cause. For the purposes of this Agreement, "Cause" shall be deemed to exist for:

(i) your willful and deliberate failure or a refusal (not resulting from your incapacity due to physical or mental illness) to comply in any material respect with the legal or ethical policies, standards or regulations of the Company (including without limitation the Company's insider trading policy), or willful and deliberate failure to follow the lawful written directions of the Chief Executive Officer or the Board of Directors, provided that written notice in reasonable detail as to the alleged failure or refusal has been given to you by the Chief Executive Officer or his authorized designate and, if the failure is capable of cure, you have had a reasonable opportunity to cure such failure;

(ii) your misconduct which is materially detrimental to the Company, or willful and deliberate failure or a refusal (not resulting from your incapacity due to physical or mental illness) in any material respect faithfully or diligently, to perform your legal and ethical duties, determined by the Company in accordance with any written agreement between you and the Company or the customary duties of your employment; provided that written notice, in reasonable detail as to the alleged failure or refusal, has been given to you by the Chief Executive Officer or his authorized designate and, if the failure is capable of cure, you have had a reasonable opportunity to cure such failure;

(iii) your deliberate concealment from the Board of any action by you in violation of any legal or ethical policy, standard or regulation set by the Company;

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(iv) any unethical or fraudulent conduct that is demonstrably injurious and materially discredits the Company or is materially detrimental to the reputation, character or standing of the Company;

- (v) dishonest conduct or a deliberate attempt by you to do injury to the Company;
- (vi) your material breach of any written employment agreement or invention assignment and confidentiality agreement between you and the Company; or
- (vii) commission of an unlawful or criminal act (serious in nature) which the Board of Directors or the Chief Executive Officer reasonably concludes would reflect adversely on the Company, or your conviction of a felony or other crime involving embezzlement or fraud involving the money or property of the Company.

11. Effect of Termination.

(a) General. Upon termination of your employment, you (or your heirs in the event of your death) will be paid (i) the Base Salary (as defined above) through the date of termination, (ii) any portion of your bonus then earned but not yet paid, and (iii) all other benefits payable in accordance with the applicable plans and programs of Cellegy, and all rights and benefits hereunder shall cease except as expressly provided herein.

(b) Termination. In the event that Cellegy terminates your employment in a termination without Cause or notifies you of Cellegy's determination not to renew this Agreement upon the expiration of any term or in the event that you terminate your employment for Good Reason (as defined below), then:

(i) you will be entitled to receive your Base Salary for a period of twelve (12) months, one-half of which shall be paid in a lump sum payment as of the date of termination and the other half of which shall be paid in six equal monthly installments on the first day of each of the six calendar months immediately following the date of termination.

(ii) any stock options granted by Cellegy to you after the Effective Time (the "**Post-Acquisition Options**") will become vested and exercisable on a pro rata basis through the date of termination (with vesting for the year in which termination occurred to be on a monthly basis for the portion of the year in which the termination occurred) and you shall have 90 days in which to exercise the options; provided, however, that if your employment is terminated in a Termination upon Change of Control as defined in Cellegy's Retention and Severance Plan for Executives (the "**Retention Plan**"), then all Post-Acquisition Options will become fully vested and exercisable as provided in the Retention Plan.

(iii) if you elect coverage under COBRA, you will receive, by means of payment by Cellegy on behalf of yourself, your spouse and your dependents of the applicable premiums, continued provision of the Company's health-related and other standard employee

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insurance coverages as are in effect immediately prior to such employment termination for a period of twelve (12) months following such termination (with you remaining responsible for such deductibles or percentage of payments under such insurance as you were responsible for contributing immediately before the employment termination). You will be responsible for all taxes relating to any payments made pursuant to this Section 10, and the amounts of any such payments will be reduced by any amounts required to be withheld or deducted by the Company from the payments. The date of the "qualifying event" for you and your spouse and dependents shall be the date of your employment termination. Notwithstanding the preceding provisions, in the event you become covered as a primary insured (that is, not as a beneficiary under a spouse's or partner's plan) under another employer's group health plan that is comparable or superior to Cellegy's health plan during the period provided for herein, you shall promptly shall inform the Company and the Company shall cease provision of continued group health insurance for you and any family.

For purposes of this paragraph, "Good Reason" shall mean: assignment to you of a title position, responsibilities or duties that are materially less than the title position, responsibilities and duties that you occupied immediately after the Effective Time (except that following a Change of Control (as defined in the Company's Retention and Severance Plan), a reduction in title position, responsibilities or duties solely by virtue of the Company being acquired and made part of a larger entity or operated as a subsidiary shall not constitute Good Reason); (ii) a material breach by the Company of any of the terms of this Agreement; or (iii) a material reduction in your compensation or benefits (other than reductions in benefits under employee benefit plans applicable to officers or employees of the Company generally); provided, in each of the foregoing cases, that you have provided written notice to the Company that an event constituting Good Reason has occurred and the Company has a reasonable opportunity, not to exceed thirty (30) days, to cure such event.

12. Indemnification

Cellegy shall indemnify and defend you and hold you harmless to the fullest extent permitted by Cellegy's bylaws and applicable law in connection with any claim, action, suit, investigation or proceeding arising out of or relating to performance by you of services for, or action by you as an officer or employee of (i) Biosyn prior to the Effective Date or (ii) Cellegy, or any parent, subsidiary or affiliate of Cellegy after the Effective Date. Expenses incurred by you in defending a claim, action, suit or investigation or criminal proceedings shall be paid for by Cellegy in advance of the final disposition thereof in accordance with Cellegy's bylaws and upon the receipt by Cellegy of your undertaking to repay said amount if it shall ultimately be determined that you are not entitled to be indemnified hereunder. You acknowledge receipt of a copy of such bylaws. Notwithstanding the foregoing, Cellegy shall not be required:

(a) (Unlawful Indemnification) to indemnify you with respect to any acts or omissions or transactions from which a court having jurisdiction in the matter shall determine that you may not be relieved of liability under any applicable state or federal law. In this respect, you acknowledge having been advised that the Securities and Exchange Commission takes the position that indemnification for liabilities arising under the federal securities laws is against public policy and is, therefore, unenforceable and

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that claims for indemnification should be submitted to appropriate courts for adjudication;

(b) (Claims Initiated by you) to indemnify or to advance expenses to you with respect to proceedings or claims initiated or brought voluntarily by you and not by way of defense, except as may expressly be required under applicable law, but such indemnification or advancement of expenses may be provided by the Company in specific cases if the Board of Directors has approved the initiation or bringing of such suit; or

(c) (No Duplication of Payments) to indemnify you for expenses or liabilities of any type whatsoever (including, without limitation, judgments, fines, ERISA, excise taxes or penalties, and amounts paid in settlement) to the extent that you have otherwise actually received payment (under any insurance policy, provision of the Company's certificate of incorporation, bylaws or otherwise) of the amounts otherwise payable hereunder.

13. Acknowledgement of No Claims; Release of Claims.

You acknowledge and agree that, except as may be expressly disclosed in the Biosyn Disclosure Schedule relating to the Exchange Agreement and provided that at the Closing of the transactions contemplated by the Exchange Agreement you receive all salary, bonus and benefits payments that are provided for in the Exchange Agreement, as of the date of this Agreement, all accrued salary, bonus pay, cash profit-sharing, termination benefits or other compensation to which you are entitled by virtue of your employment with Biosyn has been satisfied or will be satisfied by Biosyn on or before the Effective Date (other than accrued salary or reimbursements for expenses incurred in the ordinary course of business for pay periods before the Effective Date, all of which will be satisfied by Biosyn before the Effective Date). You acknowledge and agree that as of the date of this Agreement and as of the Effective Date, you do not have and will not have any claims arising from any omissions, acts or facts that have occurred up until and including the date of this Agreement and the Effective Date against Biosyn, the Company or any of their officers, shareholders, employees, directors, or agents, including without limitation any claims under any employment laws, including, but not limited to, claims of unlawful discharge, breach of contract, breach of the covenant of good faith and fair dealing, fraud, violation of public policy, defamation, emotional distress, claims for additional compensation or benefits arising out of your employment with Biosyn or your separation of employment from Biosyn in connection with the transactions contemplated by the Exchange Agreement, claims under Title VII of the 1964 Civil Rights Act, as amended, and any other laws and/or regulations relating to employment or employment discrimination. Your right to receive the severance and other benefits described in this Agreement (other than benefits required by law to be paid to you upon employment termination) is conditioned upon your execution and delivery to Cellegy of a release of claims agreement upon employment termination in the form attached as Exhibit B hereto or, if payment of severance and benefits as contemplated by this Agreement are as provided in the Retention Plan, then on the form of release provided in the Retention Plan

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14. Term.

The term of this Agreement shall be for a period of two (2) years beginning on the Effective Date, unless terminated earlier as provided in Section 9 hereof, and shall renew automatically for successive one (1) year terms unless either you or Cellegy notifies the other in writing of your or its determination not to renew this Agreement at least sixty (60) days prior to the termination of the immediately preceding term.

15. Secrecy and Non-Competition.

(a) Non-Competing Employment. You acknowledge that the agreements and covenants contained in this Section are essential to protect the value of the Company's business and assets (including resulting from the acquisition of the business of Biosyn) and, by your current employment with the Company, you have obtained and will obtain such knowledge, contacts, know-how, training and experience and there is a substantial probability that such knowledge, know-how, contacts, training and experience could be used to the substantial advantage of a competitor of the Company and to the Company's substantial detriment. Therefore, you agree that for the period commencing on the Effective Date and ending on the first anniversary of the termination of employment hereunder (such period is hereinafter referred to as the "**Restricted Period**") with respect to any geographical area in which the Company is engaged in business or actively contemplating engaging in business in the immediate future during your term of employment with the Company, you shall not participate or engage, directly or indirectly, for your benefit or on behalf of or in conjunction with any person, partnership, corporation or other entity, whether as an employee, consultant, advisor, agent, officer, director, shareholder, partner, joint venturer, investor or otherwise, in the research, development or commercialization of any technologies, intellectual property, potential products or products relating to (i) anti-microbial spermicides or intravaginal gels used for contraception or the prevention or reduction in transmission of infectious or sexually transmitted diseases, or (ii) any other business of the Company that you become substantially engaged in during the period of time that you are an employee of, or consultant to, the Company after the Effective Time (collectively, the "**Restricted Field**"), which technologies or products are competitive with any technology, intellectual property, potential products, or products or application thereof in the Restricted Field designed, contemplated to be implemented in the immediate future, under research or development, marketed, announced, leased or sold by the Company or any of its subsidiaries (which term for purposes of this Section includes the Company and/or Biosyn either before or after the Effective Date) during your term of employment with the Company or any of its subsidiaries or at the time of the termination of your employment; provided, however, that you may own any securities of any company which is engaged in such business and is publicly owned and traded but in an amount not to exceed at any one time one percent of any class of stock or securities of such company.

(b) Nondisclosure of Confidential Information. Except in connection with your employment hereunder, you shall not disclose to any person or entity or use, either during the term of your employment with the Company or any of its subsidiaries or at any time thereafter, any information not in the public domain, is generally known in the industry or has been independently developed and disclosed by others, in any form, acquired by you while employed by the Company (or any subsidiary) or any predecessor to the Company's business or, if acquired following the term of your employment with the Company, such information which, to

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your knowledge, has been acquired, directly or indirectly, from any person or entity owing a duty of confidentiality to the Company or any of its subsidiaries or affiliates, relating to the Company, its subsidiaries or affiliates, including but not limited to information regarding customers, vendors, suppliers, trade secrets, training programs, manuals or materials, technical information, contracts, systems, or other data (including the revenues, costs or profits associated with any of the Company's products or services), business plans, code books, invoices and other financial statements, computer programs, software systems, databases, discs and printouts, plans (business, technical or otherwise), customer and industry lists, correspondence, internal reports, personnel files, sales and advertising material, telephone numbers, names, addresses or any other compilation of information, written or unwritten, which is or was used in the business of the Company or any subsidiaries or affiliates thereof. You agree and acknowledge that all of such information, in any form, and copies and extracts thereof, are and shall remain the sole and exclusive property of the Company, and upon termination of your employment with the Company, you shall return to the Company the originals and all copies of any such information (whether in hard copy, electronic form or otherwise) provided to or acquired by you in

connection with the performance of your duties for the Company or any subsidiary, and shall return to the Company all files, correspondence and/or other communications received, maintained and/or originated by you during the course of your employment.

(c) No Interference. During the Restricted Period, you shall not, whether for your own account or for the account of any other individual, partnership, firm, corporation or other business organization (other than the Company), directly or indirectly solicit, endeavor to entice away from the Company or its subsidiaries, or otherwise directly interfere with the relationship of the Company or its subsidiaries with any person who is employed by or otherwise engaged to perform services for the Company or its subsidiaries (including, but not limited to, any independent sales representatives or organizations) or who is, or was within the then most recent twelve-month period, a customer or client of the Company or other entity having a business relationship with the Company, its predecessors or any of its subsidiaries. The placement of any general classified or "help wanted" advertisement and/or general solicitations to the public at large shall not constitute a violation of this Section unless your name is contained in such advertisements or solicitations.

(d) Inventions, etc. By signing this Agreement you hereby sell, transfer and assign to the Company or to any person or entity designated by the Company your entire right, title and interest in and to all inventions, ideas, disclosures and improvements, whether patented or unpatented, and copyrightable material, made or conceived by you, solely or jointly, during your employment by the Company (or any subsidiary) which relate to methods, apparatus, designs, products, processes or devices, sold, leased, used or under consideration or development by the Company (or any subsidiary), or which otherwise relate to or pertain to the business, functions or operations of the Company (or any subsidiary) or which were made or conceived during business hours or using the facilities or other resources of the Company (or any subsidiary). You shall communicate promptly and disclose to the Company, in such form as the Company requests, all information, details and data pertaining to the aforementioned inventions, ideas, disclosures and improvements; and you shall execute and deliver to the Company such formal transfers and assignments and such other papers and documents as may be necessary or required to permit the Company or any person or entity designated by the Company to file and prosecute the patent

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applications and, as to copyrightable material, to obtain copyright thereof. Any invention relating to the business of the Company (or any subsidiary) and disclosed by you within one year following the termination of your employment with the Company shall be deemed to fall within the provisions of this Section unless proved to have been first conceived and made following such termination. No later than the Effective Date, you agree to execute Cellegy's standard form of proprietary information and invention assignment agreement.

(e) Injunctive Relief. Without intending to limit the remedies available to the Company, you acknowledge that a breach of any of the covenants contained in Section hereof may result in material irreparable injury to the Company or its subsidiaries or affiliates for which there is no adequate remedy at law, that it may not be possible to measure damages for such injuries precisely and that, in the event of such a breach or threat thereof, the Company shall be entitled to obtain a temporary restraining order and/or a preliminary or permanent injunction, without the necessity of proving irreparable harm or injury as a result of such breach or threatened breach of this Section, restraining you from engaging in activities prohibited by this Section hereof or such other relief as may be required specifically to enforce any of the covenants in Section.

16. Arbitration.

In order to obtain the many benefits of arbitration over court proceedings, including speed of resolution, lower costs and fees and more flexible rules of evidence, all disputes between you and the Company arising out of or concerning the interpretation of application of this Agreement or its subject matter shall be resolved exclusively by binding arbitration in Philadelphia, Pennsylvania pursuant to the National Rules for the Resolution of Employment Disputes of the American Arbitration Association. The Company and you hereby waive their rights to have a jury trial for any such disputes. Arbitration must be demanded within 180 days of the time when the demanding party knows or should have known of the events giving rise of the claim. The arbitration opinion and award shall be in writing and shall be final, binding and enforceable by any court under the Federal Arbitration Act. Each party shall pay their own fees and costs in connection with any such arbitration and shall pay one-half of the fees of the arbitrator, but the arbitrator shall have discretion to make a different award of fees and costs in connection with rendering the arbitrator's opinion and award. The foregoing provisions are intended to supersede any provisions in the Retention Plan, including Section 9 thereof, concerning arbitration of disputes.

17. General.

(a) Assignment. You may not assign this Agreement or any of its rights and privileges hereunder to any other person, firm or corporation. Cellegy may assign this Agreement without your consent in connection with any sale of all or substantially all of Cellegy's business or assets, whether by merger, consolidation, sale of assets, sale of stock, or other similar transaction provided that the successor company agrees in writing to assume the Company's obligations under this Agreement in their entirety (and any change in employers resulting from the fact that the successor or acquiring company, rather than Cellegy, becomes the employer shall not by itself be deemed a termination of employment hereunder). This

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Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors and permitted assigns.

(b) Entire Agreement. This Agreement (together with any nondisclosure, noncompetition, proprietary information and/or invention assignment agreement(s) with Biosyn or the Company that you have executed or will execute and all other agreements and documents referred to herein) constitutes the entire agreement between the parties with reference to the subject matter hereof and, except as expressly set forth in Section 2 above, supersedes all prior negotiations, understandings, representations and agreements, if any, relating to your employment by Biosyn or Cellegy. If and to the extent any such other agreements or documents shall be inconsistent in any respect with the provisions of this Agreement, the provisions of this Agreement shall prevail.

(c) Governing Law; Consent to Jurisdiction. The provision of this Agreement shall be governed by and interpreted in accordance with the laws of the Commonwealth of Pennsylvania, notwithstanding any application of any doctrine of conflicts of laws. Without limiting the effect of the other provisions in this Agreement requiring arbitration of disputes arising hereunder, each party irrevocably consents to the exclusive jurisdiction and venue of the state and federal courts for the federal and state judicial district in which such party is entitled to initiate an arbitration proceeding in accordance with Section 16 above in connection with any action to enforce the provisions of this Agreement, to recover damages or other relief for breach or default of this Agreement, or otherwise arising under or by reason of this Agreement, and agrees that service of process in any such action may be effected by the means provided in this Agreement for delivery of notices.

(d) Severability. If any provision contained in this Agreement is determined to be void, invalid or unenforceable in whole or in part for any reason whatsoever, such determination shall not affect or impair the validity of any other provision herein, nor the validity of this Agreement as a whole. Each provision of this Agreement shall be deemed to be separate and distinct. Without limiting the foregoing, you acknowledge and agree that the covenants set forth in Section 15 above are reasonable and valid in geographical and temporal scope and in all other respects. If any of such covenants or such other provisions are found to be invalid or unenforceable by a final determination of a court of competent jurisdiction, (i) the remaining terms and provisions hereof shall be unimpaired and (ii) the invalid or unenforceable term or provision shall be deemed replaced by a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision.

(e) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

(f) Termination of Exchange Agreement. If the Exchange Agreement is terminated in accordance with its terms, then this Agreement and the obligations of the parties hereunder shall immediately terminate.

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(g) Notices. All notices and other communications required or permitted under this Agreement will be in writing and hand delivered, sent by telecopier, sent by certified first class mail, postage pre-paid, or sent by nationally recognized express courier service. Such notices and other communications will be effective: (a) upon receipt if hand delivered; or (b) three (3) days after mailing if sent by mail; and (c) one (1) business day after delivery to a national overnight courier service for next business day delivery, to the following addresses, or such other addresses as any party may notify the other parties in accordance with this Section:

If to Cellegy or Employee:

Cellegy Pharmaceuticals, Inc.
349 Oyster Point Boulevard
South San Francisco, CA 94080
Attention: Chief Financial Officer

With a copy to:

Weintraub Genshlea Chediak Sproul
400 Capitol Mall, Eleventh Floor
Sacramento, CA 95814
Attention: C. Kevin Kelso, Esq.

If to Employee:

Anne-Marie Corner
586 West Mermaid Lane
Philadelphia, PA 19118

With a copy to:

Duane Morris LLP
One Liberty Place
Philadelphia, PA 19103-7396
Attention: Kathleen M. Shay, Esq.

or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall only be effective upon receipt.

[Remainder of this page intentionally left blank]

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Please confirm your acceptance of the foregoing by signing this Agreement where indicated below. Your signature below indicates your acceptance of this Agreement and its terms and conditions, and we both intend, acknowledge and agree that this is a binding contract enforceable in accordance with these terms.

Yours very truly,

CELLEGY PHARMACEUTICALS, INC.

By: /s/ K. Michael Forrest
K. Michael Forrest,
Chief Executive Officer

I accept the terms of the agreement as outlined above:

/s/ Ann-Marie Corner
Anne-Marie Corner

Date: October , 2004

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EXHIBIT A

EMPLOYMENT RESPONSIBILITIES

1. Assume direct responsibility for the strategic direction and management of the Company's microbicide business, as well as administrative management of all employees located at the Huntingdon Valley, PA facility.
2. Prepare, obtain approval for and manage annual budgets for the microbicide business. As requested, prepare longer-range forecasts and projections.
3. Participate proactively in Cellegy's overall strategic planning process, working cooperatively with the CEO, Corporate Development, Regulatory Affairs, Clinical Research, R&D, Finance, Human Resources and Marketing/Sales.
4. As requested, attend Cellegy's Board of Directors meetings in order to provide updates and input into the strategic direction and operations of the microbicide business.
5. Assume direct responsibility for coordination with granting agencies to effectively manage relationships and ensure that adequate resources are available to support core programs.
6. As requested, attend conferences, conventions, road shows and meetings with members of the investment and medical community, as well as with other constituents in order to obtain information and/or make presentations relevant to the microbicide business.
7. Implement a proactive program designed to educate and keep the CEO and/or his designates current regarding all aspects of the microbicide business, including a planned program to meet with potential licensing partners, granting and potential granting agencies, CROs and other key organizations to accomplish objectives agreed upon from time to time.
8. As directed, and in coordination with the Vice President, Corporate Development, meet with potential licensing partners an/or M&A targets to accomplish objectives agreed upon from time to time with the CEO.
9. Seek advice and actively provide assistance to and cooperation with employees of Cellegy from various disciplines, in particular Clinical, Regulatory, Research, Development, and Finance in order to effectively manage the microbicides business.

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EXHIBIT B

RELEASE OF CLAIMS

THIS RELEASE OF CLAIMS ("**Release**") is entered into between _____ ("**Employee**") and Cellegy Pharmaceuticals, Inc. ("**Cellegy**").

1. Payment of Separation Benefits. I understand that my employment with Cellegy has terminated. Cellegy has agreed that if I choose to sign this Release on or after my last day of employment, Cellegy will provide me separation benefits (the "**Separation Benefits**") set forth in pursuant to the employment letter agreement between Cellegy and me dated _____, 2004 (the "**Agreement**"). I understand that I am not entitled to these Separation Benefits unless I sign this Release. Employee agrees to waive or terminate his or her rights to any cash severance or option or restricted stock acceleration or continued vesting under any agreement, other than as described in the Agreement (whether written or oral), with Cellegy that provides that upon a change of control or termination of employment Employee would be entitled to receive any cash severance or acceleration or continued vesting. This Release and the Agreement contain the entire understanding of Cellegy and Employee with respect to cash severance or option or restricted stock acceleration or continued vesting and supersede any prior agreements with respect to these matters. I understand that in addition to the Separation Benefits and regardless of whether I sign this Release, Cellegy has paid me all of my accrued salary and vacation earned through my date of termination and any remaining unpaid balance of my bonus that I am entitled to receive and that has not been paid.

2. Release.

(a) Each of (i) Employee and Employee's respective heirs, executors, successors and assigns, and (ii) Cellegy and its parents, subsidiaries, successor, agents, officers and directors, hereby fully and forever release each other and their respective heirs, executors, successors, agents, officers and directors, from and agree not to sue concerning, any and all claims, actions, obligations, duties, causes of action, whether now known or unknown, suspected or unsuspected, that either of them may possess based upon or arising out of any matter, cause, fact, thing, act, or omission whatsoever occurring or existing at any time prior to and including the date of Employee's termination of employment (collectively, the "**Released Matters**"), as follows:

(i) any and all claims relating to or arising from Employee's employment relationship with Cellegy and the termination of that relationship;

(ii) any and all claims relating to, or arising from, Employee's right to purchase, or actual purchase of, shares of stock of Cellegy, including, without limitation, any claims of fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

(iii) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; breach of contract, both express and

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implied; breach of a covenant of good faith and fair dealing, both express and implied or promissory estoppel;

(iv) any and all claims for violation of any federal, state or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, the

- (v) any and all claims for violation of the federal, or any state, constitution;
 - (vi) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;
- and
- (vii) any and all claims for attorneys' fees and costs.

This Release does not extend to, and does not result in, a waiver or release of any of the following: (a) any claim by Employee for workers' compensation or unemployment benefits; (b) Employee's rights to indemnity under any indemnity agreement signed by the parties, as well as under Labor Code section 2802; and (c) all rights and benefits to which Employee is entitled under the Agreement.

(b) Employee and Cellegy acknowledge that they have been advised by legal counsel and are familiar with Section 1542 of the Civil Code of the State of California, which states:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR.

Employee expressly waives any right or benefit that he has or may have under Section 1542 of the California Civil Code or any similar provision of the statutory or non-statutory law of any other jurisdiction, including Pennsylvania and Delaware.

3. Acknowledgment of Waiver of Claims under ADEA. Employee acknowledges that Employee is waiving and releasing any rights Employee may have under the Age Discrimination in Employment Act of 1967 ("**ADEA**") and that this waiver and release is knowing and voluntary. Employee and Cellegy agree that this waiver and release does not apply to any rights or claims that may arise under ADEA after the Effective Date (defined below) of this Release. Employee acknowledges that the consideration given for this Release is in addition to anything of value to which Employee was already entitled. Employee further acknowledges that Employee has been advised by this writing that:

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- (a) Employee should consult with an attorney **prior** to executing this Release;
- (b) Employee has at least twenty-one (21) days within which to consider this Release, although Employee may accept the terms of this Release at any time within those 21 days;
- (c) Employee has at least seven (7) days following the execution of this Release by the parties to revoke this Release; and
- (d) This Release will not be effective until the revocation period has expired (the "**Effective Date**").

4. Indemnity and Employee Invention Agreement. Employee and Cellegy agree that all rights and obligations of the parties under any indemnity agreement between the parties and under any invention assignment and confidentiality agreement will continue in effect.

