

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

**FORM 10-K**

(Mark one)

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

**for the Fiscal Year Ended December 31, 2008**

**OR**

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

**Commission File Number 000-26372**

**ADAMIS PHARMACEUTICALS CORPORATION**

(Exact name of registrant as specified in its charter)

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

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

**2658 Del Mar Heights Rd., #555, Del Mar, CA 19512**  
(Address of Principal Executive Offices) (zip code)

Registrant's telephone number, including area code: **(858) 401-3984**

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

**None**  
(Title of each class)

**None**  
(Name of each exchange on which registered)

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

**Common Stock, \$0.0001 par value**  
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

**YES** ☐      **NO** **x**

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

**YES** **o**      **NO** **x**

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

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

**YES** **o**      **NO** **o**

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. **x**

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

Large accelerated filer **o**      Accelerated filer **o**      Non-accelerated filer **o**      Smaller reporting company **x**

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

**YES** **o**      **NO** **x**

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 30, 2008 was \$1,593,256.

As of March 31, 2009, there were 29,834,796 shares of common stock outstanding, not giving effect to the shares issuable in connection with the merger of Cellegy Pharmaceuticals, Inc. and Adamis Pharmaceuticals Corporation and to the reverse stock split of Cellegy shares effected on April 1, 2009, as described in this Report.

**Documents Incorporated by Reference:** None

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**ADAMIS PHARMACEUTICALS CORPORATION ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31,  
2008**

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## Information Relating to Forward-Looking Statements

*This Annual Report on Form 10-K includes “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995 which provides a “safe harbor” for these types of statements. 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. These forward-looking statements include statements about our strategies, objectives and our future achievement. To the extent statements in this Annual Report involve, without limitation, our expectations for growth, estimates of future revenue, our sources and uses of cash, our liquidity needs, our future products, expense, profits, cash flow balance sheet items or any other guidance on future periods, these statements are forward-looking statements. These statements are often, but not always, made through the use of word or phrases such as “believe,” “will,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” and “would.” 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 differ materially from those discussed in this Report. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date of this Report. Important factors that could cause actual result to differ materially from those in these forward-looking statements are disclosed in this Annual Report on Form 10-K, including, without limitation, those discussion under “Item 1A. Risk Factors,” in “Item 1. Business” and in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as other risks identified from time to time in our filing’s with the Securities and Exchange Commission, press releases and other communications.*

*Unless the context otherwise requires, the terms “we,” “our,” and “the Company” refer to Adamis Pharmaceuticals Corporation, a Delaware corporation (formerly Cellegy Pharmaceuticals, Inc.), and its subsidiaries. Savvy®, Aerokid®, AeroOtic®, and Prelone® are our trademarks. We also refer to trademarks of other corporations and organizations in this document.*

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## PART I

### Introductory Note

#### *Merger of Cellegy and Adamis; Change of Corporate Name*

On February 12, 2008, Cellegy Pharmaceuticals, Inc. (“Cellegy,” and Cellegy before the effective time of the merger described below sometimes referred to as “Old Cellegy”) entered into an Agreement and Plan of Reorganization (the agreement as amended, referred to as the “Merger Agreement”) with Adamis Pharmaceuticals Corporation (“Old Adamis”) and Cellegy Holdings, Inc., a wholly-owned subsidiary of Cellegy (“Merger Sub”), providing for the acquisition of Old Cellegy by Old Adamis. The Merger Agreement provided that Merger Sub will merge with and into Old Adamis, with Old Adamis becoming a wholly-owned subsidiary of Cellegy and the surviving corporation in the merger (the “Merger”). The stockholders of Old Cellegy and Old Adamis approved the transaction at a special meeting of Adamis stockholders held on March 23, 2009, and at an annual meeting of Old Cellegy’s stockholders held on March 23, 2009.

Effective as of the close of business on April 1, 2009, Old Adamis and Old Cellegy completed the Merger transaction contemplated by the Merger Agreement. In connection with the consummation of the Merger and pursuant to the terms of the Merger Agreement, Old Cellegy changed its name from Cellegy Pharmaceuticals, Inc. to Adamis Pharmaceuticals Corporation, and Old Adamis changed its corporate name to “Adamis Corporation.”

#### *Reverse Stock Split of Old Cellegy Common Stock*

Pursuant to the terms of the Merger Agreement, immediately before the consummation of the Merger Old Cellegy effected a reverse stock split of its common stock. Pursuant to this reverse stock split, each 9.929060333 shares of common stock of Old Cellegy that were issued and outstanding immediately before the effective time of the Merger was converted into one share of common stock of the Company, and any remaining fractional shares held by a record holder of shares were rounded up to the nearest whole share.

As a result, the total number of shares of Old Cellegy that were outstanding immediately before the effective time of the Merger were converted into approximately 3,000,000 shares of post-reverse split shares of common stock of the Company.

#### *Issuance of Shares to Old Adamis Stockholders*

Pursuant to the terms of the Merger Agreement, at the effective time of the Merger, each share of Old Adamis common stock that was issued and outstanding immediately before the effective time of the Merger ceased to be outstanding and was converted into the right to receive one share of common stock of the Company. As a result, the Company expects to issue approximately 42,978,067 post-reverse split shares of common stock of the Company to persons who were Old Adamis stockholders before the effective time of the Merger, and the former Old Adamis stockholders, together with the holders of converted Old Adamis warrants, became entitled to receive shares of Company common stock and warrants representing in the aggregate approximately 93.5% of the outstanding shares of Company common stock outstanding immediately after the effective time of the Merger.

In connection with the Merger, each outstanding stock option, warrant, convertible security and other right to purchase or acquire the capital stock of Old Adamis was assumed by the Company and became an option, warrant, convertible security or other right to purchase or acquire shares of common stock of the Company, with the number of shares and exercise prices proportionately adjusted based on the exchange ratio in the Merger. Because the exchange ratio in the Merger was one-for-one, the exercise prices and numbers of shares covered by outstanding Old Adamis options, warrants and convertible securities that the Company assumed in the Merger remained the same after the Merger. As a result, an outstanding Adamis warrant to purchase 1,000,000 shares of Old Adamis common stock was assumed by the Company in the Merger and became a warrant to purchase 1,000,000 shares of common stock of the Company.

#### *Increase in Authorized Shares of Capital Stock*

Also in connection with the closing of the Merger, the Company amended its certificate of incorporation to increase the authorized number of shares of common stock from 50,000,000 to 175,000,000 and the authorized number of shares of preferred stock from 5,000,000 to 10,000,000.

At the March 23, 2009 stockholders meeting, the Company's stockholders also approved a new 2009 Equity Incentive Plan (the "Plan") which became effective upon the closing of the Merger. The Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards, and other forms of equity compensation (collectively, "stock awards"). In addition, the Plan provides for the grant of performance cash awards. The aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the Plan is 7,000,000 shares. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2010 through and including January 1, 2019, by the lesser of (a) 5.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or (b) a lesser number of shares of common stock determined by our board of directors before the start of a calendar year for which an increase applies.

*Departure of Directors or Certain Officers; Election of Directors*

At the Old Cellegy annual meeting of stockholders held on March 23, 2009, the stockholders re-elected the five persons who were directors of Old Cellegy, Richard C. Williams, Tobin B. Klar, M.D., John Q. Adams, Sr., Robert B. Rothermel and Thomas M. Steinberg, to the Old Cellegy board of directors. As was disclosed in the Form S-4 registration statement filed by the Company with the Securities and Exchange Commission, registration number 333-155322, and the joint proxy statement/prospectus included therein (the "Registration Statement" or the "Proxy Statement"), pursuant to the terms of the Merger Agreement at the closing of the Merger two Cellegy directors, Tobin B. Klar, M.D. and Thomas M. Steinberg, resigned, and three additional persons, Dennis J. Carlo, Ph.D., David J. Marguglio and Richard L. Alois, each of whom was a director and officer of Old Adamis, were appointed as directors of the Company, to serve from and after consummation of the Merger until their respective successors are duly elected and qualified, or until the earlier of their death, resignation or removal. Richard C. Williams, Robert B. Rothermel, and John Q. Adams, Sr. continued as directors of the Company. In addition, at the closing of the Merger, Richard C. Williams resigned as the Company's interim chief executive officer and Robert J. Caso resigned as the Company's chief financial officer, Dennis J. Carlo, Ph.D., the chief executive officer of Adamis, became the chief executive officer of the Company and the other executive officers of Adamis became executive officers of the Company, as described in further detail below under "Item 10. Directors and Executive Officers of the Registrant."

*Periods Covered by this Annual Report*

Cellegy's fiscal year ended on December 31, and accordingly this Annual Report on Form 10-K is with respect to Cellegy's fiscal year ended December 31, 2008. Old Adamis' fiscal year ends on March 31. The Merger transaction is treated for accounting purposes as a reverse merger, and as a result, for financial reporting purposes after the effective time of the Merger the financial statements of the Company are deemed to be financial statements of Old Adamis, and Old Adamis' March 31 fiscal year-end will be the fiscal year end of the Company. The Company will, within the time periods permitted by applicable rules, file a report on Form 8-K that includes financial audited statements of Old Adamis for the year ended March 31, 2009.

While this Annual Report on Form 10-K relates to the fiscal year of Old Cellegy, since the Merger transaction was completed before the filing of this Report, the description of the business of the registrant under Item 1, and the risk factors contained in Item 1A "Risk Factors," also relates to the business of Old Adamis and the Company as intended to be conducted following the effective time of the Merger, rather than just to the business of Old Cellegy as it existed on December 31, 2008. This Report is not intended to present comprehensive information concerning Old Adamis for the 2008 calendar year, since the Merger had not become effective as of December 31, 2008. References to "Cellegy" in the discussion below will refer to Old Cellegy before the effective time of the Merger, unless the context otherwise requires.

**ITEM 1: BUSINESS**

**Business of Cellegy**

Cellegy is a specialty pharmaceuticals company. Cellegy's wholly owned subsidiary, Biosyn, Inc., has intellectual property relating to a portfolio of proprietary product candidates known as microbicides. Biosyn's product candidates, which include both contraceptive and non-contraceptive microbicides, are used intravaginally. Biosyn's product candidates include: Savvy®, which underwent Phase 3 clinical trials in Ghana and Nigeria for reduction in the transmission of Human Immunodeficiency Virus/Acquired Immunodeficiency Disease, or HIV/AIDS, both of which were suspended in 2005 and 2006 and terminated before completion, and is the subject to a Phase 3 contraception trial in the United States. While the Savvy Phase 3 contraception trial in the United States has been completed and the analysis of the results is expected to be completed by the end of 2009, Cellegy is not directly involved with the conduct and funding thereof, and it is uncertain that Savvy will be commercialized or that Cellegy will ever realize revenues therefrom. Cellegy does not currently have any commercially available products.

During 2008 and 2009 before the effective time of the Merger, Cellegy's operations related primarily to the intellectual property rights relating to the Biosyn product candidates. The Company's intellectual property consists primarily of commercialization and territorial marketing rights for its Savvy compounds as well as related patents, trademarks, license agreements, manufacturing and formulation technologies, past research and out-license arrangements with certain philanthropic and governmental organizations. The Company monitors the progress of the Savvy Phase 3 contraception trial in the United States and through communications with the clinical regulatory organization, or CRO, that is involved in the conduct of the trial and other parties involved in conducting the trial concerning matters such as the status and progress of the trial, enrollment numbers and rates of patient enrollment, issues that arise concerning conduct of the trial and anticipated timelines regarding the trial. The Company receives reports from the CRO concerning the progress of the trial, enrollment statistics and rates, any adverse events, people leaving the trial and other requests. The Company prepares and files required reports with the United States Food and Drug Administration (the "FDA") and other applicable regulatory agencies concerning both the current contraception trial and its suspended HIV trials.

On September 12, 2007, Family Health International, or FHI, released the final results of two clinical trials halted in November 2005 and August 2006, that examined the safety and effectiveness of Savvy<sup>®</sup> (C31G vaginal gel) as a potential microbicide for the prevention of male-to-female transmission of HIV among women at high risk of infection. As of the time they were halted, the trials—in Ghana and Nigeria—were unable to show that Savvy<sup>®</sup> was more effective than a placebo gel. The FHI release noted that the trial results possibly were influenced by the fact that all participants, including those receiving the placebo gel, received risk reduction counseling and condoms. These final results are consistent with the information that Cellegy previously reported concerning FHI's initial decision to terminate the trials. Cellegy had previously announced on November 8, 2005 and on August 28, 2006 that the Data Monitoring Committees, or DMC, had reviewed interim data from the Savvy<sup>®</sup> Ghana and Nigeria Phase 3 HIV prevention trials, respectively, and made recommendations that each trial not continue. A lower than expected rate of HIV seroconversion in these trials made it uncertain that the number of events required to evaluate the effect of Savvy<sup>®</sup> on HIV could be reached, even if the trials were continued.

On January 31, 2006, Cellegy announced that it entered into a non-exclusive, developing world licensing agreement with the Contraceptive Research and Development Organization, or CONRAD, for collaboration on the development of Cellegy's entire microbicide pipeline, including Savvy, UC-781 and Cyanovirin-N. CONRAD is a nonprofit, philanthropic organization dedicated to supporting the development of better, safer, and more acceptable methods to prevent pregnancy and sexually transmitted infections, including HIV/AIDS. The agreement facilitated CONRAD's access to Cellegy's past research results, formulation developments and other technological intangibles in the microbicial field in exchange for CONRAD's funding of the remaining Phase 3 U.S. contraception trial expenses. These expenses consist primarily of providing the clinical materials necessary for the conduct of the trial, along with certain regulatory functions. Under this agreement, Cellegy retained all commercial rights to its microbicial technology.

## *Products*

Cellegy obtained rights to the product candidate Savvy with its October 2004 acquisition of Biosyn. Savvy, a microbicial gel, underwent Phase 3 trials for the reduction in transmission of HIV. Savvy also showed promising preliminary results in the prevention of other sexually transmitted diseases, or STDs, including those caused by herpes simplex virus and Chlamydia. 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 earlier trials suggested it is also spermicidal. Because of its mechanism of action, C31G has a low potential for resistance and is active against drug resistant pathogens.

A Phase 3 trial for contraception in the United States, with 1,577 women enrolled out of an expected total enrollment of 1,670 female subjects, was ongoing and was completed in the fourth quarter of 2008. Analysis of the results is expected to be completed by the end of 2009. While the Company currently retains the commercial and technological rights to Savvy (with respect to the United States and other developed countries), it is not directly involved with the oversight and funding of the Savvy Phase 3 trial for contraception. Certain Phase 3 trial expenses for Savvy, and certain other clinical and preclinical development costs for the Biosyn pipeline, are funded by grant and contract commitments through agencies including: the United States Agency for International Development, or USAID; the National Institute for Child Health and Development, or NICHD; the National Institute for Allergy and Infectious Disease, or NIAID; CONRAD; and other governmental and philanthropic organizations. It is uncertain that Savvy will be commercialized or that Cellegy will ever realize revenues therefrom. CONRAD, through its agreement entered into with Cellegy in January 2006, has undertaken a portion of the funding and oversight responsibilities in exchange for access to Biosyn's current and past research and related technological intangibles. The Company retains the right to use the results of the clinical trials. There can be no assurance that Savvy will be successfully approved for contraception or any other indications or that it would be the first of such products to enter the marketplace. There can be no assurance that Savvy could be profitably commercialized or that the Company would be able to achieve profitability with this product, if approved.

Biosyn acquired C31G Technology from the inventor of the technology, Edwin B. Michaels, in October 1996. This technology is a material component of the Savvy product candidate. 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 the 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 2017 and 2021. No payments have been made to date by the Company or Biosyn to Mr. Michaels pursuant to this agreement.

In May 2001, Biosyn entered into an exclusive license agreement with Crompton Corporation, now Chemtura, 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 of \$50,000 that was recorded as research and development. Crompton also received a warrant to purchase Biosyn common stock, which converted into a Cellegy warrant in connection with the acquisition of Biosyn by Cellegy. The warrant entitles Chemtura to purchase up to 3,933 (post-reverse split) shares of Cellegy common stock at a split adjusted exercise price of \$173.96 per share. The warrant 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 all development and product approval milestone events were achieved, potential milestone payments would equal approximately \$1,150,000. If UC-781 is successfully developed as a microbicide, then Biosyn has exclusive worldwide commercialization rights. To date, no milestone payments have been made by the Company or Biosyn to Chemtura pursuant to this agreement.

On October 18, 2007, Cellegy and CONRAD amended their license agreement to modify the non-exclusive license grant covering Cellegy's intellectual property relating to the UC-781 technology to an exclusive license; the general field and permitted uses, covering the public sector and only in developing countries, were not changed.

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 Biosyn is obligated to make its commercialized products, if any, available in developing countries, as well as available to public sector agencies in developed countries, at prices reasonably above cost or at a reasonable royalty rate.

Biosyn has previously entered into various other collaborative research and technology agreements, however Biosyn has ceased actively participating in researching the compounds or formulations covered by such agreements. The cessation of these activities is primarily due the lack of funding and the lack of technical infrastructure required in performing such research. 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. Due to cancellation of the license with the National Institutes of Health in 2007, Biosyn forfeited the rights for the commercialization of CV-N but the existing agreements between Biosyn and research institutions related to CV-N remain in effect.

The agreement pursuant to which Cellegy acquired Biosyn provides for contingent milestone payments of \$15.0 million payable to the former shareholders of Biosyn upon approval by the FDA of Savvy for contraception and HIV prevention or the first commercial sale of Savvy in the U.S. for either indication. Of that amount, \$2.0 million is payable upon the first arm's length commercial sale of Savvy in Japan based on any regulatory approval for any indication, and \$1.0 million per country is payable upon the first arm's length commercial sale of Savvy in Germany, France and the United Kingdom based on any regulatory approval for any indication. In addition, 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. Also, Chemtura Corporation is entitled to milestone payments from Biosyn upon the achievement of certain development milestones and royalties on products sales, if any, relating to the UC-781 product candidate. In addition, Cellegy has obligations under Biosyn's promissory note to the Ben Franklin Technology Center of Southeastern Pennsylvania; however, repayment of this note is based on a percentage of future revenues of Biosyn (excluding unrestricted research and development funding received by Biosyn from non-profit sources), if any, until the principal balance of approximately \$777,902 is satisfied.



Cellegy's incurred no research and development expenses in 2008. Research and development expenses were approximately \$23,000 in 2007.

### **Business of Adamis and the Company**

As a result of the Merger, the Company changed its corporate name from Cellegy Pharmaceuticals, Inc. to Adamis Pharmaceuticals Corporation, and Old Adamis changed its corporate name from Adamis Pharmaceuticals Corporation to Adamis Corporation. The Old Adamis corporation will be referred to in the discussion below as "Adamis." As a result of the Merger, Adamis is a wholly-owned subsidiary of the Company.

In the discussion below, all statements concerning market sizes, annual U.S. sales of products, U.S. prescriptions and rates of prescriptions, the incidence of diseases or conditions in the general population, and similar statistical or market information are based on data published by the following sources: IMS Health Sales Perspectives, Retail and Non-Retail Combined Report, referred to as the IMS Report; National Data Corporation's Epinephrine Prescription and Dollar data for 2007, referred to as the NDC Report; Commercial and Pipeline Insight: Allergic Rhinitis, published by Data Monitor October 2007, referred to as the Data Monitor Report; and AAAAI – American Academy of Allergy, Asthma and Immunology Allergy Statistics for the U.S. published in 2008, referred to as the AAAAI Statistics.

### **Company Overview**

Adamis was founded in June 2006 as a Delaware corporation. Adamis has two wholly-owned subsidiaries: Adamis Viral Therapies, Inc. (biotechnology), or Adamis Viral; and Adamis Laboratories, Inc. (specialty pharmaceuticals), or Adamis Labs.

Adamis Labs is a specialty pharmaceutical company that Adamis acquired in April 2007. Adamis Labs has a line of prescription products in the allergy and respiratory field that are sold through its own sales force. These products generated net revenues to Adamis of approximately \$622,000 for Adamis' fiscal year ended March 31, 2008. Adamis Labs has two new product candidates currently in the pipeline. The first new product is a pre-filled epinephrine syringe used in the emergency treatment of extreme acute allergic reactions, or anaphylactic shock. The second product is a generic inhaled nasal steroid. The company's goal is to commence commercial sales of the syringe product in the second quarter of calendar year 2009 and the nasal steroid product in the first quarter of 2011, assuming adequate funding and no unexpected delays. Based on the Company's knowledge of a previously marketed pre-filled syringe indicated for anaphylaxis, the anticipated lower price of the syringe product relative to the leading syringe products currently marketed and the ease of use of its product, the Company believes that the syringe product has the potential to compete successfully shortly after commercial introduction of the product, although there can be no assurance that this will be the case.

Adamis Viral is focused on developing patented preventative and therapeutic vaccines for a variety of viral diseases such as influenza and hepatitis. The first target indication will be avian influenza. The Company believes that avian flu is a good initial clinical application because there is a large potential demand for a vaccine or other therapeutic product. However, there are no assurances concerning whether such a product will be developed or launched. The Company hopes to initiate an initial clinical trial in the first half of 2010, if the results are successful to initiate clinical trials in the United States by the end of 2010, assuming no unexpected delays and adequate funding. Future potential disease targets might include therapeutic vaccines for Hepatitis C and Human Papillomavirus.

The Company's general business strategy is to attempt to increase sales of existing and proposed products and services from its Adamis Labs operations in order to generate cash flow to help support the vaccine product development efforts of Adamis Viral. The Company believes that the potential for increased revenues will be driven by two new products.

- The Company's goal is to commence commercial sales of a low-cost, epinephrine syringe in the second quarter of calendar year 2009 that will compete in a well-established U.S. market estimated to be over \$150 million in annual sales, based on industry data published in the NDC Report.

- Adamis Labs intends to introduce an aerosolized inhaled nasal steroid that is designed to take a small share of the U.S. market for nasal steroid products, estimated by the Company to be approximately \$3 billion in annual sales, based on the NDC Report. The Company currently believes that this product could be introduced as early as the first calendar quarter of 2011, although the actual date of introduction will depend on a number of factors and the actual launch date could be later than that date. Factors that could affect the actual launch date include the outcome of discussions with the FDA concerning the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the product, any unexpected difficulties in licensing or sublicensing intellectual property rights for other components of the product such as the inhaler, any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product, any unexpected delays or difficulties in assembling and deploying an adequate sales force to market the product, and adequate funding to support sales and marketing efforts.

To achieve these goals, as well as to support the overall strategy, the Company will need to raise a substantial amount of funding and make substantial investments in equipment, new product development and working capital. The Company estimates that approximately \$3.0 million will be required to support the final product development and initiate the commercial launch of the epinephrine syringe product, and that an additional approximately \$10.0-15.0 million or more must be invested from the date of this Report in the Adamis Labs operations to support development and commercial introduction of the aerosolized nasal steroid product candidate. The capital that is expected to be provided from expected sales of these products will be important to help fund expansion of those businesses and the research and development of the anti-viral technology. If adequate funding is obtained, clinical trials proceed successfully, regulatory approvals are obtained and sales are consistent with the Company's current expectations, following a period of initial commercial introduction, the Company believes that revenues generated by Adamis Viral's vaccine products could exceed revenues from the Adamis Labs operations.

### **Adamis Labs**

On April 23, 2007, Adamis completed the acquisition of a specialty pharmaceutical company named Healthcare Ventures Group, Inc., or HVG. HVG had previously acquired a group of allergy and respiratory products and certain related assets from a third party company. The third party also transferred to HVG members of its sales force and management team. Adamis created the Adamis Laboratories subsidiary, which then acquired HVG in a stock-for-stock exchange. Adamis issued approximately 12.6 million new shares of Adamis common stock to the shareholders of HVG. Under the terms of the transaction agreements, approximately 7.5 million of these shares were placed in escrow and are subject to restrictions on transfer as well as potential forfeiture to cover indemnification obligations and/or repurchase by the Company if certain performance targets based on revenue over a period of three years are not achieved by Adamis Labs and if the holders do not remain employed by Adamis during that period.

Adamis Labs has a small base of established products, as well as several product candidates that the Company believes have the potential to be successful products.

### **Current Products**

The current specialty pharmaceutical products are sold under a prescription and promoted to physicians who specialize in allergy, respiratory disease and pediatric medicine. The six currently marketed products include:

- **AeroHist**® Caplets (chlorpheniramine maleate 8mg, methscopolamine nitrate 2.5 mg) extended release, scored caplets. Indicated for the relief of symptoms of seasonal or perennial rhinitis.
- **AeroHist**® **Plus** Caplets (chlorpheniramine maleate 8mg, phenylephrine hydrochloride 20mg, methscopolamine nitrate 2.5 mg). Indicated for the relief of symptoms of seasonal or perennial rhinitis.
- **AeroKid**® Oral Liquid (chlorpheniramine maleate 4mg/5ml, phenylephrine hydrochloride 10mg/5ml, methscopolamine nitrate 1.25mg/5ml). Indicated for the relief of symptoms of seasonal or perennial rhinitis.
- **AeroOtic**® HC Ear Drops (chloroxymol 1mg, pramoxine hydrochloride 10mg, hydrocortisone 10mg). Indicated for the treatment of superficial infections of the external auditory canal complicated by inflammation caused by organisms susceptible to the action of the antimicrobial and to control itching and swimmer's ear.