5. Voluntary Execution of Agreement. This Release is executed voluntarily and without any duress or undue influence on the part or behalf of the parties hereto, with the full intent of releasing all claims. The parties acknowledge that:

- (a) they have read this Release;
- (b) they have been represented in the preparation, negotiation, and execution of this Release by legal counsel of their own choice or that they have voluntarily declined to seek such counsel;
- (c) they understand the terms and consequences of this Release and of the releases it contains;
- (d) they are fully aware of the legal and binding effect of this Release.

EXECUTIVE HAS CONSULTED WITH AN ATTORNEY BEFORE SIGNING THIS RELEASE AND UNDERSTANDS THAT, BY SIGNING THIS RELEASE, EXECUTIVE IS GIVING UP ANY LEGAL CLAIMS EXECUTIVE HAS AGAINST CELLEGY PHARMACEUTICALS, INC. EXCEPT AS SET FORTH HEREIN. EXECUTIVE FURTHER ACKNOWLEDGES THAT EXECUTIVE DOES SO KNOWINGLY, WILLINGLY, AND VOLUNTARILY IN EXCHANGE FOR THE BENEFITS DESCRIBED IN THE AGREEMENT.

6. Return of Company Property. Employee represents and warrants to Cellegy that Employee has returned all real or intangible property or data of Cellegy of any type whatsoever that has been in Employee's possession or control.

7. Nondisparagement. Employee agrees that Employee will not disparage Cellegy or its products, services, agents, directors, officers, shareholders, attorneys, employees, affiliates, successors or assigns, or any persons acting by, through, or in concert with any of them, with any written or oral statement.

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8. Arbitration. The mandatory binding arbitration provisions set forth in the Agreement are hereby incorporated by referenced.

9. Confidentiality. The contents, terms and conditions of this Release shall be kept confidential by Employee and may not be disclosed by Employee except to Employee's accountant or attorneys or pursuant to court order or subpoena. Employee agrees that if Employee is asked for information concerning this settlement, Employee will state only that Employee and Cellegy have reached an amicable resolution of any disputes concerning Employee's separation from Cellegy.

10. Entire Agreement. This Release sets forth the entire agreement between Employee and Cellegy with respect to the subject matter hereof and supersedes all prior negotiations and agreements, whether written or oral, relating to such subject matter.

[Remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Release as of the date set forth below.

EXECUTIVE

CELLEGY PHARMACEUTICALS, INC.

Signature

Date: _____

By: _____
Title: _____

Date: _____

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

Confidential

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EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT

THIS EXCLUSIVE LICENSE AND DISTRIBUTION LICENSE AGREEMENT (this “**Agreement**”) is made and entered into as of December 9, 2004 (the “**Effective Date**”), by and between Cellegy Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 349 Oyster Point Boulevard, San Francisco, California 94080, US (“**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. Licensee desires to obtain 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. Cellegy is willing to grant an exclusive license to Licensee under such intellectual property rights, and is willing to grant an exclusive license to Cellegy’s Marks to Licensee, each within the Territory, all as more particularly described in, and subject to the terms and conditions of, this Agreement.

AGREEMENT

NOW THEREFORE, 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;

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- (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 Exclusive License 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.

“**Baseline Price**” has the meaning set forth in Section 11.4

“**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 D 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.

“**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

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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.

“**Effective Date**” means the date set forth at the beginning of this 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 and for the treatment of one (1) or more of the symptoms associated with or related to hemorrhoids.

“**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, 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 relates 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.

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“**Licensed Product**” means the pharmaceutical product known as Rectogesic™ ointment – a 0.4% nitroglycerin ointment for the treatment of pain associated with chronic anal fissure and, if Approvals are obtained, for the treatment of one or more of the symptoms associated with or related to hemorrhoids, in the pharmaceutical presentation described in Exhibit A.

“**Licensee Product**” means one (1) of either (i) Licensee’s orally delivered estradiol glucoside product, which is currently in Phase 1 clinical studies, or, at Cellegy’s option if it elects to accept such product in lieu of the product specified in the preceding clause “(i)”, (ii) any future product, product candidate or potential product developed or acquired by Licensee in the therapeutic area of gastroenterology.

“**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 Cellegy’s nominated Third Party manufacturer of the Licensed Product.

“**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.

“**Minimum Sales**” means agreed targets for unit sales of Licensed Product in the Territory, as determined in accordance with Section 10.4.

“**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

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(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 C 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 C 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.

“**Subsequent Indication**” means the treatment of one (1) or more of the symptoms associated with or related to hemorrhoids.

“**Technical Agreement**” means the agreement between Cellegy and any Manufacturer defining the roles and responsibilities for all parties in relation to, inter alia, (i) manufacture and supply of the Licensed Product to GMP; and (ii) regarding regulatory, safety and pharmacovigilance issues, as separately provided by Cellegy to Licensee as of the date of this Agreement.

“**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.

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ARTICLE 2 GRANT OF LICENSE

2.1 **Grant.** Cellegy hereby grants to Licensee an exclusive license, with a right to sublicense as set forth herein, under all of Cellegy’s Intellectual Property Rights to 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 in connection with the 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.** 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 and delayed; and
- (b) to any of its Affiliates that are engaged primarily in the business of 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

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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

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 or 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 anal fissures or hemorrhoids or such other indications for the Licensed Product as may be added to this Agreement (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 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 a Licensee Product 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 a 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 one (1) 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 applicable 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 one (1) time 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; (iv) the effective date of termination of this Agreement by either Party as provided elsewhere in this Agreement; or (v) such time as Cellegy and Licensee enter into a definitive

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agreement regarding such a license for one (1) such Licensed Product. In addition, the right of first negotiation will also include a one time right on the part of Cellegy to be granted a license to one Licensee Product if, within thirty (30) days after Licensee delivers to Cellegy a notice containing all significant terms of the offer, Cellegy notifies Licensee that it is willing to match in all material respects (i) the financial terms (including financially in terms of upfront, milestone and royalty payments, and (ii) the key obligations and timelines (including regulatory, development and commercial) contained in any bona fide offer that Licensee has received for the Licensed Product from a Third Party.

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) 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. Attached hereto as Exhibit C 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

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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. Attached hereto as Exhibit D 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 of the 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

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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

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. 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 MANAGEMENT OF THE COLLABORATION

4.1 Steering Committee.

(a) Upon execution of this Agreement, Cellegy and Licensee shall establish 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 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. In any event, the Steering Committee will meet thirty (30) days after the execution of this Agreement or as soon as practicable as mutually agreed by 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

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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 that Cellegy has already obtained in the United Kingdom, prior to submitting any Approval application, the Steering Committee shall discuss the scope and content of such Approval application. The Steering Committee may 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) review and approve the Marketing Plans, such approval not to be unreasonably withheld or delayed.

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

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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 the United Kingdom 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 submitted no later than three (3) months after the Effective Date of this Agreement, 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 of this Agreement. 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, 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: 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 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

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reasonable access to relevant experts in relation to the Cellegy Information for the purpose of obtaining Approvals.

(b) With respect to the Subsequent Indication, Cellegy shall be responsible for the conduct of such clinical trials or studies as Cellegy may in its discretion undertake. If Cellegy determines to pursue Approvals for the Licensed Product for the Subsequent Indication in the Territory, Cellegy shall submit to Licensee the information and data that it has developed to be included in the initial application for Approval, such information and data shall be agreed between the parties as adequate and appropriate for an application for Approval of the Subsequent Indication for the Licensed Product in a Major European Country. Licensee shall use Commercially Reasonable and Diligent Efforts, subject to this Agreement, to seek Approval for the Licensed Product for the Subsequent Indication in the United Kingdom (or such other country in the Territory as the Steering Committee may approve) and to obtain at its sole expense all Approvals that are necessary for the sale of the Licensed Product within the Territory for the Subsequent Indication, including without limitation: any additional clinical trials, studies or data that may be required in order to obtain or maintain Approvals for the Licensed Product in each country in the Territory for the Subsequent Indication, comply with any and all applicable Laws in relation to the importation, storage, Development, promotion, marketing, distribution or sale of the Licensed Product in the Territory under this Agreement for the Subsequent Indication, 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, and 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 for the Subsequent Indication, including allowing Licensee reasonable access to relevant experts in relation to the Cellegy Information for the purpose of obtaining Approvals. The other provisions of this Agreement shall, as nearly as possible, apply with respect to the Licensed Product for the Subsequent Indication.

(c) 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 on which Licensee is assigned the Approval of the Licensed Product from the Relevant Regulatory Authority in the United Kingdom provided that the dossier used in the United Kingdom is acceptable for use in an M.R.P. 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 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

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Licensed Product in other countries in the Territory no later than [*] after the completion of the M.R.P. application 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.

(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 Reversion of Product Rights in Certain Circumstances. If further clinical development is required for Approval of the Initial Indication 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. If, after the initial application for Approval for the License Product for the Subsequent Indication is filed, further clinical development is required for Approval of the Subsequent Indication 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 with respect to the Subsequent Indication 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 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.

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5.5 Approval Application in the United Kingdom. Cellegy shall do all that is necessary to assign or transfer the Approval (by itself or Cellegy's Affiliate holding the Approval) in the United Kingdom to Licensee, including (if required) notifying the Relevant Regulatory Authority in the United Kingdom of such a change.

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, 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 Licensed Product, 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 for the Initial Indication (with the exception of the Approval for the United Kingdom that has been obtained) (and, if Cellegy conducts the clinical studies described in Section 5.1 above with respect to the Subsequent Indication, then Approvals for the Subsequent Indication) 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 Initial Indication (and/or Subsequent Indication, as the case may be) in the Territory. All clinical trials for use of the Licensed Product in the Initial Indication (and/or Subsequent Indication, as the case may be) 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. At the completion of each clinical trial initiated by Licensee after the Effective Date of this Agreement, Licensee shall prepare a written report, in compliance with the relevant ICH guidelines summarizing the results of such clinical trial, and

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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 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. Cellegy will use Commercially Reasonable and Diligent Efforts to provide the clinical supplies of the Licensed Product that Licensee may reasonably request, at Licensee's expense at a purchase price to Licensee determined on a pass-through cost basis based on Cellegy's manufacturing cost per unit. Cellegy may enter into one or more manufacturing and supply agreement(s) (or similar arrangements) with Third Party contract manufacturer(s) for such clinical supplies, and such agreements or arrangements shall provide for reasonable rights of access by Licensee's quality representatives to inspect the premises of such manufacturer(s) relating to such pharmacovigilance and quality issues as Licensee reasonably considers appropriate.

5.9 Cellegy Obligations. Promptly following entering into this Agreement Cellegy shall:

(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) except as provided in Section 5.8 above, at its cost promptly provide to Licensee a sufficient quantity of the Licensed Product as is 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 to procure the assistance of any third party supplier of raw materials to Cellegy, in meeting the demands of the Relevant Regulatory Authority relating to any application and any grant, maintenance, variation or renewal of Approvals;

(e) deliver to Licensee the Technical Agreement that Cellegy has entered into with the Manufacturer; and

(f) notify Licensee and promptly provide all relevant assistance and supporting documentation to Licensee, should Cellegy make any alteration to the Licensed Product, or the manufacture, or packing of the Licensed Product that needs to be notified to a Relevant Regulatory Authority.

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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: Cellegy represents and warrants that it shall bear the responsibility *vis-à-vis* Licensee and/or the Affiliate and/or the Sublicensee named by Licensee as the holder of the Approvals for complying with the regulatory requirements applicable to the manufacture and storage (until such time as the Licensed Product is delivered to Licensee or such Affiliate or Sublicensee) 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. Cellegy shall use all Commercially Reasonable and Diligent efforts to notify Licensee of the relevant insurance policies maintained by any Manufacturer of raw materials used in the manufacture of the Licensed Product, to the extent such information is available.

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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, 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 such Third Party, 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.

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.

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 (with all payments to be made in U.S. Dollars):

(a) One Million Dollars (\$1,000,000), within five (5) business days after the date this Agreement is executed and delivered by both parties hereto.

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(b) With respect to [*] the amounts set forth below, payable [*]

Event	Amount
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

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) [*]

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
REPORTS AND ACCOUNTING

9.1 Quarterly 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 "**Sales Report**") covering such preceding calendar quarter (the "**Sales Period**") showing:

(a) the Net Sales of the Licensed Product in each country of the Territory during the Sales Period, on a country-by-country and unit basis; and

(b) the exchange rates used in determining the amount of Net Sales in 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 Sales 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 Sales Period.

With respect to sales of Licensed Product invoiced in Dollars, the Net Sales and sales prices shall be expressed in Dollars. With respect to sales of Licensed Product invoiced in a currency other than Dollars, the Net Sales and sales prices shall be expressed in the domestic currency of the

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country where such sale was made together with the Dollar equivalent 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 Sales 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 shall be deducted from the amount of such upfront and milestone payments 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. Amounts shown to have accrued by each Sales Report provided for hereunder shall be due and payable on the date such Sales Report is due. Payment may be made in advance of such due date. All 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 selected by Cellegy or auditor selected by Cellegy and having an obligation of confidentiality (the "**Auditor**") to have access during normal business hours to those records of Licensee and its Affiliates as may be reasonably necessary to verify the accuracy of the Sales 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 the Auditor subject to the same terms and conditions as stated herein.

(c) If the Auditor's report shows any underpayment of amounts due to Cellegy, 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 is in excess of [*] of the total due to Cellegy with respect

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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 is in excess of [*] of the total amount 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.

9.4 Disagreement with Auditor Findings. If either Party disagrees with the determination made above by the Auditor and such disagreement over the amount in question is in excess of [*] then the Party who disagrees with such amount shall (i) provide written notice to the other Party within thirty (30) days (ii) discuss such disagreement with the other Party; and (iii) reserve all rights under Section 18.14 and Article 16 of this Agreement.

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 [*] following receipt of Marketing Authorization 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, 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

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(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 payment of the Baseline Price multiplied by the number of units of the Licensed Product equivalent to [*] (based on [*] will be due with respect to the Major European Countries, and a minimum payment of [*] 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 receipt of Marketing Authorization, 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) Licensee shall achieve agreed annual minimum unit sales of Licensed Product in the Territory representing [*] ("**Minimum Sales**"). The first year's agreed annual Minimum Sales figure is set forth in the relevant Marketing Plan in the form delivered by Licensee to Cellegy as of the Effective Date. In the event that all Approvals pursuant to the MRP are not obtained within [*] following the Launch Date in the first country of the Territory the Parties shall meet to discuss the Minimum Sales accordingly.

(b) If Licensee fails to achieve the Minimum Sales in a given year then Licensee shall pay to Cellegy [*], such amount to be paid within [*] 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 amount described in the first sentence of this subparagraph 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 are subject to review and revision as described in Section 11.4 below.

(d) At any time commencing with "Year 3", if Licensee fails to achieve the minimum sales set out in the Marketing Plan for any particular country in the Territory, for any [*] consecutive years, then if the Steering Committee cannot agree (without the occurrence of a deadlock) on mutually satisfactory modifications to the minimum sales amounts for such

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

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) 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 at any worldwide location, including Canada or any other locations outside of the United States of America and locations within or outside the Territory as long as such site is EU cGMP approved and can manufacture according to the Approvals. The Manufacturer shall not change following Approval without Licensee's consent, which consent shall not be unreasonably withheld or delayed, with Licensee being given no less than [*] notice of any such proposed change.

(b) During the term of this Agreement, Cellegy shall use Commercially Reasonable and Diligent Efforts to provide an adequate supply of raw materials to Manufacture in order to fulfill its obligations under this Agreement and supply the Licensed Product to Licensee in accordance with Licensee's orders. Cellegy agrees to solicit and to allow Licensee's input and advice on manufacturing issues that may arise from time to time in relation to the Licensed Product and will not take any intentional action with regard to the manufacturing of the Licensed Product that will disadvantage Licensee's ability to Develop, use, promote, distribute or sell the Licensed Product in the Territory.

(c) Cellegy shall be solely responsible for conducting, or having conducted, at its own expense, all manufacturing activities relating to the Licensed Product. Licensee agrees that, until terminated by Licensee as set forth herein, Licensee will purchase from Cellegy (and will not make or have made) all units of the Licensed Product distributed in the Territory.

(d) If Cellegy is unable to supply any of the Licensed Product ordered by Licensee in accordance with the terms of this Agreement for two consecutive requested deliveries, then Licensee may enter into direct arrangements with the Manufacturer for supply of the Licensed Product, until such time as Cellegy is able to resume supplying the Licensed Product.

11.2 Forecasts.

(a) Licensee shall, at least [*] before the Launch Date, provide Cellegy for each country in the Territory with a first forecast of its estimated requirements for the Product until

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the end of the following calendar year. Such forecast shall set forth the quantity of Licensed Product that Licensee intends to purchase in the current and the following calendar year. Thereafter, during the term of this Agreement, Licensee shall provide Cellegy with a quarterly written forecast of its requirements for the Licensed Product for a rolling [*] period, setting forth the quantity of Licensed Product (including total unit volume, on a country-by-country basis), that Licensee intends to purchase in the following [*] period. Each such first quarter projection in the [*] forecast shall constitute a firm commitment order by Licensee for such quantities of Licensed Product.

(b) The forecasts are subject to review and revision as described in Section 11.3 below.

11.3 Product Packaging and Labeling.

(a) Licensee agrees to provide Cellegy (or, if Cellegy requests, Manufacturer) with all artwork and package design desired for the Licensed Product in the Territory, and Cellegy shall procure the Manufacturer's agreement to pack and label the Licensed Product pursuant to Licensee's standard export procedure.

(b) Both parties will cooperate and use Commercially Reasonable and Diligent efforts with the Relevant Regulatory Authorities to minimize variation between country specific packaging and labeling requirements.

11.4 Pricing. In addition to the other payments set forth above, for so long as Licensee purchases Licensed Product from Cellegy, Licensee will pay Cellegy the purchase price for Licensed Product as set forth below. For each order of Licensed Product, Licensee shall pay Cellegy within [*] of the receipt by Licensee of the invoice for such order, such invoice not to be received before the date of delivery FCA Manufacturer's premises (Incoterms 2000). The purchase price that Licensee shall pay Cellegy for units of the Licensed Product shall be determined as follows:

(a) Licensee agrees to pay to Cellegy the greater of either (i) [*] of Licensee's Net Sales price for Licensed Product sales in the Territory to Third Parties (or, where Licensee sells a Licensed Product to an Affiliate or Sublicensee that resells the Licensed Product to a Third Party at a higher price, then [*] of such entity's Net Sales price to such other Third Party) in arm's-length transactions, or (ii) [*] (USD) per [*] tube of Licensed Product (such [*] price referred to as the "**Baseline Price**"). Licensee agrees to provide a list of Net Sales prices on a country-by-country and unit basis within the Territory. When Licensee places an order, Cellegy's invoice for such order shall reflect the Baseline Price. Licensee shall include sufficient information in the Sales Report regarding Licensed Product sales to enable Cellegy and Licensee to determine whether the amounts described in clause "(i)" of the first sentence of this subparagraph for sales in the various countries in the Territory of the Licensed Product purchased in such order were higher, or lower, than the Baseline Price. If such amount for such units of Licensed Product in such countries were higher than the Baseline Price, then Licensee shall deliver with the Sales Report the difference between such amount and the Baseline Price.

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

Conversion of prices into U.S. dollars shall be made as of the end of the quarter in which the Net Sales occurred.

(b) At Licensee's request, in the event an equivalent product containing nitroglycerin as the only active ingredient is launched in any country of the Territory that is in direct competition with the Licensed Product and is likely to have an adverse impact on the sales of the Licensed Product, the Parties shall meet to review the Baseline Price and the Minimum Sales.

(c) At Licensee's request, the Baseline Price and Minimum Sales will be subject to review by Cellegy in the event of material fluctuations in currency exchange rates that become a significant obstacle to the ongoing commercialization of the Licensed Product within one or more countries in the Territory.

(d) The Parties may, by mutual agreement, such agreement not to be unreasonably withheld, change the price of the Licensed Product to reflect:

(i) a decrease in any government subsidy for the Licensed Products; or

(ii) any change in Cellegy's costs of manufacture of Licensed Products (including labor, rent and overheads).

The Parties agree to provide such information as the other Party may reasonably request relating to requests made pursuant to this Section to change the price of the Licensed Product.

(e) Each Party will use reasonable commercial efforts to notify the other on reasonable notice of any circumstances, which may give rise to any change to the purchase price for Licensed Product and provide full details of the circumstances and the proposed new price.

(f) A change to the price of Licensed Product will be effective [*] or more, as agreed between the parties, after both parties have agreed in writing to such price change; provided, however, that if the new Price is higher than the then-current price, the then-current price will apply to any orders during such [*] period only for the quantity of Licensed Product that in the aggregate does not exceed the average monthly quantity of Licensed Product sold during the [*] preceding the month in which the parties agreed in writing to the new price, and the new price shall apply to any quantities ordered during such period that are in excess of such monthly average.

(g) Both Parties agree to work in mutual cooperation to manage the cost, production, packaging, delivery and availability of the Licensed Product for sale in the Territory.

(h) If the Parties mutually agree in writing to additional package size(s) or to replace the 30gm tube, then the Parties shall in good faith mutually agree on a pricing formula and purchase prices for such additional or different package size(s) similar to that established for the 30gm tube, utilizing assumptions similar to those underlying the pricing determinations set

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forth above. If the Parties are unable to agree, then the dispute shall be resolved by binding arbitration as provided in this Agreement at Section 18.14.

11.5 Cellegy Report. Cellegy agrees to provide an inventory status report on a monthly basis that details the number of units of the Licensed Product in manufacturing, finished goods, in-transit and on order.

11.6 Timing of Firm Orders. Firm orders from Licensee for the Licensed Product shall be placed at least four (4) months before delivery date by fax or email indicating the ordered quantities of the Licensed Product, the designated country, labeling, packaging the desired date and place of delivery. Licensee and Cellegy will use all Commercially Reasonable and Diligent Efforts to agree to establish ordering quantities that will facilitate minimum ordering patterns to suit manufacturing requirements so that orders are placed in minimum quantities that are set to match reasonable minimum lots sizes announced by Manufacturer of the Licensed Product. An order shall not be cancelable by Licensee, and if Licensee fails to make purchases provided for in an order, Licensee shall be responsible for the price of the order except in the case of Defective Product under Section 11.11.

11.7 Delivery. Licensee shall promptly provide to Cellegy, upon Cellegy's request, confirmation that all Approvals necessary to import and sell the Licensed Product in the Territory have been obtained. If such evidence is not received by Cellegy upon request, Cellegy shall be entitled to hold shipment of the Licensed Product until such evidence is received. Cellegy shall use Commercially Reasonable and Diligent Efforts to deliver the quantity of the Licensed Product ordered firm and properly according to this Agreement by Licensee as far as the ordered quantities comply with the respective forecast and provided that Cellegy did not reject the respective forecast within one month after receipt of the respective forecast. However, notwithstanding anything else in this Agreement, Cellegy shall not be bound to deliver quantities exceeding twenty-five percent (25%) of the respective forecast for the second quarter of each projection period, but shall use all Commercially Reasonable and Diligent Efforts to deliver in the required quantities. The Licensed Product required to be supplied by Cellegy during a particular month shall be shipped no later than the last day of that month and in accordance with a schedule agreed upon in writing between Licensee and Cellegy. In the event that Cellegy anticipates a forward supply issue and/or experiences a back order, Cellegy will promptly notify Licensee and provide written notice of the delay, projected time to remedy the issue and any impact the back order is expected to have on Cellegy's ability to maintain adequate supply of the Licensed Product to meet demand in the Territory.

11.8 Title and Risk of Loss. All Licensed Product shall be delivered F.C.A. Manufacturer's premises (Incoterms 2000). Title to Licensed Product and all risk of loss shall pass from Cellegy to Licensee at the time and place of such delivery by Cellegy, notwithstanding that Cellegy may retain rights of possession or repossession to ensure collection of the purchase price thereof. Licensee shall be solely responsible for insuring Licensed Product after such delivery.

11.9 Export Controls. Cellegy's obligation to sell and deliver Licensed Product to Licensee shall be subject in all respects to such laws and regulations of the United States of

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America, Canada and the Territory as shall from time to time govern, respectively, the sale and delivery of goods abroad by persons subject to the jurisdiction of the United States of America and Canada and the sale and delivery of goods in the Territory. Subject to the right of the Licensee to export, re-export or transship any of the Licensed Product to another country within the Territory, Licensee shall not directly or indirectly export, re-export or transship any of the Licensed Product, except as shall be permitted by the laws and regulations of the United States of America, Canada and the Territory in effect from time to time. Upon the reasonable request by Cellegy, Licensee shall give written assurances against such export, re-export or transshipment.

11.10 Manufacture and Supply Warranty.

(a) Cellegy represents and warrants to Licensee that the Licensed Product manufactured and supplied under this Agreement will upon delivery and for the duration of shelf life: (1) conform to the approved specifications for the Licensed Product contained in the relevant Approvals; (2) be manufactured, tested, and (subject to Licensee's contributions under (11.3) labeled and packaged in accordance with the Approvals relating to the manufacture, labeling, packaging and testing of the Licensed Product; and (3) will be manufactured in accordance with GMP.

(b) Warranty Limitation; Disclaimer. Except as expressly set forth in this Agreement, the sole warranty 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.**

11.11 Defective Product.

(a) If Licensee notifies Cellegy within forty-five (45) days of the date of arrival in the Territory of any shipment of the Licensed Product that Licensee believes any of the Licensed Product does not conform to the warranties set out in Section 11.10, as limited by Section 3.1, on QC inspection on arrival in the Territory (the “**Defective Product**”), the Parties agree to consult with each other in order to resolve the issue. If a recall is based upon any Relevant Regulatory Authority objection or concern, Cellegy will cooperate fully and expediently to assist Licensee in meeting the objections and concerns of such Relevant Regulatory Authority.

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(b) If such consultation does not resolve the discrepancy within a further forty-five (45) days from receipt of the notice, the parties agree to nominate an independent analyst, acceptable to both parties (the “**Independent Analyst**”), that will carry out tests on representative samples taken from such shipment, and the results of such tests will be binding on the parties.

(c) If the Independent Analyst determines that the Defective Product does not conform to the warranties set out in Section 11.10 (as limited by Article 3.1), Cellegy will, at its expense, replace any such Defective Product and reimburse Licensee for the costs of the Independent Analyst.

(d) If the Independent Analyst determines that the Defective Product does conform to the warranties set out in Section 11.10 (as limited by Section 3.1), then Licensee will reimburse Cellegy for the costs of the Independent Analyst.

(e) In the case of Defective Product being supplied to Licensee Cellegy shall use Commercially Reasonable and Diligent Efforts to ensure that Licensee is provided with replacement Licensed Product to ensure the continued supply of Licensed Product in the Territory.

11.12 Recalls.

(a) Subject to Licensee’s right to initiate a Licensed Product recall pursuant to subparagraph (b) below, the Parties may by mutual written agreement 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.

(c) The parties may submit a sample of the Licensed Product to an Independent Analyst for a report. The cost of the report of the Independent Analyst will be paid by the party against which the report is unfavorable.

(d) If an Independent Analyst finds that the sole reason for the recall of the Licensed Product is the action or inaction of Cellegy, then Cellegy will be liable for the cost of the recall and will reimburse Licensee for all reasonable costs and expenses of such recall and will provide replacement quantities of Licensed Product, free of charge. If an Independent Analyst finds that the sole reason for the recall of the Licensed Product is the action or inaction of Licensee, then Licensee will be liable for all such costs and expenses and will reimburse Cellegy for all reasonable costs and expenses (and the cost of any replacement quantities of Licensed Product) incurred by Cellegy in connection with such recall. If an Independent Analyst finds that the action or inaction of both Cellegy and Licensee were reasons for the recall, then Cellegy and Licensee will each be responsible for one-half of such costs of the recall unless the report of the Independent Analyst allocates responsibility in a different proportion.

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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 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.

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

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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.

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.

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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.

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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, except that Cellegy shall receive a portion equivalent to the amounts it would have received in accordance with the terms of this Agreement as if such amount were Net Sales by Licensee of units of Licensed Product ordered by Licensee from Cellegy. 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 action brought with respect to the Licensed Product based on alleged defects in the manufacture or supply of the Licensed Product or other adverse claim

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regarding the Licensed Product (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 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 claims, except those arising from the negligence or willful default of Licensee, and all legal expenses and costs incurred in that regard. 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 design or manufacturing defects in 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 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.

(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 importation, storage, Development, promotion, marketing, distribution, or sale, of the Licensed Product based on action or inaction of Licensee, Affiliates,

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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.

(b) 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

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“**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.

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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 the Cellegy Patent Rights in a particular country (or, for countries in which none of Cellegy's Patents are filed or in which Cellegy Patents have been revoked or are otherwise not in effect, the date of the last to expire of Cellegy's Patents in the last country in the Territory) or (ii) ten years from the Launch Date, determined on a country-by-country basis and by indication. 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

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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

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 Approvals is not obtained, through no fault of Licensee, in all Major European Countries within [*] 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.

16.5 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

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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.

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(e) 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;

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

(g) 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

(h) 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

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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.
349 Oyster Point Boulevard
San Francisco, California 94080
Attention: John Chandler
Telephone No.: (650) 616-2200
Facsimile No.: (650)616-2222

With a required copy to:

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

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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; 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. 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.

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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 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 San Francisco,

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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

California, 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 San Francisco, California 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 London edition of the Financial Times and in effect from time to time) plus [*] of such rate 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 Limited Guarantee. ProStrakan Group Limited, 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 E.

[Remainder of this page intentionally left blank]

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

By: _____

By: _____

Its: _____

Its: _____

PROSTRAKAN GROUP LIMITED, only as to

Section 18.18 and the Guarantee

By _____

Its: _____

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

**EXHIBIT A
LICENSED PRODUCT**

Packaged in a [*] tube.

**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
- Slovak Republic
- Slovenia

Spain
 Sweden
 Switzerland
 United Kingdom
 Republic of Yugoslavia

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EXHIBIT C
PATENTS RIGHTS

“*Cellegy Patents*”

<u>Cellegy Ref. No.</u>	<u>Description or Title</u>	<u>Country</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Patent or Publication No.</u>	<u>Issue/Pub Date</u>	<u>Status</u>	<u>Summary</u>	
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

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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

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EXHIBIT D

CELLEGY MARKS

<u>Name</u>	<u>Status</u>	<u>Country</u>	<u>Registration Date</u>	<u>Renewal</u>
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

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EXHIBIT E
PROSTRAKAN GROUP LIMITED GUARANTEE

ProStrakan Group Limited (“**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.

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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

**AGREEMENT
DATED AS OF OCTOBER 8, 1996
BY AND AMONG
BIOSYN, INC.,
EDWIN B. MICHAELS
AND
E.B. MICHAELS RESEARCH ASSOCIATES, INC.**

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AGREEMENT

AGREEMENT dated this 8th day of October, 1996 ("Agreement") by and among BIOSYN, INC., a Pennsylvania corporation ("Buyer"), EDWIN B. MICHAELS, an individual ("Michaels"), and E. B. MICHAELS RESEARCH ASSOCIATES, INC., a Connecticut corporation ("Research Associates") (collectively, Michaels and Research Associates are referred to herein as "Sellers").

RECITALS:

Whereas, Michaels has developed certain broad spectrum antimicrobial compositions and practice known as "C31G® Technology", which compositions and practice are described and protected by certain patents, patent applications and Know-How of which Michaels is the inventor, which patents, patent applications, Know-How and related trademarks have been assigned to Research Associates and are set forth in Schedule 1 attached hereto;

Whereas, Research Associates is the owner of all right, title and interest in and to the aforesaid patents and patent applications and Know-How specifically related to C31G® technology;

Whereas, Buyer has the expertise, capacity and interest to develop compositions based upon and to develop useful products using the C31G® Technology or will license or sell the C31G® technology to a third party who has the expertise, capacity and interest to develop compositions based upon and to develop useful products using the C31G® Technology;

Whereas, Buyer and Research Associates have entered into a certain License Agreement dated January 3, 1994 ("License Agreement") pursuant to which Research Associates granted Buyer an exclusive world-wide license for certain uses of C31G® Technology for certain products;

Now, therefore, in consideration of the mutual covenants, agreements, representations and warranties contained herein, and in reliance thereon; Buyer and Sellers, intending to be legally bound, agree as follows:

SECTION 1. DEFINITIONS.

Capitalized terms, unless defined elsewhere in this Agreement, shall be used as defined in Section 1 of this Agreement.

"Affiliates" shall mean any Person who controls, is controlled by or is under common control with the designated party.

"Agreement" shall mean this Agreement.

"Biosyn Stock" shall mean shares of stock of Biosyn, Inc. issued to E.B. Michaels Research Associates Inc. prior to or on the Closing Date.

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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

"Buyer" shall mean Biosyn, Inc., a Pennsylvania corporation.

"C31G® Technology" shall mean certain broad spectrum antimicrobial compositions and uses thereof falling within the scope of any of the claims of any of the patents or patent applications listed in Schedule 1 and Know-How, trade secrets, trademarks and other data set forth on Schedule 1.

"Cash Payments" shall mean the cash payment in the amount of [*] to be paid by Buyer to Research Associates and the cash payment in the amount of [*] to be paid by Buyer to Michaels pursuant to Section 4(a).

"Closing Date" shall mean the date of this Agreement.

"Contracts" shall mean all contracts relating to C31G® Technology.

“Contract with Raymond Lee” means any agreement between Research Associates and Raymond Lee and/or Lee Associates International including any renewal of the agreement of November 20, 1993.

“Extensions” shall mean any extension of the term or period of enforceability of a patent or any part thereof whether granted by a government authority or a court. Government Authority shall include but is not limited to an administrative agency that approves the marketing of pharmaceuticals, medical devices, health care products or cosmetic products, legislative body or patent office.

“Financial Statements” shall mean the balance sheets of Buyer dated December 31, 1994 and 1995, and related statements of operations, shareholders’ equity and cash flows for the years ended December 31, 1994 and 1995 and the unaudited trial balance for the first six months of 1996.

“Governmental Authority” shall mean the government of the United States, any state or political subdivision thereof, or any foreign country and any entity exercising executive, legislative, regulatory or administrative functions of or pertaining to government.

“Improvements” shall mean any improvements whether patentable or unpatentable, including Know-How, developed by either Michaels or Research Associates at any time either before the Closing Date or during the period when Michaels is retained by Biosyn as a consultant as set out in Section 4 (f) which are useful for the development, manufacture, use or sale of any product that uses C31G® Technology.

“Indemnified Party” shall have the meaning defined in Section 13.

“Inventory” shall have the meaning defined in Schedule 1.

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“Know-How” shall mean copies of all information and documentation in Sellers’ possession or under Sellers’ control, which is necessary for or useful in the development, improvement, manufacture, use, sale, registration, or receipt of appropriate marketing approval of or for any products using the C31G® Technology, or any Improvements, the Research Associates Assets or the Michaels Assets and all information, whether patentable or otherwise, which is available to Sellers (excluding that which is in the public domain or the property of Third Parties) and is required or useful for the development, manufacture, use or sale of any products using the C31G® Technology or any Improvements, the Research Associates Assets or the Michaels Assets.

“Liens” shall mean and include all mortgages, liens, pledges, charges, title retention or security agreements, claims, restrictions, leases, options, rights of first offer or first refusal, confidentiality or secrecy agreements, noncompetition agreements, defects of title or other encumbrances, burdens or rights of others.

“Losses” shall mean all claims, damages, losses, liabilities, costs and expenses, including reasonable attorneys’ fees and disbursements and any other legal costs.

“Michaels Assets” shall mean (i) the assets listed on Schedule 1 together with an assignment of all rights of Michaels in and to, including rights to enforce the terms of, all agreements, contracts, licenses, assignments, indemnities, confidentiality agreements and noncompetition agreements specifically relating to C31G® Technology including those listed in Schedule 2 and including without limitation all existing unpatented inventions and invention disclosures directly relating to the use of C31G® Technology; publications and copyrights relating to C31G® Technology; trade secrets, Know-How and show-how, all relating to C31G® Technology; copies of formulae and written chemistry relating to C31G® Technology plus (ii) all rights of Michaels transferred under Section 2.3.

“Michaels” shall mean Edwin B. Michaels, an individual.

“Net Sales” shall mean the aggregate invoice price billed by Buyer for sales of Products by Buyer, its Affiliates or Subsequent Purchaser of the Assets to Third Parties. In computing Net Sales of Products there shall be deducted from the gross figures the following expenses: (i) transportation charges, including insurance, determined in accordance with Buyer’s standard accounting practice used in the ordinary course of its business and consistent with custom in the industry; (ii) sales and excise taxes and duties paid or allowed by a selling party and any other similar governmental charges’ imposed upon the production, importation, use or sale of such-Product; (iii) normal quantity discounts, cash credits, not as a part of a substitute for a retroactive price roll-back or equivalent thereof, in the ordinary course of Buyer’s business; and (iv) rebates, allowances or credits to customers on account of rejected or returned Products, in the ordinary course of business, but not as a part of or a substitute for a retroactive price roll back or equivalent thereof. Sales between or among Buyer and its Affiliates shall be excluded from the computation of Net Sales except where such Affiliates are end users, but, as noted in the definition above, the term Net Sales shall include other subsequent final sales to Third Parties by such Affiliates.

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“Permits” shall mean all governmental permits, licenses, registrations, orders and approvals relating to the use of the Purchased Assets, to the extent such permits, licenses, registrations, orders and approvals are transferrable to Buyer (collectively, the “Permits”).

“Person” shall mean an individual, partnership, corporation, business trust, joint stock company, trust, unincorporated association, joint venture, limited liability company or any other entity of whatever nature.

“Products” shall mean any products which contain, use, or are made by utilizing C31G® Technology.

“Purchase Price” shall mean the Cash Payments and the Royalty Payments.

“Purchased Assets” shall mean the C31G® Technology, Research Associates Assets, the Michaels Assets and the Improvements.

“Research Associates” shall mean E.B. Michaels Research Associates, Inc., a Connecticut corporation.

“Research Associates Assets” shall mean (i) the assets listed on Schedule 1 together with an assignment of all rights of Research Associates in and to, including rights to enforce the terms of, all agreements, contracts, licenses, assignments, indemnities, confidentiality agreements and noncompetition agreements specifically relating to C31G® Technology including those listed in Schedule 2 and any agreements relating to the assignment of inventions relating to C31G® Technology made by prior and present employees of Research Associates and any analogous agreements with any other Person with respect to the C31G® Technology plus (ii) all rights of Research Associates transferred under Section 2.3. For the avoidance of doubt it is expressly agreed that shares of stock of Buyer (“Biosyn Stock”) currently owned by Research Associates are specifically excluded from the definition of “Research Associates Assets” and from this sale.

“Royalty Payments” shall mean the royalties to be paid to Research Associates pursuant to Section 4.

“Royalty Period” shall mean from the date of this Agreement until December 31, 2011 or, if longer, so long as a valid patent claim from a patent or application listed in Schedule 1, including any Extensions thereof, relating to C31G® Technology is covering a Product and the Product maintains exclusivity in the market as a result of such patent claim.

“Sellers” shall mean Michaels and Research Associates.

“Subsequent Purchaser of the Assets” shall mean any person who purchases any or all of the Purchased Assets being sold by Sellers to Buyer pursuant to this Agreement.

“Taxes” shall mean all taxes and other governmental charges which an individual,

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corporation or partnership may be required to pay, withhold or collect, imposed by any federal, territorial, state, local or foreign government or any agency or political subdivision of any such government.

“Third Party(ies)” shall mean any party other than a party to this Agreement or its or his Affiliates.

SECTION 2. ASSETS TO BE ACQUIRED.

2.1 Research Associates Assets. Subject to the terms and conditions of this Agreement, and in reliance on the representations, warranties and covenants contained herein, Research Associates hereby sells, conveys, assigns, transfers and delivers to Buyer, and Buyer hereby purchases and acquires all of Research Associates’ right, title and interest in and to the Research Associates Assets; for the avoidance of doubt it is expressly agreed that Research Associates will keep the originals of laboratory notebooks relating to C31G® Technology and other documents relating to written chemistry but will provide copies of such documents to the Buyer within one (1) month after the Closing Date. Research Associates use of retained documents shall, however, be subject to the provisions of Section 14.1 which controls Sellers rights to compete with Buyer.

2.2 Michaels Assets. Subject to the terms and conditions of this Agreement, and in reliance on the representations, warranties and covenants contained herein, Michaels hereby sells, conveys, assigns, transfers and delivers to Buyer, and Buyer hereby purchases and acquires all of Michaels’ right, title and interest in and to the Michaels Assets. For the avoidance of doubt it is expressly agreed that Michaels will keep the originals of laboratory notebooks relating to C31G® Technology and other documents relating to written chemistry but will provide copies of such documents to the Buyer within one (1) month after the Closing Date. Michaels use of retained documents shall, however, be subject to the provisions of Section 14.1 which controls Sellers’ rights to compete with Buyer.

2.3 Improvements. Sellers each hereby sells, conveys, assigns and transfers to Buyer and Buyer hereby purchases and acquires all of each of Sellers’ right, title and interest in, to, and under all Improvements.

SECTION 3. NO ASSUMPTION OF LIABILITIES.

Sellers shall transfer the Purchased Assets to Buyer free and clear of all Liens and except as set out hereinafter in this Section 3, Seller shall convey no other liabilities or obligations to Buyer. However, Buyer expressly assumes the liabilities and obligations arising after the Closing Date of Research Associates pursuant to the Contract with Raymond Lee, and liabilities and obligations arising after the Closing Date under or relating to contracts, licenses or any other agreements listed on Schedule 2 including the obligation to supply. For purposes of this Section 3, the phrase “liabilities and obligations” shall include, without limitation, any direct or indirect indebtedness, guaranty, endorsement, claim, loss, damage, deficiency, cost, expense, obligation or responsibility, fixed or unfixed, Down or unknown, asserted or unasserted, choate or inchoate, liquidated or unliquidated, secured or unsecured, whether arising in contract, tort or otherwise, arising after the

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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

Closing Date. “Liabilities and obligations” also include but are not limited to, any liability for property damage, death or personal injury suffered after the Closing Date.

SECTION 4. THE PURCHASE PRICE AND RELAYED MATTERS.

Purchase Price.

(a) In consideration of the sale, conveyance, assignment, transfer and delivery of the Purchased Assets, upon execution of this Agreement by all parties hereto, Buyer shall pay the respective Cash Payment due to each Seller on the Closing Date in immediately available funds except as provided in

(b) During the Royalty Period, Buyer shall annually pay to Research Associates, as royalties or other compensation for Products sold or otherwise disposed of by Buyer or its affiliates, the sum of:

(1) [*] of the Net Sales up to [*] of the Products.

(1) [*] of the Net Sales over [*] of the Products.

(c) During the Royalty period, Buyer shall annually pay to Research Associates [*] of any fees received by Buyer or its affiliates for licensing any or all of the Purchased Assets including [*] of any upfront, milestone and/or royalty payments received from the licensee.

(d) During the Royalty period in the event that Buyer or its affiliates licenses or crosslicenses any or all of the Purchased Assets to a third party, wherein the major part of the consideration for said license or crosslicense is not monetary, section 4(b) shall apply mutatis mutandis.

(e) Buyer hereby agrees that any sale of any or all of the Purchased Assets to a Subsequent Purchaser of the Assets will include as a condition of sale the obligation to continue paying royalties to Research Associates as set out in section 4(b), (c) and (d).

(f) Buyer shall pay Michaels a fee to provide certain consultancy services in the amount of [*] per annum payable quarterly on the first business day of each quarter beginning October 1, 1996 and continuing quarterly thereafter. In consideration of the payments Michaels will for the period from October 1, 1996 to three years after the Closing Date make himself available to Buyer from time to time for consultation with regard to further exploitation of the C31G® Technology. The arrangement set forth in this paragraph 4(f) may be extended into a fourth and subsequent years upon written agreement of Michaels and the Buyer. In the event the Buyer or its affiliates agrees to sell all or substantially all of the Purchased Assets to a Subsequent Purchaser of the Assets, either Buyer or Michaels may terminate the consultancy, or with Michaels' consent, Buyer may assign its rights and obligations relating to Michaels' consultancy to the Subsequent Purchaser of the Assets.

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(g) Any payments due to Research Associates due under this agreement will be paid to Research Associates or a person or entity identified in writing by an authorized representative of Research Associates.

(h) Products shall be considered to have been "sold or otherwise disposed" when billed out, or when delivered, or when paid for, whichever shall occur first; provided, however, that upon the expiration of the Royalty Period, any products made on or prior to the date of such expiration, which have been sold or otherwise disposed of as of such date shall be subject to royalty at that time.

(i) As used herein, Products "otherwise disposed of" means: (A) Products not sold but delivered by Buyer to others (including, by way of illustration, and not limitation, deliveries on consignment or memorandum of deliveries for export) regardless of the basis for compensation, if any; and (B) Products not sold as such, but sold by Buyer as components or constituents of other products or of systems sold as such; provided, however, that in any event, Products "otherwise disposed of" shall not include Products used in clinical trials.

(j) Where Products are not sold, but are "otherwise disposed of," "Net Sales" for the purpose of computing royalties shall be computed based upon the Net Sales figures at which products of similar kind and quality, sold in similar quantities, are then currently being offered for sale by Buyer.

(k) Buyer shall have complete control of the manufacture and/or sale of Products and the terms and conditions of such sale including the pricing thereof. Buyer shall have complete discretion regarding the terms and conditions of sale of Products. Buyer reserves the exclusive right to adjust, increase and/or change selling prices and discount structures and other terms and conditions involving the sale and pricing of the Products.

(l) In order to ensure that Research Associates receives the full Royalty Payments contemplated by this Agreement, Buyer agrees that, if any Products are sold for resale to any of Buyer's Affiliates, Royalty Payments shall be computed upon the Net Sales of such Affiliates, rather than Buyer's net selling price.

(m) Buyer shall make quarterly written statements for each quarter to Research Associates within sixty (60) days after the first day of the following quarter during the Royalty Period, and, as of such dates, setting forth in each such statement the licensing income received by Buyer and the amount and description of Products sold or otherwise disposed of during the preceding quarter whether by Buyer, its affiliates or any third party, and the Net Sales figures upon which such royalties are payable as provided in Paragraphs (b), (c) and (d) of Section 4 of this Agreement, the deductions from the invoice prices of Products, and the amount of the royalties due. The first such statement shall include Products sold or otherwise disposed of between the date of the execution of this Agreement and the date of such statement. Payment of the royalties due shall accompany each statement provided herein.

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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

(n) Buyer shall keep records and books of account showing the quantity of all Products sold or otherwise disposed of under this Agreement, and such records shall be in sufficient detail to enable the royalties payable to Research Associates to be ascertained. Within sixty (60) days after the close of each calendar year during the Royalty Period, Buyer shall furnish to Research Associates a statement of the aggregate amount of royalties due to Research Associates for such calendar year (or, as the case may be, part thereof), which statement shall be certified by a certified public accountant to be an accurate reflection of the records of Buyer for such a calendar year (or, as the case may be, part thereof). Research Associates or its authorized representative shall have the option and right at any reasonable time during normal business hours and without unreasonable disruption of Buyer's business, once during any calendar year during the Royalty Period, to examine and audit such records and books of account to the extent necessary to verify the statements provided for in paragraph 4(m) above, such examination to be made at the sole expense of Research Associates, subject to the next sentence. If, as a result of any such

examination, Research Associates determines that, with respect to the period being examined, (i) there has been an underpayment of the aggregate amount of royalties and other payments which should have been paid, Buyer shall immediately pay the sum due to Seller and if the discrepancy is in excess of [*], Buyer shall reimburse Research Associates for the reasonable, documented cost of such examination and the reasonable, documented cost (including reasonable attorneys' fees), if any, of the recovery by Research Associates of such underpayment, or (ii) there has been an overpayment of royalties the overpayment will be credited against further royalties.

(o) Any license agreement concluded by Buyer with a licensee for use of C31G® Technology shall include provisions that are substantially the same as those of paragraphs (m) and (n) of this Section 4.

SECTION 5. BIOSYN STOCK

All shares of Biosyn Stock issued to Research Associates prior to or on the Closing Date shall continue to have all rights, including those rights related to dividends and voting, afforded all other holders of common stock of Biosyn indefinitely notwithstanding the lapse of anti-dilution protection on the Closing Date. In the event of an Initial Public Offering and if other substantial shareholders are permitted to make some of their shares available for sale as part of the offering, then Research Associates shall be entitled to sell the same percentage of its holdings of the Biosyn Stock as other substantial shareholders. Schedule 3 lists the number of shares of Biosyn Stock issued to Research Associates and its percentage of the total shares of stock issued by Biosyn. Schedule 3 also includes a list of the number of shares issued to Research Associates and the dates and reasons for issuance of the stock to Research Associates.

SECTION 6. REPRESENTATIONS AND WARRANTIES OF RESEARCH ASSOCIATES.

Research Associates represents and warrants to Buyer that:

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6.1 Authority. Research Associates has full power and authority to execute and deliver this Agreement, and the instruments of transfer and other documents delivered or to be delivered pursuant hereto to which it is a party, to perform all the terms and conditions hereof and thereof to be performed by it and to consummate the transactions contemplated hereby and thereby. This Agreement and instruments of transfer and other documents delivered or to be delivered by Research Associates in connection with this Agreement have been duly authorized and approved by all necessary and proper action of Research Associates (including all necessary shareholder action) and constitute, and will constitute, the valid and binding obligations of Research Associates, enforceable in accordance with their respective terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws or equitable principles from time to time in effect relating to or affecting the rights of creditors generally.

6.2 Organization and Good Standing. Research Associates is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Connecticut, with full power and authority to carry on its business as presently conducted by it and is not registered as a foreign corporation in any state.

6.3 Compliance with Laws. To the best of its knowledge, Research Associates is operating the Research Associates Assets in compliance in all respects with all requirements of all federal, state and local laws, regulations, judgments, injunctions, decrees, court orders and administrative orders regarding such operations.

6.4 Permits. To the best of its knowledge, the Permits are the only permits, franchises, licenses or authorizations used in the operation of the business of Research Associates. All Permits are in full force and effect and no suspension or cancellation of any have been threatened. No claims have been made by any Third Parties relating to the Permits and no such claim is contemplated by any Governmental Authority or other Person.

6.5 Purchased Assets. Research Associates has good and marketable title to, and all right, title and interest in, all the Research Associates Assets being transferred and conveyed pursuant to this agreement, and will transfer and convey assets being transferred and conveyed according to this agreement to Buyer free and clear of all Liens and no person or entity has any valid claim of ownership to any of the Purchased Assets.

6.6 Inventory. The Inventory of Research Associates is Products listed on Schedule 1 to which title has not yet passed or which has not been delivered to a customer and consists of items that are of a quality and quantity useable or saleable in the normal course of the business of Research Associates.

6.7 Contracts. (a) Schedule 2 sets forth a list of all Contracts and a true and correct copy of each Contract listed in Schedule 2 has previously been made available to Buyer. To the best of its knowledge, all Contracts are binding and in full force and effect, and Research Associates and

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Michaels have performed all obligations required to be performed by them under each Contract, and no condition exists or event has occurred which with notice or lapse of time would constitute a default or a basis for delay or non-performance by Research Associates or Michaels, and to the best of their knowledge, no other party to any such Contract is in default thereunder.

(b) To the best of its knowledge, none of the Contracts contains any provision giving any party thereto the right to terminate such agreement by reason of the execution of this Agreement or the consummation of the transactions contemplated herein, and none of the terms of any Contract will be adversely altered in any material respect by reason of the execution of this Agreement or the consummation of the transactions contemplated herein.

6.8 Solvency. The transfer of the Research Associates Assets by Research Associates in return for the Purchase Price will not render Research Associates insolvent or unable to pay its debts as they become due in the ordinary course.