- **Allergy Extracts** - allergy extracts, sterile vials, and diluents used in preparation of allergy therapy.
- **Prelone**® (prednisolone syrup, USP, 15 mg per 5 ml). Indicated in various diseases and disorders including allergic states and respiratory diseases.

Net revenues to Adamis from sales of these products from April 23, 2007, the date on which Adamis acquired Adamis Labs, through Adamis' fiscal year ended March 31, 2008, were approximately \$622,000. During Adamis' fiscal year ended March 31, 2008, three customers, Cardinal Health, McKesson and AmerisourceBergen, accounted for approximately 38%, 35% and 11%, respectively, of Adamis' revenues. The products have not been heavily promoted in the past due to funding limitations and the competitive market for antihistamine/decongestant products. The Company believes there is limited growth potential for these products, due in part to the widespread substitution of generic products at the dispensing pharmacy level for the conditions indicated for the Adamis Labs products.

The Prelone product is the subject of an ANDA approval from the FDA. As the Company believes is common with many drug products, the Prelone product is manufactured by a third party manufacturer which holds the ANDA approval relating to the product. Adamis owns the trademark and intellectual property rights relating to the product and distributes the product pursuant to those rights.

#### *Product Pipeline*

Two new product candidates in the allergy and respiratory field are in the Adamis Labs development pipeline. The rate of development and timing of market launch will depend on several factors, including the amount of funding that the Company receives. If adequate funding is obtained to develop and market the products, the Company believes that these two product candidates could generate significant revenues.

The first product, a single-dose epinephrine syringe, is expected to be commercially launched during the second quarter of calendar 2009. The second product, an aerosolized inhaled nasal steroid product for the treatment of seasonal and perennial allergic rhinitis, is targeted for commercial availability in the first quarter of calendar year 2011, assuming adequate funding to support product development and launch and no unanticipated delays in obtaining regulatory approvals. Adamis Labs has secured an agreement with Catalent Pharma Solutions, Inc. for sterile manufacturing product supply for the epinephrine syringe product candidate and is in discussions with an aerosol inhaler supplier for the aerosolized nasal steroid product candidate.

#### *Epinephrine Pre-Filled Syringe*

There is a well-defined, growing market in the United States for patient-administered emergency epinephrine injectors used in the treatment of anaphylaxis. Based on information in the NDC Report, the Company estimates that annual U.S. sales for emergency epinephrine injectors were approximately \$150 million in 2006 and have historically grown at a rate of approximately 15% per year. Currently, the emergency epinephrine market is dominated by one brand, EpiPen®, which the Company believes is relatively high priced. The Company believes there is an opportunity to bring to market a simpler, more intuitive and user-friendly, lower-cost product that should be competitive with existing products.

Anaphylaxis is usually triggered by an allergic reaction to medication, food, insect stings, skin allergies or latex allergies. This sudden, whole body allergic reaction results in a potentially life threatening medical emergency. The recognized treatment of choice for anaphylaxis is aqueous epinephrine (adrenaline) delivered by injection.

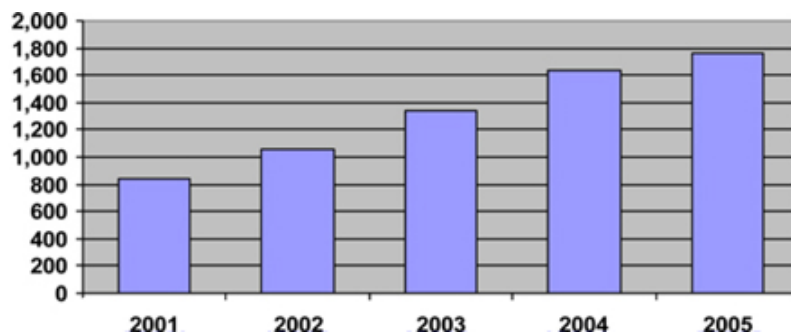
There are two major causes of consumption of emergency epinephrine injectors: use when a patient experiences an anaphylactic attack, or expiration of the product. Of the two, expiration is by far the largest cause of consumption. The epinephrine contained in injectors has a limited shelf life, and on average a new prescription must be obtained every 12 to 18 months. As a result, based on information in the AAAAI Statistics, the Company estimates that at least 70% of all epinephrine injectors expire unused.

EpiPen®, EpiPen® Jr., and Twinject® are the only patient-administered epinephrine products available for sale as emergency treatment of anaphylaxis in the United States. Based on information in the IMS Report, the U.S. epinephrine injector market was approximately \$149 million in sales in 2005. EpiPen® and EpiPen® Jr. combined represented over approximately 99% of all sales in the U.S. The physicians that prescribe self-administered epinephrine are relatively concentrated, with over 70% of prescriptions originating from allergists and primary care physicians, according to the IMS Report.

Based on information in the AAAAI Statistics, the U.S., an estimated 5% of the population suffers from insect sting anaphylaxis, up to 6% are latex sensitive and up to 1.5% of adults and 5% of children under three years of age experience food related anaphylaxis. Adamis believes that anaphylaxis may be under-diagnosed. In January 2001, a published study by AAAAI revealed that up to 40 million Americans (15% of the total population) may be at risk for anaphylaxis, a significantly higher number than the historically estimated at-risk population. According to information in the AAAAI Statistics, approximately 3,000 people in the U.S. die each year from anaphylaxis.

The number of prescriptions has grown annually as the risk of anaphylaxis has become more widely understood. According to the IMS Report, total prescriptions for EpiPen products more than doubled in the five year period from 2001 to 2005. The Company estimates that the growth rate of annual prescriptions will decline to a growth rate of approximately 4-5% per year by 2010.

**Annual Prescriptions for Emergency Epinephrine (000)**



EpiPen<sup>®</sup> was originally developed by Meridian Medical Technologies, Inc. as an auto-injection system for use by military personnel. It was designed for self-administration as an antidote for chemical warfare agents and morphine. Meridian Medical Systems, which is the manufacturer of the EpiPen and EpiPen Jr., continues to focus on products for the military, and its major customer is the United States Department of Defense. The EpiPen<sup>®</sup> products were introduced to the market in 1982, and were the only epinephrine injectors for allergic emergencies that were available until 2005. In August 2005, another company introduced a competing product, Twinject<sup>®</sup> Dual Pack 0.3mg epinephrine auto injectors, which, the Company believes due to pricing and ease of use issues, has enjoyed only a small market share in the United States. Twinject is currently owned by Sciele Pharma, Inc.

The Company believes that there are barriers to market entry for new competitors based on epinephrine's susceptibility to contamination, sensitivity to heat and light and a short shelf-life, as well as the need for a competitor to possess the expertise to overcome the packaging and delivery challenges of introducing a competing product to the market. The Company also believes that the size of the market is too small to be a major focus of the large pharmaceutical companies, although there can be no guarantees that this will be the case.

The Company believes that the primary opportunity lies in the 0.3 mg segment, which constitutes approximately 72% of the total market (measured as a percent of U.S. sales), based on EpiPen unit sales history and the NDC Report. When sales of dual packs of EpiPen and Twinject are converted to single units, the total target market in the U.S. is about 2.5 million single units per year.

The Company believes that there is an opportunity for a simpler, low-cost, more intuitive and user-friendly pre-filled syringe to compete in this largest segment of the market. The Company believes that its new product can compete effectively against EpiPen<sup>®</sup> based on the following factors, among others:

- **Market Knowledge.** Mr. Aloï, president of Adamis Labs, (formerly a Director at Center Laboratories of Long Island, New York) was responsible for the U.S. introduction of EpiPen and EpiPen Jr brands and helped to craft the marketing and sales strategy that saw EpiPen brands grow by double digits in units and dollars annually.
- **Market Presence.** Adamis Labs already provides allergenic extracts for processing into desensitization or immunotherapy injections to the same allergy physician group that would prescribe the pre-filled syringe.
- **Lower Price.** The Company believes that a lower-priced option would be particularly attractive to individuals potentially susceptible to anaphylaxis as well as managed healthcare drug reimbursement plans providing patient prescription reimbursement. The Company expects to introduce the Epi Syringe at a price point reflecting a discount to the price of the market leader, EpiPen, in part to make the product more attractive to customers. At this price, the Company believes it can still obtain significant gross margins.
- **Ease of Use.** The EpiPen<sup>®</sup>, EpiPen<sup>®</sup> Jr., and Twinject<sup>®</sup> are powerful spring-loaded devices. If not administered properly, they can misfire or be misused. Adamis' Epi pre-filled 0.3mg syringe will allow patients to self-administer (self-inject) a pre-measured epinephrine dose quickly with a device that does not have moving parts that the user cannot control, which the Company believes may increase product safety.

There are three key supply components used in the manufacture of Epi Syringe: the pre-filled syringe containing the epinephrine; the formulation solution; a specially designed plunger rod that expels only the appropriate emergency amount of 0.3mg of epinephrine; and the plastic carrying case. Adamis owns a proprietary epinephrine liquid formulation. Adamis has secured component suppliers that will ship all components to the manufacturer which will complete a finished labeled product. The Company estimates that as of the date of this Report, pending adequate funding, the project development will complete and commercial launch will take place in the second quarter of calendar 2009.

The Company believes that the market for emergency epinephrine injectors will grow, driven by increasing awareness, lower cost alternatives, and promotion by new market entrants. The Company expects that the total market unit growth rate will continue to grow as additional lower priced epinephrine products are introduced, but total dollar market will plateau as a result as the market matures with multiple lower priced products. The Company believes that the Epi Syringe product may acquire a share of the market in a manner somewhat similar to the pattern established by generic drugs, in that the price differential between the expected price of the Adamis syringe product and the price at which the market-leading product is currently sold will motivate purchasers and reimbursing payors to choose the lower cost alternative. The Company also believes, however, that if its product competes successfully, at least one of the current competitors may introduce a competing, low-priced, pre-filled syringe while maintaining the price points of its existing product lines. The Company believes that such a competing product might have a comparable or lower price than the Adamis product. The Company believes that the syringe product has the potential to compete successfully shortly after commercial introduction of the product, although there can be no assurance that this will be the case.

#### *Inhaled Nasal Steroid*

Adamis Labs is developing an aerosolized inhaled nasal steroid for the treatment of seasonal and perennial allergic rhinitis. The active ingredient is beclomethasone dipropionate, a synthetic steroid that demonstrates potent glucocorticoid activity. Glucocorticosteroids are hormones produced by the adrenal cortex. Corticosteroids inhibit inflammation in allergic reactions by interfering with the synthesis of prostaglandins and leukotrienes, chemicals that are normally synthesized as part of the inflammatory process. The Company refers to the product as Beclomethasone Aerosolized Nasal Steroid, or BANS.

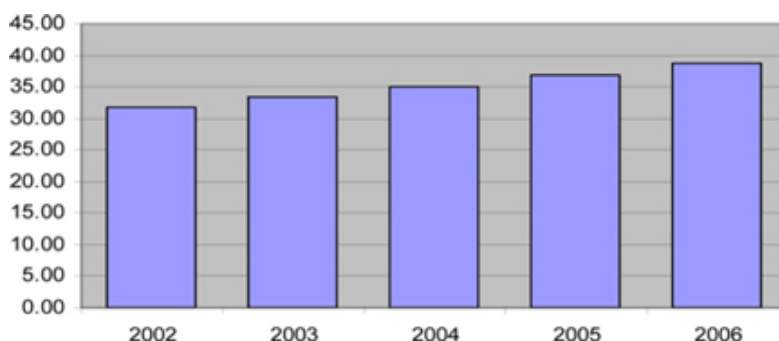
The market for inhaled nasal steroids, or INS, as estimated by the Company based on the DataMonitor Report, is about \$3 billion annually in the U.S. and growing steadily. Although the market is dominated by two multi-national pharmaceutical companies, the Company believes there is a niche that can be exploited, and that an Adamis product candidate can achieve a small percentage share of this large market.

INS products are sold under prescription for seasonal allergic rhinitis. In addition to inhaled nasal steroids, many different types of products treat the symptoms of allergic rhinitis: oral antihistamines and decongestants are among the most popular for self-medication/patient treatment. All physician specialties report that the majority of their allergic rhinitis patients receive intranasal steroids, either alone or in combination with oral antihistamines. In general, physicians view intranasal steroids as safe and effective.

There are four major physician specialties that treat patients with allergic rhinitis: Allergists, Otolaryngologists, or ENTs; Primary Care Physicians, or PCPs; and Pediatricians. Allergists, along with ENTs, tend to be the most aggressive in terms of pharmacological treatment of allergic rhinitis. On an individual basis, the allergist is the largest prescriber of products within the INS category. ENT physicians contribute half as many prescriptions as allergists, but that is still about five times the volume of the average primary care physician.

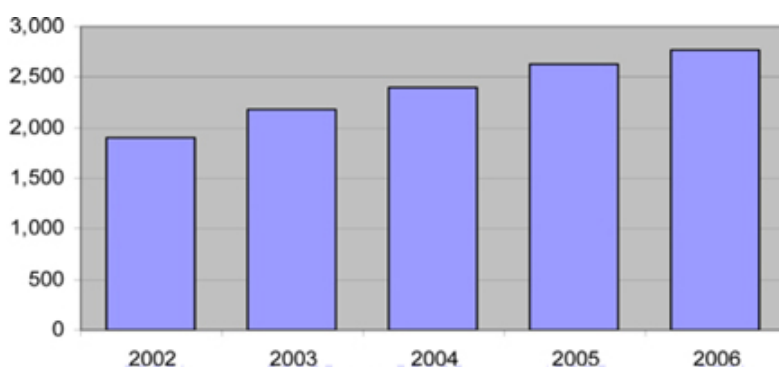
The INS market is highly seasonal with most of the sales occurring in two periods: a spring season from April through May or June; and a fall season occurring in September and October. Based on information in the DataMonitor Report, the Company estimates that the INS market grew at an annual rate of over 5% from 31.7 million prescriptions in 2002 to an estimated 38.7 million prescriptions in 2006.

**Total U.S. Prescriptions for Inhaled Nasal Steroids 2002-2006e (millions)**



In the same period, total U.S. market sales grew from \$1.89 billion in 2002 to an estimated \$3 billion for 2006. This average growth rate is about 10% per year, and resulted primarily from steady price increases.

**Total U.S. Sales of Prescription Inhaled Nasal Steroids 2002-2006e (\$ millions)**



The Company expects that the growth rate in average price increases will decline and reach zero by 2011, due to increasing competition from generic products.

Currently, the INS market is dominated by aqueous solution formulations delivered by a pump. These aqueous pump spray formulations have replaced CFC propellant INS products, which once dominated the INS market. The propellant inhaled nasal steroids that were previously available have been discontinued due to CFC concerns for the environment. Based on information in the IMS Report concerning 2005 sales, the two leading products account for over 70% of total product sales in this market.

Product	2005 Sales (millions)	Market Share
Flonase <sup>®</sup>	\$ 1,208	46.4%
Nasonex <sup>®</sup>	\$ 705	27.1%
Nasacort <sup>®</sup> AQ	\$ 348	13.4%
Rhinocort <sup>®</sup>	\$ 325	12.5%
Nasarel <sup>®</sup>	\$ 17	0.6%
Total	\$ 2,603	100.0%

The Company believes that in general, prescribing physicians view all INS products as being generally similar in terms of efficacy and safety. As a result, the INS market is sensitive to promotion, and companies spend a great deal of effort and money each year in the attempt to differentiate these products from one another. The Company believes that large amounts are spent on direct-to-consumer advertising for the two largest holders of market share, Flonase<sup>®</sup>, marketed by GlaxoSmithKline, and Nasonex<sup>®</sup>, marketed by Schering. In addition to direct-to-consumer advertisement, GSK and Schering also spend large amounts of dollars in personal promotion detailing physicians and distributing samples as well as journal advertisement.

The Company does not anticipate competing directly against the two leading companies in this market by attempting to out-spend or out-promote them in the marketplace. The Company believes that its market opportunity lies in taking a small portion of the market with a new aerosolized HFA version of a well-established product at a substantial discount to the current prices of the leading branded products.

The Company expects BANS to be considered a “new” drug by the FDA, and accordingly the Company believes that it will be required to submit data for a Section 505(b)(2) application for approval to market. Total time to develop the BANS product is expected to be approximately 24 months from the date of this report, assuming sufficient funding and no unexpected delays. The table below shows the estimated development timeline for the BANS product.

**Developmental Timeline for BANS**  
(beclomethasone dipropionate)

Major Action	Estimated Months	Quarter of Completion						
		Q1	Q2	Q3	Q4	Q5	Q6	Q7
Manufacture Product	4							
Clinical Trials	2							
FDA Review of ANDA	18							

Factors that could affect the actual launch date for the BANS product candidate include the outcome of discussions with the FDA concerning the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the product, any unexpected difficulties in licensing or sublicensing intellectual property rights for other components of the product such as the inhaler, any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product, any unexpected delays or difficulties in assembling and deploying an adequate sales force to market the product, and adequate funding to support sales and marketing efforts.

**Adamis Viral Therapies**

The Adamis Viral Technologies subsidiary is focused on developing patented vaccine technology that has the potential to provide protection against a number of different viral infectious agents. This novel vaccination strategy, which employs DNA plasmids, appears, based on preclinical studies conducted to date, to have the ability to “train” a person’s immune system to recognize and mount a defense against particular aspects of a virus’ structure. If successful, the Company believes this technology will give physicians a new tool in generating immunity against a number of viral infections that have been difficult to target in the past.

The first target indication will be avian influenza. Avian flu is a particularly good initial clinical application because there is a large potential demand. Subsequent disease targets might include therapeutic vaccines for Hepatitis C and Human Papillomavirus.

The technology that provides the basis of Adamis Viral Therapies' research and development was developed by Dr. Maurizio Zanetti, M.D., a professor at the Department of Medicine at the University of California, San Diego. Dr. Zanetti has developed and patented a method of DNA vaccination by somatic transgene immunization, or STI. The Company has entered into a world-wide exclusive license with Dr. Zanetti, through a company of which he is the sole owner, Nevagen, LLC, to utilize the technology within the field of viral infectious agents. The Company believes that the technology has broad applications and is targeting influenza for its initial proof of concept.

STI has already been tested in Phase I studies in man for other vaccine applications. An immune response was elicited in the study, and the results suggested that the procedure was safe. Testing for influenza is currently at the preclinical stage. If successful, STI may provide a vaccine for immunity to all forms of influenza, including avian flu, although of course there are no guarantees that any of the trials will be successful or that a commercial product will be developed or marketed.

Current flu vaccines act by giving the immune system a preview of certain proteins expected to be found on the coat of the flu virus; however, the influenza virus changes its coat every season. The changes make each year's new version of the flu unrecognizable to the immune system, and therefore immunity to influenza must be reestablished with a new vaccine every fall. The following summarizes the method proposed by the Company to develop long lasting and cross-reactive immunity using STI:

- Draw a small amount of blood from patient
- Separate the white blood cells
- Add plasmid (DNA) to the white blood cells
- Incubate overnight to allow the plasmid to enter the white blood cells ( *ex vivo* transgenesis)
- Inject white blood cells back to the individual to induce immunity to the pathogen of choice, i.e., influenza, hepatitis, etc.).

The Company intends to initiate a clinical "proof of concept" trial, currently anticipated to be conducted in Thailand for the avian flu vaccine in the first half of 2010. Preliminary discussions have been held with potential Thai partners regarding the conduct of this trial. The Company's current plan is to test a small number of human patients (approximately 80) to demonstrate that the Company's procedure induces both a cell-mediated and antibody response. An antibody response, as measured by increased concentration of antibodies, is generally accepted by the FDA as an indicator of increased immunity to the disease. The Company would further seek to demonstrate a dose-response relationship for the treatment. If the results of the initial trial are successful, the Company intends to file an Investigative New Drug application, or IND, with the FDA and begin trials in the United States in 2010, assuming adequate funding and no unexpected delays. If the Company's assumptions regarding the development process and sufficient funding are correct, the Company believes the product could be available for public use in the second half of 2012.

There are a number of factors, including those identified in "Item 1A. Risk Factors," that could cause actual events to differ from the Company's expectations concerning the timeline for product development and the regulatory approval process. The Company believes that it will be able to obtain sufficient funding for its clinical trials and product launches, but there can be no assurance that this will be the case. Similarly, there are no assurances that the clinical trials will be successful or that the Company will be able to submit an application for, or obtain approval from the FDA for, an avian flu or vaccine product.

#### *Overview of History of the Flu*

Avian influenza is a highly contagious virus that affects birds and causes high mortality rates among chickens, ducks, geese, etc. Humans that come into contact with contaminated birds can become infected. However, the more widespread concern is the possible mutation of the current form of avian flu. Some experts predict that the virus will combine with existing human flu viruses at some point and mutate to allow human-to-human transfer. The result could be a worldwide pandemic.

A pandemic occurs when a virus changes dramatically and spreads easily across the world. A pandemic is not as common as an epidemic. A flu epidemic happens nearly every year when a virus spreads rapidly through a population. The history of major flu outbreaks is summarized in the table below.



### **1918-1919: Spanish flu pandemic**

- The virus is thought to have spread through troop movements in World War I.
- Estimated 20-40% percent of the world's population fell ill during the outbreak.
- Unlike other flu viruses, Spanish flu killed healthy adults - approximately 500,000 in the U.S. and up to 50 million worldwide.

### **1957: Asian flu pandemic**

- Started in China and claimed an estimated 70,000 lives in the U.S. - mostly among elderly population.
- Experts identified the virus quickly and created a vaccine available in limited quantities.

### **1968: Hong Kong flu pandemic**

- Flu pandemic killed about 34,000 in the U.S., mostly among the elderly population.
- This was the mildest pandemic of the 20th century, perhaps because a similar flu virus created some cross immunity to the new strain.

### **1976: Swine flu scare**

- The “killer virus” was identified in Fort Dix, New Jersey.
- Over 40 million Americans were vaccinated and the virus did not spread.

### **1977: Russian flu scare**

- A flu virus, similar to the avian flu that circulated in 1957, spread around the world.
- Mostly children and adults under age 23 were infected with the new virus.
- Some experts explain that young people, not exposed to the 1957 virus, were susceptible.

### **1997: Avian flu scare**

- An avian flu outbreak hospitalized 18 people in Hong Kong with an infection seen before only in birds.
- Officials ordered all chickens slaughtered after six people died.

### *Potential Impact of Avian Flu Pandemic*

In March 2007, the Lowry Institute published a report entitled *Global Macroeconomic Consequences of Pandemic Influenza*. The report considered the impact of four possible scenarios:

- Mild, in which the pandemic is similar to the 1968-69 Hong Kong flu;
- Moderate, similar to the 1957 Asian flu;
- Severe, similar to the 1918-19 Spanish flu;
- An “ultra” scenario that is worse than the Spanish flu outbreak;

The report estimated that a mild pandemic could kill 1.4 million people and cost \$330 billion. In the “ultra” scenario, they estimate that:

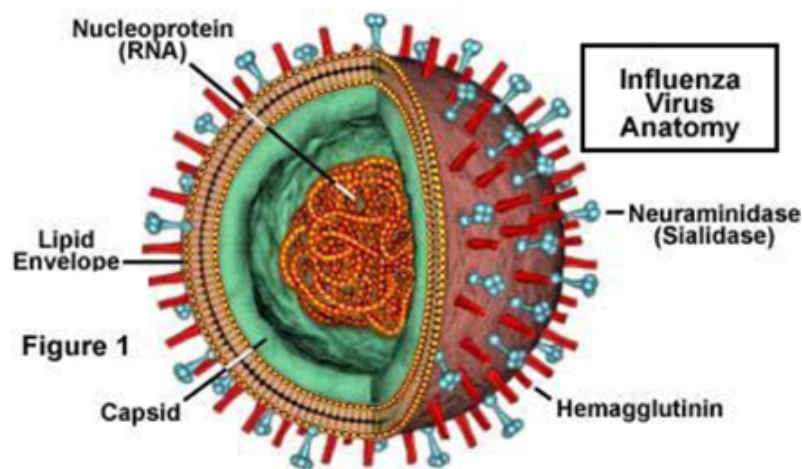
- as many as 142 million people around the world could die;
- global economic losses would be \$4.4 trillion - the equivalent of wiping out the Japanese economy's annual output; and
- there would be a large-scale collapse of Asian economic activity causing global trade flows to dry up.

### *The Flu Virus*

Influenza viruses are classified as type A, B, or C based upon their protein composition. Type A viruses are found in many kinds of animals, including ducks, chickens, pigs, whales, and also in humans. The type B virus widely circulates in humans. Type C has been found in humans, pigs, and dogs and causes mild respiratory infections, but does not spark epidemics. Type A influenza is the most dangerous of the three. It is believed responsible for the global flu outbreaks of 1918, 1957 and 1968.

Type A viruses are subdivided into subtypes based on the protein layers projecting in spikes from the surface of the individual virus. There are two different kinds of spikes on each virus: one is the protein hemagglutinin, or HA, which allows the virus to “stick” to a host cell and initiate infection; the other is a protein called neuraminidase, or NA, which enables newly formed viruses to exit the host cell. Scientists have characterized approximately 16 HA varieties and 9 NA varieties.