SECTION 7. REPRESENTATIONS AND WARRANTIES OF SELLERS

Sellers jointly and severally represent and warrant to Buyer that:

7.1 Neither the execution and delivery by Sellers of this Agreement or the instruments of transfer or any other documents delivered or to be delivered pursuant hereto by either or both Sellers or the performance by Sellers hereunder or thereunder, nor the consummation of the transactions contemplated hereby or thereby, will violate, conflict with, result in the breach of or accelerate the performance required by any of the terms, conditions or provisions of the articles of incorporation or by-laws of Research Associates or any covenant, agreement or understanding to which either Seller is a party or any order, ruling, decree, judgment, arbitration award or stipulation to which either Seller is subject, or constitute a default thereunder or result in the creation or imposition of any Lien upon any of the Purchased Assets, or allow any Person to accelerate any debt secured by any Purchased Asset.

7.2 To the best of Sellers' knowledge, no consent, approval or authorization of, filing or registration with, or notification to, any Governmental Authority is required in connection with the execution and delivery of this Agreement by Sellers, the performance of their obligations hereunder or the consummation of the transactions contemplated hereby. No consent, approval or authorization of any Person is required in connection with the execution or delivery of this Agreement by Sellers, the transfer to Buyer of the Purchased Assets, or the performance by Sellers of any other obligation under this Agreement.

7.3 Neither Seller is engaged in, or a party to, any legal action, suit, investigation or other proceeding, except as referred to in Section 13.2 of the Agreement, by or before any court, arbitrator or administrative agency that relates to the Purchased Assets, and except as referred to in Section 13.2, neither Seller knows of any basis for any such action, investigation or proceeding. There are no outstanding orders, rulings, decrees, judgments or stipulations or proceedings to which either Seller is a party or by which either Seller is bound, by or with any court, arbitrator or

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administrative agency that relate to the Purchased Assets.

7.4 Neither Seller is a party to any license, contract, agreement (other than those listed on Schedule 2) with respect to, and has not made any sale, pledge or other transfer of, and has not granted any outstanding or unexpired right or option agreement, grant or obligation, whether written or oral, to purchase or acquire, all or any part of the Purchased Assets, except as contemplated by this Agreement or under the License Agreement.

7.5 Except for those patents and patent applications listed in Schedule 1 as expired, abandoned or lapsed, all patents and patent applications included in the Purchased Assets and listed in Schedule 1 are in force. The Sellers have no knowledge of any facts or claims which may bring validity of the patents into question. All patent applications, except for those listed in Schedule 1 as expired, abandoned or lapsed, included in the Purchased Assets are pending, in good standing and are being diligently pursued. There are no currently pending U.S. patent applications directly relating to C31G® Technology belonging to either Seller except as identified in Schedule 1. Sellers own the entire right, title and interest in and to their respective patents and patent applications without qualification, limitation, burden or encumbrance of any kind. Schedule 2 lists all licenses to or contracts with any Third Party or relating to patents, patent applications, patent rights, trademarks or trademark rights, trade secrets, Know-How or show-how.

7.6 To the best of Sellers' knowledge, no infringement of any United States or foreign patent, trademark or copyright right has occurred or resulted from or is in any way involved in connection with the activities of the Sellers in the manufacture, license, sale and/or use by the Sellers of the C31G® technology, products and/or proposed products or by the receipt or use of such technology, products and/or proposed products by their customers for the purposes for which sold, or the promotion and advertising by them of their products and services. There is no pending or, threatened action, suit, proceeding or claim by others that the Sellers are infringing, or otherwise violating i) any patent rights, trademarks or trademark rights, copyright rights, licenses or royalty arrangements, trade secrets, Know-How, or proprietary techniques, including processes and substances, or rights thereto of others, or (ii) any discovery, invention or process that is the subject of a patent application filed by any Third Party or that Sellers have competed unfairly. There is no right of any Third Party (other than as listed on Schedule 2) to, or any infringement of, any of Sellers' patents, patent applications, licensed patents, patent rights, trademark or trademark rights, copyright rights, licenses or royalty arrangements, trade secrets, Know-How or proprietary techniques, including processes and substances; and there is no pending or, to the Sellers' knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of the patents licensed by Sellers, or of the validity or ownership of Sellers' trademarks or copyright rights. Seller has no copies of any patentability, infringement or validity searches with respect to any patents listed on Schedule 1 or applications from which the patents listed on Schedule 1 were issued.

7.7 None of the patents or patent applications listed on Schedule 1 is involved in any interference, conflict or opposition proceeding nor has any such proceeding been threatened.

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7.8 To the best of Sellers' knowledge, none of the patents or patent applications listed on Schedule 1 is being infringed by any Third Party. Sellers have no information that any Third Party will undertake activities which will infringe any of the patents listed on Schedule 1. There is no reason to know or suspect that any person has sought, is seeking, or will seek to obtain patent coverage on any invention or development used in the conduct of the business of the Sellers or which is the subject of any of the patents and patent applications listed on Schedule 1 apart from the patentee(s) and applicant(s) currently referred to in such patents and patent applications. All agreements, contracts, licenses, assignments, indemnities and the like related to the Purchased Assets are valid and binding and in full force and effect and there are no defaults thereunder, nor are there any facts or claims which would bring such validity and enforceability into question. None of the rights of Sellers thereunder will be impaired by the consummation of the transactions contemplated by this Agreement, and all of the rights of Sellers thereunder will be enforceable by Buyer after the Closing Date without the consent or agreement of any other party.

7.9 Except for the expired, lapsed or abandoned patents and patent applications listed on Schedule 1 or for those patents, patent applications or publications for which no maintenance fees, annuities, taxes or the like are required to keep the patent, application or publication in force all maintenance fees, annuities, taxes and the like for any other patent or patent application listed on Schedule 1 are up to date.

7.10 There are no obligations to assign any of the patents, patent application or trademarks listed on Schedule 1 to any third party.

7.11 Except as identified on Schedule 1, neither Seller owns any registered copyrights.

7.12 Sellers own or possess sufficient licenses or other rights to use all patent rights, trademarks, service marks, inventions, processes, formulae, designs, trade names, trade secrets, trade dress, technology, Know-How, proprietary and confidential information and copyrights necessary to conduct the business now being conducted by Sellers. Sellers have obtained no licenses from any third party specifically to practice any of its C31G® Technology.

7.13 The Research Associates Assets and the Michaels Assets are all of the assets owned by Sellers specifically relating to C31G® Technology.

7.14 No representations or warranties made by either Seller in this Agreement and no statements made by either Seller in any certificate, schedule, exhibit or other writing delivered by each Seller or referred to in or pursuant to this Agreement contain, or at the date of its delivery will contain, any untrue statement of a material fact or omit or will omit any statement of a material fact necessary to make complete, accurate and not misleading every representation, warranty and statement of each Seller set forth in this Agreement or any such certificate, schedule, exhibit or other writing.

SECTION 8. REPRESENTATIONS AND WARRANTIES OF MICHAELS.

Michaels represents and warrants to Buyer that:

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8.1 Enforceability. Michaels has the capacity and full power and authority to execute and deliver this Agreement, and the instruments of transfer and other documents delivered or to be delivered pursuant hereto to which he is a party, to perform all the terms and conditions hereof to be performed by him and to consummate the transactions contemplated hereby and thereby. This Agreement and instruments of transfer and other documents delivered or to be delivered by Michaels in connection with this Agreement constitute, and will constitute, the valid and binding obligations of Michaels enforceable in accordance with their respective terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws or equitable principles from time to time in effect relating to or affecting the rights of creditors generally.

8.2 Intellectual Property. Michaels is transferring, assigning and conveying to Buyer all of his right, title and interest in and to the Michaels Assets. Michaels has executed the necessary formal documents to assign the patents and patent applications listed on Schedule 1 which are now in force to Research Associates. In the event that there is a question regarding the assignment of any such patents or patent applications, Michaels shall assist Buyer in verifying that such patents and patent applications were assigned to Research Associates on or prior to the Closing Date and if necessary, after the Closing Date as provided in Section 10.2.

8.3 Purchased Asset. Michaels has good and marketable title to, and all right, title and interest in, all the Michaels Assets, and will transfer and convey the Michaels Assets to Buyer, free and clear of all Liens.

SECTION 9. REPRESENTATIONS AND WARRANTIES OF BWER.

Buyer represents and warrants to Sellers that:

9.1 Organization, Good Standing and Corporate Authority. Buyer is a corporation duly incorporated, validly existing and in good standing under the laws of the Commonwealth of Pennsylvania, with full power and authority to carry on its business as presently conducted by it and is duly qualified and in good standing as a foreign corporation in all states where the conduct of its business would require registration as a foreign corporation. Buyer has full power and authority to execute this Agreement, to perform all the terms and conditions hereof to be performed by it and to consummate the transactions contemplated hereby. This Agreement has been duly authorized and approved by all necessary and proper action of Buyer (including all necessary shareholder action) and constitutes, and will constitute the valid and binding obligation of Buyer, enforceable in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws or equitable principles from time to time in effect relating to or affecting the rights of creditors generally.

9.2 No Violation. Neither the execution and delivery by Buyer of this Agreement or any other documents delivered or to be delivered pursuant hereto by Buyer or the performance by Buyer hereunder or thereunder, nor the consummation of the transactions contemplated hereby or

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thereby, will violate, conflict with, result in the breach of or accelerate the performance required by any of the terms, conditions or provisions of the articles of incorporation or by-laws of Buyer or any covenant, agreement or understanding to which Buyer is a party or any order, ruling, decree, judgment, arbitration award or stipulation to which Buyer is subject, or constitute a default thereunder.

9.3 Consents and Approvals of Governmental Authorities and Others. To the best of Buyer's knowledge, no approval or authorization of, filing or registration with, or notification to, any Governmental Authority is required in connection with the execution and delivery of this Agreement by Buyer or the performance of its obligations hereunder or the consummation of the transactions contemplated hereby other than filings required to transfer the Purchased Assets to Buyer.

9.4 Financial Statements. The Financial Statements have been delivered to Seller and have been prepared in accordance with GAAP consistently applied throughout the periods involved except as may be noted therein, are true and correct and present fairly the financial condition of Buyer. There has not been since the date of the Financial Statements any material adverse change in the condition (financial or other), properties, assets, liabilities or prospects of Buyer that affect the Purchased Assets or the ability of Buyer to consummate the transactions contemplated by this Agreement.

9.5 Solvency. The purchase of the Purchased Assets by Buyer in return for the Purchase Price will not render Buyer insolvent or unable to pay its debts as they become due in the ordinary course or leave Buyer with an unreasonably small capital for the business in which it will engage.

9.6 Buyer has not pledged nor is under any obligation to pledge any or all of the Purchased Assets in a manner which will impair or prevent Buyer from meeting its obligations under Section 4.

SECTION 10. POST CLOSING DATE OBLIGATIONS.

10.1 Taxes. Sellers agree that they will pay all sales, use and transfer Taxes, if any, arising from the sale of the Purchased Assets from Sellers to Buyer pursuant to this Agreement. Sellers agree that they will pay all income and corporate taxes, if any, arising from the sale of the Purchased Assets. Buyer

shall not be responsible for any Taxes of either Seller of any nature.

10.2 Further Assurances. From time to time after the Closing Date, at Buyer's request and without further consideration, Sellers will execute and deliver such other and further instruments of conveyance, assignment and transfer, and take such other action, as Buyer may reasonably request for the more effective conveyance and transfer of the Purchased Assets to Buyer or to otherwise effect the purposes of this Agreement. In connection with the foregoing and without limitation thereof, Sellers shall, subject to reimbursement of Sellers' reasonable expenses, cooperate with Buyer in obtaining execution of any documents and obtaining all information and testimony by current or former employees of Sellers with respect to existing patents, pending patent applications,

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filing and obtaining new patents relating to C3IG® Technology and filing and obtaining new patents for the Purchased Assets and in obtaining any Permits that are not assignable by this Agreement. Sellers also agree, subject to reimbursement of Seller's reasonable expenses, to execute all necessary or desirable documents and give all information and testimony and otherwise, to cooperate with Buyer in any effort by Buyer to register, extend, reissue or maintain existing patents, obtain new patents or file patent applications for the Improvements both in the United States and in countries other than the United States, and maintain trademark registrations protecting the Purchased Assets. Buyer will reimburse Seller for any payments made prior to closing to keep the patents, patent applications or trademarks listed on Schedule 1 in force where the actual due date of such payment is after the Closing Date.

10.3 Assignments. Research Associates hereby covenants that it will assign to Buyer all Contracts listed on Schedule 2 by and between Research Associates and any Third Party relating to C31G® Technology and obtain any consents to such assignments within thirty (30) days after the Closing Date.

10.4 Patent or Trademark Prosecution. Trademark Proceedings Before Trademark Office and Litigation. Sellers shall disclose to Buyer the complete texts of all patent rights, as well as all information received concerning the institution or possible institution of any interference, opposition cancellation, reexamination, reissue, revocation, nullification or any official proceeding involving the patents, patent applications and trademarks listed in Schedule 1. Sellers agree to communicate to Buyer promptly and fully regarding any information either Seller may receive as to the course of all patent prosecutions or other proceedings relating to the Purchased Assets. Sellers shall hold all information disclosed to it under this Section 10.4 as confidential subject to the provisions of Section 17.2 hereof.

In the event of the institution of any suit by a Third Party against Sellers, Buyer or Buyer's licensee for patent or trademark infringement involving the manufacture, use, sale, distribution or marketing of Products using Purchased Assets, the Sellers shall promptly notify Buyer in writing. Sellers and Buyer shall assist one another and cooperate in any such litigation at the other's request; the cost of such assistance by Sellers shall be borne by the Buyers.

In the event that either of Sellers becomes aware of the actual or threatened infringement of the Purchased Assets, the Buyer shall be notified promptly in writing of such fact. Any patent or trademark litigation involving the Purchased Assets, or processes or intermediates for the production of any Product, shall be under the control and direction of Buyer and at its sole expense; provided, however, that Sellers may participate and be separately represented in any such litigation at their own expense.

Sellers shall keep Buyer informed of the status of their respective activities regarding any litigation or settlement thereof concerning the Purchased Assets.

10.5 Sellers will endeavor to refer inquiries that they receive about Purchased Assets to Buyer. However, Sellers shall be under no liability to Buyer in respect of any inquiry that is not so

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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

referred.

SECTION 11. CONDITIONS TO BUYER'S OBLIGATIONS.

Buyer's obligations under this Agreement shall be subject to the fulfillment by Sellers of the following:

11.1 Instruments of Conveyance. Etc. Sellers shall execute and deliver such bills of sale, assignments and instruments of transfer and conveyance and certificates of title as shall be reasonably required by Buyer for the transfer to Buyer of all of Sellers' right, title and interest in and to the Purchased Assets free and clear of all Liens.

11.2 Delivery. Sellers shall deliver physical possession of information and tangible property included in the Purchased Assets, and all consents and assignments of the Contracts to Buyer.

11.3 Officer's Certificate. Research Associates shall deliver a certificate executed by the Secretary of Research Associates certifying copies of the articles of incorporation and by laws of Research Associates and the authorizing resolutions of Research Associates.

SECTION 12. SURVIVAL OF REPRESENTATIONS, WARRANTIES AND COVENANTS.

All representations and warranties and covenants made by Sellers or Buyer as to any fact or condition existing on or before the Closing Date in this Agreement, in any Schedule or in any certificate delivered pursuant hereto, shall survive the Closing Date.

SECTION 13. INDEMNIFICATION.

13.1 Indemnity by Sellers. Sellers jointly and severally shall defend, indemnify and hold Buyer and each of the officers, directors, employees subsidiaries and Affiliates of Buyer harmless from and against all Losses incurred by them arising out of or resulting from (a) the failure of any representation or warranty of Sellers contained herein, in any Schedule hereto or in any certificate of Sellers delivered pursuant hereto to be true and correct, or (b) the breach of any covenant by Sellers contained herein.

13.2 [*]Indemnity. Sellers jointly and severally shall defend, indemnify and hold Buyer and each of the officers, directors, employees, subsidiaries and Affiliates of Buyer harmless from and against all awards, judgments, claims, settlements and any reasonable legal fees (“Galla Losses”) Buyer incurs as a result of any legal action, suit, or other proceeding by or before any court, arbitrator or administrative agency (“Law Suit”) that is brought by [*], his heirs or assigns (collectively “[*]”), against Buyer, its successors or assigns directly relating to Buyer’s purchase of the Purchased Assets from Sellers. Sellers shall only indemnify Buyer for settlements to which Seller has consented, and Sellers shall not unreasonably withhold its consent. EBMRA will have the right to be consulted on any Law Suit brought by [*] against Biosyn.

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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

13.3 Indemnity by Buyer. Buyer shall defend, indemnify and hold Sellers harmless from and against all Losses arising out of or resulting from (a) the failure of any representation or warranty of Buyer contained herein or in any Schedule hereto or in any certificate delivered hereto to be true and correct, or (b) the breach of any covenant by Buyer contained herein. Buyer shall further indemnify Sellers jointly and severally from any and all Losses arising out of any action brought against Seller in respect of any death, personal injury, illness, property damage or products liability, infringement of intellectual property rights or any other cause arising from any use or sale of any product based on Purchased Assets sold by Buyer, Buyer’s affiliate, licensee of Buyer or Subsequent Purchaser of the Assets unless said action is brought on the basis of actual fault by one of the Sellers. Buyer shall indemnify Research Associates and/or Michaels against any claims brought against Research Associates and/or Michaels resulting from Buyer’s failure to perform its obligations under any license, contract, agreement listed on Schedule 2 and the Contract with [*]. To ensure that it can meet its obligation under this provision, Buyer shall maintain insurance at a level commensurate with good business practice in the pharmaceutical industry.

13.4 Security Interest. (a) As security for the prompt and unconditional payment and performance of Sellers’ obligation to indemnify Buyer under Section 13.2 of this Agreement, [*] (“Collateral”) of the Cash Payment of [*] payable to Research Associates on the Closing Date will be withheld by Buyer and will be held by Buyer in a separate, interest bearing account at PNC Bank, National Association. All interest shall be paid to EBMRA quarterly. The Collateral including any interest accrued thereon and minus any payments made pursuant to Section 13.4(b), shall be returned to Research Associates or to a person or entity identified in writing by an authorized representative of Research Associates in immediately available funds on the earlier of: (i) one year from the Closing Date; or (ii) delivery to Buyer by Sellers of written proof of accord, release and satisfaction of all claims of Galla against Biosyn.

(b) Prior to the return of the Collateral, the Collateral may be used only for the following purposes: (i) Buyer may in its sole discretion and at any time or times after the occurrence and during the continuance of Sellers’ failure to perform or pay its obligations under Section 13.2 of this Agreement for a period of thirty (30) days after reasonable notice to Research Associates of the obligation to indemnify under Section 13.2, apply the Collateral to any [*] Losses incurred by Buyer; or (ii) In the event a Law Suit is brought by Galla against Sellers, the Sellers will, upon delivering to Buyer evidence that [*] filed a Law Suit against Sellers, have the right to be reimbursed from the Collateral in an amount not to exceed [*] for any awards, judgments, claims, settlements, legal costs and attorney’s fees connected with the Law Suit.

(c) At the end of the period set out in paragraph 13.4 (a), Buyer shall pay the Collateral together with any interest accrued thereon and minus any disbursements that have been made pursuant to paragraph 13.4(b) by immediately available funds. After payment in full of the Galla Losses, if any, any of the remaining Collateral held in escrow shall be paid over to Research Associates or to a person or entity identified in writing by an authorized representative of Research Associates.

13.5 Notice of Claim. Promptly after service of notice of any claim or of process on Buyer

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or on Sellers (hereinafter in this Section 13.5, the “Indemnified Party”) by any Third Party, or promptly after obtaining actual knowledge by the Indemnified Party of any other claim, in any matter in respect of which indemnity may be sought pursuant to this Section 13, the Indemnified Party shall promptly notify Buyer or Sellers, as applicable, (hereinafter in this Section 13.5, the “Indemnifying Party”) of the receipt thereof. In the case of any action or proceeding by a Third Party, the Indemnifying Party shall have the right to participate in, or assume, at its in expense, the defense of any such claim or process or settlement thereof. After notice from the Indemnifying Party of its election so to assume the defense thereof, the Indemnified Party shall not be liable to the Indemnifying Party for any legal or other expense in connection with such defense. Such defense shall be conducted expeditiously (but with due regard for obtaining the most favorable outcome reasonably likely under the circumstances, taking into account costs and expenditures) and the Indemnified Party shall be advised of all developments. With respect to any matter which is the subject of any such claim and as to which the Indemnified Party fails to give the Indemnifying Party such notice as aforesaid, and such failure adversely affects the ability of the Indemnifying Party to defend such claim or increases the amount of indemnification which the Indemnifying Party is obligated to pay hereunder, the amount of indemnification which the Indemnified Party shall be entitled to receive shall be reduced to an amount which the Indemnified Party would have been entitled to receive had such notice been timely given.

SECTION 14. COMPETITION.

14.1 Noncompetition. For a period of three (3) years after the Closing Date neither Seller nor any of its respective Affiliates shall engage, directly or indirectly, in developing business for itself, himself or a third party relating to compositions for topical use of antimicrobial or antiviral agents.

14.2 Remedies. Sellers agree that if they commit or threaten to commit a breach of Section 14.1, Buyer shall have the right to seek and obtain appropriate injunctive and other equitable remedies therefor, in addition to any other rights and remedies that may be available at law, it being acknowledged and agreed that any such breach would cause irreparable injury to Buyer and that money damages would not provide an adequate remedy therefor.

SECTION 15. COSTS INCIDENT TO PREPARATION OF AGREEMENT.

15.1 Except for the items specified in Sections 10.2, 13 and 15.2 each of the parties hereto shall pay, without right of reimbursement from any other, all costs incurred by it incident to the preparation, execution and delivery of this Agreement and the performance of its obligations hereunder, including without limitation fees and disbursements of legal counsel, accountants and consultants employed by the respective parties hereto in connection with the transactions contemplated by this Agreement.

15.2 All costs including government fees associated with preparing, filing and recording of assignments of intellectual property rights, applications for governmental approval, other recorded rights from Sellers to Buyers or to provide for conveyance of Purchased Assets to Buyer will be

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borne by Buyers and the costs will be advanced to Sellers.

SECTION 16. RELEASE.

Sellers hereby release and hold harmless Buyer from all claims, obligations and liabilities of any nature whatsoever, hereafter arising, relating to the License Agreement, certain letters dated September 13, 1994 and December 20, 1993 between Buyer and Research Associates relating to the creation of a joint venture between Buyer and Research Associates (collectively, "Letter Agreements") and any other transactions between Buyer and Sellers. Buyer and Research Associates agree that effective as of the Closing Date the Letter Agreements and the License Agreement shall terminate except for preexisting obligations and liabilities between Buyer and Research Associates arising from the Letter Agreements and the License Agreement, and except for those described in Paragraphs 10.1, 10.2, 10.3, 10.4, 10.5 and 13.1 of the License Agreement.

SECTION 17. GENERAL.

17.1 parties in Interest. This Agreement shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors and permitted assigns. This Agreement is not made for the benefit of any Person not a party hereto, and nothing in this Agreement will be construed as giving any Person, other than the parties hereto and their respective successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement, or any provision hereof.

17.2 Public Statements/Confidentiality. Each Seller shall treat as confidential and proprietary and shall not use or reveal or disclose to any Third Party either directly or indirectly any confidential information received from Buyer or any confidential information relating to the Purchased Assets or any other matter contemplated by this Agreement without first obtaining the written consent of Buyer, except (a) as may be otherwise provided herein; (b) as may be required to be disclosed to a court or governmental agency; (c) as may be necessary to assist Buyer to file or prosecute patent applications concerning any Products; (d) as may be necessary to carry out any litigation concerning the Purchased Assets; or (e) as may otherwise be required by law. Sellers shall take reasonable measures to assure that no unauthorized use or disclosure is made by others (including without limitation its respective employees, agents and Affiliates) to whom access to such information is granted. Buyer shall treat as confidential and proprietary and shall not use or reveal or disclose to any Third Party either directly or indirectly any confidential information that does not relate to the Purchased Assets received from Research Associates during the term of the License Agreement for a period of five (5) years from the date of this Agreement without first obtaining the written consent of Research Associates, except (a) as may be otherwise provided herein; (b) as may be required to be disclosed to a court or governmental agency; (c) as may be necessary to assist Buyer to file or prosecute patent applications concerning any Products; (d) as may be necessary to carry out any litigation concerning the Purchased Assets; or (e) as may otherwise be required by law.

17.3 Choice of Law. This

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Agreement shall be governed by, construed, interpreted and the rights of the parties determined in accordance with the laws, including equitable principles but without regard to principles of conflict of laws, of the Commonwealth of Pennsylvania.

Sellers and Buyer hereby consent to process being served in any suit, action or proceeding of the nature referred to and in any court having jurisdiction by the mailing of a copy thereof by registered or certified first-class mail, postage prepaid, return receipt requested to the address set forth in Section 17.4.

Nothing in Section 17.3 shall affect the right of Sellers and Buyer to serve process in any manner permitted by law or affect the right of Sellers and Buyer to bring proceedings in the courts of any jurisdiction or jurisdictions. Nothing herein shall limit either party from obtaining injunctive relief for irreparable hardship, in a court of equity.

17.4 Notices. Any notice, request, consent, waiver or other communication required or permitted to be given hereunder shall be effective only if in writing and shall be deemed sufficiently given only in person or sent by certified or registered mail, postage prepaid, return receipt requested, addressed as follows:

If to Sellers:

E.B. Michaels Research Associates, Inc.
56 Rogers Avenue, Unit S
Milford, CT 06460

and

Edwin B. Michaels
56 Rogers Avenue, Unit S

with a copy to:

John Richards Ladas & Parry
26 West 61 Street
New York NY 10023

If to Buyer:

Anne-Marie Corner
President and Chief Executive Officer Biosyn, Inc.
3401 Market Street
Philadelphia, PA 19104

with a copy to:

Raymond D. Agran
Ballard Spahr Andrews & Ingersoll
1735 Market Street, 51st Floor
Philadelphia, PA 19103

or to such other Person or address as either such party may have specified in a notice duly given by the sender as provided herein. Such notice or communication shall be deemed to have been given as of the date so delivered.