Type A subtypes are classified by a naming system that includes the place the strain was first found, a lab identification number, the year of discovery, and, in parentheses, the variety of HA and NA it possesses, for example, A/Hong Kong/156/97 (H5N1). If the virus infects non-humans, the host species is included before the geographical site, as in A/Chicken/Hong Kong/G9/97 (H9N2). There are no type B or C subtypes.



Influenza virus is one of the most mutable of viruses. These genetic changes may be small and continuous or large and abrupt. Small, continuous changes happen in type A and type B influenza as the virus makes copies of itself. The process is called antigenic drift. The drifting is frequent enough to make the new strain of virus often unrecognizable to the human immune system. Type A influenza also undergoes infrequent and sudden changes, called antigenic shift. Antigenic shift occurs when two different flu strains infect the same cell and exchange genetic material. The novel assortment of HA or NA proteins in a shifted virus creates a new influenza A subtype.

Because people have little or no immunity to such a new subtype, its appearance tends to cause very severe flu epidemics or pandemics. Due to either antigenic drift or shift, a new flu vaccine must be produced each year to combat that year's prevalent strains.

In nature, the flu virus is found in wild aquatic birds such as ducks and shore birds. It has persisted in these birds for millions of years and does not typically harm them. But the frequently mutating bird (avian) flu viruses can readily jump the species barrier from wild birds to domesticated ducks and then to chickens.

From there, the next stop in the infectious chain is often pigs. Pigs can be infected by both bird influenza and the form of influenza that infects humans. In a setting such as a farm, where chickens, humans and pigs live in close proximity, pigs act as an influenza virus mixing bowl. If a pig is infected with avian and human flu simultaneously, the two types of virus may exchange genes. Such a “re-assorted” flu virus can sometimes spread from pigs to people depending on the precise assortment of bird-type flu proteins that are transported into the human population; the flu may be more or less severe.

In 1997, for the first time, scientists found that bird influenza skipped the transitional step from bird to pig and infected humans directly. Alarmed health officials feared a worldwide epidemic or a pandemic. Fortunately, the virus could not pass between people and thus did not spark an epidemic. Scientists speculate that chickens may now also have the receptor used by human-type viruses.

The recent spread of strains of avian influenza (H5N1) has highlighted the threat posed by pandemic influenza. The H5N1 virus is one of 16 different known subtypes of avian influenza (bird flu) viruses. All influenza viruses (human and avian) are of significant concern to health officials because of their ability to mutate rapidly and their propensity for acquiring genes from viruses that infect other animal species.

H5N1 viruses have been found in birds around the world. As the spread of H5N1 infection among birds increases, so too does the opportunity for H5N1 to be transmitted directly from birds to humans. Recently, human H5N1 infection has occurred throughout Southeast Asia, most prominently in Indonesia, during large H5N1 outbreaks among poultry, causing great concern among health officials.

If cases of human infections increase, people simultaneously infected with human and avian influenza strains could become a “mixing vessel” for the disease. The result could be the emergence of a lethal H5N1 influenza virus that is easily transmitted from person to person. Such an easily transmissible virus could result in an epidemic with severe public health consequences similar to the pandemic of 1918.

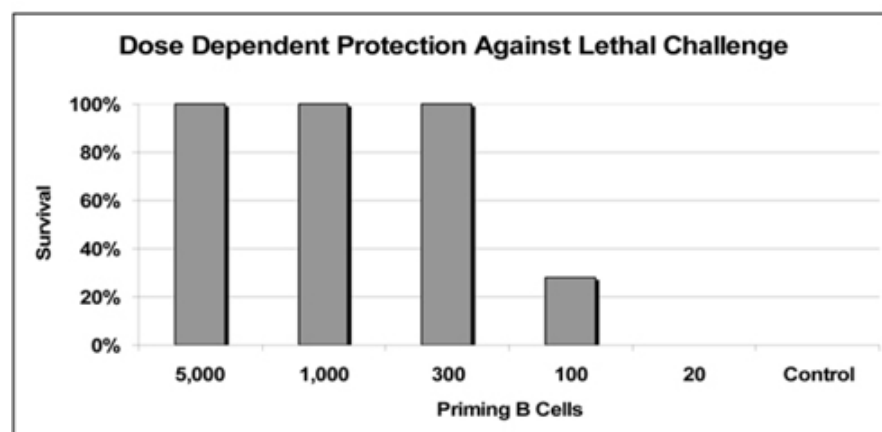
Currently, available anti-viral drugs and vaccines have limited efficacy, and may become even less efficacious as the virus continues to mutate. The challenge is to develop a vaccine that induces an immune response that will protect against various strains of the flu virus.

#### *Preclinical Animal Studies*

Recently, experiments conducted by third parties for Adamis utilizing the STI technology in mice have shown that T-cell immunity can be induced *in vivo* by a single intravenous inoculation of naïve B lymphocytes genetically programmed by *ex vivo* transgenesis. Transgenesis is accomplished by administering a plasmid DNA under control of a B cell specific promoter. The process is entirely spontaneous and mimics the process of viral infection, which is intracellular replication. Results show the induction of systemic effector CD4 and CD8 T-cell responses within 14 days after administration of the transgenic B cells. Durable immunologic memory is also induced. It has been demonstrated that a single injection of  $5 \times 10^3$  transgenic B lymphocyte induces complete protection from a lethal virus challenge. The following outlines the protocol used in the mouse trial:

- a small amount of blood was drawn from mice
- B cells were separated from the blood and transfected with DNA from flu virus
- transfected lymphocytes, or priming B cells, were re-infused into the mice
- 14-21 days after re-infusion a lethal challenge of virus was administered via aerosol
- for controls, mice were injected with priming B cells transfected with DNA not specific for the flu

A single injection of transgenic B lymphocytes in this trial was sufficient to generate specific CD8 T-cell memory responses, which protected mice from a lethal viral challenge. The immune response that was induced was a reaction against the common components of the influenza virus, and was cross-reactive, meaning that it reacted against various types of flu virus (avian or any other). Thus, this type of vaccine may be utilized to protect individuals from various strains of influenza that may occur.



### License Agreement

On July 28, 2006, Adamis entered into a worldwide exclusive license agreement with Dr. Zanetti, through a company of which he is the sole owner, Nevagen, to utilize the technology within the field of viral infectious agents. The intellectual property, or IP, licensed by Adamis includes the use of the technology known as “Transgenic Lymphocyte Technology,” or TLI, covered by patent applications titled “Somatic Transgene Immunization and related methods” including but not limited to “*ex vivo* treatment of an individual’s lymphocytes with plasmid (non-viral) DNA and administration of treated lymphocytes to the same individual.” The vaccine is constituted of the individual’s lymphocytes harboring plasmid DNA, for example, DNA coding for selected epitopes of influenza virus. The IP includes rights under two issued U.S. patents, three U.S. patent applications and related patent applications filed in European Union, Japan and Canada. The U.S. patent was issued on October 9, 2007 and will expire on April 27, 2019, 20 years from the filing date of the earliest U.S. non-provisional application upon which the patent claims priority.

The field for this exclusive license is the prevention and treatment and detection of viral infectious diseases. The geographic area covered by the exclusive license is worldwide. The license will terminate with the expiration of the U.S. patent for the IP.

As part of the initial license fee Adamis granted Dr. Zanetti the right to purchase 1.0 million shares of Adamis common stock at a price of \$0.001 per share, and he subsequently exercised that right. In addition, Adamis paid the licensor an initial license fee of \$55,000. For the first product, Adamis will make payments upon reaching specified milestones in clinical development and submission of an application regulatory approval, potentially aggregating \$900,000 if all milestone payments were made. As of March 31, 2009, no milestones have been achieved and no milestone payments have been made. The agreement also provides that Adamis will pay the licensor royalties, in the low single digits, payable on net sales received by Adamis of products covered by the IP. If additional technologies are required to be licensed to produce a functional product, the royalty rate will be reduced by the amount of the royalty paid to the other licensor, but not more than one-half the specified royalty rate. Royalties and incremental payments with respect to influenza will continue until reaching a cumulative total of \$10.0 million.

Adamis and the licensor have the right to sublicense with written permission of the other party. In the event that the licensor sublicenses or sells the improved technology to a third party, then a portion of the total payments, to be decided by mutual agreement, will be due to Adamis. If Adamis sublicenses the IP for use in influenza to a third party, the licensor will be paid a fixed percentage of all license fees, royalties, and milestone payments, in addition to royalties due and payable based on net sales.

If the IP is sublicensed by Adamis to another company for any indication in the field covered by the license agreement other than with respect to influenza, the licensor will be paid a portion of all license fees, royalties and milestone payments, with the percentage declining over time based on the year in which the sublicense is granted. Certain incremental non-flu sublicensing payments described in the license agreement are specifically excluded from the royalty cap.

All improvements of the IP conceived of, or reduced to practice by Adamis, or made jointly by Adamis and the licensor will be owned by Adamis. Adamis granted Nevagen a royalty-free nonexclusive license to use any improvements made on the existing technology for research purposes only. Adamis has agreed to grant to Nevagen a royalty-free license for any improvement needed for the commercialization of the IP for Nevagen's use outside the field licensed to Adamis. If Nevagen sublicenses or sells the improved technology to a third party, then a portion of the total payments, to be decided by mutual agreement, will be due to Adamis.

Adamis will have the right of first offer to license the following additional technology from the licensor, if and when it becomes available:

- Technology for the application of related intellectual property as a prophylactic or therapeutic cancer vaccine; and
- Any additional technology developed by the licensor related to the IP.

Adamis has the right to terminate the agreement if it is determined that no viable product can come from the technology. Upon such termination, Adamis would be required to transfer and assign to the licensor all filings, rights and other information in its control if termination occurs. Adamis would retain the same royalty rights for license, or sublicense, agreements if the technology is later developed into a product. Either party may terminate the license agreement in the event of a material breach of the agreement by the other party that has not been cured or corrected within 90 days of notice of the breach.

#### *Development Process*

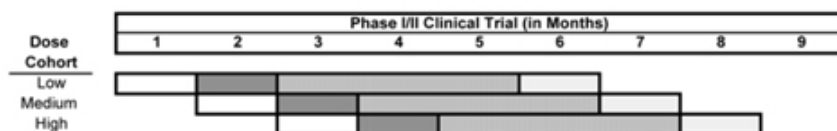
The statements below, and elsewhere in this Annual Report on Form 10-K, concerning anticipated future events concerning the development process of the Company's vaccine product candidates, the clinical trial process, and the regulatory approval process including the actions of the FDA, are subject to several uncertainties and contingencies that could cause actual results to differ in material respects from the results and timelines anticipated in the discussion below. Some of these uncertainties and contingencies are described below under the heading "Item 1A. Risk Factors." There is no guarantee that the Company will be able to complete clinical development and obtain approval from the FDA for any vaccine product candidate.

Without direct discussions with the FDA, it is difficult to precisely plan clinical development of a new therapeutic treatment. However, the FDA has announced that it will seek ways to accelerate the development and approval process for new vaccines against avian influenza. Based on the Company's interpretations of the FDA's position, the Company has developed a plan for clinical development that includes seeking to formally apply for marketing approval by mid-2012.

*Preclinical Development.* The Company anticipates filing for an Investigational New Drug Application, or IND, based on previously published data on this technology. The Company believes that having this data could shorten the process of preclinical development and preparation of the IND, although there can be no assurance that this will be the case. The Company believes that clinical trials could start within 60-90 days after acceptance of the IND by the FDA. The total time to complete an IND application is expected to be about one year following receipt of sufficient funding.

*Phase I/II Trial.* The Phase I/II clinical trial that would be specified in the IND would probably be conducted in one center and require about 8-1/2 months in total, as illustrated in the table below. The Company estimates the total cost of the clinical trial to be about \$250,000. After completion of the anticipated Phase I/II trial, the Company expects that it would meet with the FDA to review the trial results and determine whether another Phase II trial will be required or whether the next trial would be a Phase III trial, assuming a successful Phase I/II trial.

### Timeline for Phase I/II Clinical Trial for Influenza Vaccine



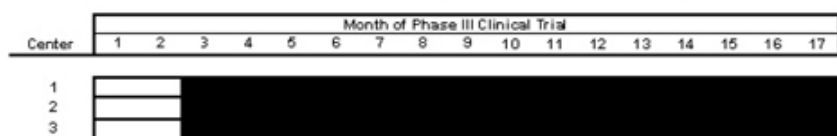
- Key:**
- Enrollment of subjects - 1 month
  - Treatment period - 1 month elapsed time
  - Testing & follow-up monitoring - 3 months
  - Data analysis and report preparation - 1 month

#### Critical Assumptions:

1. Enrollment requires 1 month - healthy adults with no previous exposure to avian influenza.
2. The treatment is as follows:
  - A. An initial blood sample is taken from the subject  
The blood is tested to establish titers for influenza antibodies  
Blood components are separated
  - B. Plasmid of influenza DNA is added to the leukocytes, and incubated overnight
  - C. Blood cells are re injected into the subject
3. Three dose cohorts of five subjects, each cohort having successively higher dose levels  
Within each cohort, the five patients are treated one time, spaced at one-week intervals  
Each dose cohort is staggered by one month
4. Subjects are tested after one month for influenza antibodies and cell mediated immunity
5. Subjects are monitored for two more months, with monthly testing
6. Data analysis requires 1 month for each cohort.

**Phase III Trial.** The timing and cost of the Phase III clinical trial will depend on the results of the Phase I/II clinical trial, the amount of capital the Company is able to raise and requirements of the FDA. For planning purposes, the Company estimates that the Phase III trial will be a multiple center study and require a total of approximately 17 months, primarily due to the need to monitor and test patients after the vaccination. The Company estimates that the cost of the trial will be approximately \$10.7 million.

### Timeline for Phase III Clinical Trial for Influenza Vaccine



- Key**
- Enrollment of subjects - 2 months
  - Treatment period - 1 month
  - Follow-up testing and monitoring - 12 months
  - Data analysis and report preparation - 2 months

#### Assumptions

- Subjects are healthy adults with no existing antibodies for avian influenza.
- Subjects receive one vaccination at the dose level established in the Phase I/II trial.
- Each of the 3 centers run the clinical trial in parallel.
- Each center immunizes 140 subjects
- Treatment by each center for all 140 patients can be accomplished in one month.
- All subjects are tested for antibody levels and cell mediated immunity over the following 12 months

Absent unexpected developments, the Company believes it may be able to submit its NDA for the influenza vaccine by late 2011 and, if approved, the product could be available for public use in the mid-2012 time period. However, there is no guarantee that the Company will be able to submit NDA in such a time frame or obtain approval from the FDA. The FDA has recently announced guidelines for accelerated approval of influenza vaccines. These timeframes are significantly shorter than the average review process. The FDA NDA filing fee could be as much as \$2.0 million. Even if the Phase 3 trial is successful, the FDA approval process could take substantially longer than the Company anticipates, and there can be no assurances that the FDA will eventually approve the Company's influenza vaccine product for marketing.

### ***Cost of Development***

The Company estimates that the total cost of clinical development for the avian influenza vaccine is in the range of approximately \$20.0-\$25.0 million. Of this amount, approximately \$5.0-\$10.0 million will be internal research and development expenses associated with optimizing the effectiveness of the influenza DNA plasmid, management of the clinical trials, and other activities conducted by the Company personnel; and the Company estimates that about \$15.0 million will be spent on activities anticipated to be conducted by third parties, such as:

- Production of the plasmid
- Preclinical studies
- Phase I/II clinical trials
- Phase III clinical trials
- FDA Application fees

If clinical trials for the influenza vaccine are progressing successfully, depending on a number of factors, including the status of the Company's other business activities and products, the amount of funds that the Company has raised, and the Company's other capital needs, as well as the terms of any such partnership, the Company anticipates that it may seek to form a strategic partnership with a large, international pharmaceutical company capable of commercializing the Company's product in markets outside of the United States, in the U.S. markets, or worldwide. In addition, the Company has also considered an alliance with one or more nongovernmental organizations, such as the Red Cross, as a viable method of commercializing some of the Company's products domestically.

### **Sources and Availability of Raw Materials**

The Company purchases, in the ordinary course of business, necessary raw materials, components and supplies essential to its operations from several suppliers in the U.S. and overseas. Adamis Labs has entered into a contract with a contract manufacturing organization for the development and production of its epinephrine syringe product, and a contract with a different contract manufacturing organization for the development and production of its BANS product candidate. The Company intends to monitor these situations and to seek to provide a continued supply of both raw materials and components.

### **Sales and Marketing**

Adamis Labs' field force includes sales management, customer service representatives, trade relations/reimbursement specialists and executive management. The Company's expansion plan, depending upon securing adequate funding, includes hiring and training approximately 15-30 additional sales representatives to be strategically deployed in the most valuable prescribing U.S. markets by the launch of the epi syringe product candidate. For future field force expansion and before the launch of the Company's aerosolized inhaled nasal steroid, the Company has identified the top prescribing markets in the U.S. by utilizing physician data aligned with zip code alignment data. The Company expects to expand to approximately 50 specialty field force sales representatives before introducing the aerosolized nasal steroid product. Physician calls by the Company's sales force are expected to be to the highest prescribers of emergency epinephrine injectors in each market and then modified, if required, when the aerosolized nasal steroid product introduction occurs.

## Governmental Regulation

The production and marketing of the Company's products and potential products and its ongoing research and development, preclinical testing and clinical trial activities are currently subject to extensive regulation and review by numerous governmental authorities in the United States and will face similar regulation and review for overseas approval and sales from governmental authorities outside of the United States. Most of the products the Company is currently developing must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, harder and more costly to bring the Company's potential products to market, and the Company cannot guarantee that any of its potential products will be approved. The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If the Company or its collaboration partners do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Withdrawal or rejection of FDA or other government entity approval of the Company's potential products may also adversely affect the Company's business. Such rejection may be encountered due to, among other reasons, lack of efficacy during clinical trials, unforeseen safety issues, inability to follow patients after treatment in clinical trials, inconsistencies between early clinical trial results and results obtained in later clinical trials, varying interpretations of data generated by clinical trials, or changes in regulatory policy during the period of product development in the United States and abroad. In the United States, there is stringent FDA oversight in product clearance and enforcement activities, causing medical product development to experience longer approval cycles, greater risk and uncertainty, and higher expenses. Internationally, there is a risk that the Company may not be successful in meeting the quality standards or other certification requirements. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted, or may prevent the Company from broadening the uses of the Company's current or potential products for different applications. In addition, the Company may not receive FDA approval to export the Company's potential products in the future, and countries to which potential products are to be exported may not approve them for import.

Manufacturing facilities for the Company's products will also be subject to continual governmental review and inspection. The FDA has stated publicly that compliance with manufacturing regulations will continue to be strictly scrutinized. To the extent the Company decides to manufacture its own products, a governmental authority may challenge the Company's compliance with applicable federal, state and foreign regulations. In addition, any discovery of previously unknown problems with one of the Company's potential products or facilities may result in restrictions on the potential product or the facility. If the Company decides to outsource the commercial production of its products, any challenge by a regulatory authority of the compliance of the manufacturer could hinder the Company's ability to bring its products to market.

To the extent that the Company is able to successfully advance a product candidate through clinical trials, it will be required to obtain regulatory approval prior to marketing and selling such product. The Company is subject to extensive government regulation that increases the cost and uncertainty associated with its efforts to gain regulatory approval of its product candidates. Preclinical development, clinical trials, manufacturing, and commercialization of its product candidates are all subject to extensive regulation by U.S. and foreign governmental authorities. It takes many years and significant expenditures to obtain the required regulatory approvals for biological products. Satisfaction of regulatory requirements depends upon the type, complexity and novelty of the product candidate and requires substantial resources. The Company cannot be certain that any of its product candidates will be shown to be safe and effective, or that it will ultimately receive approval from the FDA or foreign regulatory authorities to market these products. In addition, even if granted, product approvals and designations such as "fast-track" may be withdrawn or limited at a later time.

The process of obtaining FDA and other required regulatory approvals is expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity or novelty of the product. The process of obtaining FDA and other required regulatory approvals for many of the Company's products under development is further complicated because some of these products use non-traditional or novel materials in non-traditional or novel ways. For example:

- the FDA has not established guidelines concerning the scope of clinical trials required for gene-based therapeutic and vaccine products;
- the FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products; and
- current regulations and guidance are subject to substantial review by various governmental agencies.



Therefore, U.S. or foreign regulations could prevent or delay regulatory approval of Adamis' products or limit its ability to develop and commercialize products. These delays could:

- impose costly procedures;
- diminish any competitive advantages; or
- negatively affect results of operations and cash flows.

The Company believes that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product the Company must sponsor and file a regulatory application for each proposed use. The Company must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The results obtained so far in clinical trials may not be replicated in future trials. This may prevent any of the potential products from receiving FDA approval.

The Company will utilize recombinant DNA molecules in its product candidates, and therefore must comply with guidelines instituted by the NIH and its Office of Biotechnology Activities. The NIH could restrict or delay the development of its product candidates. In March 2004, the NIH Office of Biotechnology Activities and the FDA Center for Biologics Evaluation and Research launched the jointly developed Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. In its current form, GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials, and includes special security features designed to protect patient privacy and confidential commercial information. These security features may be inadequate in design or enforcement, potentially resulting in disclosure of confidential commercial information.

The FDA and the NIH are considering rules and regulations that would require public disclosure of additional commercial development data that is presently confidential. In addition, the NIH, in collaboration with the FDA, has developed an Internet site, ClinicalTrials.gov, which provides public access to information on clinical trials for a wide range of diseases and conditions. Such disclosures of confidential commercial information, whether by implementation of new rules or regulations, by inadequacy of GeMCRIS security features, or by intentional posting on the Internet, may result in loss of advantage of competitive secrets.

A rule published in 2002 by the FDA, known commonly as the "Animal Rule," established requirements for demonstrating effectiveness of drugs and biological products in settings where human clinical trials for efficacy are not feasible or ethical. The rule requires as conditions for market approval the demonstration of safety and biological activity in humans, and the demonstration of effectiveness under rigorous test conditions in up to two appropriate species of animal. The Company believes that with appropriate guidance from the FDA, it may seek and win market approval under the Animal Rule for certain DNA-based products for which human clinical efficacy trials are not feasible or ethical. At the moment, however, it cannot determine whether the Animal Rule would be applied to any products of the Company, or if applied, that its application would result in expedited development time or regulatory review.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which the Company may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payers. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

The Company, or its collaborative partners, are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of the Company's potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

In addition to regulations imposed by the FDA, the Company may also be subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of biotechnology applications. The Company cannot predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to its business, or whether the Company would be able to comply with any applicable regulations.

Even if the Company's products are approved by regulatory authorities, if it fails to comply with ongoing regulatory requirements, or if there are unanticipated problems with the products, these products could be subject to restrictions or withdrawal from the market. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with the products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

As a result of these factors, the Company may not successfully begin or complete clinical trials in the time periods estimated, if at all. Moreover, if the Company incurs costs and delays in development programs or fails to successfully develop and commercialize products based upon its technologies, the Company may not become profitable, and its stock price could decline.

## ***FDA Approval Process***

### ***General***

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and regulates biological drug products under both the Public Health Service Act, or PHS Act, and its implementing regulations, as well as the FDCA. The Company's product candidates include both biological drug products and drug products. The process required by the FDA before the Company's drug and biological drug product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies all performed in accordance with the FDA's current Good Laboratory Practice, or cGMP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a new drug application, or NDA, for drug products, or a Biologic License Application, or BLA, for biological drug products;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA or BLA prior to any commercial marketing, sale or shipment of the drug or biological drug.

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development, and the FDA must grant permission before each clinical trial can begin. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practices, or GCPs, regulations and regulations for informed consent.

For purposes of an NDA or BLA submission and approval, human clinical trials are typically conducted in the following three sequential phases, which may overlap:

- Phase I Clinical Trials. Studies are initially conducted in a limited population to test the product candidate primarily for safety, dose tolerance, pharmacokinetics and, for vaccine products, immunogenicity, in healthy humans or in patients. In some cases, a sponsor may decide to conduct what is referred to as a “Phase Ib” evaluation, which is a second, safety-focused Phase I clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently approved drugs;
- Phase II Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase III clinical trials. In some cases, a sponsor may decide to run what is referred to as a “Phase IIb” evaluation, which is a second, confirmatory Phase II clinical trial;
- Phase III Clinical Trials. These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites; and
- Phase IV Clinical Trials. In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor’s agreement to conduct additional clinical trials to further assess the drug’s safety and effectiveness after NDA or BLA approval. Such post-approval trials are typically referred to as Phase IV studies.

There can be no assurance that Phase I, Phase II trials or Phase III will be completed successfully within any specific time period, if at all, with respect to any of the Company’s potential products subject to such testing.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA and BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product’s pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA or BLA is substantial, and there can be no assurance that any approval will be granted on a timely basis, if at all. Under federal law, the submission of most NDAs and BLAs are additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved new drug application is also subject to annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may deny approval of an NDA or BLA if the applicable regulatory criteria are not satisfied, or it may require additional information including clinical or CMC data. Even if such data are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the Company or its collaborators interpret data. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with Good Clinical Practices, or GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices, or cGMP, is satisfactory and the NDA or BLA contains data that provides substantial evidence that the drug is safe and effective in the indication studied. Failure to comply with GMP or other applicable regulatory requirements may result in withdrawal of marketing approval, criminal prosecution, civil penalties, recall or seizure of products, warning letters, total or partial suspension of production, suspension of clinical trials, FDA refusal to review pending marketing approval applications or supplements to approved applications, or injunctions, as well as other legal or regulatory action against Adamis or its corporate partners.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues an approval letter, an approvable letter or a not-approvable letter. Both approvable and not-approvable letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

### ***Adamis Labs Products***

Several of Adamis Labs' products, including AeroHist Caplets, AeroHist Plus Caplets, AeroKid Oral Liquid and AeroOtic HC Ear Drops, were not the subject of a new drug application or abbreviated new drug application and have not been approved for marketing by the FDA. These products have been marketed for many years and, the Company believes, are similarly situated to products marketed by many companies that are marketed without an approved new drug application or abbreviated new drug application. The products are drug listed with the FDA in the National Drug Code Directory but such listing does not constitute FDA approval of the products. In June 2006, the FDA issued a Compliance Policy Guide for Marketed Unapproved Drugs, which addressed some of the considerations utilized by the FDA in exercising its discretion with respect to products marketed without FDA approval. The guide does not establish legally enforceable responsibilities on the FDA and generally only represents the agency's current thinking on a topic. The guide emphasizes that any product that is being marketed without required FDA approvals is subject to FDA enforcement action at any time. If the FDA were to issue a Federal Register Notice outlining revised conditions for marketing, which could include calling for the submission of an application for products such as the Company's cough/cold products, then Adamis would take appropriate action so as to be in compliance with any such policies. The FDA might also require clinical trials in support of any such applications, and the Company would need to evaluate its alternatives in light of the costs required to conduct such trials, which could be substantial, compared to the economic benefit to the Company from such products. The FDA could also exercise its discretion to proceed against the Company and/or other companies that market similar products without an FDA approval and require immediate withdrawal of the products from the market, to prohibit the Company from marketing these products without first conducting required trials and obtaining approvals, or to impose other penalties on the Company. Some of Adamis Labs' unapproved products include extended release formulations, which may subject the Company to a higher risk of FDA enforcement action. Such actions could have a material adverse effect on the Company's business, financial condition and results of operations.

The Prelone product is the subject of an ANDA approval from the FDA. As the Company believes is common with many drug products, the Prelone product is manufactured by a third party manufacturer which holds the ANDA approval relating to the product. The Company owns the trademark and intellectual property rights relating to the product and distributes the product pursuant to those rights.

***Abbreviated New Drug Applications***

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

***Section 505(b)(2) New Drug Applications***

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is subject to existing exclusivity for the reference product and is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs and biological drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biological drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug concurrent with or any time after the filing of the IND for the drug or biological drug candidate. The FDA must determine if the candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If fast track designation is obtained, the FDA may initiate review of sections of an NDA or BLA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the time period specified in PDUFA, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast track designated candidate may also qualify for one or more of the following programs:

- **Priority Review.** Under FDA policies, a drug or biological drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA or BLA is accepted for filing, if the candidate provides a significant improvement compared to marketed drugs or biological drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug or biological drug candidate would ordinarily meet the FDA's criteria for priority review, however, fast track designation is not required to be eligible for priority review.
- **Accelerated Approval.** Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug and biological drug candidates that have been studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either an endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A candidate approved on the basis of a surrogate endpoint is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to validate the surrogate endpoint or confirm the effect of the drug candidate on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will result in the FDA withdrawing the drug or biological drug from the market on an expedited basis. All promotional materials for drug and biological drug candidates approved under accelerated regulations are subject to prior review by the FDA.

When appropriate, the Company intends to seek fast track designation, accelerated approval or priority review for its biological drug candidates.

Satisfaction of FDA regulations and approval requirements or similar requirements of foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug or biological drug candidate is intended to treat a chronic disease, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug or biological drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our drug and biological drug candidates on a timely basis, or at all. Even if a drug or biological drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug or biological drug may result in restrictions on the product or even complete withdrawal of the drug or biological drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug or biological drug candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

FDA regulations set forth procedures under which parties can petition the FDA to take or refrain from taking certain actions. NDA applicants occasionally submit such citizen petitions requesting that the FDA deny or delay approval of an ANDA, or impose specific additional requirements for approval on ANDAs for a particular drug product. Many such petitions are eventually denied by the FDA, but the submission of such petitions, especially when submitted near the end of an ANDA review, has often delayed the approval of an ANDA while the FDA considers and responds to the issues presented. Congress included provisions to address this practice in the recently enacted FDA Amendments Act of 2007, or FDAAA. The FDAAA prohibits the FDA from delaying approval of an ANDA due to the submission of a citizen petition unless the delay is necessary to protect the public health, and requires that the FDA take final action on any such petition within 180 days of its submission. In addition, the FDAAA requires that petitioners certify, among other things, the date upon which the petitioner first became aware of the information that forms the basis of the request and the name of the person or entity funding the petition.

### ***Post-Approval Requirements***

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The distribution of prescription pharmaceutical products is also subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

### ***Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

### ***New Legislation***

On September 27, 2007, the President of the United States signed into law the Food and Drug Administration Amendments Act of 2007, or FDAAA. The legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, it significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

While the above provisions of the FDAAA, among others, will undoubtedly have a significant effect on the pharmaceutical industry, the extent of that effect is not yet known. As regulations, guidance and interpretations are issued by the FDA relating to the new legislation, its impact on the industry, as well as our business, will become clearer. The changes and new requirements it imposes on the drug review and approval process and post-approval activities could make it more difficult, and certainly more costly, to obtain approval for new pharmaceutical products, or to produce, market, and distribute existing products.

### ***Approval Outside the United States***

In order to market any product outside of the United States, the Company must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

To date, the Company has not initiated any discussions with the European Medicines Agency, or EMEA, or any other foreign regulatory authorities with respect to seeking regulatory approval for any indication in Europe or in any other country outside the United States. As in the United States, the regulatory approval process in Europe and in other countries is a lengthy and challenging process. If the Company fails to comply with applicable foreign regulatory requirements, it may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### ***Competition***

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many of our competitors, including biotechnology and pharmaceutical companies, academic institutions and other research organizations, are actively engaged in the discovery, research and development of products that could compete directly or indirectly with our products under development.

*Adamis Labs Allergy Products.* Adamis Labs' current line of allergy and respiratory products compete with numerous prescription and non-prescription over-the-counter products targeting similar conditions, including, in the seasonal or perennial rhinitis areas, cough and cold, as well as prescription generic products. In addition, a number of companies, including GSK, Merck, and AstraZeneca, produce pharmaceutical products, such as antihistamines, corticosteroids and anti-leukotriene agents, which manage allergy symptoms.

*Epinephrine Syringe.* Adamis' syringe product, if developed, launched and marketed, is expected to compete against other self-administered epinephrine products, including EpiPen, EpiPen Jr. and Twinject.



**BANS.** Adamis' inhaled nasal steroid BANS products if developed, launched and marketed, is expected to compete with several inhaled nasal steroid products that are currently marketed, including Flonase, marketed by GlaxoSmithKline, Nasonex, marketed by Schering, Nasacort AQ, marketed by Aventis and Rhinocort, marketed by AstraZeneca.

**Vaccine Technology.** If the Company successfully develops a vaccine product for avian or other kinds of influenza based on the STI technology, that product is expected to compete with traditional and emerging influenza vaccines from companies currently marketing these products, including GSK, Novartis, Sanofi-Pasteur, Medimmune/AstraZeneca and CSL. In addition, the Company is aware of several companies developing potentially competing universal vaccines for influenza, including Acambis, VaxInnate, Merck, Vical and Dynavax Technologies Corporation, and other companies of which the Company is not aware are also likely developing products intended to address influenza and other indications targeted by the Company.

**Savvy.** 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-microbicidal products such as condoms. There is also a number of existing contraception products currently on the market which could greatly limit the marketability of the Savvy contraception product candidate. As a result, there can be no assurance that Biosyn's products under development will be able to compete successfully with existing products or other innovative products under development.

Many of the entities developing and marketing these competing products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than the Company. Smaller or early-stage companies may also prove to be significant competitors, particularly for collaborative agreements with large, established companies and access to capital. These entities may also compete with Adamis in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to, or necessary for, the Company's programs.

### **Product Liability Insurance**

The manufacture and sale of human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. The Company currently has only limited product liability insurance, and there can be no assurance that the Company will be able to maintain existing or obtain additional product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. An inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could inhibit the Company's business. A product liability claim brought against the Company its insurance coverage, if any, could have a material adverse effect upon its business, financial condition and results of operations.

The pharmaceutical industry is characterized by extensive research efforts and rapid and significant technological change and intense competition. The Company 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. The Company's competitors may succeed in developing technologies and products that are safer, more effective or less costly than any developed by the Company, thus rendering its technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience than the Company.

### **Patents and Proprietary Technologies**

Patents and other proprietary rights are important to the Company's business. The Company's policy is to file patent applications and protect inventions and improvements to inventions that are commercially important to the development of its business. The Company also relies on trade secrets, know-how, confidentiality agreements, continuing technology innovations and licensing opportunities to protect its technology and develop and maintain its competitive position.

It is our policy to require our employees to execute an invention assignment and confidentiality agreement upon employment. Each agreement provides that all confidential information developed or made known to the employee during the course of employment 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 will be the exclusive property of the Company. 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.

Adamis is the exclusive licensee, under the license agreement with Nevagen, of rights under two issued U.S. patents, three U.S. patent applications and related patent applications filed in the European Union, Japan and Canada, relating to the STI technology, in the field of prevention and treatment and detection of viral infectious diseases.

The licensed intellectual property, or IP, includes the use of the technology known as “Transgenic Lymphocyte Technologym,” or TLI, covered by patent applications entitled “Somatic Transgene Immunization and Related Methods” and related know how. TLI includes, but is not limited to, creating a vaccine by exposing an individual’s lymphocytes to plasmid DNA encoding certain epitopes and re-administering the treated lymphocytes to the individual. The vaccines are made up of the individual’s lymphocytes harboring plasmid DNA encoding epitopes, e.g., selected epitopes of influenza virus. Virtually all of the Company’s current viral product candidates, including the avian influenza candidate, are based on technology covered by these patents and applications.

The IP includes rights under the following patents, including all divisionals, continuations, continuations-in-part, reexaminations and reissues:

- US Patent # 5,658,762 entitled DNA MOLECULES, EXPRESSION VECTORS AND HOST CELLS EXPRESSING ANTIGENIZED ANTIBODIES, filed June 6, 1995, granted August 19, 1997. The expiration date for this patent is 2014.
- US Patent # 7,279,462 entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, filed April 27, 1999, granted October 9, 2007. The expiration date for this patent is 2019.
- PCT Patent Application US00/11372/ WO 00/64488 entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, filed April 27, 2000.
- European Patent Application 009301284.7 entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, international filing date April 27, 2000.
- Canadian Patent Application # 2,369, 616 entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, international filing date April 27, 2000.
- Japan Patent Application #2000-613478 entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, international filing date April 27, 2000.
- US Patent Application No. 10,030,003 entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, international filing date April 27, 2000.
- US Patent Application No. 11,640,778, entitled SOMATIC TRANSGENE IMMUNIZATION AND RELATED METHODS, filed December 16, 2006.

The Company currently hold five patents worldwide relating to Savvy gel for contraception and the reduction in transmission of HIV infection. These patents expire at various dates between 2017 and 2021. The Company is not aware of any organization that currently has legally blocking proprietary rights relating to the Company’s Savvy product candidate. However, 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. 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.

The Company’s failure to obtain patent protection or otherwise protect its proprietary technology or proposed products may have a material adverse effect on the Company’s competitive position and business prospects. The patent application process takes several years and entails considerable expense. There is no assurance that additional patents will issue from these applications or, if patents do issue, that the claims allowed will be sufficient to protect the Company’s technology.

The patent positions of pharmaceutical and biotechnology firms are often uncertain and involve complex legal and factual questions. Furthermore, the breadth of claims allowed in biotechnology patents is unpredictable. The Company cannot be certain that others have not filed patent applications for technology covered by the pending STI applications or that the licensor of the STI technology was the first to invent the technology that is the subject of such patent applications. Competitors may have filed applications for, or may have received patents and may obtain additional patents and proprietary rights relating to compounds, products or processes that block or compete with those of the Company. The Company is aware of patent applications filed and patents issued to third parties relating to HFA propellant technology and aerosolized inhalers, and there can be no assurance that any patent applications or patents will not have a material adverse effect on potential products the Company is developing or may seek to develop in the future.

Patent litigation is widespread in the biotechnology industry. Litigation may be necessary to defend against or assert claims of infringement, to enforce patents issued to the Company, to protect trade secrets or know-how owned or licensed by the Company, or to determine the scope and validity of the proprietary rights of third parties. Although no third party has asserted that the Company is infringing such third party's patent rights or other intellectual property, there can be no assurance that litigation asserting such claims will not be initiated, that the Company would prevail in any such litigation or that the Company would be able to obtain any necessary licenses on reasonable terms, if at all. Any such claims against the Company, with or without merit, as well as claims initiated by the Company against third parties, can be time-consuming and expensive to defend or prosecute and to resolve. If other companies prepare and file patent applications in the United States that claim technology also claimed by the Company, it may have to participate in interference proceedings to determine priority of invention which could result in substantial cost to the Company even if the outcome is favorable to the Company. There can be no assurance that third parties will not independently develop equivalent proprietary information or techniques, will not gain access to the Company's trade secrets or disclose such technology to the public or that the Company can maintain and protect unpatented proprietary technology. The Company typically requires its employees, consultants, collaborators, advisors and corporate partners to execute confidentiality agreements upon commencement of employment or other relationships with the Company. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for the Company's technology in the event of unauthorized use or disclosure of such information, that the parties to such agreements will not breach such agreements or that the Company's trade secrets will not otherwise become known or be discovered independently by its competitors.

## **Employees**

As of December 31, 2008, Adamis, including its subsidiaries, employed 14 full-time employees. Most employees are located in Florida and are engaged in activities relating to the Adamis Labs operations. Adamis plans to continue to expand its product development programs. To support this growth, the Company will need to expand managerial, operations, development, regulatory, sales, commercialization, finance and other functions. As of December 31, 2008, Cellegy had two full-time employees. In addition, Cellegy utilized the services of professional consultants, as well as regulatory and clinical research organizations to supplement its internal staff's activities. None of the Company's 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 SEC, including reports on the following forms:

- (i) annual report on Form 10-K,
- (ii) quarterly reports on Form 10-Q,
- (iii) current reports on Form 8-K, and
- (iv) 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> or by calling 1-800-SEC-0330. Upon written request to the Company at Adamis Pharmaceuticals Corporation, 2658 Del Mar Heights Road, #555, Del Mar, CA 92014, Attention: Chief Financial Officer, the Company will provide a copy of the annual report on Form 10-K to any stockholder.

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

The following discussion of risk factors relates not only to the business of Cellegy, but also to the business of Adamis and the combined Company as conducted and as proposed to be conducted.

***The Company will require additional financing.***

The Company will require additional cash resources to continue operations at substantially their current level during 2009, assuming no significant unexpected expenses. As of December 31, 2008, the Company and its subsidiaries together had cash and cash equivalents of approximately \$129,000. The Company estimates that capital needs during calendar year 2009 will include approximately \$3.3 million for product development and approximately \$2.3 million of the combined Company ongoing sales, general and administrative activities and expenses. These funds will be needed at various times throughout the first half of the calendar 2009 year. Additional funding will be used to satisfy existing obligations and liabilities and future working capital needs, to build working capital reserves and to fund a number of projects, which may include the following:

- develop and market the Adamis Labs epinephrine syringe product and the generic nasal steroid product candidate;
- pursue the development of other product candidates;
- fund clinical trials and seek regulatory approvals;
- expand the Company's research and development activities;
- access manufacturing and commercialization capabilities;
- implement additional internal systems and infrastructure;
- maintain, defend and expand the scope of the Company's intellectual property portfolio; and
- hire additional management, sales, research, development and clinical personnel.

Statements in this Report, including concerning the Company's anticipated or hoped-for target dates for commercial introduction of its epinephrine syringe product and its nasal steroid and vaccine product candidates, and for the commencement of clinical trials relating to the steroid and vaccine product candidates, assume that the Company will have sufficient funding to support the timely introduction of products and the conduct of clinical trials. Failure to have sufficient funding could require the Company to delay product launches or clinical trials, which would have an adverse effect on its business and results of operations and which could increase the need for additional financing in the future.

The Company has financed its operations to date primarily through the sale of equity securities. At December 31, 2008, Cellegy had current liabilities of approximately \$256,000, including accounts payable of approximately \$72,000 including general operating expenses, and approximately \$184,000 accrued expenses and other current liabilities related primarily to legal, accounting and payroll items. Until the Company can generate a sufficient amount of revenue to finance its cash requirements, which the Company may never do, the Company expects to finance future cash needs primarily through public or private equity offerings, debt financings, or licensing revenues from strategic collaborations. Sales of additional equity securities will dilute current stockholders' ownership percentage in the Company. The Company does not know whether additional financing will be available on acceptable terms, or at all. If the Company is not able to secure additional equity or debt financing when needed on acceptable terms, the Company may have to sell some of its assets or enter into a strategic collaboration for one or more of the Company's product candidate programs at an earlier stage of development than would otherwise be desired. This could lower the economic value of these collaborations to the Company. In addition, the Company may have to delay, reduce the scope of, or eliminate one or more of its clinical trials or research and development programs, or ultimately, cease operations.

If adequate funding is not obtained, the board of directors will be required to explore alternatives for the Company's business and assets. These alternatives might include seeking the dissolution and liquidation of the Company, seeking to merge or combine with another company, selling or licensing some of the Company's intellectual property, or initiating bankruptcy proceedings. There can be no assurance that any third party will be interested in merging with the Company or would agree to a price and other terms that the Company would deem adequate. If the Company filed for bankruptcy protection, the Company would most likely not be able to raise any type of funding from any source. In that event, the creditors of the Company would have first claim on the value of the assets of the Company which, other than remaining cash, would most likely be liquidated in a bankruptcy sale. The Company can give no assurance as to the magnitude of the net proceeds of such sale and whether such proceeds would be sufficient to satisfy the Company's obligations to its creditors, let alone to permit any distribution to its equity holders.

***The Company has incurred losses since inception and anticipates that the Company will continue to incur losses. The Company may never achieve or sustain profitability.***

Cellegy incurred net losses of approximately \$1.5 million and \$1.9 million for its fiscal years ended December 31, 2008 and 2007, respectively. The Company's net operating losses are expected to continue as a result of increasing marketing and sales expenses, research and development expenses, clinical trial activity and preparation for regulatory submissions necessary to support regulatory approval of its products. These losses may increase as the Company continues its research and development activities, seeks regulatory approvals for its product candidates and commercializes any approved products. These losses may cause, among other things, the Company's stockholders' equity and working capital to decrease. The future earnings and cash flow from operations of the Company's business are dependent, in part, on its ability to further develop its products and on revenues and profitability from sales of products and product candidates of its Adamis Labs operations. There can be no assurance that the Company will grow and be profitable. There can be no assurance that the Company will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. The Company expects to have quarter-to-quarter fluctuations in expenses, some of which could be significant, due to expanded manufacturing, marketing, research, development, and clinical trial activities. If product candidates fail in clinical trials or do not gain regulatory approval, or if the Company's products do not achieve market acceptance, the Company may never become profitable. The Company will need to increase product marketing and brand awareness and conduct significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, are expected to result in substantial operating losses for the foreseeable future. Even if the Company does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis.

Substantial doubt exists about the Company's ability to continue as a going concern. We have received a "going concern" opinion from our independent registered public accounting firm, which may negatively impact our business. Cellegy's audit opinions from its independent registered public accounting firm regarding the consolidated financial statements for the years ended December 31, 2008 and 2007 include an explanatory paragraph indicating that Cellegy has incurred recurring losses from operations and has negative working capital, liabilities that exceed its assets and recurring cash flow deficiencies and that these factors raise substantial doubt about its ability to continue as a going concern. Without additional funds from debt or equity financing, sales of assets, intellectual property or technologies, or from a business combination or a similar transaction, the Company will exhaust its resources and will be unable to continue operations. These factors raise substantial doubt about the Company's ability to continue as a going concern.

***The Company's limited operating history may make it difficult to evaluate its business to date and the Company's future viability.***

The Company is in the early stage of operations and development, and has only a limited operating history on which to base an evaluation of its business and prospects. Moreover, Adamis acquired Adamis Labs during calendar year 2007, and integrating those businesses with the Company's other business activities could be challenging. The Company will be subject to the risks inherent in the ownership and operation of a company with a limited operating history such as regulatory setbacks and delays, fluctuations in expenses, competition, the general strength of regional and national economies, and governmental regulation. Any failure to successfully address these risks and uncertainties could seriously harm the Company's business and prospects. The Company may not succeed given the technological, marketing, strategic and competitive challenges it will face. The likelihood of the Company's success must be considered in light of the expenses, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new drug development technology, and the competitive and regulatory environment in which the Company operates or may choose to operate in the future.

***Some of the Company's potential products and technologies are in early stages of development.***

The development of new pharmaceutical products is a highly risky undertaking, and there can be no assurance that any future research and development efforts the Company might undertake will be successful. The Company's potential products in the influenza and other viral fields will require extensive additional research and development before any commercial introduction, and development work on the epinephrine syringe product and the generic nasal steroid product must still be completed. There can be no assurance that any future research, development or clinical trial efforts will result in viable products or meet efficacy standards. Future clinical or preclinical results may be negative or insufficient to allow the Company to successfully market its product candidates. Obtaining needed data and results may take longer than planned or may not be obtained at all. Any such delays or setbacks could have an adverse effect on the ability of the Company to achieve its financial goals.

***The Company is subject to substantial government regulation, which could materially adversely affect the Company's business.***

The production and marketing of the Company's products and potential products and its ongoing research and development, pre-clinical testing and clinical trial activities are currently subject to extensive regulation and review by numerous governmental authorities in the United States and will face similar regulation and review for overseas approval and sales from governmental authorities outside of the United States. Some of the product candidates that the Company is currently developing must undergo rigorous pre-clinical and clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, harder and more costly to bring the Company's potential products to market, and the Company cannot guarantee that any of its potential products will be approved. The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If the Company or its collaboration partners do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Withdrawal or rejection of FDA or other government entity approval of the Company's potential products may also adversely affect Adamis' business. Such rejection may be encountered due to, among other reasons, lack of efficacy during clinical trials, unforeseen safety issues, inability to follow patients after treatment in clinical trials, inconsistencies between early clinical trial results and results obtained in later clinical trials, varying interpretations of data generated by clinical trials, or changes in regulatory policy during the period of product development in the United States and abroad. In the United States, there is stringent FDA oversight in product clearance and enforcement activities, causing medical product development to experience longer approval cycles, greater risk and uncertainty, and higher expenses. Internationally, there is a risk that the Company may not be successful in meeting the quality standards or other certification requirements. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted, or may prevent the Company from broadening the uses of the Company's current or potential products for different applications. In addition, the Company may not receive FDA approval to export the Company's potential products in the future, and countries to which potential products are to be exported may not approve them for import.

Manufacturing facilities for the Company's products will also be subject to continual governmental review and inspection. The FDA has stated publicly that compliance with manufacturing regulations will continue to be strictly scrutinized. To the extent the Company decides to manufacture its own products, a governmental authority may challenge the Company's compliance with applicable federal, state and foreign regulations. In addition, any discovery of previously unknown problems with one of the Company's potential products or facilities may result in restrictions on the potential product or the facility. If the Company decides to outsource the commercial production of its products, any challenge by a regulatory authority of the compliance of the manufacturer could hinder the Company's ability to bring its products to market.

***Some of Adamis Labs' products which have been drug listed with the FDA are marketed without an approved new drug application or abbreviated new drug application. The FDA could at some future date seek to prevent marketing of these products, require that such products be marketed only after submission and approval of drug applications, or take other regulatory action against the Company with respect to these products, which could have an adverse effect on the Company.***

Several of Adamis Labs' products, including AeroHist Caplets, AeroHist Plus Caplets, AeroKid Oral Liquid and AeroOtic HC Ear Drops, were not the subject of a new drug application or abbreviated new drug application, or ANDA, and have not been approved for marketing by the FDA. These products have been marketed for many years and, the Company believes, are similarly situated to products marketed by many companies that are marketed without an approved new drug application or abbreviated new drug application. The products are drug listed with the FDA in the National Drug Code Directory but such listing does not constitute FDA approval of the products. In June 2006, the FDA issued a Compliance Policy Guide for Marketed Unapproved Drugs, which addressed some of the considerations utilized by the FDA in exercising its discretion with respect to products marketed without FDA approval. The guide does not establish legally enforceable responsibilities on the FDA and generally only represents the agency's current thinking on a topic. The guide emphasizes that any product that is being marketed without required FDA approvals is subject to FDA enforcement action at any time. If the FDA were to issue a Federal Register Notice outlining revised conditions for marketing, which could include calling for the submission of an application for products such as the Company's cough/cold products, then the Company would take appropriate action so as to be in compliance with any such policies. The FDA might also require clinical trials in support of any such applications, and the Company would need to evaluate its alternatives in light of the costs required to conduct such trials, which could be substantial, compared to the economic benefit to the Company from such products. The FDA could also exercise its discretion to proceed against the Company and/or other companies that market similar products without an FDA approval and require immediate withdrawal of the products from the market, to prohibit the Company from marketing these products without first conducting required trials and obtaining approvals, or to impose other penalties on the Company. Some of Adamis Labs' unapproved products include extended release formulations, which may subject the Company to a higher risk of FDA enforcement action. Such actions could have a material adverse effect on the Company's business, financial condition and results of operations.