17.5 Entire Agreement. This Agreement (including the schedules and exhibits attached hereto) and the documents referred to herein as having been entered into by any of the parties hereto or delivered by a party hereto to another party hereto constitute the entire agreement and understanding of the parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements and understandings, representations and warranties, whether oral or written, relating to the subject matter hereof.

17.6 Modification. This Agreement may be amended, modified and supplemented only by written agreement of the parties hereto.

17.7 No Waiver. No delay or failure on the part of any party in exercising any rights hereunder, and no partial or single exercise thereof, will constitute a waiver of such rights or of any other rights hereunder. The rights and remedies provided in this Agreement are cumulative and are not exclusive of any rights or remedies a party may otherwise have at law or in equity.

17.8 Severability. The unenforceability or invalidity of any Section or subsection or provision of this Agreement shall not affect the enforceability or validity of the balance of this Agreement. If any provision of this Agreement is so broad as to be unenforceable, such provision shall be interpreted to be only as broad as is enforceable.

17.9 Headings. The headings of the Sections and subsections contained in this Agreement are for reference and purposes only and shall not in any way affect the meaning, interpretation, enforceability or validity of this Agreement.

17.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which so executed will be deemed to be an original, but all of which

together will constitute one and the same agreement.

17.11 Construction. Within this Agreement, the singular shall include the plural and the plural shall include the singular, and any gender shall include all other genders, all as the meaning and the context of this Agreement shall require.

17.12 Continuation Provisions. In the event Buyer enters into any agreement to license or sell any or all of the Purchased Assets the following sections of this Agreement must be included in said agreement: Sections 4 (b), (c), (d), (e), (g), (h), (i), (j), (m) and (n), Section 5 and Section 13.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

BIOSYN, INC.
By: _____
Title: _____

E.B. MICHAELS RESEARCH ASSOCIATES, INC.
By: _____
Title: _____

EDWIN B. MICHAELS
By: _____
Edwin B. Michaels

Schedule 1

COUNTRY	PATENT	APPLN #	PUBL #	PUBL. DATE	GRANT DATE	EXPIRATION DATE
ARIPO	AP327				March 21, 1994	March 23, 2012
AUSTRALIA	606861	8770872		Sept. 9, 1987	July 9, 1991	, 17, 2007
	661968	9182227		Oct. 21, 1992	Dec. 12, 1995	July 17, 2011
"	663506	9219835		Oct. 21, 1992	, 6, 1996	March 20, 2012
"		9476835		April 3, 1995		Sept. 9, 2014
Australia	EP294391				Feb. 2, 1994	Feb. 17, 2007
Belgium	EP294391				Feb. 2, 1994	Feb. 17, 2007
Canada	1315693				April 6, 1993	April 6, 2010
"		2106683				July 17, 2011
"		2106682				March 20, 2010
"		2171294				Sept. 9, 2014
	1052272 (expire					
	1052273					
	(expired)					
	1058074					
	(expired)					
EPO	294391				Feb. 2, 1994	Feb. 17, 2007
"	576585				Dec. 20, 1995	March 20, 2012
"		94927365.0				Sept. 9, 2014

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"		91913586.3	576425			July 17, 2011
EPO		Div.				July 17, 2011
		96108577.6				
France	0294391				Feb. 2, 1994	Feb. 17, 2007
"	0578385				Dec. 20, 1995	March 20, 2012
	073191	2406539		June 22, 1979		
West Germany	3789020.4				Feb. 2, 1994	Feb. 18, 2007
"	P69206976.3				Dec. 20, 1995	March 21, 2012
	2747355.8		2818351		Nov. 9, 1978	
	(expired)					
Italy	EP294291				Feb. 2, 1978	Feb. 17, 2007
"	EP576585				Dec. 20, 1995	March 20, 2012
Japan	1645253		54064 41	May 24, 197		
	(abandoned)					
"	2548265	501613/87	1502111	July 27, 1989	Aug. 8, 1996	Feb. 17, 2007
"		512474/91	6505700	June 30, 1994		July 17, 2011
"		508849/92	6506216	July 14, 1994		March 20, 2012
Ko		702779/93				
"		701254/96				Sept. 9, 2014
Luxemboug	EP294391				M 2, 1994	M 18, 2007

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Malaysia		PI9402403				
Mexico	Utility model	93230				Sept. 10, 2013
		(abandoned)				
"		9 7042				Sept. 13, 2014
Netherlands	EP294391				, 2, 1994	, 2, 1994
"	EP576585				Dec. 20, 1995	March 20, 2012
O.A.P.I.	9911				Sept. 15, 1994	July , 2011
Russia		93056144/00				July , 2011
Rep. of South Africa	1991/94				June 28, 1995	Sept. 12, 201
	1981/92				Nov. 25, 1992	
Sweden	87901931-3				Feb. 2, 1994	Feb. 18, 2007
Switzerland	EP294391				Feb. 2, 1994	7, 2007
"	EP576585				Dec. 20, 199	Mar. 20, 2012
United Kingdom	1584847				July 19, 1978	March 31, 1996
	(expired					
"	P294391				Feb. 2, 1994	Feb. 17, 2007
"	EP576585				Dec. 20, 1995	March 20, 2012
U.S.	4839158				June 13, 1989	June 13, 2006

“	5314917	May 24, 1994	May 24, 2011
U.S.	5244652	Sept. 14, 1993	Sept. 14, 2010
		Jan	Jan

		Feb	Feb
		Ap	Ap
“			
“	4183952	Jan. 15, 1980	Jan. 15, 1997
	4107328 (expired)		
	4145436 (expired)		
	4062976 (expired)		
	4075350 (expired)		
	08/223, 096		

PCT APPLICATIONS

PCT/7US87/00384, published as WO 8704922 (expired)
PCT/US91/05060, published as WO 9216201 (expired)
PCT/US92/02427, published as WO 9216182 (expired)
PCT/US94/10067, published as WO9597692 (expired)

(b) Trademarks - Registered U.S. Trademark Registration No. 1,621,919 for “C31G®” and the following foreign Trademarks: European Community (Community Trademark) - “C31G®”; South Korea - “C31G®”, and Republic of South Africa - “C31G®”

(c) all existing unpatented inventions, invention disclosures, multinational invention registrations, patents and patent applications, both U.S. and foreign, (including, but not limited to, all provisionals, reissues, divisions, continuations, continuations-in-part, extensions and reexaminations) and all rights therein provided by law, multinational treaties or conventions which directly relate to C31G® Technology; publications and copyrights which relate specifically to C31G® Technology; trade secrets, Know How and show-how which relate specifically to C31G® Technology; copies of formulae and written chemistry which relate specifically to C31G® Technology; and all common law and registered trademarks, trademark registrations, applications for trademark registrations, tradenames, trade dress, brand names, and logos together with the goodwill associated therewith and symbolized thereby (collectively, “Trademark”) which relate to C31G® Technology; service marks other than E.B. Michaels Research Associates, Inc., E.B. Michaels Research Associates and EBMRA; and an assignment of any licenses therefore (which relate to C31G® Technology) to or from either Seller subject to the terms and conditions thereof which relate specifically to C31G® Technology; and to the extent permitted by any license agreement that has been concluded relating to C31G® Technology; customer, dealer and supplier lists and correspondence relating to C31G® Technology; serial number records relating to C31G® Technology; engineering, manufacturing, design, installation and other technical drawings and specifications, calculations and manufacturing and production processes, techniques and batch records relating to C31G® Technology; scientific, technical, research and development information relating to C31G® Technology; FDA inspection reports relating to C31G® Technology; operating, maintenance and repair manuals and instruction books relating to C31G® Technology; cost and estimating information, and other business records relating to C31G® Technology; consultant’s reports; bills of material, copies of lab notebooks and other data records, test data and selected test material samples relating to C31G® Technology; and all technical data (including, but not limited to, data stored electronically or on other format, together with an assignment of any Third Party licenses necessary to use such data) directly relating to the Purchased Assets.

(d) Permits. All governmental permits, licenses, registrations, orders and approvals relating to the use of the C31G® Technology, to the extent such permits, licenses, registration, orders and approvals are transferrable to Buyer (collectively, the “Permits”).

(e) Contracts listed on Schedule 2.

(f) Commercial Information. Details of contacts with potential users of C31G® Technology and contract manufacturers of products utilizing C31G® Technology and in particular of Topicare.

(g) Inventory. Such quantity of Topicare that as of the Closing Date is still owned by Research Associates.

(h) Rights to use and to have transferred to the Buyer’s name submissions made to the United States Food and Drug Administration for the inclusion of C31G® Products in the FDA’s OTC proposed antiplaque proposed monograph permitting over-the-counter

Schedule 2

- 1) Oratec license of February 5, 1992, modified by addendum dated December 31, 1992 and further clarified by a letter of Intent of December 31, 1992,- Second Addendum to License Agreement of May 4, 1995 for C31G® liquid dentrifice and Letter of June 26, 1996
- 2) Il Dong license of April 1, 1993 for Topicare (personal care products)
- 3) 11 Dong license of April 1, 1993 for C31G® Liquid Dentrifice
- 4) U.S. Summit Company (M) DSN BI3D (Supply agreement) (there is no document formalizing this agreement)
- 5) Contract with [*]

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SCHEDULE 3
COMMON STOCK DISTRIBUTIONS TO EBMRA BY BIOSYN

<u>Certificate #</u>	<u>Date</u>	<u>Amount</u>	<u>Reason</u>
080 (cancelled 12/94 and reissued as 113 114)	1/3/94	45,000	Minimums and royalty reduction
081 (cancelled 12/94 and reissued as 113/114)	1/3/94	41,334	Minimums and royalty reduction
088	4/25/94	3,572	Antidilution (cancelled)
113	12/94	82,027	Part of reissuance of certificate #80/81
114	12/94	4,317	Part of reissuance of certificate #80/81
146	5/10/96	7,500	Minimums
147	9/6/96	7,932	Antidilution (cancelled)
148	9/18/96	19,004	Reissuance of certificate #88/147 and Antidilution
149	10/7/96	15,000	Antidilution/final issuance
		127,848	

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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

**PUBLIC HEALTH SERVICE
PATENT LICENSE AGREEMENT—EXCLUSIVE**

COVER PAGE

For PHS internal use only:

Patent License Number: **L-025-01/0**

US Patent Numbers 5,821,081; 5,843,882; 5,962,653; 5,962,668; 5,998,587; 6,015,876; 6,245,737; 6,420,336; and 6,428,790; and US Patent Applications Numbers [*].

Licensee: **Biosyn, Inc.**

Cooperative Research and Development Agreement (CRADA) Number (if applicable): N/A

Additional Remarks:

Public Benefit(s): Microbicide to protect against infection by HIV

This Patent License Agreement, hereinafter referred to as the “**Agreement**”, consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) and/or Patent Application(s)), Appendix B (Field of Use and Territory), Appendix C (Royalties), Appendix D (Modifications), Appendix E (Benchmarks and Performance), Appendix F (Commercial Development Plan) and Appendix G (Developing Countries). The Parties to this **Agreement** are:

- 1) The National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), or the Food and Drug Administration (“FDA”), hereinafter singly or collectively referred to as “**PHS**”, agencies of the United States Public Health Service within the Department of Health and Human Services (“**DHHS**”); and
- 2) The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as “**Licensee**”.

CONFIDENTIAL

PHS PATENT LICENSE AGREEMENT—EXCLUSIVE

PHS and **Licensee** agree as follows:

1. BACKGROUND

- 1.01 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.
- 1.02 By assignment of rights from **PHS** employees and other inventors, **DHHS**, on behalf of the United States Government, owns intellectual property rights claimed in any United States and/or foreign patent applications or patents corresponding to the assigned inventions. **DHHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.
- 1.03 The Secretary of **DHHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions.
- 1.04 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.05 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, and/or marketable products for public use and benefit.

2. DEFINITIONS

- 2.01 “**Benchmarks**” mean the performance milestones that are set forth in Appendix E.

- 2.02 “**Commercial Development Plan**” means the written commercialization plan attached as Appendix F.
- 2.03 “**First Commercial Sale**” means the (a) first shipment of **Licensed Products** to an unrelated third party by or on behalf of **Licensee** or its sublicensees, or (b) the first performance of a **Licensed Process** for an unrelated third party by **Licensee** or its sublicensees, in each case by or on behalf of **Licensee** in exchange for cash (or some equivalent to which value can be assigned for the purpose of determining **Net Sales**) in excess of fully burdened manufacturing cost. Notwithstanding the foregoing, **First Commercial Sale** shall not include transfers at or below cost by or on behalf of **Licensee** or its sublicensees of **Licensed Products**, or the practice of **Licensed Processes**, in connection with compassionate use, emergency use, treatment Investigational New Drug Applications (IND’s), or the like authorized by the U.S. Food and Drug Administration (FDA) or corresponding foreign agencies.
- 2.04 “**Government**” means the Government of the United States of America.
- 2.05 “**Licensed Biological Materials**” means:
- a) Plasmid constructs encoding the wild type or mutant forms of the Cyanovirin-N gene, and;
 - b) Polyclonal antibodies and hybridoma cell lines producing monoclonal antibodies specific for wild type or mutant forms of Cyanovirin-N.
- 2.06 “**Licensed Field of Use**” means the field of use identified in Appendix B.
- 2.07 “**Licensed Patent Rights**” shall mean:

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- a) Patent applications (including provisional patent applications and PCT patent applications) and/or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;
- b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; iv) priority patent application(s) of a) above; and v) any reissues, reexaminations, and extensions and reregistrations of all such patents;
- c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign and U.S. patent applications and patents to a) and b) above, including those listed in Appendix A.

Licensed Patent Rights shall *not* include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in a) above.

- 2.08 “**Licensed Process(es)**” means processes which, in the course of being practiced would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.09 “**Licensed Product(s)**” means tangible materials which, in the course of manufacture, use, sale, or importation would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.10 “**Licensed Territory**” means the geographical area identified in Appendix B.
- 2.11 “**Net Sales**” means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of **Licensee** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by **Licensee**, or sublicensees, and on its payroll, or for the cost of collections.

In the event **PHS**, on a country-by-country basis, is receiving earned royalties under this **Agreement** from any **Licensed Product** sold in a form containing **Licensed Product(s)** and at least one other ingredient, product or component having a specific pharmacological effect (i.e., an anti-infective or anti-inflammatory, but not a diluent, carrier, perfume etc.) (a “**Combination Product**”) which is sold separate and apart from the **Licensed Product(s)** in the **Combination Product**, **Net Sales** for such **Combination Product** will be calculated by multiplying the actual **Net Sales** of the **Combination Product** by the fraction $A/(A+B)$, where A is the **Net Sales** price per dose of the **Licensed Product(s)** if sold separately and B is the **Net Sales** price per dose of the other ingredient(s), product(s) or component(s) in the **Combination Product**, if sold separately. If the other ingredient(s), product(s) or component(s) is not sold separately in a country, **Net Sales** for such **Combination Product** will be calculated by multiplying the actual **Net Sales** of the

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Combination Product by the fraction A/C , where A is the **Net Sales** price per dose of the **Licensed Product(s)**, if sold separately in said country, and C is the **Net Sales** price per dose of the **Combination Product**. If neither the **Licensed Product(s)** nor the other ingredient(s), product(s) or component(s) is sold separately in a country, then **Net Sales** for the **Combination Product** shall be determined by multiplying the **Net Sales** of the **Combination Product** by $X/(X+Y)$, where X is the number of **Licensed Products** and Y the number of other ingredients, products or components in the **Combination Product**.

Notwithstanding the above determination of **Net Sales** of **Combination Product**, in no event shall the **Net Sales** used to calculate earned royalty due on a **Combination Product** be reduced by more than fifty (50%) percent of the actual **Net Sales** of the **Combination Product**.

- 2.12 **“Practical Application”** means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.
- 2.13 **“Research License”** means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or **Licensed Processes** as defined by the **Licensed Patent Rights** in the **Licensed Field of Use** for purposes of research and not for purposes of commercial manufacture, sale, distribution or for development for such commercial purposes.
- 2.14 **“Developing Country”** means countries eligible for support from the Global Alliance for Vaccine Initiatives (GAVI) or successor organization, or which at the effective date of this Agreement are those countries with a Gross National Product of less than US \$1,000 per capita per year, and at the effective date of this **Agreement** include those listed in Appendix G.
- 2.15 **“Public Sector”** means the U.S. government and/or the government of a **Developing Country**, or any nonprofit entity empowered by the U.S. government and/or the government of a **Developing Country** to act for said government in matters applicable to this **Agreement**, organizations within the United Nations system including the World Health Organization and UNICEF, and other non-profit organizations when they purchase drugs or vaccines for delivery, manufacture and/or sale in the U.S. and **Developing Countries**.
- 2.16 **“Private Sector”** means all other parties other than the **Public Sector**.

3. GRANT OF RIGHTS

- 3.01 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Field of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Field of Use**.
- 3.02 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to **Licensed Patent Rights**. **PHS** represents to **Licensee** that as of the Effective Date of this **Agreement**, **PHS** is unaware of any other **PHS** patent rights that block or limit the **Licensed Patent Rights**.
- 3.03 **PHS** grants **Licensee** the benefit of any patent term extensions and reregistrations applicable to the **Licensed Patent Rights** and any Orphan Drug Act registrations applicable to **Licensed Products** and **Licensed Processes** and any comparable extensions and registrations in the **Licensed Territory**. **PHS** agrees to reasonably cooperate, such as by submitting applications to appropriate

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governmental agencies, at the request and sole expense of **Licensee**, in connection with applying for and obtaining such extensions and registrations.

- 3.04 To the extent permitted by law, governmental regulation, and **PHS** policy, and other agreements between **PHS** and third parties, and for purposes only of seeking regulatory approval to commercialize **Licensed Products** and **Licensed Processes** in the **Licensed Field of Use**, **PHS** agrees to consider in good faith any requests from **Licensee** to make its preclinical and clinical data, if any, relating to **Licensed Products** and **Licensed Processes** available nonexclusively to **Licensee**, such requests shall be considered on an expedited basis and shall not be unreasonably denied and, in particular, where access by **Licensee** to such data may expedite obtaining approval from applicable regulatory agencies.
- 3.05 In addition to the above-mentioned rights, **PHS** grants to **Licensee**, subject to royalties as described herein, the use of **Licensed Biological Materials** required for use of the **Licensed Patent Rights** granted hereunder.

4. SUBLICENSING

- 4.01 Upon written approval by **PHS**, which approval will not be unreasonably withheld, **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**. Such sublicensing arrangements shall be deemed to have been accepted by **PHS** if **PHS** does not object within Forty Five (45) days of **Licensee**'s written request for approval of a sublicense.
- 4.02 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.01-5.04, 8.01, 10.01, 10.02, 12.05, and 13.05-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements. **PHS** acknowledges that some of the obligations in these Paragraphs may not appropriately apply to sublicensees, and agrees to reasonably consider limitations added by **Licensee** to such Paragraphs in a sublicense agreement to the extent permitted by law.
- 4.03 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between such sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. Such conversion is subject to **PHS** approval, which approval shall not be unreasonably withheld, and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.
- 4.04 **Licensee** agrees to forward to **PHS** a copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of such agreement. To the extent permitted by law, **PHS** agrees to maintain each such sublicense agreement as commercial and financial information obtained from a person and as privileged and confidential pursuant to the provisions of Section 9.09 of this **Agreement**.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.01 **PHS** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or not-for-profit, public health international organization pursuant to any existing or future treaty or agreement to which the Government is a signatory. Prior to **First Commercial Sale** and to the extent that **Licensee** has available material, **Licensee** agrees to provide **PHS**, subject to appropriate Materials Transfer Agreements, reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use, at a cost no greater than **Licensee's** fully burdened cost; i.e., direct costs of manufacturing plus overhead costs.

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5.02 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through performance of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

5.03 **Licensee** acknowledges that **PHS** may enter into future Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. **Licensee** agrees not to unreasonably deny requests for a **Research License** from such future collaborators with **PHS** when acquiring such rights is necessary in order to make a Cooperative Research and Development Agreement (CRADA) project feasible. **Licensee** may request an opportunity to join as a party to the proposed Cooperative Research and Development Agreement (CRADA). **PHS** agrees to notify **Licensee** in writing as soon as practicable, and before execution, that it is contemplating a CRADA with a research plan that overlaps with the **Licensed Field of Use** of this **Agreement**.

5.04 In addition to the reserved license of Paragraph 5.01 above, **PHS** reserves the right to grant nonexclusive **Research Licenses** directly or to require **Licensee** to grant nonexclusive **Research Licenses** in the **Licensed Field of Use**, on reasonable terms. The purpose of this **Research License** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, **PHS** shall consult with **Licensee** before granting to commercial entities a **Research License** in the **Licensed Field of Use** or providing to them research samples of materials made through the **Licensed Processes** for use in the **Licensed Field of Use**, except that **PHS** may not distribute such **Licensed Products** or materials provided to **PHS** by **Licensee** pursuant to Section 5.01.

5.05 In the event that **PHS** makes any filings or submissions such as an IND or NDA (or foreign equivalent) to the Food and Drug Administration (or foreign equivalent) in order to conduct clinical trials or seek regulatory approval of a **Licensed Product** in **Licensed Fields of Use**, **PHS** agrees to provide **Licensee** with an automatic right of reference to such filings, including all data, reports and documents submitted in connection therewith. **PHS** agrees to sign appropriate documentation to permit such reference and to promptly notify **Licensee** upon making such filings.

6. ROYALTIES AND REIMBURSEMENT

6.01 **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date that this **Agreement** becomes effective.

6.02 **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.03 **Licensee** agrees to pay **PHS** earned royalties on **Net Sales** as set forth in Appendix C.

6.04 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.

6.05 **Licensee** agrees to pay **PHS** sublicensing royalties as set forth in Appendix C.

6.06 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that a) the application has been abandoned and not continued, b) the patent expires or irrevocably lapses, or c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.07 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

[*] 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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6.08 On sales of **Licensed Products** by **Licensee** to sublicensees or on sales made in other than an arm's-length transaction, the value of the **Net Sales** attributed under this Article 6 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.

6.09 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **PHS** prior to the effective date of this **Agreement**, **Licensee** shall pay to **PHS** [*] (which is [*] of total patent cost in Appendix A), as an additional royalty, within thirty (30) days from the date that this **Agreement** becomes effective. In addition, **Licensee** shall pay to **PHS** another [*] within thirty (30) days from the date that an NDA has been filed.

6.10 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **PHS** on or after the effective date of this **Agreement**, **PHS**, at its sole option, may require **Licensee**:

(a) To pay **PHS** on an annual basis, within sixty (60) days of **PHS**'s submission of a statement and request for payment, a royalty amount equivalent to all such patent expenses incurred during the previous calendar year(s) for the **Licensed Patent Rights** corresponding to those listed in Appendix A, divided equally among all commercialization licensees of the **Licensed Patent Rights** corresponding to those listed in Appendix A, as applicable, that are on record as of the date on which the statement and request for payment are sent by **PHS** to **Licensee**, and limited specifically to those commercialization license(s) under which licensee(s) are responsible for paying a share of patent expenses, and specifically excluding any license(s) which are for internal research use and/or for research reagent sales; or

(b) To pay such expenses directly to the law firm employed by **PHS** to handle such functions. However, in such event, **PHS** and not **Licensee** shall be the client of such law firm.

In no instance shall the amount due from **Licensee** be more than [*] as patent cost payment per year.

Under exceptional circumstances, **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain such patent applications or patents and shall provide to **PHS** copies of each invoice associated with such services as well as documentation that such invoices have been paid.

6.11 In the event that **PHS** provides exclusive or nonexclusive commercialization licenses to more than two (2) licensees under the **Licensed Patent Rights** corresponding to any specific patents and/or patent applications to any additional licensee(s), limited specifically to those commercialization license(s) under which licensee(s) are responsible for paying a share of patent expenses, and specifically excluding any license(s) which are for internal research use and/or for research reagent sales, **Licensee** shall receive as a credit a proportional share of any and all patent expenses previously paid or due by **Licensee** under Paragraphs 6.09 and 6.10 of this **Agreement** for those specific patents and/or patent applications, based upon a proportional reallocation of patent expenses among all exclusive or nonexclusive commercialization licensees as specified in this Paragraph 6.10. **PHS** will notify **Licensee** within ninety (90) of grant of any additional licenses under the **Licensed Patent Rights**, and the credit described in this Paragraph 6.11 shall be applied against **Licensee**'s next invoice for its share of any current and/or future patent expenses payable under Paragraphs 6.09 and 6.10, minimum annual royalties, and/or earned royalties.

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6.12 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any **Licensed Patent Rights** upon ninety (90) days written notice to **PHS** and owe no payment obligation under Article 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of such written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.01 **PHS** agrees to take responsibility for, but to consult with the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish, upon execution of this **Agreement** and on a continuous basis thereafter as long as the **Agreement** is in effect, copies of relevant patent-related documents to **Licensee**, including all drafts of patent applications filings, domestic and foreign, amendments thereto, related correspondence and other related documents, sufficiently in advance to allow **Licensee** to comment thereon prior to filing or submission and at least fourteen (14) days in advance if possible. During the term of this **Agreement**, **PHS** shall never allow other licensees to assume responsibility for the preparation, filing prosecution and maintenance of the **Licensed Patent Rights** without consultation with and prior approval of **Licensee**.

7.02 Each party shall promptly inform the other as to all matters that come to its attention that may materially affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and **PHS** shall permit **Licensee** to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights** in both the United States and foreign countries, and **PHS** shall consider all reasonable comments and suggestions of **Licensee**.

8. RECORD KEEPING

8.01 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. Such records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for an annual inspection at the expense of **PHS** by an accountant or other designated auditor selected by **PHS** and reasonably acceptable to **Licensee** for the sole purpose of verifying reports and payments hereunder. The accountant or auditor shall execute a reasonable confidentiality agreement with **Licensee** and shall only disclose to **PHS** information relating to the accuracy of reports and payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any late charges as required by Paragraph 9.08 of this Agreement. All payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due. If the inspection shows an overpayment by **Licensee**, then **Licensee** will credit the overpayment to future royalty payments. However in no event shall royalties paid **PHS** be less than the minimum annual royalty.