***The Company intends to rely on third parties to conduct its clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, the Company may be unable to obtain, or may experience delays in obtaining, regulatory approval, or may not be successful in commercializing the Company's planned and future products.***

Like many companies its size, the Company does not have the ability to conduct preclinical or clinical studies for its product candidates without the assistance of third parties who conduct the studies on its behalf. These third parties are usually toxicology facilities and clinical research organizations, or CROs, that have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as all associated tasks connected with these studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. The Company intends to rely on third parties to conduct clinical trials of its product candidates and to use different toxicology facilities and CROs for its pre-clinical and clinical studies.

The Company's reliance on these third parties for development activities will reduce its control over these activities. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the Company's clinical protocols or for other reasons, the Company's clinical trials may be extended, delayed or terminated. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, the Company may be required to replace them. Although the Company believes there are a number of third-party contractors it could engage to continue these activities, replacing a third-party contractor may result in a delay of the affected trial. Accordingly, the Company may not be able to obtain regulatory approval for or successfully commercialize its product candidates.

***Delays in the commencement or completion of clinical testing of the Company's product candidates could result in increased costs to the Company and delay its ability to generate significant revenues.***

Delays in the commencement or completion of clinical testing could significantly impact the Company's product development costs. The Company does not know whether current or planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- obtaining sufficient quantities of clinical trial materials for any or all product candidates;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- recruiting participants for a clinical trial.

In addition, once a clinical trial has begun, it may be suspended or terminated by the Company or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements;

- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- failure to achieve certain efficacy and/or safety standards; or
- lack of adequate funding to continue the clinical trial.

Clinical trials require sufficient participant enrollment, which is a function of many factors, including the size of the target population, the nature of the trial protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disease, the eligibility criteria for the Company's clinical trials and competing trials. Delays in enrollment can result in increased costs and longer development times. The Company's failure to enroll participants in its clinical trials could delay the completion of the clinical trials beyond current expectations. In addition, the FDA could require the Company to conduct clinical trials with a larger number of participants than it may project for any of its product candidates. As a result of these factors, the Company may not be able to enroll a sufficient number of participants in a timely or cost-effective manner.

Furthermore, enrolled participants may drop out of clinical trials, which could impair the validity or statistical significance of the clinical trials. A number of factors can influence the discontinuation rate, including, but not limited to: the inclusion of a placebo in a trial; possible lack of effect of the product candidate being tested at one or more of the dose levels being tested; adverse side effects experienced, whether or not related to the product candidate; and the availability of numerous alternative treatment options that may induce participants to discontinue from the trial.

The Company, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time if Adamis or they believe the participants in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

***The Company is subject to the risk of clinical trial and product liability lawsuits.***

The testing of human health care product candidates entails an inherent risk of allegations of clinical trial liability, while the marketing and sale of approved products entails an inherent risk of allegations of product liability. As the Company conducts additional clinical trials and introduces products into the United States market, the risk of adverse events increases and the Company's requirements for liability insurance coverage are likely to increase. The Company is subject to the risk that substantial liability claims from the testing or marketing of pharmaceutical products could be asserted against it in the future. There can be no assurance that the Company will be able to 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, the Company's current and future coverage may not be adequate to protect the Company from all of the liabilities that it may incur. If losses from liability claims exceed the Company's insurance coverage, the Company may incur substantial liabilities that exceed its financial resources. In addition, a product or clinical trial liability action against the Company would be expensive and time-consuming to defend, even if the Company ultimately prevailed. If the Company is required to pay a claim, the Company may not have sufficient financial resources and its business and results of operations may be harmed.

***The Company does not have commercial-scale manufacturing capability, and it lacks commercial manufacturing experience. The Company will likely rely on third parties to manufacture and supply its product candidates.***

The Company does not own or operate manufacturing facilities for clinical or commercial production of product candidates. The Company does not have any experience in drug formulation or manufacturing, and it will lack the resources and the capability to manufacture any of the Company's product candidates on a clinical or commercial scale. Accordingly, the Company expects to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of the Company's contract manufacturers could delay clinical development, regulatory approval or commercialization of the Company's current or future product candidates, depriving the Company of potential product revenue and resulting in additional losses.



The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control (including stability of the product candidate and quality assurance testing), shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If the Company's third-party contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations or under applicable regulations, the Company's ability to provide product candidates to patients in its clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of the Company's clinical trials, increase the costs associated with maintaining the Company's clinical trial programs and, depending upon the period of delay, require the Company to commence new trials at significant additional expense or terminate the trials completely.

The Company's products can only be manufactured in a facility that has undergone a satisfactory inspection by the FDA and other relevant regulatory authorities. For these reasons, the Company may not be able to replace manufacturing capacity for its products quickly if it or its contract manufacturer(s) were unable to use manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure, or other difficulty, or if such facilities were deemed not in compliance with the regulatory requirements and such non-compliance could not be rapidly rectified. An inability or reduced capacity to manufacture the Company products would have a material adverse effect on the combined entity's business, financial condition, and results of operations.

***If the Company fails to obtain acceptable prices or appropriate reimbursement for its products, its ability to successfully commercialize its products will be impaired.***

Government and insurance reimbursements for healthcare expenditures play an important role for all healthcare providers, including physicians and pharmaceutical companies such as the Company that plan to offer various products in the United States and other countries in the future. The Company's ability to earn sufficient returns on its products and potential products will depend in part on the extent to which reimbursement for the costs of such products will be available from government health administration authorities, private health coverage insurers, managed care organizations, and other organizations. In the United States, the Company's ability to have its products eligible for Medicare, Medicaid or private insurance reimbursement will be an important factor in determining the ultimate success of its products. If, for any reason, Medicare, Medicaid or the insurance companies decline to provide reimbursement for the Company's products, its ability to commercialize its products would be adversely affected. There can be no assurance that the Company's potential drug products will be eligible for reimbursement.

There has been a trend toward declining government and private insurance expenditures for many healthcare items. Third-party payors are increasingly challenging the price of medical and pharmaceutical products.

If purchasers or users of the Company's products and related treatments are not able to obtain appropriate reimbursement for the cost of using such products, they may forego or reduce such use. Even if the Company's products are approved for reimbursement by Medicare, Medicaid and private insurers, of which there can be no assurance, the amount of reimbursement may be reduced at times, or even eliminated. This would have a material adverse effect on the Company's business, financial condition and results of operations.

Significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products, and there can be no assurance that adequate third-party coverage will be available.

***Legislative or regulatory reform of the healthcare system may affect the Company's ability to sell its products profitably.***

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system in ways that could impact the Company's ability to sell its products profitably. In recent years, new legislation has been enacted in the United States at the federal and state levels that effects major changes in the healthcare system, either nationally or at the state level. These new laws include a prescription drug benefit plan for Medicare beneficiaries and certain changes in Medicare reimbursement. Given the recent enactment of these laws, it is still too early to determine their impact on the biotechnology and pharmaceutical industries and the Company's business. Further, federal and state proposals are likely. The adoption of these proposals and pending proposals may affect the Company's ability to raise capital, obtain additional collaborators or profitably market its products. Such proposals may reduce the Company's revenues, increase its expenses or limit the markets for its products. In particular, the Company expects to experience pricing pressures in connection with the sale of its products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

***The Company has limited sales, marketing and distribution experience.***

The Company has limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that the Company will be able to establish sales, marketing, and distribution capabilities or make arrangements with its current collaborators or others to perform such activities or that such efforts will be successful. If the Company decides to market any of its new products directly, it must either acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to the Company or, even if available, divert the attention of its management and key personnel, and have a negative impact on further product development efforts.

***The Company may seek to enter into collaborative arrangements to develop and commercialize its products. These collaborations, if secured, may not be successful.***

The Company may seek to enter into collaborative arrangements to develop and commercialize some of its potential products both in North America and international markets. There can be no assurance that the Company will be able to negotiate collaborative arrangements on favorable terms or at all or that its current or future collaborative arrangements will be successful.

The Company's strategy for the future research, development, and commercialization of its products is expected to be based in part on entering into various arrangements with corporate collaborators, licensors, licensees, health care institutions and principal investigators and others, and its commercial success is dependent upon these outside parties performing their respective contractual obligations responsibly and with integrity. The amount and timing of resources such third parties will devote to these activities may not be within the Company's control. There can be no assurance that such parties will perform their obligations as expected. There can be no assurance that the Company's collaborators will devote adequate resources to its products.

***Even if the Company receives regulatory approval to market its product candidates, such products may not gain the market acceptance among physicians, patients, healthcare payors and the medical community.***

Any products that the Company may develop may not gain market acceptance among physicians, patients, healthcare payors and the medical community even if they ultimately receive regulatory approval. If these products do not achieve an adequate level of acceptance, the Company, or future collaborators, may not be able to generate material product revenues and the Company may not become profitable. The degree of market acceptance of any of the Company's product candidates, if approved for commercial sale, will depend on a number of factors, including:

- demonstration of efficacy and safety in clinical trials;
- the prevalence and severity of any unexpected side effects;
- the introduction and availability of generic substitutes for any of the Company's products, potentially at lower prices (which, in turn, will depend on the strength of the Company's intellectual property protection for such products);
- potential or perceived advantages over alternative treatments;
- the timing of market entry relative to competitive treatments;
- the ability to offer the Company's product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- sufficient third party coverage or reimbursement; and
- the product labeling or product insert (including any warnings) required by the FDA or regulatory authorities in other countries.

***If the Company is not successful in acquiring or licensing additional product candidates on acceptable terms, if at all, the Company's business may be adversely affected.***

As part of its strategy, the Company may acquire or license additional product candidates that it believes have growth potential. There are no assurances that the Company will be able to identify promising product candidates. Even if the Company is successful in identifying promising product candidates, the Company may not be able to reach an agreement for the acquisition or license of the product candidates with their owners on acceptable terms or at all.

The Company may not be able to successfully identify any other commercial products or product candidates to in-license, acquire or internally develop. Moreover, negotiating and implementing an economically viable in-licensing arrangement or acquisition is a lengthy and complex process. Other companies, including those with substantially greater resources, may compete with the Company for the in-licensing or acquisition of product candidates and approved products. The Company may not be able to acquire or in-license the rights to additional product candidates and approved products on terms that it finds acceptable, or at all. If it is unable to in-license or acquire additional commercial products or product candidates, the Company's ability to grow its business or increase its profits could be severely limited.

***If the Company's competitors develop and market products that are more effective than the Company's product candidates or obtain regulatory and marketing approval for similar products before the Company does, the Company's commercial opportunity may be reduced or eliminated.***

The development and commercialization of new pharmaceutical products which target influenza and other viral conditions, and allergy and other respiratory conditions addressed by the current and future products of Adamis Labs, is competitive, and the Company will face competition from numerous sources, including major biotechnology and pharmaceutical companies worldwide. Many of the Company's competitors have substantially greater financial and technical resources, and development, production and marketing capabilities than the Company does. In addition, many of these companies have more experience than the Company in pre-clinical testing, clinical trials and manufacturing of compounds, as well as in obtaining FDA and foreign regulatory approvals. The Company will also compete with academic institutions, governmental agencies and private organizations that are conducting research in the same fields. Competition among these entities to recruit and retain highly qualified scientific, technical and professional personnel and consultants is also intense. As a result, there is a risk that one of the competitors of the Company will develop a more effective product for the same indications for which the Company is developing a product or, alternatively, bring a similar product to market before the Company can do so. Failure of the Company to successfully compete will adversely impact the ability to raise additional capital and ultimately achieve profitable operations.

***The Company faces intense competition from larger companies and may not have the resources required to develop innovative products. The Company's product candidates are subject to competition from existing products.***

The pharmaceutical industry is subject to rapid and significant technological change. The Company's is much smaller in terms of size and resources than many of their 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. The Company's competitors may succeed in developing technologies and products that are safer and more effective than any product or product candidates that the Company may develop and could render its technology and potential products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources, clinical production and marketing capabilities and regulatory experience. In addition, any products of the Company will likely be subject to competition from existing products. As a result, any future products of the Company may never be able to compete successfully with existing products or with innovative products under development by other organizations.

***If the Company suffers negative publicity concerning the safety of its products in development, its sales may be harmed and Adamis may be forced to withdraw such products.***

If concerns should arise about the safety of any of the Company's products that are marketed, regardless of whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research, such concerns could adversely affect the market for these products. Similarly, negative publicity could result in an increased number of product liability claims, whether or not these claims are supported by applicable law.

***The Company's failure to protect adequately or to enforce its intellectual property rights or secure rights to third party patents could materially harm its proprietary position in the marketplace or prevent the commercialization of its products.***

The Company's success will depend in part on its ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into its technologies and products. The patents and patent applications in the Company's existing patent portfolio are either owned by the Company or licensed to the Company. The Company's ability to protect its product candidates from unauthorized use or infringement by third parties depends substantially on its ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, the Company's ability to obtain and enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved.

There is a substantial backlog of patent applications at the United States Patent and Trademark Office. 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 the Company's products or methods will be issued as patents, or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. The Company may not be able to obtain patent rights on products, treatment methods or manufacturing processes that it may develop or to which the Company may obtain license or other rights. Even if the Company does obtain patents, rights under any issued patents may not provide it with sufficient protection for the Company's product candidates or provide sufficient protection to afford the Company a commercial advantage against its competitors or their competitive products or processes. It is possible that no patents will be issued from any pending or future patent applications owned by the Company or licensed to the Company. Others may challenge, seek to invalidate, infringe or circumvent any patents the Company owns or licenses. Alternatively, the Company may in the future be required to initiate litigation against third parties to enforce its intellectual property rights. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to the Company. Any adverse outcome could subject the Company to significant liabilities, require the Company to license disputed rights from others, or require the Company to cease selling its future products.

In addition, many other organizations are engaged in research and product development efforts that may overlap with the Company's products. For example, with regard to the Savvy product candidates Tibotec Pharmaceuticals, which is owned by Johnson & Johnson, is engaged in the development of innovative HIV/AIDS drugs and anti-infectives, and many companies are engaged in efforts to develop HIV/AIDS therapeutic products. In addition, Ortho Pharmaceuticals and many other companies offer contraceptive vaginal gel 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 the Company. These rights may prevent the Company from commercializing technology, or may require the Company to obtain a license from the organizations to use the technology. The Company 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. As with other companies in the pharmaceutical industry, the Company is subject to the risk that persons located in other countries will engage in development, marketing or sales activities of products that would infringe the Company's patent rights if such activities were conducted in the United States.

The Company's patents also may not afford protection against competitors with similar technology. The Company may not have identified all patents, published applications or published literature that affect its business either by blocking the Company's ability to commercialize its product candidates, by preventing the patentability of its products or by covering the same or similar technologies that may affect the Company's ability to market or license its product candidates. For example, patent applications filed with the United States Patent and Trademark Office, or USPTO, are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications filed with the USPTO remain confidential for the entire time before issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, the Company or its licensors might not have been the first to invent, or the first to file, patent applications on the Company's product candidates or for their use. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending these rights in foreign jurisdictions. If the Company encounters such difficulties or is otherwise precluded from effectively protecting its intellectual property rights in either the United States or foreign jurisdictions, the Company's business prospects could be substantially harmed.

***If the Company is unable to retain its management, research, development, and clinical teams and scientific advisors or to attract additional qualified personnel, the Company's product operations and development efforts may be seriously jeopardized.***

The Company's success is dependent upon the efforts of a small management team and staff, including Dennis J. Carlo, Ph.D., its Chief Executive Officer. The employment of Mr. Carlo may be terminated at any time by either the Company or Mr. Carlo. The Company does not have key man life insurance policies covering any of its executive officers or key employees. If key individuals leave the Company, the Company 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 operation of the Company's business.

The loss of the services of any principal member of the Company's management and research, development and clinical teams could significantly delay or prevent the achievement of the Company's scientific and business objectives. Competition among biotechnology and pharmaceutical companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to the Company's success. The Company may be unable to attract and retain key personnel on acceptable terms, if at all. The Company does not maintain "key person" life insurance on any of its officers, employees or consultants.

The Company has relationships with consultants and scientific advisors who will continue to assist the Company in formulating and executing its research, development, regulatory and clinical strategies. These consultants and scientific advisors are not employees of Adamis or the Company and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to the Company. The Company will have only limited control over the activities of these consultants and scientific advisors and can generally expect these individuals to devote only limited time to the Company's activities. The Company also relies on these consultants to evaluate potential compounds and products, which may be important in developing a long-term product pipeline for the Company. Consultants also assist the Company in preparing and submitting regulatory filings. The Company's scientific advisors provide scientific and technical guidance on the company's drug discovery and development. Failure of any of these persons to devote sufficient time and resources to the Company's programs could harm its business. In addition, these advisors may have arrangements with other companies to assist those companies in developing technologies that may compete with the Company's products.

***The Company may not achieve the benefits that were expected from the Merger, which may have a material adverse effect on the Company's business, financial condition and operating results.***

Cellegy and Adamis entered into the merger agreement with the expectation that the Merger will result in benefits to the Company. Post-merger challenges include the following:

- maintaining an OTC Bulletin Board listing or a stock exchange listing to promote liquidity for stockholders of the Company and potentially greater access to capital;
- retaining the management and employees of the Company;
- obtaining additional financing required to fund operations; and
- developing new product candidates that utilize the assets and resources of the Company.

If the Company is not successful in addressing these and other challenges, then the benefits of the merger may not be realized and, as a result, the Company's operating results and the market price of the Company's common stock may be adversely affected.

***The Company's common stock price is expected to be volatile, and the market price of its common stock may drop following the merger.***

The market price of the Company's common stock may decline following the closing of the Adamis/Cellegy Merger for a number of reasons, including the following:

- if the Company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by the Company or financial or industry analysts;
- if the Company is unable to obtain required financing;

- if the effect of the Merger on the Company's business and prospects is not consistent with the expectations of the Company or financial or industry analysts;
- if revenues and net income from sales of the Company's products are less than investors' expectations; or
- if the Company's product research and development efforts do not meet investors' expectations.

The market price of the Company's common stock could also be subject to significant fluctuations following the Merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the Company's common stock to fluctuate include:

- the results of the Company's current and any future clinical trials of its product candidates;
- the timing and results of ongoing preclinical studies and planned clinical trials of the Company's preclinical product candidates;
- the entry into, or termination of, key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of the Company's product candidates;
- the initiation of, material developments in, or conclusion of, litigation to enforce or defend any of the Company's intellectual property rights;
- failure of any of the Company's product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect the Company's research and development expenditures;
- the results of clinical trials conducted by others on drugs that would compete with the Company's product candidates;
- issues in manufacturing the Company's product candidates or any approved products;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by competitors of the Company;
- changes in estimates or recommendations by securities analysts, if any, who cover the Company's common stock;
- future sales of the Company's common stock;
- period-to-period fluctuations in the Company's financial results;
- publicity or announcements regarding regulatory developments relating to the Company's products;
- clinical trial results, particularly the outcome of more advanced studies; or negative responses from both domestic and foreign regulatory authorities with regard to the approvability of the Company's products;
- period-to-period fluctuations in the Company's financial results, including the Company's cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- common stock sales in the public market by one or more of the Company's larger stockholders, officers or directors;

- its filing for protection under federal bankruptcy laws;
- a negative outcome in any litigation or potential legal proceedings; or
- other potentially negative financial announcements including: a review of any of the Company's filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in the Company's filings with the SEC.

Following the merger, stockholders of the Company may sell a significant number of shares of common stock of the Company that they received in the Merger. Such holders previously had no ready market for their Adamis shares and might be eager to sell some or all of their shares once the Merger is completed. Significant sales could adversely affect the market price for the Company's common stock for a period of time after completion of the Merger.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the Company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the Company's profitability and reputation.

***The Company's common stock will initially be traded on the OTC Bulletin Board and be subject to additional trading restrictions as a "penny stock," which could adversely affect the liquidity and price of such stock.***

The Company's common stock is currently traded on the OTC Bulletin Board. Because the Company's common stock will not initially be listed on any national securities exchange, such shares will also be subject to the regulations regarding trading in "penny stocks," which are securities trading for less than \$5.00 per share. The following is a list of the general restrictions on the sale of penny stocks:

- Before the sale of penny stock by a broker-dealer to a new purchaser, the broker-dealer must determine whether the purchaser is suitable to invest in penny stocks. To make that determination, a broker-dealer must obtain, from a prospective investor, information regarding the purchaser's financial condition and investment experience and objectives. Subsequently, the broker-dealer must deliver to the purchaser a written statement setting forth the basis of the suitability finding and obtain the purchaser's signature on such statement.
- A broker-dealer must obtain from the purchaser an agreement to purchase the securities. This agreement must be obtained for every purchase until the purchaser becomes an "established customer." A broker-dealer may not effect a purchase of a penny stock less than two business days after a broker-dealer sends such agreement to the purchaser.
- The Securities Exchange Act of 1934, or the Exchange Act, requires that before effecting any transaction in any penny stock, a broker-dealer must provide the purchaser with a "risk disclosure document" that contains, among other things, a description of the penny stock market and how it functions and the risks associated with such investment. These disclosure rules are applicable to both purchases and sales by investors.
- A dealer that sells penny stock must send to the purchaser, within ten days after the end of each calendar month, a written account statement including prescribed information relating to the security.

These requirements can severely limit the liquidity of securities in the secondary market because few brokers or dealers are likely to be willing to undertake these compliance activities. As a result of the Company's common stock not being listed on a national securities exchange and the rules and restrictions regarding penny stock transactions, an investor's ability to sell to a third party and the Company's ability to raise additional capital may be limited. The Company makes no guarantee that its market-makers will continue to make a market in its common stock, or that any market for its common stock will continue.

***The Company's shares of common stock may never be approved for listing on a national securities exchange, which may adversely affect the stockholders' ability to sell shares of the Company's common stock.***

The Company's common stock is currently traded on the OTC Bulletin Board. If at some future date the Company seeks to be listed on the Nasdaq Capital Market or other national securities exchange, it would need to satisfy the requirements for initial listing on the exchange. The initial listing qualification standards are stringent and include both quantitative and qualitative requirements. Although the Company may at a future date explore various actions to meet the minimum initial listing requirements for a listing on a national securities exchange, there is no guarantee that any such actions will be successful in bringing it into compliance with such requirements.

If the Company fails to achieve listing of its common stock on a national securities exchange, the Company's common shares may continue to be traded on the OTC Bulletin Board, the Pink Sheets, or other over-the-counter markets in the United States, although there can be no assurance that its common shares will remain eligible for trading on any such alternative markets or exchanges in the United States.

In the event that the Company is not able to obtain a listing on a national securities exchange or maintain its reporting on the OTC Bulletin Board, Pink Sheets or other quotation service for its common shares, it may be more difficult for stockholders to sell their common shares in the United States. Moreover, if the common stock of the Company remains quoted on the OTC Bulletin Board, Pink Sheets or other over-the-counter market, the liquidity will likely be less, and therefore the price will be more volatile, than if its common stock was listed on a national securities exchange. Stockholders may not be able to sell their common shares in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if the Company's common shares fail to achieve listing on a national securities exchange, the price of its common shares may decline. In addition, a decline in the price of the Company's common shares could impair its ability to achieve a national securities exchange listing or to obtain financing in the future.

***The Company's principal stockholders will have significant influence over the Company, and your interests may conflict with the interests of those persons.***

The Company's five largest stockholders beneficially own approximately 49% of the outstanding the Company common stock. As a result, those stockholders will be able to exert a significant degree of influence or actual control over the Company's management and affairs after the merger and over matters requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets, and any other significant corporate transaction. The interests of these persons may not always coincide with the interests of the Company or its other stockholders. For example, such persons could delay or prevent a change of control of the Company even if such a change of control would benefit the Company's other stockholders. The significant concentration of stock ownership may adversely affect the trading price of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

**The Company's corporate compliance programs cannot guarantee that the Company is in compliance with all potentially applicable regulations.**

The development, manufacturing, pricing, sales, and reimbursement of pharmaceutical products, together with the Company's 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. The Company is a small company and it relies on third parties to conduct certain important functions. The Company relies on a third party clinical regulatory organization, Health Decisions, Inc., pursuant to an agreement between the Company and the National Institute of Child Health and Human Development, to conduct its Phase 3 Savvy clinical trial, and will rely on third parties to assist in evaluation of the results of that trial. In addition, the Company also has significantly fewer employees than many other companies that have the same or fewer product candidates in clinical development. If the Company fails to comply with any of these regulations, the Company could be subject to a range of regulatory actions, including suspension or termination of clinical trials, restrictions on its products or manufacturing processes, or other sanctions or litigation. In addition, as a publicly traded company the Company is subject to significant regulations, including the Sarbanes-Oxley Act of 2002. While the Company has developed and instituted a corporate compliance program and continues to update the program in response to newly implemented or changing regulatory requirements, the Company cannot assure you that it is now or will be in compliance with all such applicable laws and regulations. Failure to comply with potentially applicable laws and regulations could also lead to the imposition of fines, cause the value of Cellegy's common stock to decline and impede the Company's ability to raise capital or lead to the failure of Cellegy's common stock to continue to be traded on the OTC Bulletin Board.



***If the Company is unable to favorably assess the effectiveness of its internal controls over financial reporting, or if the Company's independent registered public accounting firm is unable to provide an unqualified attestation report on the Company's assessment, the price of the Company's common stock could be adversely affected.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, the Company's management is required to report on the effectiveness of its internal control over financial reporting as part of its annual reports for fiscal years ending after December 15, 2007, and the Company's independent auditor will be required to attest to the effectiveness of the Company's internal control over financial reporting, for the fiscal year ending March 31, 2010. Before the Merger, Adamis, as a private company, was not subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. For financial periods after the closing of the Merger, if management identifies one or more material weaknesses in the Company's internal control over financial reporting that are not remediated, the Company will be unable to assert that its internal controls are effective. Any failure to have effective internal control over financial reporting could cause investors to lose confidence in the accuracy and completeness of the Company's financial reports, which could lead to a substantial price decline in the Company's common stock.

In addition, although the Company believes that it currently has adequate finance and accounting systems, procedures and controls for its business, in light of the closing of the merger with Adamis, the Company may decide to upgrade the existing, and implement additional, procedures and controls to incorporate Adamis' business operations. These updates may require significant time and expense, and there can be no guarantee that the Company will be successful in implementing them. If the Company is unable to complete any required modifications to its internal control reporting or if the Company's independent registered public accounting firm is unable to provide the Company with an unqualified report as to the effectiveness of its internal control over financial reporting, investors could lose confidence in the reliability of the Company's internal control over financial reporting, which could lead to a substantial price decline in the Company's common stock.

***The Company has never paid cash dividends on its common stock, and neither company anticipates that the Company will pay any cash dividends on its common stock in the foreseeable future.***

The Company has never declared or paid cash dividends on its common stock. The Company does not anticipate that it will pay any cash dividends on its common stock in the foreseeable future. The Company intends to retain all available funds and any future earnings to fund the development and growth of its business. Accordingly, the stockholders of the Company will not receive a return on their investment unless the value of the Company's shares increases, which may or may not occur.

#### **ITEM 1B: UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2: PROPERTIES**

Following completion of the Merger, the Company intends to lease space for its executive offices in or near Del Mar, California. Adamis currently leases approximately 5,200 square feet of office and approximately 1,800 square feet of warehouse space in Boca Raton and Coconut Creek, Florida, relating to its Adamis Labs operations. The term of the office lease expired in December 2008. The leases are continuing on a month-to-month basis, and Adamis expects either to enter into extensions of the leases or enter into new lease arrangements. The Company is currently evaluating its space requirements and expects to either extend its current leases or move into new facilities that will better accommodate its needs.

#### **ITEM 3: LEGAL PROCEEDINGS**

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

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

None. No matter was submitted during the fourth quarter of 2008 to a vote of the Company's stockholders.

## PART II

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

#### Price Range of Common Stock

During 2008, the Company's common stock traded on the OTC Bulletin Board, sometimes referred to as the OTCBB, under the symbol "CLGY.OB." In April, 2009, and in connection with its merger with Adamis, the Company changed its common stock symbol to "ADMP" and the common stock currently trades on the OTCBB. The following table sets forth the range of high and low closing sales prices for the common stock as reported on The NASDAQ Small Cap Market and OTCBB for the periods indicated below. The prices in the table below reflect prices of the pre-reverse split shares of common stock and have not been adjusted to give effect to the Reverse Split of the common stock that occurred in April 2009.

	High	Low
<b>2007</b>		
First Quarter	\$ 0.10	\$ 0.03
Second Quarter	\$ 0.11	\$ 0.09
Third Quarter	\$ 0.09	\$ 0.06
Fourth Quarter	\$ 0.08	\$ 0.04
<b>2008</b>		
First Quarter	\$ 0.10	\$ 0.02
Second Quarter	\$ 0.10	\$ 0.04
Third Quarter	\$ 0.09	\$ 0.04
Fourth Quarter	\$ 0.07	\$ 0.01
<b>2009</b>		
First Quarter through March 31, 2009	\$ 0.07	\$ 0.02

As of April 15, 2009, there were approximately 245 holders of record common stock, excluding beneficial holders of stock held in street name.

#### Dividend Policy

We have never declared or paid any cash dividends on its common stock, and we do not intend to do so in the foreseeable future. Accordingly, the stockholders of the Company will not receive a return on their investment unless the value of the Company's shares increases, which may or may not occur. Any future determination to pay cash dividends will be at the discretion of the Company's board of directors and will depend upon its financial condition, operating results, capital requirements, any applicable contractual restrictions and such other factors as the Company's board of directors deems relevant.

#### Equity Compensation Plan Information

See the information under Item 12 of this Report, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters," which is incorporated herein by reference.

#### Recent Sales of Unregistered Securities

None.

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

Except where the context otherwise requires, the following discussion and analysis relates only to Old Cellegy and Old Cellegy's fiscal year ended December 31, 2008. It does not include financial results of Old Adamis or a discussion of any products or developments concerning the business of Old Adamis, except where specifically discussed. Following the April 1, 2009, effective date of the merger transaction between Cellegy and Adamis, the business of the Company will consist primarily of the business and intended business of Old Adamis.

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements and accompanying notes of the Company appearing elsewhere in this Report. This discussion of Cellegy's financial condition and results of operations contains certain statements that are not strictly historical and are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties that exist in Cellegy's operations, development efforts and business environment, including those set forth in this Item 7, and in the sections entitled "1A. Risk Factors" and "1. Business" in this Report and uncertainties described elsewhere in this Report. All forward-looking statements included in this Report are based on information available to the Company as of the date hereof, and except as may be required under the Securities Exchange Act of 1934 and the rules and regulations promulgated thereunder, the Company assumes no obligation to update any such forward-looking statement.

## General

The Company is a specialty biopharmaceutical company. Cellegy's operations during 2008 related primarily to the intellectual property rights relating to the Biosyn product candidates. Cellegy's wholly owned subsidiary, Biosyn, Inc., has intellectual property relating to a portfolio of proprietary product candidates known as microbicides. Cellegy's intellectual property consists primarily of commercialization and territorial marketing rights for its Savvy compounds as well as related patents, trademarks, license agreements, manufacturing and formulation technologies, past research and out-license arrangements with certain philanthropic and governmental organizations. Biosyn's product candidates, which include both contraceptive and non-contraceptive microbicides, are used intravaginally. Biosyn's product candidates include Savvy®, which underwent Phase 3 clinical trials in Ghana and Nigeria for reduction in the transmission of Human Immunodeficiency Virus/Acquired Immunodeficiency Disease, or HIV/AIDS, both of which were suspended in 2005 and 2006 and terminated before completion, and is currently in a Phase 3 contraception trial in the United States. Cellegy monitors the progress of the Savvy Phase 3 contraception trial in the United States and through communications with the clinical regulatory organization, or CRO, that is involved in the conduct of the trial and other parties involved in conducting the trial concerning matters such as the status and progress of the trial, enrollment numbers and rates of patient enrollment, issues that arise concerning conduct of the trial and anticipated timelines regarding the trial. Cellegy receives reports from the CRO concerning the progress of the trial, enrollment statistics and rates, any adverse events, people leaving the trial and other requests. Cellegy is required to prepare and file reports with the FDA and other applicable regulatory agencies concerning both the current contraception trial and its suspended HIV trials. While the Savvy Phase 3 contraception trial in the United States has been completed and the analysis of the results is expected to be completed by the end of 2009, Cellegy is not directly involved with the conduct and funding thereof, and it is uncertain whether Savvy will be commercialized or whether Cellegy will ever realize revenues therefrom.

On August 28, 2006, Cellegy announced that Family Health International planned to stop the Savvy Phase 3 trial being conducted in Nigeria with enrollment of approximately 2,000 patients, to determine whether Savvy is safe and effective for reducing women's risk of acquiring HIV infection. In November 2005, a similar trial being conducted in Ghana with enrollment of approximately 2,100 patients was stopped for similar reasons. Each of the trials was part of an international effort to evaluate microbicides as a tool to reduce the risk of HIV infection in people at high risk. The decision to stop these trials followed recommendations by the studies' external independent Data Monitoring Committee, or DMC. After reviewing the study interim data, DMC members concluded that the trials as designed were unlikely to provide statistically significant evidence that Savvy protects against HIV, because of a lower than expected rate of HIV seroconversion in the trial, which was less than half of the expected rate. This lower rate was possibly due in part to procedures designed to ensure ethical trial design, including counseling on HIV prevention and distribution of condoms. Without obvious signals of effectiveness in the interim data, the study would be unlikely to detect a reduction in the HIV risk at a level deemed statistically significant if it were to continue. On September 12, 2007, FHI released the final results of two clinical trials halted in November 2005 and August 2006 that examined the safety and effectiveness of Savvy® (C31G vaginal gel) as a potential microbicide for the prevention of male-to-female transmission of HIV among women at high risk of infection. The trials—in Ghana and Nigeria—were unable to show that Savvy® was more effective than a placebo gel. The FHI release noted that the trial results possibly were influenced by the fact that all participants, including those receiving the placebo gel, received risk reduction counseling and condoms.

On November 28, 2006, Cellegy completed the sale to ProStrakan for \$9.0 million of its rights to Cellegesic, Fortigel, Tostrex, Rectogesic, Tostrelle, and related intellectual property assets. ProStrakan also assumed various existing distribution and other agreements relating to the assets and intellectual property. Cellegy's stockholders approved the transaction at a special meeting of stockholders held on November 22, 2006.

On October 18, 2007, Cellegy and CONRAD amended their license agreement to modify the non-exclusive license grant to CONRAD covering Cellegy's intellectual property relating to its UC-781 technology to an exclusive license; the general field and permitted uses, covering the public sector and only in developing countries, were not changed.

## Critical Accounting Policies and 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.

*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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

*Research and Development.* Research and development expenses include expenses associated with regulatory filings for ongoing clinical trials and are charged to expense as they are incurred.

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 expenses. 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 consist of demand deposits and short term money market funds. The carrying value of cash and cash equivalents approximates fair value as of December 31, 2008 and 2007. As of December 31, 2008, the Company's cash and cash equivalents are maintained at two financial institutions in the United States. Deposits in these financial institutions may, from time to time, exceed federally insured limits.

*Concentration of Credit Risk.* As of December 31, 2008, the Company had its cash in demand deposits and in money market funds.

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

	<u>Estimated Useful Lives</u>
Furniture and fixtures	3 years
Office equipment	3 years

*Stock-based Compensation.* For the years ended December 31, 2008 and 2007, for stock options granted prior to the adoption of SFAS No. 123R, there is no difference between reported amounts and pro forma net loss and basic and diluted income per common share if compensation expense for the Company's various stock option plans had been determined based upon estimated fair values at the grant dates in accordance with SFAS No. 123.

Cellegy values its options on the date of grant using the Black-Scholes valuation model. The Company did not grant any stock options during 2008 and 2007.

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

*Accounting for Merger Related Costs.* For the year ended December 31, 2008, Cellegy incurred certain accounting, legal and other filing costs in conjunction with its pending merger with Adamis. These costs were expensed as incurred.

## Results of Operations

Statements below concerning expected future expenses or other activities relate to Cellegy on a standalone basis and do not give any effect to the proposed merger transaction with Adamis.

### *Years Ended December 31, 2008 and 2007*

Research and development expenses include expenses associated with regulatory filings for ongoing clinical trials and are charged to expense as they are incurred.

Cellegy had no research and development expenses in 2008. Research and development expenses were approximately \$23,000 in 2007. Research and development expenses, which were primarily related to the costs of clinical trials and/or regulatory filings, represented 1% of our total operating expenses in 2007. Cellegy expects that research and development spending will be conducted for the foreseeable future in connection with the development of Adamis product candidates.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses (“SG&A”) were approximately \$1,322,000 and \$1,799,000 in 2008 and 2007, respectively. SG&A expenses decreased approximately \$477,000 as compared to 2007 due primarily to additional staff reductions, lower rent expense, lower legal, accounting and other professional fees and generally lower expense levels overall due to the reduced level of business activities in 2008. The overall decrease in SG&A expense levels in 2008 was somewhat offset by merger related legal and accounting fees incurred in 2008.

*Other Income (Expense).* Cellegy recognized interest and other income of approximately \$59,000, in 2008 and \$93,000, in 2007. Included in 2008 is interest income of approximately \$44,000 recorded in connection with the note receivable issued to Adamis. Included in 2007 is a gain on forgiveness of debt of approximately \$5,000. The overall decrease in interest income is due to the lower level of invested cash in 2008.

Cellegy recognized interest and other expense of approximately \$271,000 in 2008 and \$198,000 in 2007. Interest expense recorded in each year related primarily to interest accreted in connection with the Ben Franklin note.

### *Liquidity and Capital Resources*

Our cash and cash equivalents were approximately \$129,000 and \$1,800,000 at December 31, 2008 and 2007, respectively. Cash and cash equivalents decreased approximately \$1.7 million during 2008 as compared to 2007 due primarily to operating expenses incurred in connection with Cellegy’s present level of operations and merger expenses.

Net cash used in operating activities for 2008 and 2007 were approximately \$1.2 million and \$1.9 million, respectively, due primarily to Cellegy’s current level of operations and merger and acquisition costs. The Company expects net cash used in operating activities to increase going forward following the merger transaction with Adamis as it completes product development, launches new products, engages in additional product research and development activities and pursues additional expansion of its sales base and other business activities.

Net cash used in investing activities was \$500,000 for 2008, which related to the promissory note issued to Adamis in connection the merger agreement.

Net cash used in financing activities was \$40,000 in 2007, which related to the settlement and repayment of a promissory note with MPI, Inc.

On February 12, 2008, Cellegy entered into a definitive merger agreement providing for the acquisition of Cellegy by Adamis Pharmaceuticals Corporation. In connection with the signing of the merger agreement, Cellegy issued to Adamis an unsecured convertible promissory note pursuant to which Cellegy agreed to lend Adamis \$500,000 to provide funds to Adamis during the pendency of the merger transaction. Any principal outstanding under the promissory note accrues interest at 10% per annum. On April 1, 2009, Cellegy completed the merger transaction with Adamis. In connection with the closing of the merger transaction, the promissory note converted into shares of Adamis stock, and these shares were immediately cancelled.

We prepared the consolidated financial statements assuming that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. In preparing these consolidated financial statements, consideration was given to Cellegy's future business alternatives as described below, which may preclude Cellegy from realizing the value of certain assets during their future course of business.

Before the effectiveness of the merger transaction with Adamis, Cellegy's operations related primarily to the management of intellectual property rights of its Biosyn subsidiary and the administration of the clinical and regulatory affairs of its Savvy Phase 3 contraception and trial. The Savvy Phase 3 contraception trial in the United States has been completed and the analysis of the results is expected to be completed by the end of 2009. It is uncertain as to whether Savvy will be commercialized or whether Cellegy will ever realize revenues therefrom.

Following completion of the Adamis merger transaction, we expect future cash flows to be derived primarily from sales of Adamis' products.

The Company will require additional cash resources to continue operations at substantially their current level during 2009, assuming no unexpected expenses. The Company expects to finance future cash needs primarily through proceeds from equity or debt financings, loans, and/or collaborative agreements with corporate partners. Even if development and marketing efforts are successful for the Company's new products, substantial time may pass before significant revenues will be realized, and during this period the Company will require additional funds, the availability of which cannot be assured. Consequently, the Company is subject to the risks associated with early stage companies, including the need for additional financings; the uncertainty of research and development efforts resulting in successful commercial products, as well as the marketing and customer acceptance of such products; competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; and dependence on corporate partners and collaborators. To achieve successful operations, the Company will require additional capital to continue research and development and marketing efforts. No assurance can be given as to the timing or ultimate success of obtaining future funding.

Additional financing will be required to satisfy existing obligations, liabilities and future working capital needs, to build working capital reserves to support product development and marketing efforts for the Adamis Labs products, continue product research and development on vaccine technology, and fund any product or company acquisition opportunities, and cash flow from the Adamis Labs' operations are not expected to provide sufficient cash to fund the Company's overall cash requirements for the foreseeable future. The Company's future capital requirements will also depend upon numerous factors, including the following:

- the progress and costs of development programs;
- the commercial success of new products that are introduced;
- patient recruitment and enrollment in future clinical trials;
- the scope, timing and results of pre-clinical testing and clinical trials;
- the costs involved in seeking regulatory approvals for product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations and strategic alliances;
- the cost of manufacturing and commercialization activities;
- the results of operations;
- the cost, timing and outcome of regulatory reviews;

- the rate of technological advances;
- ongoing determinations of the potential commercial success of products under development;
- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

To obtain additional capital when needed, the Company will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements; however, there can be no assurance that funding will be available on favorable terms, if at all. There are no assurances that the Company will be able to successfully develop its products under development or that its products, if successfully developed, will generate revenues sufficient to enable it to earn a profit. If the Company is unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of development efforts that may appear to be promising to the Company, the sale of certain assets and the reduction in overall operating activities. If adequate funding is not obtained, the board of directors might also be required to explore other alternatives for the Company's business and assets. These alternatives might include seeking the dissolution and liquidation of the Company, seeking to merge or combine with another company, selling or licensing some of the Company's intellectual property, or initiating bankruptcy proceedings. There can be no assurance that any third party will be interested in merging with the Company or would agree to a price and other terms that the Company would deem adequate. If the Company filed for bankruptcy protection, the Company would most likely not be able to raise any type of funding from any source. In that event, the creditors of the Company would have first claim on the value of the assets of the Company which, other than remaining cash, would most likely be liquidated in a bankruptcy sale. The Company can give no assurance as to the magnitude of the net proceeds of such sale and whether such proceeds would be sufficient to satisfy the Company's obligations to its creditors, let alone to permit any distribution to its equity holders.

Cellegy has incurred recurring losses from operations and has negative working capital, liabilities that exceed its assets and recurring cash flow deficiencies. All of the above factors, among others, raise substantial doubt about our ability to continue as a going concern. The condensed consolidated 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 business combination or other agreements, therefore making it more difficult to obtain required financing on favorable terms or at all. Such an outcome may 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.

#### **Off Balance Sheet Arrangements**

At December 31, 2008, the Company did not have any off balance sheet arrangements.

#### **Recent Accounting Pronouncements**

##### *SFAS No. 157, Fair Value Measurements*

SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), has been issued by the Financial Accounting Standards Board (the "FASB"). This new standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value but does not expand the use of fair value in any new circumstances. Currently, over 40 accounting standards within GAAP require (or permit) entities to measure assets and liabilities at fair value. The standard clarifies that for items that are not actively traded, such as certain kinds of derivatives, fair value should reflect the price in a transaction with a market participant, including an adjustment for risk, not just the Company's mark-to-model value. SFAS 157 also requires expanded disclosure of the effect on earnings for items measured using unobservable data. Under SFAS 157, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. In this standard, FASB clarified the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, SFAS 157 establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, for example, the reporting entity's own data. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy.

In February 2008, the FASB issued FSP SFAS No. 157-1, "Application of FASB Statement No. 157 to FASB Statement No. 13 and Its Related Interpretive Accounting Pronouncements That Address Leasing Transactions," and FSP SFAS No. 157-2, "Effective Date of FASB Statement No. 157." FSP SFAS No. 157-1 removes leasing from the scope of SFAS No. 157. FSP SFAS No. 157-2 delays the effective date of SFAS No. 157 for the Company from its fiscal 2009 to its fiscal 2010 year for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The Company does not expect its adoption of the provisions of FSP SFAS No. 157-1 and FSP SFAS No. 157-2 will have a material effect on its financial condition, results of operations or cash flows.

In February 2007, FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities." Under SFAS No. 159, a company may elect to measure at fair value various eligible items that are not currently required to be so measured. Eligible items include, but are not limited to, accounts receivable, available-for-sale securities, equity method investments, accounts payable and firm commitments. SFAS No. 159 is effective in fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of its fiscal 2009 year.

#### *SFAS No. 141 (Revised 2007), Business Combinations*

On December 4, 2007, the FASB issued SFAS No. 141 (Revised 2007), *Business Combinations* ("SFAS 141R"). Under SFAS 141R, an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition date fair value with limited exceptions. SFAS 141R will change the accounting treatment for certain specific items, including:

- acquisition costs will be generally expensed as incurred;
- non-controlling interests will be valued at fair value at the acquisition date;
- acquired contingent liabilities will be recorded at fair value at the acquisition date;
- in-process research and development will be recorded at fair value as an indefinite-lived intangible asset at the acquisition date until the completion or abandonment of the associated research and development efforts;
- restructuring costs associated with a business combination will be generally expensed subsequent to the acquisition date; and
- changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense.

SFAS 141R also includes a substantial number of new disclosure requirements. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Earlier adoption is prohibited.

#### *SFAS No. 160, "Non-controlling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51"*

On December 4, 2007, the FASB issued SFAS No. 160, "Non-controlling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51" ("SFAS 160"). SFAS 160 establishes new accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a non-controlling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the non-controlling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the non-controlling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its non-controlling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited.



In June 2007, the FASB ratified EITF Issue No. 07-3, “Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities.” EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development activities to be recorded as an asset and expensing the payments when the research and development activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into in fiscal years beginning after December 15, 2007. The Company currently recognizes these non-refundable advanced payments as an asset upon payment, and expenses costs as goods are used and services are provided. There was no effect on the Company’s financial statement from the adoption of this pronouncement.

In July 2006, the FASB issued FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes, an Interpretation of SFAS No. 109, Accounting for Income Taxes,” (“FIN 48”) which clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet and the measurement attribute for financial statement disclosure of tax positions taken or expected to be taken on a tax return. The Company adopted FIN 48 effective on January 1, 2007 , and there was no material effect on its results of operations or financial position.

## **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-18 of this report.

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

None.

## **ITEM 9A(T): CONTROLS AND PROCEDURES**

### *Evaluation of Disclosure Controls and Procedures*

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) as of the end of the period covered by this Form 10-K. Based on their evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures were effective.

### *Internal Control over Financial Reporting*

Management’s report on Cellegy’s internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) in the Exchange Act), is included in this Annual Report on Form 10-K, under the headings, “Management’s Annual Report on Internal Control Over Financial Reporting” and is incorporated herein by reference. This report shall not be deemed to be filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, unless Cellegy specifically states that the report is to be considered “filed” under the Exchange Act or incorporates it by reference into a filing under the Securities Act of the Exchange Act.

### *Management’s Annual Report on Internal Control over Financial Reporting*

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

With the participation of the Chief Executive Officer and the Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework and criteria established in *Internal Control—Integrated Framework*, issued by the Committee of Sponsoring Organizations (“COSO”) of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2008.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to the attestation by our registered public accounting firm pursuant to the rules of the SEC that permit us to provide only management’s report in this Annual Report.

#### *Changes in Internal Controls*

There have been no changes in Cellegy’s internal controls over financial reporting during the Company’s fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, Cellegy’s internal controls over financial reporting.

#### **ITEM 9B: OTHER INFORMATION**

None.

### **PART III**

#### **ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

##### **Directors**

As of December 31, 2008, the board of directors of Cellegy consisted of five persons: Richard C. Williams; Tobin B. Klar, M.D.; John Q. Adamis, Sr.; Robert B. Rothermel; and Thomas M. Steinberg. In connection with the closing of the merger of Cellegy and Adamis, effective April 1, 2009, Ms. Klar and Mr. Steinberg resigned from the board of directors and Dennis J. Carlo, Richard L. Aloï and David J. Marguglio, all of whom were directors and officers of Adamis, were appointed directors of the Company. Directors serve until the next meeting of stockholders of the Company or until their respective successors are elected and qualified or until the death, resignation or removal of the director.

The following table set forth certain information concerning the current directors of the Company:

<b>Name</b>	<b>Age</b>	<b>Principal Occupation</b>	<b>Director Since</b>
Richard C. Williams	65	President, Conner-Thoele Ltd.; Chairman of the Board of Directors	2003
John Q. Adams, Sr. (1)(2)(3)	71	President, J.Q. Enterprises	2003
Richard L. Aloï	54	President, Adamis Laboratories	2009
Dennis J. Carlo	65	Chief Executive Officer, Adamis Pharmaceuticals	2009
David J. Marguglio	38	Vice President of Business Development and Investor Relations, Adamis	2009
Robert B. Rothermel(1)	65	Partner, CroBern Management Partnership	2004

(1) Member of Audit Committee.

(2) Member of Compensation Committee.

(3) Member of Nominating and Governance Committee.

Following the merger transaction between Cellegy and Adamis, the board of directors (the “Board”) of the Company intends to review the composition of the committees of the Board and appoint additional members of the current board to various committees. Until additional members are appointed to these committees, the functions of the compensation committee and the nominating and governance committee will be performed by the Board with the directors who are also employees of the Company not participating in voting with respect to matters relating to such functions.