8.02 **Licensee** agrees to have an audit of **Net Sales** and royalties conducted by an independent auditor at least every two (2) years if annual royalty-bearing sales of the **Licensed Product** or **Licensed Processes** performed for third parties are over [*]. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalty funds owed to the **Government** under this **Agreement**, and whether the royalty amount owed has been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **PHS** shall pay for the entire cost of the audit. If an inspection shows an underreporting or underpayment in excess of [*] for any 12 month period, then **Licensee** shall reimburse **PHS** for cost of the audit at

the time Licensee pays the unreported royalties, including late charges as required by Paragraph 9.08 of this **Agreement**. All payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due. If the inspection shows an overpayment by **Licensee**, then **Licensee** will credit the overpayment to future royalty payments, however in no event shall royalties paid **PHS** be less than the minimum annual royalty.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

- 9.01 Prior to signing this **Agreement**, **Licensee** has provided to **PHS** the **Commercial Development Plan** at Appendix F, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** have been determined and set forth in Appendix E.
- 9.02 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for the **Licensed Field of Use** within ninety (90) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee**'s public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for such differences. In any such annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee**'s performance under this **Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written consent by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if such request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 CFR 404.3(d). **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **PHS** to address any **Licensed Field of Use** not specifically addressed in the plan originally submitted.
- 9.03 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix E and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.
- 9.04 Commencing with the **First Commercial Sale** by **Licensee** or a sublicensee, **Licensee** shall submit to **PHS** within ninety (90) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, if any, and payments from sublicensees on which a royalty payment is owed to **PHS**, if any, and the amount of royalty accordingly due. With each such royalty report, **Licensee** shall submit payment of the earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine royalties due.
- 9.05 **Licensee** agrees to forward semi-annually to **PHS** a copy of such reports received by **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to **PHS** by **Licensee** for activities under the sublicense.

- 9.06 Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, P.O. Box 360120, Pittsburgh, PA 15251-6120. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be borne or paid entirely by **Licensee**. The royalty report required by Paragraph 9.04 of this **Agreement** shall accompany each such payment, and a copy of such report shall also be mailed to **PHS** at its address for notices indicated on the Signature Page of this **Agreement**.
- 9.07 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay any such tax and be responsible for all filings with appropriate agencies of foreign governments.
- 9.08 Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.09 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of such records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. § 552 shall be subject to the predisclosure notification requirements of 45 CFR § 5.65(d).

10. PERFORMANCE

- 10.01 **Licensee** shall use commercially reasonable efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. “Commercially reasonable efforts” for the purposes of this provision shall include adherence by **Licensee** to the **Commercial Development Plan** at Appendix F and performance of the **Benchmarks** at Appendix E. For purposes of this Article 10, **Licensee’s** efforts shall be deemed to include the efforts of its sublicensees.
- 10.02 Upon the **First Commercial Sale**, until the expiration of this **Agreement**, **Licensee** shall use commercially reasonable efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public. For the purposes of this Article 10, **Licensee’s** efforts shall be deemed to include the efforts of its sublicensees.

11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.01 **PHS** and **Licensee** agree to notify each other promptly of each infringement of the **Licensed Patent Rights** in the **Licensed Field of Use**; as well as any material facts which may affect the validity, scope or enforceability of the **Licensed Patent Rights**, in each case, of which either party becomes aware.
- 11.02 Pursuant to this **Agreement** and the provisions of Chapter 29 of title 35, United States Code, **Licensee** may, notwithstanding the existence of any other license grants by **PHS** under the **Licensed Patent Rights**: a) bring suit in its own name, at its own expense, and on its own behalf for infringement of the **Licensed Patent Rights** in the **Licensed Field of Use**; b) in any such suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take such actions at their own expense. If **Licensee** desires to initiate a suit for patent infringement, **Licensee** shall notify **PHS** in writing. If **PHS** does not notify **Licensee** of its intent to pursue legal action within ninety (90) days, **Licensee** will be free to initiate suit. **PHS** shall have a continuing right to intervene in such suit at its own expense. **Licensee** shall take no

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action to compel the **Government** either to initiate or to join in any such suit for patent infringement. However, in the event that **Licensee** is forced to take action in order to maintain such suit, then any such action by **Licensee** shall not be considered to be a material breach of this **Agreement**. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action, including any and all costs incurred by the **Government** in opposing any such motion or other action. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit. **PHS** shall advise all other licensees under the **Licensed Patent Rights** of any litigation pursuant to this Paragraph and of **Licensee’s** request that they join said litigation, at **Licensee’s** expense, if necessary in order for the **Licensee** to have standing to bring or to maintain such litigation. In the event that **Licensee** is not able to maintain a lawsuit because the necessary parties do not participate, all royalty obligations under this Agreement shall be reduced as described in Appendix C.

- 11.03 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.02, pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code or other statutes, **Licensee** may, after consultation with other exclusive licensees of **Licensed Patent Rights**: a) defend the suit in its own name, at its own expense, and on its own behalf for the **Licensed Patent Rights**; b) in any such suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take such actions and shall have a continuing right to intervene in such suit at their own expense. If **PHS** does not notify **Licensee** of its intent to respond to the legal action within a reasonable time, **Licensee** will be free to do so. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such declaratory judgment action, however, any such action by **Licensee** shall not be considered to be a material breach of this **Agreement**. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action. If **Licensee** elects not to defend against such declaratory judgment action, **PHS**, at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit. **PHS** shall advise all other licensees under the **Licensed Patent Rights** of any litigation pursuant to this Paragraph and of **Licensee’s** request that they join said litigation, at **Licensee’s** expense, if necessary in order for the **Licensee** to have standing to bring or to maintain such litigation. Also, if **PHS** grants the right to litigate under this Paragraph to any other licensee of **Licensed Patent Rights**, such license shall provide an opportunity for **Licensee** to consult in advance with **PHS** and such other licensee before suit is brought and before any settlement is reached that might affect **Licensee’s** rights under this **Agreement**.
- 11.04 In any action under Paragraphs 11.02 or 11.03, the expenses including costs, fees, attorney fees, and disbursements, shall be paid by **Licensee**. The value of any recovery made by **Licensee** through court judgment or settlement, after deduction of said expenses, shall be treated as **Net Sales** and subject to earned royalties.
- 11.05 **PHS** shall cooperate fully with **Licensee** in connection with any action under Paragraphs 11.02 or 11.03. **PHS** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by **Licensee**.

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12. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 12.01 **PHS** offers no warranties other than those specified in Article 1.

- 12.02 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties. However, **PHS** represents that it has complied with the duty of disclosure at the U.S. Patent and Trademark Office and that it is unaware of any facts or reasons why the **Licensed Patent Rights** would not be valid.
- 12.03 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.
- 12.04 **PHS** does not represent that it will commence legal actions against third parties infringing the **Licensed Patent Rights**.
- 12.05 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of: a) the use by or on behalf of **Licensee**, its sublicensees, directors, employees, or third parties under contract to **Licensee** of any **Licensed Patent Rights**; or b) the design, manufacture, distribution, or use of any **Licensed Products, Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**. **Licensee** agrees to maintain a liability insurance program consistent with sound business practice. Notwithstanding any other provision to the contrary, **Licensee** shall have no indemnification obligation in connection with or arising out of: (a) the use by or on behalf of the indemnified parties identified above of any **Licensed Product** or **Licensed Process** for experimental or research purposes, or (b) the design, manufacture, distribution or use of any **Licensed Product** or **Licensed Process** by or on behalf of such indemnified parties for experimental or research purposes.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

- 13.01 This **Agreement** is effective when signed by all parties and shall extend on a country-by-country basis to the expiration of the last to expire of the **Licensed Patent Rights** in each country unless sooner terminated as provided in this Article 13.
- 13.02 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Article 13.05, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding amounts owed through procedures provided by the Federal Debt Collection Act.
- 13.03 In the event of the commencement of a bankruptcy proceeding by or against **Licensee** under the Bankruptcy Code that is not dismissed within ninety (90) days after it is filed, **PHS** may, at its option, terminate this **Agreement**. In the event of a bankruptcy of **Licensee** (unless **PHS** has already terminated this **Agreement**), all rights to **Licensed Patent Rights** granted to **Licensee** under this **Agreement** to the extent same survive prior to filing of such bankruptcy are, and shall be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, as amended from time to time (the "Bankruptcy code"), licenses of right to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that **Licensee**, as a

licensee of such rights under this **Agreement**, shall retain and may fully exercise all its rights and elections under the Bankruptcy Code.

- 13.04 **Licensee** shall have a unilateral right to terminate this **Agreement** and/or any licenses in any country or territory by giving **PHS** sixty (60) days written notice to that effect.
- 13.05 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**: 1) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS**'s reasonable satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**; 2) has not achieved the **Benchmarks** as may be modified under Paragraph 9.02; 3) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the **Agreement**; 4) has committed a material breach of a covenant or agreement contained in the **Agreement**; 5) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences; 6) cannot reasonably satisfy unmet health and safety needs within the **Licensed Field of Use** or 7) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.02 unless waived. In making this determination, **PHS** will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.02. Prior to invoking its rights under this Paragraph 13.05 upon any of the triggers described in items 1) through 7) above, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS**'s concerns as to the previous items 1) through 7). If **Licensee** fails to alleviate **PHS**'s concerns as to the previous items 1) through 7) during such 90-day period or fails to initiate corrective action to **PHS**'s satisfaction during such 90-day period, **PHS** may terminate this **Agreement**.
- 13.06 When the public health and safety so require, and after written notice to **Licensee** providing **Licensee** a ninety (90) day opportunity to respond, **PHS** shall have the right to require **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in the **Licensed Field of Use** under the **Licensed Patent Rights**, unless **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. **PHS** will not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with **Licensee**. If **Licensee** is required to grant sublicense(s) under this Paragraph 13.06, **Licensee** agrees to provide **PHS** and said sublicensee(s) with all data, documents and materials generated or produced by or on behalf of **Licensee** that would be or could be used in regulatory filings with the Food and Drug Administration (or foreign equivalent regulatory agency). **Licensee** agrees that such data, documents and/or materials can be used by **PHS** or said sublicensee(s) to prepare regulatory filings with the Food and Drug Administration (or equivalent foreign regulatory agencies). **Licensee** may charge a fee to said sublicensee(s) that is equal to its direct costs only (i.e., no overhead shall be compensated) for producing said data, documents and materials that said sublicensee(s) actually use in their regulatory filings.

- 13.07 **PHS** reserves the right according to 35 U.S.C. § 209(f)(4) to terminate or modify this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of this **Agreement** and such requirements are not reasonably satisfied by **Licensee**.
- 13.08 Within thirty (30) days of receipt of written notice of **PHS's** unilateral decision to modify or terminate this **Agreement** pursuant to the express provisions in this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR 404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency

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decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

- 13.09 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report, as per Paragraphs 9.02, 9.04 and 9.05, shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **PHS** pursuant to Paragraph 4.03. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of the destruction thereof.
- 13.10 In the event **Licensee** unilaterally terminates this **Agreement** under Paragraph 13.04 or this **Agreement** is terminated for cause by **PHS** under Paragraphs 13.02, 13.03 or 13.05, **Licensee** agrees to provide **PHS** with all data, documents and materials generated or produced by or on behalf of **Licensee** that would be or could be used in regulatory filings with the Food and Drug Administration (or foreign equivalent regulatory agencies). **Licensee** agrees that such data, documents and/or materials can be used by **PHS** or future third party licensee(s) of **Licensed Patent Rights** to prepare regulatory filings with the Food and Drug Administration (or equivalent foreign regulatory agencies).

14. GENERAL PROVISIONS

- 14.01 Neither Party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of either the **Licensee** or the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by either the **Licensee** or the **Government** or excuse a similar subsequent failure to perform any such term or condition by either party.
- 14.02 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 14.03 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.04 If either Party desires a modification to this **Agreement**, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.05 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.06 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party. Notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service.

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- 14.07 This **Agreement** shall not be assigned by **Licensee** except: a) with the prior written consent of **PHS**, such consent not to be withheld unreasonably; b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**; or c) in connection with a merger, consolidation or reorganization. **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**.
- 14.08 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **DHHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

- 14.09 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant Agency of the U.S. **Government** or written assurances by **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate “Patent Pending” status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve **PHS** patent rights in such countries.
- 14.11 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of NIH, CDC, **PHS**, or **DHHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written consent of **PHS**. **Licensee** may publicly identify the existence of this **Agreement** and is not prohibited from using publicly available factual information regarding **Licensed Patent Rights**, **Licensed Products**, and **Licensed Processes**, specifically including, but not limited to, the names of the inventors as appearing on the **Licensed Patent Rights** and their associated NIH institutes, without such consent.
- 14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.
- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Paragraphs 4.03, 8.01, 9.05-9.07, 12.01-12.05, 13.08, 13.09, and 14.12 of this **Agreement** shall survive termination of this **Agreement**.

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SIGNATURES BEGIN ON NEXT PAGE

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PHS PATENT LICENSE AGREEMENT—*EXCLUSIVE*

SIGNATURE PAGE

For **PHS**:

Steven M. Ferguson, M.B.A.
Acting Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Date

Mailing Address for Notices:

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by:

Signature of Authorized Official

Date

Anne-Marie Corner

Printed Name

President and CEO

Title

Official and Mailing Address for Notices:

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

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

APPENDIX A—Patent(s) or Patent Application(s)

Patent(s) or Patent Application(s):

1. U.S. Patent No. 5,843,882, filed April 27, 1995 from USSN 08/429,965, issued December 1, 1998, entitled: “Antiviral Proteins and Peptides, DNA, DNA-coding Sequences Therefor, and Uses Thereof” (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker and James B. McMahon) (E-117-95/0)
2. U.S. Patent No. 5,821, 081, filed April 26, 1996 from USSN 08/638,610, issued October 13, 1998, entitled: “Nucleic Acids Encoding Antiviral Proteins and Peptides, Vectors and Host Cells Comprising Same, and Methods of Producing the Antiviral Proteins and Peptides” (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker and James B. McMahon) (E-117-95/1)
3. U.S. Patent No. 5,962,653, filed Nov. 13, 1997, issued Oct. 05, 1999, from SN 08/969,584 (DIV of SN 08/429,965 E-117-95/0), entitled: “Methods of Obtaining Antiviral Proteins and Antiviral Peptides from Nostoc Ellipsosporum” (Inventors: Michael R. Boyd and Kirk R. Gustafson) (E-117-95/2)
4. U.S. Patent No. 6,015,876, filed November 13, 1997 from USSN 08/969,378, issued January 18, 2000, entitled: “Method of Using Cyanovirins” (Inventor: Michael R. Boyd) (E-117-95/3)
5. U.S. Patent No. 5,962,668, filed Nov. 13, 1997, issued Oct. 05, 1999, from SN 08/970,179 (DIV of SN 08/638,610, E-117-95/1), entitled: “ Nucleic Acid Encoding Antiviral Proteins and Peptides Fused to Effector Proteins” (Inventors: Michael R. Boyd and Robert H. Shoemaker) (E-117-95/4)

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7. U.S. Patent No. 5,998,587, filed November 13, 1997 from USSN 08/969,249, issued December 7, 1999, entitled: “Anti-cyanovirin Antibody “ (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker and James B. McMahon) (E-117-95/6)
8. U. S. Patent No. 6,245,737, filed Aug. 19, 1998, issued Jun. 12, 2001,from SN 09/137,134 (CON of SN 08/429,965, E-117-95/0), entitled: “ Conjugates of Antiviral Proteins or Peptides and Virus or Viral Envelope Glycoproteins” (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker and James B. McMahon) (E-117-95/7)

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10. U.S. Patent No. 6,428,790, filed October 12, 1999, entitled: “Cyanovirin Conjugates and Matrix-Anchored Cyanovirin and Related Compositions and Methods of Use” (Inventor: Michael R. Boyd) (E-074-99/1)

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12. U.S. Patent Application 09/427,873, filed October 27, 1999, entitled: “Methods of Using Cyanovirins to Inhibit Viral Infection” (Inventor: Michael R. Boyd) (E-074-99/3)

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14. U.S. Patent Application 09/815,079, filed March 22, 2001, entitled: “Glycosylation-Resistant Cyanovirins and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production and methods of Using Nonglycosylated Cyanovirins” (Inventor: Michael R. Boyd) (E-074-99/7)

APPENDIX B—Licensed Field of Use and Territory

Licensed Fields of Use:

Compositions, devices and methods for the prevention of infection by HIV and other sexually transmitted pathogens, by topical, but not systemic, administration, utilizing cyanovirin-N, anti-HIV mutants of cyanovirin-N, including glycosylation-resistant mutants of cyanovirin-N, and anti-HIV fragments of both, including conjugated forms of cyanovirin-N, mutants of cyanovirin-N, and anti-HIV fragments of both, to increase the in vivo half-life, but excluding pegylated cyanovirin-N, pegylated mutants of cyanovirin-N, and pegylated anti-HIV fragments of both. For the avoidance of doubt, such compositions shall include sustained release formulations; devices shall include all drug delivery systems, including but not limited to condoms, sponges, vaginal rings, suppositories, IUDs and other solid matrices; and topical administration shall include administration to mucosal membranes, including vaginal, anal and oral membranes.

Licensed Territory:

Worldwide

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

APPENDIX C—Royalties

Royalties:

Licensee agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of [*].

Licensee agrees to pay to **PHS** a nonrefundable minimum annual royalty in the amounts as follows: [*], starting [*]; [*] starting [*] and [*] starting [*], after [*].

Licensee agrees to pay **PHS** earned royalties on **Net Sales** by or on behalf of **Licensee** as follows:

1. [*]:

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2. [*]

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4. [*]

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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

Licensee agrees to pay **PHS** the following one-time only benchmark royalties:

1. [*] payable within sixty (60) days of [*].

2. [*] payable within sixty (60) days [*].

3. [*] payable within ninety (90) days after [*]

4. [*] payable within ninety (90) days after [*].

Licensee agrees to pay **PHS** sublicensing royalties, within ninety (90) days of receipt by **Licensee**, as follows:

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

1. **Licensee** agrees to pay **PHS** earned royalties on **Net Sales** by sublicensee(s):

a) [*]

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b) [*]

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2. **Licensee** agrees to pay **PHS** additional sublicensing royalties as follows:

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APPENDIX D—Modifications

Modifications are included in the main text of this **License Agreement**.

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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

APPENDIX E—Benchmarks and Performance

Licensee agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

1. [*]

2. [*]

3. [*]

4. [*]

5. [*]

6. Developing World Access

It is **Licensee's** intent to provide **Licensed Product(s)** to the **Public Sector** in the quantity desired by the **Public Sector** and at the price described below. **Licensee** therefore agrees:

a) To provide a written report to **PHS**, within six months of a **Licensed Product** being approved for marketing in the U.S. or Europe detailing the potential **Public Sector** requirement for **Licensed Product(s)** to fulfill the public health need in **Developing Countries**, said report shall include the effect of any approved competing products being offered to the **Public Sector**. The report shall describe how **Licensee** intends to fulfill said **Public Sector** requirement for **Licensed Product(s)**. A similar report shall be required within six months of marketing approval of the [*] of **Licensed Product(s)**. **Licensee** shall amend the **Commercial Development Plan** and this Benchmarks and Performance Appendix as appropriate.

b) The price at which each **Licensed Product** is sold to the **Public Sector** shall be i) preferential to the lowest **Private Sector** price, and ii) set at the lowest possible level permitting a commercially reasonable return on worldwide sales of each said **Licensed Product**.

c) A **Licensed Product** shall be sold to the **Public Sector** within two years of marketing approval of said **Licensed Product** in the U.S. or Europe, and thereafter **Licensee** agrees to use commercially reasonable efforts to meet any delivery date and in the quantities required in any order placed for **Licensed Product(s)** placed by the **Public Sector**.

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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

APPENDIX F—Commercial Development Plan

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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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APPENDIX G—Developing Countries

The list of developing countries as the following:

- 1 Afghanistan
- 2 Albania
- 3 Angola
- 4 Armenia
- 5 Azerbaijan
- 6 Bahamas
- 7 Belize
- 8 Bangladesh
- 9 Barbados
- 10 Benin
- 11 Bhutan
- 12 Bolivia
- 13 Bosnia & Herzegov
- 14 Botswana
- 15 Burkina Faso
- 16 Burundi
- 17 Cambodia
- 18 Cameroon
- 19 Central Afr Rep
- 20 Chad
- 21 China
- 22 Comoros
- 23 Congo, Dem Rep
- 24 Congo, Rep
- 25 Côte d'Ivoire
- 26 Cuba
- 27 Dominican Republic
- 28 Djibouti
- 29 Eritrea
- 30 Ethiopia
- 31 Gambia
- 32 Georgia
- 33 Ghana
- 34 Guinea

35 Guinea-Bissau
36 Guatemala
37 Guyana
38 Haiti
39 Honduras
40 India
41 Indonesia
42 Kenya
43 Korea, DPR
44 Kyrgyz Republic
45 Lao PDR
46 Lesotho
47 Liberia
48 Madagascar
49 Malawi

50 Mali
51 Mauritania
52 Moldova
53 Mongolia
54 Mozambique
55 Myanmar
56 Namibia
57 Nepal
58 Nicaragua
59 Niger
60 Nigeria
61 Pakistan
62 Panama
63 Papua New Guinea
64 Rwanda
65 São Thomé
66 Senegal
67 Sierra Leone
68 Solomon Islands
69 Somalia
70 South Africa
71 Sri Lanka
72 Sudan
73 Suriname
74 Swaziland
75 Thailand
76 Tajikistan
77 Tanzania
78 Togo
79 Trinidad
80 Tobago
81 Turkmenistan
82 Ukraine
83 Uganda
84 Uzbekistan
85 Vietnam
86 Yemen
87 Zambia
88 Zimbabwe

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Execution Copy

LICENSE AGREEMENT
between
CROMPTON CORPORATION
and
BIOSYN, INC.

THIS AGREEMENT, effective as of the 22nd day of May, 2001 by and between CROMPTON CORPORATION (“Crompton”), a corporation organized and existing under the laws of the State of Delaware and having a place of business at Benson Road, Middlebury, Connecticut 06749, and BIOSYN, INC. (“Biosyn”), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having its principal place of business at 3401 Market Street, Suite 300, Philadelphia, Pennsylvania 19104.

WITNESSETH:

WHEREAS, Crompton owns or controls United States Patents No. [*], and a patent application that is the United States equivalent of International Application [*], and corresponding foreign patents and patent applications relating to compounds useful against the replication of the Human Immunodeficiency Virus (“HIV”) and compounds having microbicidal properties, and Crompton owns or controls technology relating to such patents, patent applications and compounds and to formulations, pharmaceutical compositions and methods and processes for treating or inhibiting the replication of HIV and/or inactivating pathogenic microbes;

WHEREAS, Crompton wishes to grant to Biosyn an exclusive worldwide license to make, use and sell formulations and compositions utilizing the UC 781 Technology (as hereinafter defined), but only for the Permitted Field of Use (as hereinafter defined); and

WHEREAS, Biosyn wishes to obtain an exclusive worldwide license to make, use and sell formulations and compositions utilizing the UC 781 Technology (as hereinafter defined), but only for the Permitted Field of Use (as hereinafter defined).

NOW, THEREFORE, in consideration of the mutual covenants and agreements of the parties contained herein, the parties agree as follows:

1. Definitions

1.1 “Affiliate” shall mean a direct or indirect subsidiary of a party.

1.2 “Crompton” shall mean Crompton Corporation, a Delaware corporation, acting directly or through an Affiliate.

1.3 “License” shall have the meaning assigned to such term in Section 2.1 of this Agreement.

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

1.4 “Milestones” shall mean the Milestones provided for in Article 5 of this Agreement, “Milestone” shall mean one of the Milestones and “First Milestone”, “Second Milestone” and “Third Milestone” shall have the meanings provided for those terms in Article 5 of this Agreement.

1.5 “Net Sales” shall have the meaning assigned to such term in Section 8.1 of this Agreement.

1.6 “Patents” shall mean United States Patents No. [*]and [*], and the patent application that is the United States equivalent of International Application WO [*]and any patent that issues therefrom, and any continuation, continuation-in-part, division, provisional, reissue, reexamination, renewal or extension thereof, and the corresponding foreign patents and patent applications listed in Attachment A to this Agreement. “Patents” shall also include any new United States or foreign patent or patent application obtained or filed by or on behalf of Crompton or its affiliates relating to the UC 781 Technology.

1.7 “Permitted Field of Use” shall mean use as a human topical microbicide, alone or in combination with other compounds, for application to the skin, mucosal and/or epithelial tissue as an active ingredient in formulations such as creams, foams, jellies, or other similar formulations, including contraceptive and other vaginal delivery devices such as sponges, intrauterine devices, diaphragms and condoms; but Permitted Field of Use does not include, and specifically excludes:

(a) non-human uses;

(b) human application for both systemic therapeutic uses and systemic post-exposure prophylactic uses; and

(c) uses when applied to or incorporated into any surface (except for human surfaces consisting of skin, mucosal and/or epithelial tissue) or device (except contraceptive and other vaginal delivery devices as provided for above in this Section 1.7) including, but not limited to, gloves, aprons, tubing and filters.

1.8 “Product” shall mean any formulation, composition, device or other product that utilizes in any way the UC 781 Technology.

1.9 “UC 781” shall mean the compound comprising [*].

1.10 "UC 781 Technology" shall mean any and all technology, compounds, formulations, pharmaceutical compositions and methods and processes covered by a Valid Claim in the Patents and/or other proprietary technology and know-how (including manufacturing process technology) related to UC 781 or any of the Patents. The UC 781 Technology shall also include any improvements in any of the UC 781 Technology.