*Richard C. Williams.* Mr. Williams became Chairman and Interim Chief Executive Officer in January 2005. He first joined the Company 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 from 2000 to 2001 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 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 Q. Adams, Sr.* Mr. Adams became a director of the Company in November 2003. He is President of J.Q Enterprises, a holding company for his interests. He has had a long career in the pharmaceutical industry and has started three companies: Baylor Laboratories, sold to Norwich Eaton Pharmaceuticals; his second company, Allerderm, Inc., sold to Virbac Inc. in France; and Adams Laboratories, a pharmaceutical company focused on respiratory therapy, sold to Medeva Pharmaceuticals, where from 1991 to 1995, Mr. Adams was a director and was also President of Medeva Americas. Mr. Adams later repurchased Adams Laboratories from Medeva in 1997 and served as Chairman and CEO; he resigned as CEO in May 2003. Adams Laboratories was renamed Adams Respiratory Therapeutics, Inc. and became a public company in 2005, and Mr. Adams resigned in October 2005 as Chairman of the Board. He currently serves on the Board of Directors of Respirics, Inc. a private company based in North Carolina. He also retains memberships and board positions in several professional and philanthropic organizations including the American College of Allergy. He is also an Honorary Fellow of the American Academy of Otolaryngology-Head and Neck Surgery. Mr. Adams holds a degree in Biology from Heidelberg College and was elected to the board of trustees in 2006.

*Richard L. Aloï.* Mr. Aloï became an officer and a director of the Company in April 2009 in connection with the closing of the merger transaction between Cellegy and Adamis. He is President of Adamis Laboratories. He joined Adamis in connection with Adamis’ acquisition of Adamis Labs in April 2007. He founded Aero Pharmaceuticals in 1997 and served as its President from 1997 to 2007. He developed Aero into a distributor of allergen extracts and related products, and managed Aero’s transition to a specialty pharmaceutical provider. From 1979 to 1997, before founding Aero, Mr. Aloï was Director of Sales and Marketing at Center Laboratories (a division of E. Merck), a manufacturer of allergenic extracts and prescription respiratory products, including the market leading epinephrine auto-injector. At Center Laboratories, Mr. Aloï oversaw a 50-person marketing group which included over 35 field sales representatives. His earlier positions within Center Laboratories included Sales Representative, Regional Manager, and National Sales Manager. Mr. Aloï has served in leadership and advisory roles for industry groups, including the Allergen Product Manufacturers Association, the American College of Allergy Asthma & Immunology, and the American Academy of Allergy Asthma & Immunology. Mr. Aloï received a B.A. in Political Science from Boston College in 1976.

*Dennis J. Carlo, Ph.D.* Dr. Carlo became Chief Executive Officer and a director of the Company in April 2009 in connection with the closing of the merger transaction between Cellegy and Adamis. He has been Adamis’ President Chief Executive officer since October 2006. From 1982 to 1987, he served as Vice President of Research and Development and Therapeutic Manufacturing at Hybritech Inc., which was acquired by Eli Lilly & Co in 1985. After the sale to Lilly, Dr. Carlo, along with Dr. Jonas Salk, James Glavin and Kevin Kimberland, founded Immune Response Corporation, a public company, where he served as its President and Chief Executive Officer from 1994 to 2002. He served as president of Telos Pharmaceuticals, a private biotechnology company, from 2003 to 2006. Dr. Carlo has extensive experience in the development of vaccines and biologics. Early in his career, as Director of developmental and basic cellular immunology and Director of bacterial vaccines and immunology at Merck & Co., he oversaw research and product development for PNEUMOVAX (14-valent polysaccharide vaccine), MENINGOVAX A, MENINGOVAX C, MENINGOVAX A-C, and *H. influenza* type b, and also directed a multi-disciplinary task force whose goal was the development of novel adjuvants. At Hybritech, he managed a successful program to carry out research and development in the area of monoclonal antibody and cancer therapy. At Immune Response Corporation, he established a program for an AIDS therapeutic vaccine and led the product development in clinical trials. Dr. Carlo received a B.S. degree in microbiology from Ohio State University and has a Ph.D. in Immunology and Medical Microbiology from Ohio State University.

*David J. Marguglio* . Mr. Marguglio became Vice President of Business Development and Investor Relations and a director of the Company in April 2009 in connection with the closing of the merger transaction between Cellegy and Adamis. He has been Adamis' Vice President of Business Development and Investor Relations since its inception in June 2006. From 1996 to 2006, he has held various positions of Vice President with Citigroup Global Markets, Smith Barney and Merrill Lynch. Before entering the financial industry, from 1994 to 1996, he founded and ran two different startup companies, the latter of which was eventually acquired by a Fortune 100 company. From 1993 to 1994, he served as financial counsel for the commercial litigation division of a national law firm. Mr. Marguglio is a licensed securities representative, securities agent, and investment advisor. He received a degree in finance and business management from the Hankamer School of Business at Baylor University.

*Robert B. Rothermel*. Mr. Rothermel became a director of the Company in January 2004. He is currently a partner of CroBern Management Partnership, a healthcare management and venture capital firm. In November 2002, he retired from Deloitte & Touche, where in his last position, he was the global leader of the firm's Enterprise Risk Services practice. He previously served as the lead audit engagement partner for several multi-national corporations, and has led professional services in specialty areas such as IPOs, acquisitions, divestitures, restructurings, and litigation. Mr. Rothermel holds a B.S. degree in business administration from Bowling Green State University.

## Board Composition

The board of directors, sometimes referred to as the Board, and the Nominating and Governance Committee of the Board, have each determined that Messrs. Adams and Rothermel and, during 2008 and the period in 2009 during which they served as directors, Mr. Steinberg and Ms. Klar qualify as independent directors in accordance with the listing requirements of the NASDAQ Stock Market, or NASDAQ, based on representations from each director that they meet the relevant NASDAQ and SEC definitions and a review of any relevant transactions or relationships between each director, any member of his or her family, and the Company, its senior management and its independent registered public accounting firm. The NASDAQ definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director, nor any of his family members, has engaged in various types of business dealings with us. In addition, the board and the committee made a subjective determination as to each independent director that no relationship exists that, in the opinion of the board or the committee, would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, the Company's directors reviewed and discussed information provided by the directors and the Company with regard to each director's business and personal activities as they may relate to the Company and its management.

## Executive Officers

In connection with the closing of the merger transaction between Cellegy and Adamis, Richard C. Williams resigned as interim chief executive officer of the Company and Robert J. Caso resigned as vice president and chief financial officer of the Company.

Cellegy's current executive officers include the following persons:

Name	Age	Position
Dennis J. Carlo, Ph.D.	65	President and Chief Executive Officer
Richard L. Aloï	54	President, Adamis Laboratories
Robert O. Hopkins	48	Vice President, Finance and Chief Financial Officer
David J. Marguglio	38	Vice President of Business Development and Investor Relations

Information concerning Messrs. Carlo, Aloï and Marguglio appears above under the heading, "Directors."

*Robert O. Hopkins*. Mr. Hopkins became Vice President, Finance and Chief Financial Officer of the Company in connection with the closing of the merger transaction between Cellegy and Adamis. He joined Adamis in April 2007 as Vice President, Finance and Chief Financial Officer. From 2000 to 2004, he was an Executive Vice President and the Chief Financial Officer of Chatham Capital Corp. In that position he managed financial operations for a corporation that held several hospitals, an extensive life sciences operation and a number of other business units within its portfolio. Mr. Hopkins served as Chief Financial Officer of Veritel Corp from 1999 and 2000, a biometric software company. He has also served as Chief Operating Officer for Circle Trust Company from 2004 to 2005, during which time he was responsible for corporate reorganization after acquiring a troubled trust company. From 2005 until Mr. Hopkins joined Adamis in April 2007, he consulted for Acumen Enterprises providing analysis and business plans for the various projects with which the company was involved. From 1997 to 1999, Mr. Hopkins was Senior Vice President for Finance for the Mariner Post-Acute Network, Atlanta, Georgia. In this position he was responsible for financial management of a division consisting of 12 long-term, acute care hospitals. Among his previous medical-related experience, he has served as Assistant Administrator of Finance for Kindred Hospitals; President and Chief Executive Officer of Doctors Hospital of Hyde Park; and Vice President of Accounting for Cancer Treatment Centers of America. Mr. Hopkins received a B.S. degree in Finance from Indiana State University and an M.B.A. from Lake Forest Graduate School of Management.

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

## **Board of Directors Meeting Attendance and Committees**

During the fiscal year ended December 31, 2008, the board held two meetings. Except for Ms. Klar, each person who was a director during fiscal 2008 participated in at least 75% or more of the aggregate number of the meetings of the Board held during the time that such person was a director and any committee on which he or she served.

Standing committees of the Board include an Audit Committee, a Nominating and Governance Committee and a Compensation Committee.

### **Audit Committee**

Messrs. Adams, Rothermel and Steinberg were the members of the Audit Committee during 2008. The current members of the committee are Mr. Adams and Mr. Rothermel. During 2008 Mr. Rothermel was the chair of the committee. During fiscal 2008 the Audit Committee held four meetings. The Audit Committee assists the full Board in its general oversight of our financial reporting, internal controls and audit functions, and is directly responsible for the appointment, compensation and oversight of the work of our independent registered public accounting firm. Subject to an approved charter, the Audit Committee reviews our financial results, accounting practices, internal control systems and the fee arrangements with our independent auditors as well as their independence and performance, and meets with our independent auditors concerning the scope and terms of their engagement and the results of their audits. The Board has determined that each member of the Audit Committee is “independent” as defined by the applicable NASDAQ rules and by the Sarbanes-Oxley Act of 2002 and regulations of the SEC, and that Mr. Rothermel qualifies as an “audit committee financial expert” as defined in such regulations. The Board has adopted a written charter for the Audit Committee, a copy of which was filed as an exhibit to the Proxy Statement.

### **Compensation Committee**

Messrs. Adams and Steinberg were the members of the Compensation Committee during 2008 and 2009 until the merger transaction with Adamis when Mr. Steinberg resigned as director. The Board has determined that each member of the Compensation Committee during 2008 is “independent” as defined in the applicable NASDAQ Listing Standards. The Compensation Committee did not meet during 2008. The compensation committee has adopted a written charter, a copy of which was filed as an exhibit to the Proxy Statement. Our compensation committee assists the Board in reviewing compensation arrangements for executive officers. Principal functions of the compensation committee include: (i) reviewing and recommending approval of compensation arrangements (including severance provisions) of our chief executive officer and our other executive officers; (ii) to the extent the Board delegates such authority to the committee, administering our equity incentive plans and agreements; (iii) reviewing and making recommendations to the Board with respect to incentive compensation and equity plans; and (iv) performing other duties regarding compensation for employees and consultants as the Board may from time to time delegate to the committee. Subject to provisions of any applicable employment agreements, the compensation committee typically reviews base salary levels and total compensation for executive officers at least annually. With respect to equity compensation, the compensation committee or the Board grants stock options or other equity awards, often after receiving a recommendation from our chief executive officer (except in the case of awards to the chief executive officer). The compensation committee has authority to retain its own compensation consultants and to obtain advice and assistance from internal or external legal, accounting or other advisors. The committee did not retain any compensation consultants in connection with establishing compensation levels for officers for 2008. Management plays a role in the compensation-setting process. The most significant aspects of management’s role are to evaluate employee performance and recommend salary levels and equity compensation awards. Our chief executive officer usually makes recommendations to the compensation committee and the Board concerning compensation for other executive officers. Our chief executive officer is a member of the Board but does not participate in Board decisions regarding any aspect of his own compensation. The compensation committee administers the Company’s incentive and equity plans, including the 1995 Equity Incentive Plan, 1995 Directors’ Stock Option Plan, the 2005 Equity Incentive Plan and the 2009 Equity Incentive Plan.

None of the members of the Compensation Committee during 2008 served during 2008 on the compensation committee (or equivalent), or the board of directors, of another entity whose executive officer(s) served on our Compensation Committee or board of directors.

### **Nominating and Governance Committee**

Messrs. Adams and Steinberg and Dr. Klar were the members of the Nominating and Governance Committee during 2008 and 2009 until the merger transaction with Adamis when Mr. Steinberg resigned as director. Dr. Klar was the chair of the committee during that time. The Board has determined that the members of the committee during 2008, were “independent” as defined in the applicable NASDAQ Listing Standards. The committee did not meet during 2008. Subject to an approved charter, the general functions of the Nominating and Governance Committee are (i) to recruit, evaluate and nominate candidates to be presented for appointment or election to serve as members of the Board, (ii) to recommend nominees for Board committees, (iii) to recommend corporate governance guidelines applicable to the Company, and (iv) to review the Board’s performance. The nominating and governance committee has adopted a written charter, a copy of which was filed as an exhibit to the Proxy Statement.

### **Director Nomination Process**

The Nominating and Governance Committee will consider director candidates recommended by stockholders. Stockholders who wish to recommend to the committee candidates for election to the Board of Directors must do so in writing. The recommendation should be sent to the Secretary of the Company, 2658 Del Mar Heights Road, Del Mar, CA 92014, who will, in turn, forward the recommendation to the Nominating and Governance Committee. The recommendation must set forth (i) the name and address as they appear on the Company’s books of the stockholder making the recommendation and the class and number of shares of capital stock of the Company beneficially owned by such stockholder and (ii) the name of the candidate and all information relating to the candidate that is required to be disclosed in solicitations of proxies for election of directors under the federal proxy rules. The recommendation must be accompanied by the candidate’s written consent to being named in the Company’s proxy statement as a nominee for election to the Board and to serving as a director, if elected. Stockholders must also comply with all requirements of the Company’s bylaws with respect to nomination of persons for election to the Board of Directors. The Company may also require any proposed nominee to furnish such other information as the Company or the committee may reasonably require to determine the eligibility and qualifications of the nominee to serve as a director. In performing its evaluation and review, the committee generally does not differentiate between candidates proposed by stockholders and other proposed nominees, except that the committee may consider, as one of the factors in its evaluation of stockholder recommended candidates, the size and duration of the interest of the recommending stockholder or stockholder group in the equity of the Company.

The Nominating and Governance Committee believes that persons nominated for election to the board of directors should possess sufficient business or financial experience and a willingness to devote the time and effort necessary to discharge the responsibilities of a director. This experience can include, but is not limited to, service on other boards of directors or active involvement with other boards of directors and experience in the industry in which the Company conducts its business. In addition to the above criteria (which may be modified from time to time), the committee may consider such other factors as it deems in the best interests of the company and its stockholders or that it believes may enhance the effectiveness and responsiveness of the Board and its committees. The committee believes that the qualifications and strengths of an individual in totality, rather than any specific factor, should be primary, with a view to nominating persons for the election to the Board of Directors whose backgrounds, integrity, and personal characteristics indicate that they will make a contribution to the Board of Directors. The Company is generally of the view that the continuing service of qualified incumbents promotes stability and continuity in the board room, giving the Company the benefit of the familiarity and insight into the Company’s affairs that its directors have accumulated during their tenure, while contributing to the Board’s ability to work as a collective body. Accordingly, it is the general policy of the committee, absent special circumstances, to nominate qualified incumbent directors who continue to satisfy the committee’s criteria for membership on the Board, whom the committee believes will continue to make important contributions to the Board and who consent to stand for reelection and, if reelected, to continue their service on the Board. The committee will review and evaluate each candidate who it believes merits serious consideration, taking into account all available information concerning the candidate, the qualifications for Board membership established by the committee, the existing composition and mix of talent and expertise on the Board and other factors that it deems relevant. In conducting its review and evaluation, the committee may solicit the views of management and other members of the Board and may, if deemed helpful, conduct interviews of proposed candidates.

The Nominating and Governance Committee intends to identify candidates for election to the Board of Directors through the personal knowledge and experience of the members of the committee and third-party recommendations. To date, the committee has not retained or paid any third party to identify or evaluate, or assist in identifying or evaluating, potential director nominees, although it reserves the right to do so. New candidates will be evaluated based upon their backgrounds and/or interviews with members of the committee. The Nominating and Corporate Governance Committee may request references and additional information from the candidate prior to reaching a conclusion. Once a candidate has been identified, the committee reviews the individual's experience and background, and may discuss the proposed nominee with the source of the recommendation. The committee is under no obligation to formally respond to recommendations, although as a matter of practice, it will attempt to do so.

The Company did not receive any recommended nominations from stockholders in connection with the Company's annual meeting of stockholders held on March 23, 2009.

### **Stockholder Communication Policy**

Stockholders may send communications to the Board of Directors or individual members of the Board of Directors by writing to them, care of Secretary, Adamis Pharmaceuticals Corporation, 2658 Del Mar Heights Rd., #555, Del Mar, CA 92014, who will forward the communication to the intended director or directors. If the stockholder wishes the communication to be confidential, then the communication should be provided in a form that will maintain confidentiality.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, file reports of ownership and changes in ownership (Forms 3, 4 and 5) with the SEC. Executive officers, directors and greater-than-10% holders are required to furnish us with copies of all of these forms which they file.

Based solely on our review of these reports or written representations from certain reporting persons, we believe that during 2008, all filing requirements applicable to our officers, directors, greater-than-10% beneficial owners and other persons subject to Section 16(a) of the Exchange Act were met.

### **Code of Business Conduct and Ethics**

The Board has adopted a Code of Business Conduct and Ethics that applies to all directors, officers and employees of the company. The company will provide any person, without charge, a copy of the Code. Requests for a copy of the Code may be made by writing to the Company at Adamis Pharmaceuticals Corporation, 2658 Del Mar Heights Rd., #555, Del Mar, CA Attention: Chief Financial Officer. The Company intends to disclose any amendment to, or a waiver from, a provision of its code of business conduct and ethics that applies to its principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of its code of business conduct and ethics by posting such information on its website, which is expected to be [www.adamispharmaceuticals.com](http://www.adamispharmaceuticals.com).

## **ITEM 11: EXECUTIVE COMPENSATION**

### **Summary Compensation Table**

All share, per share and exercise price numbers and amounts in this Item have been adjusted to reflect the 1:9.929060333 reverse split of the Company's outstanding common stock effected on April 1, 2009 in connection with the closing of the merger transaction between Cellegy and Adamis.

The following table sets forth all compensation awarded, earned or paid for services rendered in all capacities to Cellegy during fiscal year 2008 and 2007 to (i) each person who served as Cellegy's chief executive officer during 2008, or "CEO," (ii) each person who served as Cellegy's principal financial officer, or CFO, during 2008, (iii) the three most highly compensated officers other than the chief executive officer and principal financial officer who were serving as executive officers at the end of 2008 and whose total compensation for such year exceeded \$100,000 (of which there were no such persons), and (iv) up to two additional individuals for whom disclosures would have been provided in this table, but for the fact that such persons were not serving as executive officers as of the end of 2008 (collectively with the CEO and CFO, referred to as the "Named Officers").

Name and Principal Position	Year	Salary(\$)	Bonus(\$)	Option Awards\$(1)	All Other Compensation (\$)	Total (\$)
Richard C. Williams Chairman and Interim Chief Executive Officer	2008	\$ 273,770	\$ —	\$ —	\$ —	\$ 273,770
	2007	294,022	—	—	—	294,022
Robert J. Caso Vice President, Chief Financial Officer	2008	182,103			100,000(2)	282,103
	2007	200,000		29,207	—	229,207

(1) The amounts in this column represent amounts recognized for financial reporting purposes in 2008 and 2007 in accordance with SFAS 123(R). Mr. Caso has an option to purchase 10,072 shares of common stock at an exercise price of \$17.38 per share. The option is fully vested.

(2) Includes a retention payment made to Mr. Caso in July 2008 of \$100,000.

In 2008, the following actions were taken concerning the compensation of our Named Officers:

- We did not pay any bonuses in 2009 with respect to the 2008 year, and we did not pay any bonuses to any Named Officer with respect to the 2008 year. In order to induce Mr. Caso to remain with Cellegy, in November 2007, we entered into a retention arrangement and made a retention payment of \$100,000 to Mr. Caso in July 2008.
- We did not make any option or other equity awards to any of the Named Officers during 2007, or 2008.

#### **Outstanding Equity Awards at Fiscal Year-End**

The following table provides information as of December 31, 2008 regarding unexercised stock options held by each of our Named Officers.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Richard C. Williams	60,429	—	\$ 49.65	11/06/2013
	40,286	—	28.70	11/06/2013
Robert J. Caso	6,715(1)	3,357	17.38	03/30/2015

(1) The shares of common stock underlying this option vest in three equal annual installments beginning March 30, 2006. The option is currently fully vested.

#### **Potential Payments Upon Termination or Change in Control**

Cellegy had an employment agreement with Robert J. Caso, who became our Chief Financial Officer in March 2005 and who resigned effective April 1, 2009 in connection with the merger transaction between Cellegy and Adamis. On November 14, 2007, Cellegy and Mr. Caso entered into a retention agreement. The agreement provides that if Mr. Caso does not voluntarily terminate his employment with Cellegy and is not terminated for cause or performance related reasons (or as result of death or disability), in each case before the earlier to occur of (i) June 30, 2008 and (ii) the closing of a change in control transaction (as defined in the agreement), such period referred to as the Retention Period, then Cellegy will pay Mr. Caso, on or before the date of the next normal payroll period after the end of the Retention Period when Cellegy processes payments an amount representing a sum equal to six months of his base salary in effect on the date of the agreement. Mr. Caso agreed that (i) during the Retention Period he will cooperate with Cellegy in implementing such strategic alternatives as Cellegy may choose to pursue; (ii) except for the payment described above, he will not be entitled to receive severance or similar payments upon a termination of his employment; and (iii) to sign a general release of claims in favor of Cellegy at the time of his termination of employment. This retention payment replaced, and was in lieu of, any payment that Mr. Caso would have been entitled to receive under any Company retention or severance plan, and was conditioned upon Mr. Caso executing, at the time of his termination of employment, a general release of claims. The retention amount was paid in July 2008.



Under the terms of the option agreement relating to the option held by Mr. Caso, upon a change in control of Cellegy, vesting of the option may accelerate and the option may become exercisable in full. The option became fully vested in connection with the merger of Cellegy and Adamis. However, the exercise price of the option was \$1.75 per share on a pre-reverse split basis, and as of December 31, 2008, the market price of our common stock was \$0.04 per share, and as a result no compensation would be payable if a change of control event had occurred as of that date, except for the retention payment described in the preceding paragraph. Other than that noted above, there is no other contract, agreement, plan or arrangement with Mr. Caso providing for payments following or in connection with, any termination of employment, other than statutory obligations to pay accrued unused vacation time and to make health insurance available, at Mr. Caso's expense, pursuant to COBRA requirements.

Other than as described above, we do not have any contract, agreement, plan or arrangement with either such officer providing for payment to the officer at, following, or in connection with any termination, or a change of control of Cellegy or a change in such officer's responsibilities, other than statutory obligations to pay accrued but unused vacation time and obligations to provide insurance benefits, at the officer's expense pursuant to the requirements of COBRA laws. Accordingly, there are no Named Officers employed by us as of December 31, 2008, who were entitled to receive any severance payments on the date upon termination of employment.

Executive officers are eligible to participate in all of our employee benefit plans, such as medical, dental, vision and group life insurance in each case on the same basis as other employees. Under the terms of the employment agreements with our executive officers, we are obligated to reimburse each executive officer for all reasonable business other expenses incurred by them in connection with the performance of his duties and obligations under the agreement.

#### ***Employment Agreements and Change of Control Arrangements***

In November 2003, in consideration of the agreement of Richard C. Williams to serve as Chairman of the Board and a director, we agreed to pay Mr. Williams a fee of \$100,000 per year. We also granted a stock option to Mr. Williams to purchase 100,714 shares of common stock, with 40,286 shares at an exercise price of \$28.69 per share, which was the closing market price of the common stock on the grant date, and 60,428 shares at an exercise price of \$49.64 per share. The option is vested and exercisable in full immediately, although a portion of the option, covering up to 60,428 shares initially and declining over a three-year period, was subject to cancellation to the extent the portion had not been exercised, in the event that Mr. Williams voluntarily resigned as Chairman and a director within certain time periods. Following the resignation of our former chief executive officer, in January 2005 Mr. Williams became interim Chief Executive Officer. In connection with his appointment, we agreed to pay Mr. Williams a total of \$40,000 per month during his service as interim Chief Executive Officer (which amount includes the payments for services as Chairman). In January 2007, at Mr. Williams' suggestion, we reduced the rate of base compensation payable to Mr. Williams from \$40,000 per month to \$25,000 per month.

Cellegy had an employment agreement with Robert J. Caso, who became Cellegy's Chief Financial Officer in March 2005. The agreement provided for compensation at an annual rate of \$200,000 per annum. The agreement also provided for the grant of a stock option to purchase up to 10,071 shares of common stock at an exercise price equal to the fair market value of the common stock on the date of grant. Mr. Caso also became a participant in Cellegy's Retention and Severance Plan, which has been terminated, and entered into the Company's standard indemnity agreement for officers of the Company. On November 14, 2007, Cellegy and Mr. Caso, entered into a retention agreement, the terms of which are described above under the heading "Potential Payments Upon Termination or Change in Control."

Under the terms of the employment agreements with our executive officers, we are obligated to reimburse each executive officer for all reasonable business other expenses incurred by them in connection with the performance of his duties and obligations under the agreement.