1.11 "Valid Claim" shall mean a claim of any issued, unexpired Patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of

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competent jurisdiction, from which no further appeal can be taken or with respect to which an appeal is not taken within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

1.12 "Warrant" means the warrant, in the form attached to this Agreement as Attachment B, to purchase up to two hundred twenty-eight thousand (228,000) shares of duly authorized, validly issued, fully paid and nonassessable shares of the common stock of Biosyn, as provided for in Section 7.1 of this Agreement.

2. License Grant

2.1 Crompton, Crompton Manufacturing Company, Inc., Uniroyal Chemical Company, Inc. and Crompton Co./Cie each, to the extent of its respective rights in the UC 781 Technology, hereby grants to Biosyn an exclusive, worldwide license under the UC 781 Technology, with the right to grant sublicenses, to make, have made, use, import, export, sell and have sold Products, solely for the Permitted Field of Use. The license rights granted pursuant to this Section 2.1 are defined herein as the "License".

2.2 Crompton, Crompton Manufacturing Company, Inc. and Uniroyal Chemical Company, Inc. each, to the extent of its respective rights, hereby assigns to Biosyn the option, pursuant to that certain Research Agreement executed on behalf of Uniroyal Chemical Company, Inc. on July 24, 1997, on behalf of the Rega Institute for Medical Research on August 12, 1997 and by Dr. Jan Balzarini on August 12, 1997 (a copy of which is attached to this Agreement as Exhibit I), to obtain, for the Permitted Field of Use, an exclusive, worldwide license under United States Patent No. [*], which is entitled "Compositions containing two or three inhibitors of different HIV reverse transcriptases".

3. Term

3.1 This Agreement shall commence effective as of the date first above set forth and, unless earlier terminated pursuant to the terms of this Agreement, shall remain in effect until the expiration of the last-to-expire Valid Claim of the Patents.

4. Representations, Warranties and Covenants

4.1 Crompton represents and warrants to Biosyn as follows:

- (a) Crompton has been duly incorporated and is a validly existing corporation in good standing under the laws of the State of Delaware with full corporate authority to own, lease and operate its properties and conduct the business in which it is presently engaged.
- (b) Crompton has taken all actions necessary to authorize it, and to cause each of its subsidiaries executing this Agreement ("Executing Subsidiaries"), to enter into and perform its respective obligations under this Agreement and the agreements

and instruments referred to in this Agreement and to consummate the transactions contemplated hereby and thereby.

- (c) This Agreement is a legal, valid and binding obligation of Crompton, and of each of the Executing Subsidiaries to the extent of its obligations under this Agreement, enforceable in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to creditors' rights and to general equitable principles.
- (d) Crompton owns or controls, directly or indirectly, all right, title and interest in and to the UC 781 Technology and no person or entity has or shall have any claim of ownership or control with respect to the UC 781 Technology that would, in any way, affect the License hereunder; provided, however, that Crompton makes no representation or warranty that persons other than Crompton and its affiliates do not own or control proprietary technology and know-how (including manufacturing and process technology) substantially similar to proprietary technology and know-how comprising part of the UC 781 Technology.
- (e) To the best of Crompton's knowledge, the Patents are the only patents owned by Crompton and its Affiliates that cover the manufacture, use or sale of UC 781 Technology for the Permitted Field of Use. Crompton has no reason to believe that any of the Patents are or will be found to be invalid.
- (f) Crompton and each of the Executing Subsidiaries is free to perform its respective obligations under this Agreement in accordance with the terms and conditions set forth herein and there are no license rights granted by Crompton or any of its Affiliates to any other person or entity under the UC 781 Technology for the Permitted Field of Use nor are there any other license rights granted by Crompton or any of its Affiliates to any other person or entity that would encumber the License granted herein or that would conflict with the License.

- (g) Neither Crompton nor any of the Executing Subsidiaries is aware of any asserted or unasserted claims or demands that it believes have been or can be asserted against any of the Patents and that would materially adversely affect the License. Notwithstanding the foregoing, Crompton, Crompton Manufacturing Company, Inc. and Uniroyal Chemical Company, Inc. each, to the extent of its respective rights, hereby assigns to Biosyn certain rights with respect to United States Patent No. 5,968,910, as provided for in Section 2.2 of this Agreement.
- (h) To the best of Crompton's knowledge and belief, the quantities of UC 781 that are to be provided by Crompton to Biosyn pursuant to Section 6.2 of this Agreement will conform to the certificates of analysis, material data safety sheets and specifications that are to be included with the shipments of such UC 781.

4.2 Crompton covenants as follows:

- (a) Except as otherwise provided in Article 9 of this Agreement, it shall, with due diligence and good faith, use commercially reasonable efforts to maintain the Patents in full force and effect during the term of this Agreement.
- (b) If, contrary to Crompton's present best knowledge, Crompton or any of its Affiliates should own any other patent(s) that cover the UC 781 Technology for the Permitted Field of Use or the manufacture, use or sale of Products for the Permitted Field of Use, (i) Crompton agrees not to, and to cause its Affiliates not to assert such patent(s) against Biosyn or any sublicensee of Biosyn, with respect to the Permitted Field of Use and (ii) if any such patent(s) cover UC 781 in the Permitted Field of Use, Crompton hereby grants, and shall cause its appropriate Affiliate(s) to grant, a worldwide, royalty-free, exclusive license to make, use or sell UC 781 under such patent(s) in the Permitted Field of Use.
- (c) In the event (i) that Crompton or any Affiliate of Crompton shall, at any time during the term of this Agreement, develop any new compound that is not licensed to Biosyn under this Agreement but that Crompton or such Affiliate perceives to have application or utility for the Permitted Field of Use and (ii) if Crompton or such Affiliate has an interest in developing such compound for commercialization on its own or with a third party or in licensing such compound to a third party for development and commercialization, Crompton shall notify Biosyn in writing and shall negotiate exclusively with Biosyn, in good faith and for a period of ninety (90) days, or such longer period to which the parties may agree, for the grant of a license or other rights to Biosyn with respect to such compound for the Permitted Field of Use.
- (d) As promptly as practicable after the execution and delivery of this Agreement by the parties hereto, Crompton shall provide to Biosyn copies of the documents listed on Attachment C to this Agreement to the extent reasonably available to Crompton.
- (e) During the term of this Agreement and at the request of Biosyn, Crompton shall (i) cooperate with Biosyn in the transfer of know-how and technology licensed to Biosyn under this Agreement, (ii) provide reasonable access to Crompton's scientific and manufacturing technical personnel to assist Biosyn in understanding the know-how and technology licensed to Biosyn under this Agreement and (iii) otherwise provide reasonable assistance to Biosyn with respect to the UC 781 Technology.
- (f) Crompton will file or cause to be filed with the United States Patent and Trademark Office proper documents of assignment and/or name changes so that the actual owner of the Patents is shown as the record owner of the Patents.

4.3 Biosyn represents and warrants to Crompton as follows:

- (a) Biosyn has been duly incorporated and is validly subsisting under the laws of the Commonwealth of Pennsylvania with full corporate authority to own, lease and operate its properties and conduct the business in which it is presently engaged.
- (b) All of the issued and outstanding capital stock of Biosyn has been duly authorized and is validly issued and fully paid and nonassessable.
- (c) Biosyn has all requisite corporate power and authority to enter into and perform all of its obligations under this Agreement and to carry out the transactions contemplated hereby in accordance with the terms and conditions set forth herein.
- (d) Biosyn has all requisite power and authority to issue the shares of common stock issuable upon exercise of the Warrant and such shares of common stock will, upon their issuance in accordance with the terms of the Warrant (including payment for such shares), be duly and validly issued, fully paid and nonassessable and free of any pre-emptive rights. Certain rights held by certain shareholders to subscribe to any issuance of equity securities by Biosyn have been waived with regard to the issuance of the Warrant and the shares of common stock of Biosyn issuable upon exercise of the Warrant.
- (e) Biosyn has taken all actions necessary to authorize it to enter into and perform its obligations under this Agreement and the agreements and instruments referred to in this Agreement and to consummate the transactions contemplated hereby and thereby.
- (f) This Agreement is a legal valid and binding obligation of Biosyn, enforceable in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to creditors' rights and to general equitable principles.
- (g) The execution and delivery by Biosyn of this Agreement and the agreements and instruments referred to in this Agreement, the consummation by Biosyn of the transactions contemplated herein and therein, and the performance by Biosyn of its obligations hereunder and thereunder, do not and will not result in a breach or violation of any of the terms and provisions of, or constitute a default under, (i) any agreement or instrument to which it is party or by which it is bound except for those subscription rights held by certain shareholders that have been waived with regard to the issuance of the Warrant and the shares of common stock of Biosyn issuable upon exercise of the Warrant or (ii) its articles of incorporation or by-laws.

- (h) As of the date of this Agreement, the authorized capital stock of Biosyn consists of twenty-five million (25,000,000) shares of common stock, par value \$0.01 per share (“Common Stock”), and one hundred thousand (100,000) shares of preferred stock, par value \$0.01 per share, twenty-one thousand (21,000) shares of which have been designated “Series A Participating Preferred Stock” and twenty-one thousand (21,000) shares of which have been designated as “Series B Participating

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Preferred Stock”. The issued and outstanding shares of capital stock are as set forth on Attachment D to this Agreement. Other than as set forth on such Attachment D and other than the Warrant, there are no rights, subscriptions, warrants or agreements of any kind outstanding to purchase any capital stock of Biosyn and no conversion rights with respect to capital stock of Biosyn.

4.4 Biosyn covenants as follows:

- (a) Biosyn shall, with due diligence and good faith, but subject to the provisions of Article 5 of this Agreement, use commercially reasonable efforts to achieve each Milestone in a timely manner and to commercialize the Products as promptly as reasonably practicable consistent with sound and reasonable business practice and judgment. Attachment E to this Agreement sets forth Biosyn’s general, and non-binding, development plan with respect to a potential compound or formulation utilizing the UC 781 Technology for the Permitted Field of Use, which development plan Crompton acknowledges to be commercially reasonable and which development plan Crompton recognizes not to contain all specific plans and details related to the planned development of any Product and to be subject to modification as appropriate throughout such development process.
- (b) Biosyn shall keep Crompton informed (i) of progress toward achievement of the Milestones, (ii) of plans, developments and achievements relating to the marketing of Products throughout the world and (iii) of efforts to obtain regulatory approvals with respect to the Products and the marketing of the Products and the status of such efforts. The parties shall meet at times and places mutually agreeable or shall participate in telephone conferences from time to time to enable Biosyn to report to Crompton on the foregoing matters. Such reporting, whether by telephone or in meetings, shall take place not less frequently than semiannually.
- (c) Biosyn shall reserve for issuance upon exercise of the Warrant, such number of shares of its Common Stock as shall, at the time, be issuable upon exercise of the Warrant.

5. Milestones

5.1 Biosyn shall file with the United States Food and Drug Administration (“FDA”) for a United States Investigational New Drug Application (or with an equivalent foreign regulatory authority for a foreign equivalent in (a) [*], (b) [*] or (c) [*]) that will describe protocols for the first in-human testing for the UC 781 Technology in Phase I or Phase I/II testing. Such filing shall comprise achievement of the First Milestone. If the First Milestone has not been achieved on or before the date that is eighteen (18) months from the date of this Agreement, Biosyn and Crompton shall meet to discuss, in good faith, the reasons for the failure to achieve such First Milestone, suggested cures and the anticipated time period to achieve such Milestone. If, after such discussion, Crompton is unwilling to extend the date for achievement of such Milestone, Crompton shall have the right to terminate the License.

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5.2 [*] shall comprise achievement of the Second Milestone. If the Second Milestone has not been achieved on or before the date that is [*] Biosyn and Crompton shall meet to discuss, in good faith, the reasons for the failure to achieve such Second Milestone, suggested cures and the anticipated time period to achieve such Milestone. If, after such discussion, Crompton is unwilling to extend the date for achievement of such Second Milestone, Crompton shall have the right to terminate the License.

5.3 [*] shall comprise achievement of the Third Milestone. If the Third Milestone has not been achieved on or before the date that is [*] Biosyn and Crompton shall meet to discuss, in good faith, the reasons for the failure to achieve such Third Milestone, suggested cures and the anticipated time period to achieve such Milestone. If, after such discussion, Crompton is unwilling to extend the date for achievement of such Third Milestone, Crompton shall have the right to terminate the License.

- 5.4 (a) If Biosyn shall fail to achieve any of the Milestones and if Crompton shall exercise its right to terminate the License in accordance with Sections 5.1, 5.2 or 5.3 of this Agreement, Crompton shall have the option to purchase all development work theretofore undertaken by Biosyn in respect of UC 781 and the UC 781 Technology for the Permitted Field of Use and all of Biosyn’s rights therein (collectively, the “Development Work”) at an option exercise price equal to Biosyn’s cost incurred in such Development Work consisting of out-of-pocket expenditures paid to third parties plus an amount for overhead and internal labor costs calculated by using the rates then in effect for Biosyn with the National Institute of Health as established in accordance with FAR 42.705-1 (“Development Costs”). Such option shall be exercised, if at all, by notice to Biosyn given within ninety (90) days after the date of Crompton’s notice to Biosyn terminating the License.
- (b) In the event that Biosyn shall determine, at any time prior to the achievement of the Third Milestone that it does not intend to continue to pursue the development and testing of, seeking regulatory approval for, and sale, marketing or other offering of, any Product, Biosyn shall give prompt written notice of such determination to Crompton and Crompton shall have the option to purchase the Development

Work at an option exercise price consisting of the Development Costs. Such option shall be exercised, if at all, by notice to Biosyn given within ninety (90) days after the date of Crompton's receipt of Biosyn's notice of such determination.

- (c) In the event that Crompton shall exercise either of the options provided for in this Section 5.4 in respect of the Development Work, Biosyn shall provide reasonable assistance and cooperation in transferring the Development Work to Crompton. Crompton shall bear the reasonable out-of-pocket costs incurred by Biosyn to effect such transfer.

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6. Developmental Efforts

6.1 All developmental expenses for Products including, but not limited to, all costs of the conduct of testing and other trials will be borne by Biosyn.

6.2 Crompton has available a quantity of UC 781 manufactured in accordance with good manufacturing practices and maintained under good laboratory practices conditions. Notwithstanding the provisions of Section 6.1 of this Agreement, Crompton shall provide to Biosyn up to [*]grams of such UC 781 to assist Biosyn in connection with its efforts to develop, test and obtain regulatory approval for Products. Biosyn shall take delivery of [*] grams of such UC 781 promptly after the date of this Agreement and shall have the right, but not the obligation, to take delivery of all or part of the remaining [*] grams at any time and from time to time thereafter, provided that if Biosyn shall wish to take delivery of all or part of such remaining [*] Biosyn shall so notify Crompton not later than [*] from the date of this Agreement. Biosyn's notice shall indicate how much of such remaining [*] grams Biosyn will take and Biosyn's best estimate of the date or dates on which it will want delivery. No delivery of UC 781 under this Section 6.2 shall be for a quantity less than [*]. Biosyn shall pay Crompton the sum of [*] for each [*] gram quantity of UC 781 and such payment shall be made within thirty (30) days after delivery of such UC 781. Purification of the UC 781 shall be undertaken at Crompton's expense, but Biosyn shall provide good faith assistance in trying to arrange for such purification at a lower cost than may otherwise be available to Crompton. The UC 781 to be delivered hereunder shall have been either re-crystallized or otherwise purified in such a manner that the UC 781 so delivered is no less pure than if it had been re-crystallized; provided, however, that it is understood and agreed that the first [*]grams of UC 781 to be delivered pursuant to this Section 6.2 will be re-crystallized or otherwise purified by Crompton at its facilities and, after such re-crystallization or other purification, may not qualify as being manufactured in accordance with good manufacturing practices.

7. Initial Payment and Milestone Payments

7.1 Upon the execution of this Agreement, Biosyn shall pay to Crompton, in consideration of the License granted under this Agreement, the sum of [*] and shall deliver to Crompton the Warrant.

7.2 Upon the successful achievement of the First Milestone, Biosyn shall pay to Crompton, in consideration of the License granted under this Agreement, the sum of [*].

7.3 Upon the successful achievement of the Second Milestone, in consideration of the License granted under this Agreement, Biosyn shall pay to Crompton the sum of [*] and, in accordance with the terms of the Warrant, the Warrant shall become exercisable.

7.4 Upon the successful achievement of the Third Milestone, Biosyn shall pay to Crompton, in consideration of the License granted under this Agreement, the sum of [*].

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8. Royalty Payments

8.1 Biosyn shall pay to Crompton, during the term of this Agreement, royalties on Biosyn's Net Sales of Products. For purposes of this Agreement, "Net Sales" shall mean the gross amount billed or invoiced by Biosyn, or any person or entity acting as Biosyn's agent, for Products in the Permitted Field of Use, less the sum of the following:

- (a) sales taxes, use taxes, tariffs, import/export duties and other excise taxes imposed on sales;
- (b) amounts repaid or credited by reason of rejections, defects, recalls or returns or because of chargebacks, retroactive price reductions, refunds or billing errors not already reflected in amounts invoiced;
- (c) freight costs, import and distribution allowances and insurance charges on shipments to purchasers if included in invoiced amounts;
- (d) trade, cash and/or quantity discounts and rebates and price reductions actually given and not already reflected in amounts invoiced; and
- (e) compulsory payments and rebates directly related to the sale of Products accrued, paid or deducted pursuant to agreements, such as managed care agreements, or pursuant to governmental regulations.

Net Sales shall not be deemed to include transfers among divisions of Biosyn or to or from third party manufacturers or formulators to enable them to produce or formulate Products on behalf of Biosyn for sale by Biosyn. Net Sales shall be deemed to include payments to Biosyn by any sublicensees of all or any part of the UC 781 Technology ("Sublicense Payments"); provided that any payments to Biosyn for product development, research work, clinical studies and regulatory approvals performed by or for Biosyn shall not be included as Net Sales. As provided for in Section 10.3 of this Agreement, Net Sales shall include monies recovered, net of out-of-pocket expenses, in the prosecution of Infringements (as defined in such Section) or defense against any counterclaim of invalidity or any declaratory judgment action brought by a third party for non-infringement, invalidity or interference.

8.2 Initially the royalties under this Agreement shall be payable at the rate of [*] of Net Sales; provided, however, that when the aggregate of the payments made by Biosyn to Crompton pursuant to Article 7 of this Agreement and royalty payments made by Biosyn to Crompton pursuant to this Article 8 have reached [*], such royalty rate shall be reduced to [*] and when the aggregate of the payments made by Biosyn to Crompton pursuant to Article 7 of this Agreement and royalty payments made by Biosyn to Crompton pursuant to this Article 8 have reached [*], such royalty rate shall be reduced to [*]. In no event shall the issuance by Biosyn of the Warrant in accordance with Section 7.1 of this Agreement or the issuance by Biosyn of Common Stock upon the exercise of the Warrant be deemed a payment pursuant to Article 7 of this Agreement for purposes of this Section 8.2.

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8.3 Royalty Obligation, Reduction and Credit

- (a) Only one royalty amount shall be due and payable under this Article 8 for any Product sold by or on behalf of Biosyn, regardless of the number of Patents or the amount of UC 781 Technology covering such Product, subject to subsection (d) of Section 8.3 of this Agreement.
- (b) If Biosyn believes, based upon the practice of the rights licensed hereunder with respect only to the UC 781 Technology in the Permitted Field of Use, that such practice reasonably may infringe the patent rights of any third party (“Third Party Rights”), then payments made for a license to, or other acquisition of, such Third Party Rights shall be considered for treatment as an offset against royalties otherwise owed to Crompton under the following conditions:
 - (i) Biosyn shall notify Crompton in writing either before or after it acquires rights under such Third Party Rights, but no later than ninety (90) days after acquiring such rights. Crompton shall have ninety (90) days to respond to Biosyn’s notification.
 - (ii) If Crompton agrees in writing with Biosyn’s belief that the practice of the rights licensed hereunder with respect to the UC 781 Technology in the Permitted Field of Use reasonably may infringe the Third Party Rights referred to in Biosyn’s notice, or if Crompton fails to respond within its ninety (90) day response period, then Biosyn may have an offset against royalties otherwise owed to Crompton hereunder as specified below.
 - (iii) If Crompton notifies Biosyn in writing within such ninety (90) day period that it does not agree with Biosyn’s belief that the practice of the rights licensed hereunder with respect to the UC 781 Technology in the Permitted Field of Use reasonably may infringe such Third Party Rights, then the Chief Executive Officer of Biosyn and an Executive Vice President of Crompton shall meet to discuss and attempt to resolve the dispute. In the event that such parties are unable to resolve the dispute, Biosyn may obtain the opinion of outside legal counsel reasonably acceptable to Crompton, regarding such potential infringement of Third Party Rights.
 - (A) If such opinion of outside legal counsel agrees that the practice of the rights licensed hereunder with respect to the UC 781 Technology in the Permitted Field of Use reasonably may infringe such Third Party Rights, then Biosyn may have an offset against royalties otherwise owed to Crompton hereunder as specified below.
 - (B) If such opinion of outside legal counsel does not agree that the practice of the rights licensed hereunder with respect to the UC 781 Technology in the Permitted Field of Use reasonably may infringe such Third Party Rights, then Biosyn will not have an

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offset against royalties otherwise owed to Crompton hereunder; provided, however, that if Crompton shall ultimately acquire rights to such Third Party Rights, Crompton shall so notify Biosyn, and Biosyn shall be entitled to a royalty offset retroactive to the date of its notification to Crompton pursuant to subsection(b)(i) of this Section 8.3.

- (iv) Upon any such acquisition of rights under subsection (b)(ii) or clause (A) of subsection (b)(iii) of this Section 8.3 or as contemplated by the proviso of clause (B) of subsection (b)(iii) of this Section 8.3, [*] of the consideration paid by Biosyn in respect of such access to such Third Party Rights (whether paid in the form of up-front, milestone or royalty payments, or otherwise) shall be credited against royalties payable or becoming payable to Crompton under Article 8 of this Agreement; provided, however, that in no circumstances shall Biosyn’s acquisition of Third Party Rights result, in the aggregate, in a reduction of royalties payable to Crompton of more than [*] of the royalties that would have been payable, calculated on the basis of the royalty rate in effect, pursuant to Section 8.2 of this Agreement, at the time such royalty payment would otherwise be due. For the avoidance of doubt, the parties agree that the Third Party Rights to which this subsection (b) shall apply shall be only those, if any, that may impair the ability of Biosyn (or its sublicensees) to utilize the UC 781 Technology by itself in the Permitted Field of Use, and not those, if any, that may impair the ability of Biosyn (or its sublicensees) to utilize the UC 781 Technology in combination with other compounds, devices or products or that may impair the utilization of the UC 781 Technology because of a method of manufacture that is not included as part of the UC 781 Technology.
- (c) For purposes of this subsection (c), “Biosyn Product” shall mean a Product developed or manufactured by or for Biosyn in the Permitted Field of Use. In the event that any Biosyn Product is sold in any jurisdiction in which there is no Valid Claim in effect for any Patent (“Unprotected Jurisdiction”) and in the event that there shall be any Product offered for sale in such Unprotected Jurisdiction that is in the Permitted Field of Use (“Competitive Product”), Biosyn may be entitled to a reduction of the royalties payable on its Net Sales of such Biosyn Product in such Unprotected Jurisdiction, as provided in this subsection (c).
 - (i) If, because of any Competitive Product in the Unprotected Jurisdiction, Biosyn reduces the gross selling price of the applicable Biosyn Product in the Unprotected Jurisdiction by less than [*], there shall be no royalty reduction under this subsection (c) for

such Biosyn Product in the Unprotected Jurisdiction.

- (ii) If, because of any Competitive Product in the Unprotected Jurisdiction, Biosyn reduces the gross selling price of the applicable Biosyn Product in

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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

the Unprotected Jurisdiction by [*] or more, but not more than [*], Biosyn shall be entitled to a royalty reduction on its Net Sales of such Biosyn Product in the Unprotected Jurisdiction. Such reduction shall be a percentage of the royalty rate otherwise at the time in effect under this Agreement equal to twice Biosyn's percentage reduction in the gross selling prices of the applicable Biosyn Product in the Unprotected Jurisdiction.

- (iii) If, because of any Competitive Product in the Unprotected Jurisdiction, Biosyn reduces the gross selling price of the applicable Biosyn Product in the Unprotected Jurisdiction by more than [*], Biosyn shall be entitled to a royalty reduction on its Net Sales of such Biosyn Product in the Unprotected Jurisdiction which shall be [*] of the royalty rate otherwise at the time in effect under this Agreement.

Biosyn shall give Crompton written notice of any Competitive Product being offered or sold in any Unprotected Jurisdiction that Biosyn believes would entitle Biosyn to a royalty reduction under this subsection (c). Such notice shall include a reasonable description of the Competitive Product and the applicable Biosyn Product, and the amounts of Biosyn's original and reduced gross selling prices of the applicable Biosyn Product in the Unprotected Jurisdiction. In the event that the offer or sale of any Competitive Product in any Unprotected Jurisdiction shall, in Biosyn's judgment, make it impracticable for Biosyn to offer or sell any Biosyn Product or Products notwithstanding the royalty rate reductions provided for in this subsection (c), Biosyn may so advise Crompton. In such event, Crompton and Biosyn shall meet to negotiate in good faith an appropriate and mutually acceptable royalty reduction other than as set forth in clauses (i), (ii) and (iii) of this subsection (c).

- (d) In any jurisdiction in which any of the Patents have been filed, if Crompton shall elect, in accordance with Section 9.3 of this Agreement, not to maintain any Patent or Patents or if Crompton shall not, as provided in Article 10 of this Agreement, bring an action for an Infringement (as defined in Section 10.1 of this Agreement) or defend against any counterclaim of invalidity or any declaratory judgment action brought by a third party for non-infringement, invalidity or interference and if, as a result of such election or such failure to bring such an action or defend against such an action, there shall no longer be in such jurisdiction Valid Claims under Patents sufficient to prevent sales in such jurisdiction of competitive products utilizing all or any part of the UC 781 Technology, Biosyn shall no longer be obligated to pay royalties on its Net Sales of Products in such jurisdiction.

8.4 Upon the first commercial sale of any Product by or on behalf of Biosyn and thereafter within forty-five (45) days of the end of each calendar quarter, Biosyn shall provide Crompton with a certificate signed by an executive officer of Biosyn certifying the following information for such quarter for the Products:

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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

- (a) the number of Products sold by Biosyn (by Product type);
- (b) total of gross amounts billed or invoiced for Products sold by or on behalf of Biosyn, with a break-out showing separately billings in each applicable foreign currencies;
- (c) deductions from total amounts billed or invoiced for Products used to arrive at Net Sales of Products;
- (d) exchange rates used for each conversion of any foreign currency billings or invoices into United States dollars;
- (e) a tabulation of all initial payments, Milestone payments (excluding the issuance of the Warrant provided for in Section 7.1 and any issuance of Biosyn Common Stock upon exercise of the Warrant) and royalty payments theretofore made by Biosyn to Crompton pursuant to this Agreement; and
- (f) amounts claimed by Biosyn, pursuant to subsection (b) of Section 8.3 of this Agreement as credits against royalty amounts otherwise payable or, pursuant to subsection (c) of Section 8.3, as reduced royalties; and
- (g) Biosyn's calculation of the royalty amount payable to Crompton under this Agreement in respect of such quarter.

The royalty amounts so calculated by Biosyn in the certificates of Biosyn's executive officer shall accompany such certificates.

8.5 Biosyn shall keep full, true and accurate books and records containing sufficient detail to enable verification of the royalties payable to Crompton pursuant to this Article 8. Such books and records shall be maintained at Biosyn's principal place of business for not less than three (3) years following the end of the quarter to which they pertain. On reasonable notice and at reasonable times, Biosyn shall permit a nationally recognized independent certified public accountant (who may be a representative of Crompton's firm of auditors) appointed by Crompton and reasonably acceptable to Biosyn to examine such books and records of Biosyn as may be reasonably necessary and only to the extent necessary to verify the royalties payable to Crompton pursuant to this

Article 8; provided that such accountant shall have entered into a confidentiality agreement with Biosyn. Such examination may occur only once in each calendar year and may apply only to records pertaining to the preceding three (3) calendar years. Any such audit shall be at Crompton's expense, unless such audit shall disclose an underpayment by Biosyn greater than [*] for any particular calendar year, in which event, the cost of such audit shall be payable by Biosyn. In the event that such examination shall reveal that Biosyn has overpaid royalties under this Article 8, Biosyn shall be entitled to an immediate credit against future royalty payments for the amount of any such overpayment.

8.6 Payments provided for in this Article 8 and amounts due to Crompton under Article 7 shall, if overdue for more than fifteen (15) days, bear interest until payment has been made at the

lesser of (a) a rate equal to two percent above the "Prime Rate", as published in the *Wall Street Journal*, in effect on the payment due date and (b) the highest rate permitted by applicable law. The payment of any such interest shall not deprive Crompton of any other rights it may have at law or in equity as a consequence of the lateness of payment.

9. Patent Prosecution, Maintenance Fees and Marking

9.1 Crompton will be responsible for and will pay for the prosecution of all patent application matters, including but not limited to continuations, reissues, oppositions and appeals, relating to the Patents, except as otherwise provided in Section 9.3 of this Agreement. Beginning from and after the execution and delivery of this Agreement, Crompton shall furnish Biosyn with copies of all substantive communications between the United States Patent and Trademark Office (or any applicable foreign equivalent) and Crompton regarding pre- and post- issuance prosecution of International Application WO 97/45116 everywhere in the world, as well as copies of any responses or amendments thereto. Crompton shall provide copies of all substantive communications relating to such patent application sufficiently in advance of the proposed submission date of amendments and responses to allow Biosyn to comment thereon. Crompton shall consider any reasonable request, comment or recommendation made by Biosyn pertaining to such communication. Notwithstanding anything to the contrary above, final decisions with respect to the prosecution of such patent application shall be determined by Crompton in its sole discretion.

9.2 Crompton shall be solely responsible for all maintenance fees relating to the Patents, except as otherwise provided in Section 9.3 of this Agreement.

9.3 Crompton may, in its sole discretion, decide to abandon any pending Patent application or to refrain from paying any fee required to maintain any Patent. In such event, Crompton shall notify Biosyn, in writing, of such decision not less than forty-five (45) days before the expiration of the time when such decision would have irrevocable effect and Biosyn shall, thereupon, have the right to assume responsibility for the prosecution of such pending Patent application or the maintenance of such Patent at its sole cost and expense. If Biosyn shall assume such responsibility, Crompton shall assign such Patent application or Patent, as the case may be, to Biosyn but subject, in any such case, to any rights theretofore granted or conveyed by Crompton to other parties in respect of fields of use other than the Permitted Field of Use.

9.4 Biosyn shall mark or cause to be marked all Products with the applicable Patent numbers.

10. Enforcement of Patents

10.1 Each party shall promptly notify the other party, in writing, of any alleged Patent infringement relating to the manufacture, use and/or sale of Products for the Permitted Field of Use ("Infringement") of which it becomes aware and shall provide any evidence available to it of such Infringement.

10.2 Crompton may bring an action for an Infringement and may defend against any counterclaim of invalidity or any declaratory judgment action brought by a third party for non-infringement,

invalidity or interference. Biosyn shall cooperate with Crompton in all reasonable respects in the prosecution and/or defense of such action including, without limitation, making its employees available to testify and providing all relevant documents, records, papers, information, samples, specimens and the like, as reasonably requested by Crompton.

10.3 If Crompton does not, within ninety (90) days of notice from Biosyn of an Infringement, bring such an action for patent infringement and/or act to defend against any such counterclaim or declaratory judgment action, Biosyn shall have the right to bring suit for such infringement and to join Crompton as a party plaintiff or to use Crompton's name, if required by law, at Biosyn's sole cost and expense and with counsel of its own selection; provided, however, that Biosyn acknowledges and agrees that any other person or entity to whom Crompton shall have theretofore granted or conveyed rights under such Patent may join as a party plaintiff in such action. Crompton shall cooperate with Biosyn in all reasonable respects in the prosecution or defense of such action including, without limitation, making its employees available to testify and providing all relevant documents, records, papers, information, samples, specimens and the like, as reasonably requested by Biosyn. Biosyn may settle any such action at its own expense and through its own counsel, subject to the approval of Crompton, which approval shall not be unreasonably withheld or delayed, but Biosyn understands and acknowledges that Crompton will not, and may not be required to, approve any settlement that may materially adversely affect the rights of any other person or entity to which Crompton shall have theretofore granted or conveyed rights under the applicable Patent. In the event that Biosyn shall recover any moneys in any such action, whether by way of judgment or settlement, the excess of such recoveries, including damages and interest amounts, over Biosyn's out-of-pocket expenses in the prosecution or defense of such action shall be included as Net Sales of Products for the purpose of calculation of royalties payable to Crompton pursuant to Article 8 of this Agreement.

11. Liability and Indemnity

11.1 Biosyn shall indemnify and hold harmless Crompton and its subsidiaries, affiliates, directors, officers, employees and agents from and against any and all loss, cost, claim, damage, liability or expense (including reasonable attorneys' fees, costs of suit and costs of appeal) incurred by any of them arising out of or in connection with any claim, action, suit, proceeding or investigation ("Claim") filed or threatened including, without limitation, any Claim alleging death or injury to any person, with respect to (a) the production, manufacture, sale, marketing, distribution, shipment, transportation, handling, cleanup, use or disposal of any Product developed, manufactured or sold by or on behalf of Biosyn, (b) the negligence or willful misconduct of Biosyn and/or its subsidiaries,

affiliates, directors, officers, agents, contract manufacturers, distributors, sublicensees and other representatives and (c) the breach by Biosyn of any of its obligations under this Agreement.

11.2 Crompton shall indemnify and hold harmless Biosyn and its subsidiaries, affiliates, directors, officers, employees and agents from and against any and all loss, cost, claim, damage, liability or expense (including reasonable attorneys' fees, costs of suit and costs of appeal) incurred by any of them arising out of or in connection with any Claim filed or threatened including, without limitation, any Claim alleging death or injury to any person, with respect to

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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

(a) the breach by Crompton of any of its representations and warranties set forth in Section 4.1 of this Agreement and (b) the breach by Crompton of any of its obligations under this Agreement.

11.3 The selection of the UC 781 Technology for the development, making, use and sale of Products, and the decision to market any Products for the Permitted Field of Use, is solely Biosyn's, and Crompton does not assume any responsibility whatsoever for such development, making, use, sale or marketing. CROMPTON MAKES NO EXPRESS OR IMPLIED WARRANTY OF ANY KIND INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER THING CONCERNING THE PATENTS OR UC 781 TECHNOLOGY, NOR DOES CROMPTON MAKE ANY REPRESENTATIONS CONCERNING ANY PRODUCT THAT MAY BE MADE, USED OR SOLD. IN PARTICULAR, AND WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, CROMPTON MAKES NO REPRESENTATION OR WARRANTY THAT ANY PRODUCT WILL BE SAFE OR EFFECTIVE FOR THE PERMITTED FIELD OF USE OR WILL BE GRANTED ANY REQUIRED REGULATORY APPROVALS. Nor does Crompton make any representation or warranty that the practice by Biosyn of the rights under the License will not infringe proprietary rights of any third party. In no event shall Crompton have any liability whatsoever for damages, whether direct, indirect, special or consequential, including without limitation damages for economic loss, death or injury to persons or damage to property, in respect of any Patent, the UC 781 Technology or any Product, whether or not Crompton shall be advised, shall have reason to know or in fact shall know of the possibility of such damages.

11.4 Biosyn shall, with respect to the Product in the Permitted Field of Use, obtain and maintain in full force and effect product liability insurance in an amount and with coverage (which shall include Biosyn's indemnification obligations to Crompton pursuant to this Agreement), which is reasonable and customary in Biosyn's industry based on the developmental stage of the Product under development and which shall not be less than [*] per occurrence during such development but which shall be reviewed at the commencement of clinical trials and upon commercialization and increased as appropriate, reasonable and customary in such industry, at such stages. Biosyn shall provide Crompton with evidence of such insurance and the policies of such insurance shall require that Crompton be given notice of any cancellation of such insurance or reduction of coverage or amount and shall name Crompton as an additional insured.

12. Compliance with Law

12.1 Biosyn, its subsidiaries, affiliates, directors and officers shall, and Biosyn shall use commercially reasonable efforts to cause its agents, contract manufacturers, distributors, sublicensees and other representatives to, comply with all United States federal, state and local laws, rules and regulations and all foreign laws, rules and regulations applicable to the development, testing, production, transportation, packaging, labeling, export, import, marketing, distribution, sale and use of the Products in the Permitted Field of Use.

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13. Confidentiality

13.1 The recipient of information supplied pursuant to this Agreement shall treat the same as confidential. For purposes of this Section 13.1, the terms "recipient" and "recipient party" shall mean the party receiving information pursuant to this Agreement, its officers, directors, employees and agents. The foregoing obligations as to confidentiality shall not extend to any transmitted information that is publicly available at the date of its disclosure to the recipient party or which is, at that date, already properly in the possession of the recipient party (evidenced by writing) or which may thereafter become publicly available from sources other than the recipient party and its employees or which may properly thereafter become available to the recipient party on a non-confidential basis from a source other than the disclosing party and that is not known by the recipient party to be under an obligation of confidentiality to the disclosing party with respect thereto. For the purpose of this Section 13.1, disclosures made to the recipient party under this Agreement which are specific shall be deemed to be confidential and therefore shall not be deemed to be within the exceptions set forth in this Section 13.1 merely because they are embraced by general disclosures in the public domain or in the possession of the recipient party. In addition, any combination of features shall be deemed to be confidential and therefore shall not be deemed to be within the foregoing exceptions merely because individual features are in the public domain or in the possession of the recipient party; provided that such combination of features shall be deemed not to be confidential and to be within the exception set forth in this Section 13.1 only if the combination itself and its principle of operation are in the public domain or in the possession of the recipient party. The obligations set forth in this Section shall survive for a period of five years after the expiration or termination of this Agreement. Notwithstanding the foregoing provisions of this Section 13.1, Biosyn may disclose information supplied by or on behalf of Crompton pursuant to this Agreement to sublicensees of Biosyn's rights under Article 2 of this Agreement or any consultants, manufacturers and other third parties for the purpose of development, manufacture and/or sale of Products, but only if such sublicensees, consultants, manufacturers and other third parties, as the case may be, agree in writing to be bound by nondisclosure undertakings equivalent to those of Biosyn under this Article 13.

13.2 If either party becomes or believes that it will become legally compelled to disclose any confidential information of the other party, the party subject to such disclosure requirement shall give prompt written notice of such requirement to the other party prior to any such disclosure so that such other party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of Section 13.1 of this Agreement. The party subject to such disclosure requirement shall disclose only the portion of the confidential information that, in the reasonable judgment of its counsel, it is legally required to disclose and shall use reasonable efforts to obtain an appropriate protective order or other reasonable assurance that the confidential information being disclosed will be given confidential treatment.

13.3 Biosyn shall have the right to publish its results in scientific journals or at scientific meetings. In order that disclosure of information described in a publication will not adversely affect the patent rights or proprietary rights of Crompton, Crompton shall be given the opportunity to review any proposed manuscript or abstract for a period of thirty (30) days before it is submitted for publication. If Crompton shall reasonably determine that any proprietary information of Crompton is disclosed in the proposed manuscript or abstract, Crompton shall have the right to require that such information be deleted. If the proposed manuscript or abstract describes any patentable invention, Crompton shall have the right to request a reasonable delay

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in submission of the proposed manuscript or abstract so that Crompton can further evaluate such invention and initiate filing, if it deems it necessary, of appropriate patent applications.

14. Termination

14.1 Biosyn may terminate this Agreement at any time and for any reason or no reason upon sixty (60) days prior written notice. In the event of any such termination, the License shall immediately and automatically revert back to Crompton.

14.2 This Agreement may be terminated prior to expiration of the term hereof by either party "for cause" immediately upon notice. A party shall have the right to terminate this Agreement "for cause" in the event of: (i) any material breach of this Agreement by the other party that shall go uncorrected for a period of thirty (30) days after notice of such breach, setting forth the details thereof with reasonable particularity, has been given to the other party; or (ii) the institution against the other party of voluntary proceedings in bankruptcy or under any insolvency law or law for the relief of debtors, the making by or on behalf of the other party of an assignment for the benefit of creditors, the filing by or on behalf of the other party of an involuntary petition under any bankruptcy or insolvency law, unless such petition is dismissed or set aside within sixty (60) days from the date of its filing, or the appointment for such other party of a receiver or trustee, unless such appointment is dismissed or set aside within sixty (60) days from the date of such appointment. Termination of this Agreement, or of the License as provided for in Article 5 of this Agreement, shall not be deemed to terminate or extinguish any right accruing prior to the effectiveness of such termination. In the event of any such termination by Crompton pursuant to clause (i) of this Section 14.2, the License shall immediately and automatically revert back to Crompton. In the event of any termination of this Agreement by Biosyn pursuant to clause (i) of this Section 14.2, the License shall survive as a fully-paid, perpetual, worldwide, exclusive license in the Permitted Field of Use.

14.3 In the event of any termination of this Agreement by Biosyn pursuant to Section 14.1 of this Agreement or by Crompton pursuant to Section 14.2 of this Agreement, Crompton shall have the option in respect of the Development Work provided for in Section 5.4 of this Agreement.

15. Notice

15.1 All notices, requests, demands and other communications which are required or permitted to be given under this Agreement shall be in writing and shall be deemed to be duly given upon the delivery or mailing thereof, as the case may be, if hand delivered or sent by registered or certified mail, return receipt requested, postage prepaid, or upon delivery to an express courier service, addressed in any such case:

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if to Crompton or any Crompton Affiliate:

Crompton Corporation
Benson Road
Middlebury, Connecticut 06749
Attn: Executive Vice President and
General Manager Crop Protection Division

if to Biosyn:

Biosyn, Inc.
3401 Market Street, Suite 300
Philadelphia, Pennsylvania 19104
Attn: Chief Executive Officer

or to such other address as either party shall have specified for itself by notice to the other given in accordance with this Section 15.1.

16. Use of Name

16.1 Except as otherwise provided herein, neither party shall have any right, express or implied, to use in any manner the name of the other party or any other trade name or trademark or other identifying mark or symbol of the other party for any purpose in connection with the performance of this Agreement.

17. Announcements

17.1 All press releases and other public announcements related to the subject matter hereof shall be made only with the mutual written agreement of the parties hereto (which shall not be unreasonably withheld or delayed), except that any such public announcement required by law (including regulations of the FDA or Securities and Exchange Commission) may be made without such written agreement.

18. General

18.1 This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, provided, however, that neither party shall have the right to transfer or assign its interest in this Agreement without the prior written consent of the other party except pursuant to (a) a merger, consolidation or reorganization of the assigning party or the sale of substantially all of the assets of the assigning party or (b) an assignment, in

whole or in part, to any entity controlling, controlled by or under common control with the assigning party, provided that the assigning party remains liable for the performance and observance of the duties and obligations of the assignee under this Agreement.

18.2 This Agreement shall be governed by and construed in accordance with the laws of the State of Connecticut, United States, without giving effect to the conflicts-of-laws provisions

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thereof, except where the federal laws of the United States are applicable and have precedence; provided, however, that it is hereby acknowledged that the Warrant and the issuance of the Warrant will, as provided therein, be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania.

18.3 No waiver of any right under this Agreement shall be deemed effective unless contained in a writing signed by the party charged with such waiver, and no waiver of any right arising from any breach or failure to perform shall be deemed to be a waiver of any future such right or of any other right arising under this Agreement.

18.4 This Agreement, the agreements referred to in this Agreement and the License Agreement between Biosyn and Crompton of even date herewith relating to rights of reference and use of data related to certain Biosyn regulatory filings set forth and constitute the entire agreement between the parties hereto with respect to the subject matter hereof, and supersede any and all prior agreements, understandings, promises and representations made by either party to the other concerning the subject matter hereof and the terms applicable hereto. No other terms and conditions shall be binding on either party including terms that may be additional to or at variance with the terms hereof, unless such provision is expressly agreed to in writing signed by both parties hereto.

18.5 If any provision of this Agreement is or becomes or is deemed invalid, illegal or unenforceable in any jurisdiction to which the Agreement is sought to be enforced, (a) such provision shall be deemed amended to conform to applicable laws of such jurisdiction so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the parties, it shall be stricken; (b) the validity, legality and enforceability of such provision shall not in any way be affected or impaired thereby in any other jurisdiction; and (c) the remainder of this Agreement shall remain in full force and effect.

18.6 Except as otherwise provided herein, neither party to this Agreement shall be liable, or be in breach of any provision hereof, for any failure or delay on its part to perform any obligation (other than the obligation to make payments when due) under any provision of this Agreement because of circumstances of *force majeure*, including, but not limited to, any act of God, flood, fire, explosion, breakdown of plant, strike, lockout, labor dispute, war, insurrection, riot, sabotage, or any injunction, law, ordinance or demand or requirement of any governmental authority, or inability to procure or use materials, labor, equipment or energy sufficient to meet manufacturing needs from customary sources at customary prices and without litigation, or any other cause whatsoever, whether similar or dissimilar to those enumerated herein, beyond the reasonable control of such party. If any such event or *force majeure* shall prevent a party from performing its obligations hereunder for a period of six months or more, the other party may terminate this Agreement forthwith by written notice.

18.7 The headings of this Agreement are included only for ease of reference and shall not affect the interpretation of this Agreement in any manner.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective authorized representatives on the dates indicated below, effective as of the 22nd day of May, 2001.

BIOSYN, INC.

By: _____
Name: Anne-Marie Corner
Title: Chief Executive Officer

CROMPTON CORPORATION

By: _____
Name: Alfred F. Ingulli
Title: Executive Vice President

With respect to the matters set forth in Article 2 of the foregoing Agreement.

CROMPTON MANUFACTURING
COMPANY, INC.

By: _____
Name: Alfred F. Ingulli
Title: Executive Vice President

UNIROYAL CHEMICAL COMPANY, INC.

By: _____
Name: Walter K. Ruck
Title: President

By: _____
 Name: Walter K. Ruck
 Title: President

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

ATTACHMENT A

Foreign Patents and Patent Applications

I. USPN 5,268,389 AND 5,693,827 AND FOLLOWING FOREIGN EQUIVALENTS

[*]

COUNTRY	STATUS	APPLN. NO.	PATENT NO.
AUSTRIA	GRANTED	90915588.9	0497816
AUSTRALIA	GRANTED	66035/90	636409
BELGIUM	GRANTED	90915588.9	0497816
[*]			
[*]			
SWITZERLAND	GRANTED	90915588.9	0497816
GERMANY	GRANTED	90915588.9	69019533.8
DENMARK	GRANTED	90915588.9	0497816
FRANCE	GRANTED	90915588.9	0497816
GREAT BRITAIN	GRANTED	90915588.9	0497816
GREECE	GRANTED	90915588.9	3017128
HAITI	GRANTED		198/5
[*]			
ISRAEL	GRANTED	95956	95956
ITALY	GRANTED	90915588.9	0497816
JAPAN	GRANTED	514569/90	1967760
SOUTH KOREA	GRANTED	700831/92	0222233
LUXEMBOURG	GRANTED	90915588.9	0497816
MEXICO	GRANTED	22844	179450
NICARAGUA	GRANTED	91-009	920R.P.I.
NETHERLANDS	GRANTED	90915588.9	0497816
NEW ZEALAND	GRANTED	235653	235653
[*]			
RUSSIAN FED.	GRANTED	5011885.04	2108785
SWEDEN	GRANTED	90915588.9	0497816

TAIWAN	GRANTED	79108696	NI-58187
SOUTH AFRICA	GRANTED	90/8094	90/8094

II. USPN 5,696,151 AND THE FOLLOWING FOREIGN EQUIVALENTS

COUNTRY	STATUS	APPLICATION NO.	PATENT NO.
KENYA	GRANTED	AP/P/98/01245	AP902
GAMBIA	GRANTED	AP/P/98/01245	AP902
ZIMBABWE	GRANTED	AP/P/98/01245	AP902
GHANA	GRANTED	AP/P/98/01245	AP902
AFRICA (ARIPO)	GRANTED	AP/P/98/01245	AP902
LESOTHO	GRANTED	AP/P/98/01245	AP902
MALAWI	GRANTED	AP/P/98/01245	AP902
SUDAN	GRANTED	AP/P/98/01245	AP902
SWAZILAND	GRANTED	AP/P/98/01245	AP902
UGANDA	GRANTED	AP/P/98/01245	AP902
AUSTRALIA	GRANTED	11199/97	704086
BRAZIL	PENDING	PI9611838.5	

[*]

[*]

[*]

[*]

[*]			
HAITI	GRANTED		229-REG.5
HUNGARY	PUBLISHED	P9901990	
JAPAN	GRANTED	520533/97	3027771
[*]			
NEW ZEALAND	GRANTED	324118	324118
[*]			

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[*]			
[*]			
[*]			
SOUTH AFRICA	GRANTED	96/9490	96/9490

III. USPN 6,017,947

No filings outside of the United States.

IV. INTERNATIONAL APPLICATION PUBLICATION NO. WO/97/45116 AND THE FOLLOWING EQUIVALENTS:

COUNTRY	STATUS	APPLICATION NO.	PATENT NO.
[*]			

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ATTACHMENT B

Form of Warrant

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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

ATTACHMENT C

Documents for Transfer of UC-781 Technology

[*]

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ATTACHMENT D

Capitalization of Biosyn

**Capitalization of Biosyn, Inc.
as of May 18, 2001**

	<u>Total Outstanding</u>	<u>Convertible into or Exercisable for No. of Shares of Common Stock</u>
Common Stock	4,506,267	n/a
Series A Preferred	7,000	2,800,000
Series B Preferred	5,000	1,666,667
Warrants (other than the Warrant to be issued to Crompton per License)	n/a	563,000
Options (NQSOs & ISOs)	n/a	1,866,168

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

ATTACHMENT E

Non-binding Development Plan

[*]

EXHIBIT I

Research Agreement between Rega Institute for Medical Research
and Uniroyal Chemical Company, Inc.

Subsidiaries of Cellegy Pharmaceuticals, Inc.

Cellegy Australia Pty Ltd
Australia

Cellegy Canada Inc.
Canada

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 28, 2005

Consent of Independent Registered Public Accounting Firm

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

- (1) Registration Statements (Form S-3 Nos. 333-11457, 333-36057, 333-46087, 333-86193, 333-49466, 333-64864, 333-102485, 333-118841 and 333-121836) of Cellegy Pharmaceuticals, Inc. and in the related Prospectuses,
- (2) Registration Statement (Form S-2 No. 333-114247) of Cellegy Pharmaceuticals, Inc. and in the related Prospectus, and
- (2) Registration Statements (Form S-8 Nos. 33-96384, 333-06065, 333-32301, 333-60343, 333-42840, 333-91588, 333-114229 and 333-121838) pertaining to the 1992 Stock Option Plan, the 1995 Equity Incentive Plan, the 1995 Directors' Stock Option Plan and the Director Stock Option Agreement of Cellegy Pharmaceuticals, Inc. and options to purchase common stock granted under the Biosyn, Inc. 1999 Stock Option Plan, as amended, and non-plan options granted to Biosyn, Inc.,

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

/s/ Ernst & Young LLP

Palo Alto, California
March 28, 2005

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

I, Richard C. Williams, certify that:

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

Date: March 30, 2005

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

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

I, A. Richard Juelis, certify that:

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

Date: March 30, 2005

By: /s/ A. Richard Juelis
Vice President, Finance and Chief Financial Officer

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

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

- i. The Report fully complied with the requirements of sections 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- ii. The information contained in the Report fairly presents, in all material respects, the financial Condition and results of operations of the Company:

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

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

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

- iii. The Report fully complied with the requirements of sections 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- iv. The information contained in the Report fairly presents, in all material respects, the financial Condition and results of operations of the Company

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