## **Other**

The Compensation Committee, as plan administrator of Cellegy's stock option plans, has the authority in certain circumstances to provide for accelerated vesting of the shares of common stock subject to outstanding options held by the Named Officers as well as other optionees under the plans in connection with a change in control of Cellegy, which the 2005 Equity Incentive Plan, referred to as the 2005 Plan, defines as: (a) a dissolution or liquidation of Cellegy, (b) a merger or consolidation in which Cellegy is not the surviving corporation (other than a merger or consolidation with a wholly-owned subsidiary, a reincorporation of Cellegy in a different jurisdiction, or other transaction in which there is no substantial change in the shareholders of Cellegy or their relative stock holdings and the awards granted under the 2005 Plan are assumed, converted or replaced by the successor corporation, which assumption will be binding on all participants), (c) a merger in which Cellegy is the surviving corporation but after which the shareholders of Cellegy immediately before such merger (other than any shareholder which merges (or which owns or controls another corporation which merges) with Cellegy in such merger) cease to own their shares or other equity interests in Cellegy, (d) the sale of substantially all of the assets of Cellegy, or (e) any other transaction which qualifies as a "corporate transaction" under Section 424(a) of the Incentive Revenue Code wherein the stockholders of Cellegy give up all of their equity interest in Cellegy (except for the acquisition, sale or transfer of all or substantially all of the outstanding shares of Cellegy from or by the shareholders of Cellegy).

Under the Company's 2009 Equity Incentive Plan, the administrator of the plan may, in the written agreements relating to an award made under the plan, provide that an award may be subject to acceleration of vesting and exercisability upon or after a Change in Control, as defined in the plan. Under the plan, a Change in Control means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) any person (with certain exceptions) becomes the owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction, other than in connection with equity financing transactions; (ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving entity in such transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving entity in such transaction, in each case in substantially the same proportions relative to each other as their ownership of the outstanding voting securities of the Company immediately before such transaction; (iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation; (iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an entity, more than 50% of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions relative to each other as their ownership of the outstanding voting securities of the Company immediately before such sale, lease, license or other disposition; or (v) the members of the Board immediately after the closing of the merger transaction between Cellegy and Adamis, referred to as the Incumbent Board, cease for any reason to constitute at least a majority of the members of the Board, provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the board then still in office, such new member shall, for purposes of the plan, be considered as a member of the Incumbent Board. Notwithstanding the foregoing, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company and the plan participant will supersede the foregoing definition with respect to awards subject to such agreement. The Board may, in its sole discretion and without participant consent, amend the definition of "Change in Control" to conform to the definition of "Change of Control" under Section 409A of the Internal Revenue Code of 1986, as amended, and related Department of Treasury guidance.

### ***Compliance with Section 162(m) of the Internal Revenue Code of 1986***

Section 162(m) of the Internal Revenue Code generally disallows a tax deduction for non-qualifying compensation \$1,000,000 paid to in any taxable year to any of the individual who is the chief executive officer at the end of the taxable year and the four other highest compensated officers of Cellegy during the taxable year. Cash compensation for fiscal 2008 for any individual was not \$1,000,000, and Cellegy does not expect cash compensation for fiscal 2009 to be \$1,000,000. We manage our compensation programs in light of applicable tax provisions, including 162(m), and may revise compensation plans from time to time to maximize deductibility. However, the compensation committee and the Board has the right to approve compensation that does not qualify for deduction when and if it deems it to be in the best interests of Cellegy to do so.

## Director Compensation

The following Director Compensation Table sets forth summary information concerning the compensation paid to our non-employee directors in 2008 for services to the Company. There were no option grants or other equity awards to outside directors during 2008.

Name	Fees earned or paid in cash	Option Awards (\$)	All Other		Total (\$)
	(\$)		Compensation \$(5)		
John Q. Adams, Sr.(1)	\$ —	\$ —	\$ 2,176	\$ 2,176	
Tobi B. Klar, M.D.(2)	—	—	2,176	2,176	
Robert B. Rothermel(3)	—	—	2,176	2,176	
Thomas M. Steinberg(4)	—	—	3,319	3,319	
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 9,847</b>	<b>\$ 9,847</b>	

- (1) Includes options to purchase a total of 5,439 post reverse split shares outstanding as of December 31, 2008, of which all were exercisable as of December 31, 2008.
- (2) A total of 10,072 options were outstanding as of December 31, 2008, of which all were exercisable as of December 31, 2008.
- (3) A total of 5,439 options were outstanding as of December 31, 2008, of which all were exercisable as of December 31, 2008.
- (4) Includes options to purchase a total of 5,439 post reverse split shares outstanding as of December 31, 2008, of which all were exercisable as of December 31, 2008.
- (5) The amounts in this column reflect the compensation expense recognized for 2008 financial statement reporting purposes related to stock options in accordance with FAS 123R.

We reimburse our non-employee directors for all reasonable out-of-pocket expenses incurred in the performance of their duties as directors. Directors who are officers or employees of Cellegy are not compensated for board services in addition to their regular employee compensation.

During 2008, the Board did not receive annual retainers for service on the Board and committees of the Board.

### *Director Compensation For the Company Following the Merger*

In connection with the merger transaction between Cellegy and Adamis, the stockholders approved a new 2009 Equity Incentive Plan. Pursuant to that plan, each director of the Company who is not an employee after the effective time of the Merger, including Messrs. Williams, Rothermel and Adams, and any person who thereafter becomes a non-employee director, will automatically receive an initial grant of a non-statutory option to purchase 50,000 shares of common stock upon such person's election or appointment. These initial grants will vest 50% on the grant date, with the balance vesting in equal monthly installments over a period of three years from the grant date. In addition, any person who is a non-employee director immediately after the annual meeting of our stockholders automatically will be granted, on the annual meeting date, beginning with the first annual meeting of stockholders after the closing of the merger, a non-statutory option to purchase 25,000 shares of common stock, or the annual grant, subject to adjustment by the board of directors from time to time. These annual grants will vest in equal monthly installments over three years from the grant date. In the event of certain corporate transactions, including change in control transactions, the vesting of options held by non-employee directors who services has not terminated generally will be accelerated in full, and if the director ceases to serve as a director as a result of the transaction, the director will have 12 months from the date of cessation of service within which to exercise the option.

Consistent with the foregoing provisions, Richard C. Williams, Robert B. Rothermel and John Q. Adams, Sr., who were directors of Old Cellegy and who continued as directors of the Company, each were granted a new non-employee director stock option to purchase 50,000 post-reverse split shares of common stock, effective immediately after the effective time of the Merger. The exercise price of these options was equal to \$0.60 per share, which was the closing price of the common stock on a pre-reverse split basis on the date of grant, multiplied by the ratio of the reverse stock split (and rounded up to the nearest cent). The options vest and become exercisable as to 50% of the total shares subject to the option on the date of grant, with the balance vesting in equal monthly installments over a period of three years from the grant date, so long as the non-employee director continuously remains a director, consultant or employee of the company. In addition, following the Merger, outside directors will be eligible to receive cash outside director fee compensation pursuant to the Company's director compensation policies.

In addition, non-employee directors will also be entitled to receive cash directors fees, as follows: each non-employee director will receive an annual fee of \$25,000 per year, paid quarterly; the Chair of the Audit Committee will receive \$10,000 per year; the Chair of the Compensation Committee and the Nominating and Governance Committee will each receive \$5,000 per year; each non-employee director will receive \$1,500 for each meeting attended; and the Chair of the Board will receive an annual fee of \$125,000, which will be in lieu of any other annual, committee or meeting fees.

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

### Principal Stockholders of Cellegy

The following tables set forth information as of April 15, 2009, concerning the beneficial ownership of (i) any person known to the Company to be the beneficial owner of more than five percent of the Company's outstanding common stock, (ii) each current director of the Company, (iii) each executive officer and (iv) all current directors and officers as a group. Unless indicated otherwise below, the address of each officer or director listed below is Adamis Pharmaceuticals Corporation, 2658 Del Mar Heights Road, Suite #555, Del Mar, CA 19512.

The share numbers and percentages in the table below give effect to the merger between Cellegy and Adamis and to a 1:9.929060333 reverse split of the Cellegy common stock effected April 1, 2009 in connection with the close of the merger between Adamis and Cellegy. The table is based on 46,146,106 post-reverse split shares of common stock of the Company outstanding.

Name	Share Beneficially Owned(1)	Percent
Dennis J. Carlo(6)	8,368,000	18.2%
Rand P. Mulford (2)	3,775,000	8.2
Richard J. Aloï (8)	3,593,039	7.8
David J. Marguglio(9)	3,439,904	7.5
Thomas Parker (3)	3,305,000	7.2
Robert O. Hopkins(7)	870,750	1.9
John Q. Adams (5)	55,439	*
Robert B. Rothermel (5)	55,439	*
Richard C. Williams(4)	150,715	*
All Cellegy directors and officers (7 persons)(10)	16,533,286	35.8

\* Less than one percent.

- (1) Based upon information supplied by officers, directors and principal stockholders. Beneficial ownership is determined in accordance with rules of the SEC that deem shares to be beneficially owned by any person who has or shares voting or investment power with respect to such shares. Unless otherwise indicated, the persons named in this table have sole voting and sole investing power with respect to all shares shown as beneficially owned, subject to community property laws where applicable. Shares of common stock subject to an option that is currently exercisable or exercisable within 60 days of the date of the table are deemed to be outstanding and to be beneficially owned by the person holding such option for the purpose of computing the percentage ownership of such person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise indicated, the address of each of the persons in this table is as follows: c/o Adamis Pharmaceuticals Corporation, 2658 Del Mar Heights Road, Suite #555, Del Mar, CA 19512.
- (2) Approximately 1,575,000 of these shares are subject to repurchase rights, as described below.
- (3) Approximately 2,357,058 of these shares are subject to repurchase rights, as described below.
- (4) Represents options to purchase a total of 150,715 shares of which 127,104 are exercisable within 60 days of the date of the table.
- (5) Represents options to purchase a total of 55,439 shares of which 31,827 are exercisable within 60 days of the date of the table.
- (6) Approximately 6,368,000 of these shares are subject to repurchase rights.
- (7) All of these shares are subject to repurchase rights.

- (8) Approximately 2,645,097 of these shares are subject to repurchase rights.
- (9) Approximately 2,537,019 of these shares are subject to repurchase rights.
- (10) Includes approximately 150,000 shares issuable upon the exercise of stock options, and approximately 11,550,116 shares subject to repurchase rights.

### Stock Repurchase Agreements

Approximately 17,807,000 of the outstanding share of common stock of the Company are subject to some form of restriction agreements and may be repurchased or cancelled by the Company. The resale of all of the stock listed below is restricted, and the Company has the right of first refusal in the event of that the holder thereof proposes to sell the stock.

Shareholder Group	Restricted Shares (000,000)	Description
<b>Officers and Directors</b>		
D. Carlo	6,368,000	These shares were issued by Adamis before the merger with Cellegy to certain executive officers of the Company. These shares are subject to repurchase by the Company at \$0.001 per share if certain value or performance targets are not met, or if the shareholder ceases to be employed at any time before dates ranging from July 2009 to September 2010, depending on the date of first employment of the officer with the time-based vesting restrictions lapsing with respect to one-third of the shares originally issued subject to these arrangements on each anniversary of the date of first employment which range from July 2006 to September 2007.
R. Aloï	2,645,097	
D. Marguglio	2,537,019	
T. Parker	2,357,058	
R. Hopkins	870,750	
Total:	14,777,924	
<b>Current Employees and Consultants</b>		
	473,500	These shares are subject to repurchase by the Company at \$0.001 if the shareholder ceases to be employed at any time before dates ranging from September 2009 to October 2011, with the time-based vesting restrictions lapsing with respect to one-third of the shares originally issued subject to these arrangements on each anniversary of the date of first employment which range from September 2006 to October 2008.
<b>Former Officers and Former HVG Shareholder</b>		
		These shares are subject to repurchase by the Company at \$0.001 per share if certain value or performance targets are not met.
R. Mulford	1,575,000	
R. Frost	719,019	
Aero Pharmaceuticals	261,111	
Total:	2,555,130	
<b>Total</b>	<b>17,806,554</b>	

## Equity Compensation Plan Information

The following table sets forth, as of December 31, 2008, information with respect to our equity compensation plans, including our 1995 Equity Incentive Plan, the 1995 Directors' Stock Option Plan and the 2005 Equity Incentive Plan, and with respect to certain other options and warrants. The share and amounts have been adjusted to give effect to the reverse stock split effected on April 1, 2009 in connection with the closing of the merger transaction between Cellegy and Adamis.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	134,650(1)	\$ 38.10	—
Equity compensation plans not approved by security holders	431(2)	2.90	—
<b>Total</b>	<b>135,081</b>	<b>\$ 37.99</b>	<b>—</b>

(1) Represents shares subject to outstanding options and are fully vested with exercise prices ranging from \$13.20 to \$64.54 per share and expire between the years 2009 and 2014.

(2) Represents shares subject to outstanding options and are fully vested with exercise prices \$2.90 per share and expire the year 2014.

## ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information responsive to this Item is disclosed in Item 11: "Executive Compensation," and the disclosures under such items are incorporated herein by reference.

During 2007 and 2008, there has not been any transaction or series of similar transactions to which we were or are to be a party in which the amount involved exceeds the lower of (i) \$120,000 or (ii) one percent of the average of Cellegy's total assets at the end of 2006 and 2007, and in which any current director, executive officer or holder of more than 5% of our common stock, or members of any such person's immediate family, had or will have a direct or indirect material interest, other than compensation described in "Executive Compensation," including the payment made to Mr. Caso in July 2008 as described above under the heading, "Potential Payments Upon Termination or Change in Control." Pursuant to the charter of the Audit Committee, the Audit Committee has the responsibility to review and approve the terms of all transactions between Cellegy and any related party, as that term is defined under applicable NASDAQ listing standards; however, compensation arrangements with related parties are reviewed by the compensation committee or the entire Board, and the Board retains the authority to review and approve other related party transactions. In connection with consideration of related party transactions, the Audit Committee or the Board requires full disclosure of material facts concerning the relationship and financial interest of the relevant individuals involved in the transaction, and then determines whether the transaction is fair to Cellegy. Approval is by means of a majority of the independent directors entitled to vote on the matter.

We intend that any such future transactions will be approved by the Audit Committee of the Board of Directors and will be on terms no less favorable to our company than could be obtained from unaffiliated third parties.

## ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Audit Fees and Services

The following table presents fees for professional services rendered by Mayer, Hoffman, McCann P.C., or MHM, for the audit of our annual financial statements for the year ended December 31, 2008, and fees billed for audit-related services, tax services and all other services rendered to us by MHM for 2008.

Fees	2008	2007
Audit fees and expenses	\$ 71,416	\$ 110,811
Audit-related fees and expenses	46,917	992
Tax fees	—	—
All other fees	—	—
Total	<u>\$ 118,333</u>	<u>\$ 111,803</u>

*Audit fees and expenses.* Audit fees relate to services related to the audit of Cellegy's financial statements and review of financial statements included in Cellegy's quarterly reports on Form 10-Q, including review of registration statements filed with the SEC.

*Audit-related fees and expenses.* This category includes fees for assurance and related services that are reasonably related to the performance of the audit or review of Cellegy's financial statements and are not included under "Audit Fees," and include fees for consultations concerning financial accounting and reporting matters and merger related services.

*Tax fees.* Tax fees include fees for services rendered in connection with preparation of federal, state and foreign tax returns and other filings and tax consultation services.

*All other fees.* All other fees include amounts charged by Cellegy's auditor in connection with services not generally considered to be audit or audit related matters.

### Pre-Approval Policies

Under our pre-approval policies with respect to our independent accountants, the Audit Committee pre-approves all audit and non-audit services provided by our independent accountants prior to the engagement of the independent accountants for such services. The Chairman of the Audit Committee has the authority to approve any additional audit services and permissible non-audit services, provided the Chairman informs the Audit Committee of such approval at its next regularly scheduled meeting.

All fees reported under the headings Audit fees and expenses, Audit-related fees and expenses and Tax fees for 2008 were approved by the Audit Committee before the respective services were rendered, which concluded that the provision of such services was compatible with the maintenance of the independence of the firm providing those services in the conduct of its auditing functions. Accordingly, none of the fees reported under the headings were approved by the Audit Committee pursuant to federal regulations that permit the Audit Committee to waive its pre-approval requirement under certain circumstances.

### Audit Committee Disclosure

The Audit Committee of the Cellegy board of directors is responsible for overseeing Cellegy's accounting and financial reporting processes, the appointment, compensation, retention and oversight of Cellegy's independent registered public accounting firm, and for overseeing audits of Cellegy's financial statements. The Audit Committee pre-approves the engagement with Cellegy's independent registered public accounting firm, reviews the independence and the quality control procedures of Cellegy's independent registered public accounting firm, and meets with Cellegy's management and its independent registered public accounting firm and separately with that firm regarding the audits of Cellegy's financial statements. The registered independent public accounting firm reports directly to the Audit Committee. The Audit Committee has the authority to obtain advice and assistance from outside legal, accounting or other advisors as the Audit Committee deems necessary to carry out its duties and to receive appropriate funding, as determined by the Audit Committee, from Cellegy for such advice and assistance.

Cellegy's management is responsible for preparing Cellegy's financial statements and for its financial reporting process, accounting policies, systems of internal controls and disclosure controls and procedures. Cellegy's independent registered public accounting firm is responsible for performing an independent audit and expressing an opinion on the conformity of Cellegy's audited financial statements with accounting principles generally accepted in the United States of America.

In this context, the Audit Committee hereby reports as follows:

1. The Audit Committee has reviewed and discussed Cellegy's audited financial statements for the fiscal year ended December 31, 2008, with Cellegy's management.
2. The Audit Committee has discussed with Mayer, Hoffman, McCann, P.C. the matters required to be discussed by SAS 61 (Codification of Statements on Auditing Standards, AU §380), SAS 99 (Consideration of Fraud in a Financial Statement Audit) and Securities and Exchange Commission rules.
3. The Audit Committee has received the written disclosures and the letter from Mayer, Hoffman, McCann, P.C. required by Independence Standards Board Standard No. 1 (Independence Standards Board Standard No. 1, "Independence Discussions with Audit Committee") and has discussed with Mayer, Hoffman, McCann, P.C. their independence.
4. Based on the review and discussions referred to in paragraphs (1) through (3) above, the Audit Committee recommended to the Cellegy's board of directors that the audited financial statements be included in Cellegy's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, for filing with the Securities and Exchange Commission.

The foregoing report is provided by the undersigned members of the Audit Committee.

#### AUDIT COMMITTEE

Robert B. Rothermel, Chair  
John Q. Adams, Sr.

#### ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

##### Exhibits

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

#### EXHIBIT INDEX

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference	
			Form/File No.	Date
2.1	Agreement and Plan of Reorganization dated as of February 12, 2008, by and among Cellegy, Cellegy Holdings, Inc. and Adamis Pharmaceuticals Corporation (the " <b>Merger Agreement</b> ").		8-K	2/13/08
2.2	Agreement dated November 11, 2008, between the Company and Adamis amending the Merger Agreement.		8-K	11/13/08
2.3	Agreement dated January 8, 2009, between the Company and Adamis amending the Merger Agreement.		8-K	1/8/09
2.4	Agreement and Plan of Share Exchange dated as of October 7, 2004, by and between the Company and Biosyn, Inc.		8-K	10/26/04
3.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	4/3/09
3.2	Amended and Restated Certificate of Incorporation of the Registrant		8-K	4/3/09
3.3	Amended and Restated Bylaws of the Company		S-4/A 333-155322	1/12/09



4.1	Specimen stock certificate for common stock.	8-K	4/3/09
10.1	2005 Equity Incentive Plan	10-K	3/31/06
10.2	Form of Option Agreement under the 2005 Equity Incentive Plan.	10-K	3/31/06
*10.3	1995 Equity Incentive Plan	10-Q	8/13/02
*10.4	1995 Directors' Stock Option Plan.	10-Q	8/13/02
*10.5	Form of Option Agreement under the 1995 Directors' Stock Option Plan.	S-8 333-91588	9/7/04
*10.6	Employment Agreement, effective January 1, 2003, between Cellegy and K. Michael Forrest.	10-K	4/6/04
10.7	Exclusive License Agreement dated as of December 31, 2002, by and between Cellegy and PDI, Inc.	10-K	3/21/03
*10.8	Retention and Severance Plan and Form of Agreement of Plan Participation under Retention and Severance Plan.	10-Q	5/8/03
*10.9	Letter agreement dated November 5, 2003, between Cellegy and Richard C. Williams.	10-K	4/6/04
*10.10	Stock option agreement dated November 5, 2003, between Cellegy and Richard C. Williams.	10-K	4/6/04
*10.11	Form of Indemnity Agreement between Cellegy and its directors and executive officers.	Proxy Statement	4/28/04
10.12	Registration Rights Agreement dated as of October 7, 2004, between Cellegy and certain former stockholders of Biosyn, Inc.	8-K	10/26/04
10.13	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-K	3/31/05
10.14	Patent License Agreement by and among Biosyn, Inc., and certain agencies of the United States Public Health Service.	10-K	3/31/05
10.15	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.)	10-K	3/31/05
10.16	License Agreement dated January 30, 2006, by and between CONRAD, Eastern Virginia Medical School, and Biosyn, Inc. (Confidential treatment has been requested for portions of this agreement.)	10-K	4/02/07
*10.17	Retention Letter Agreement dated November 14, 2007, between Cellegy and Robert J. Caso.	8-K	11/14/2007
*10.18	2009 Equity Incentive Plan.	8-K	4/3/2009
*10.19	Form of Option Agreement under 2009 Equity Incentive Plan.	8-K	4/3/2009

10.20	Convertible Promissory Note dated February 12, 2008 between the Registrant and Adamis Pharmaceuticals Corporation.	S-4/A 333-155322	1/12/09
10.21	Amendment to License Agreement dated as of March 15, 2006, by and between Crompton Corporation and Biosyn, Inc.	S-4/A 333-155322	1/12/09
10.22	Funding Agreement dated October 12, 1992, by and between Ben Franklin Technology Center of Southeaster Pennsylvania and Biosyn, Inc.	S-4/A 333-155322	1/12/09
10.23	License Agreement dated July 28, 2006, by and between Nevagen, LLC and Adamis Pharmaceuticals Corporation.	S-4/A 333-155322	1/12/09
10.24	Amendment to License Agreement dated December 29, 2008, by and between Nevagen, LLC and Adamis Pharmaceuticals Corporation.	S-4/A 333-155322	1/12/09
*10.25	Stock Repurchase Agreement dated November 3, 2008, by and between Richard Aloï and Adamis Pharmaceuticals Corporation.	S-4/A 333-155322	1/12/09
*10.26	Stock Repurchase Agreement dated November 3, 2008, by and between Dennis J. Carlo and Adamis Pharmaceuticals Corporation	S-4/A 333-155322	1/12/09
*10.27	Stock Repurchase Agreement dated November 3, 2008, by and between Robert Hopkins and Adamis Pharmaceuticals Corporation	S-4/A 333-155322	1/12/09
*10.28	Stock Repurchase Agreement dated November 3, 2008, by and between David J. Marguglio and Adamis Pharmaceuticals Corporation.	S-4/A 333-155322	1/12/09
10.29	Amendment to License Agreement dated October 18, 2007, by and between CONRAD, Eastern Virginia Medical School, and Biosyn, Inc.	S-4/A 333-155322	1/12/09
10.30	Lease Agreement dated January 1, 2007, by and between HRM II Ltd and Healthcare Ventures Group.	S-4/A 333-155322	1/12/09
10.31	Amendment to Lease Agreement dated October 30, 2007, by and between HRM II Ltd and Healthcare Ventures Group.	S-4/A 333-155322	1/12/09
10.32	Clinical Trial Agreement between Biosyn, Inc. and the National Institute of Child Health and Human Development.	S-4/A 333-155322	1/12/09
21.1	Subsidiaries of the Registrant		
23.1	Consent of Mayer Hoffman McCann P.C., Independent Registered Public Accounting Firm.		
24.1	Power of Attorney (See signature page)		

\* Represents a compensatory plan or arrangement.

## SIGNATURES

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

### ADAMIS PHARAMCEUTICALS CORPORATION

By: /s/ DENNIS J. CARLO  
Dennis J. Carlo  
Chief Executive Officer

Dated: May 12, 2009

## Power of Attorney

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

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

Name	Title	Date
<b>Principal Executive Officer:</b>		
<u>/s/ DENNIS J. CARLO</u> Dennis J. Carlo	Chief Executive Officer and Director	May 12, 2009
<b>Principal Financial Officer and Principal Accounting Officer:</b>		
<u>/s/ ROBERT O. HOPKINS</u> Robert O. Hopkins	Vice President, Finance, Chief Financial Officer and Secretary	May 12, 2009
<b>Directors:</b>		
<u>/s/ RICHARD C. WILLIAMS</u> Richard C. Williams	Chairman of the Board	May 12, 2009
<u>/s/ JOHN Q. ADAMS</u> John Q. Adams, Sr.	Director	May 12, 2009
<u>/s/ ROBERT B. ROTHERMEL</u> Robert B. Rothermel	Director	May 12, 2009
<u>/s/ DAVID J. MARGUGLIO</u> David J. Marguglio	Director	May 12, 2009
<u>/s/ RICHARD L. ALOI</u> Richard L. Aloï	Director	May 12, 2009

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***Report of Independent Registered Public Accounting Firm***

To the Board of Directors and Stockholders

**Cellegy Pharmaceuticals, Inc.**

We have audited the accompanying consolidated balance sheets of Cellegy Pharmaceuticals Inc. and its subsidiary (the “Company”) as of December 31, 2008 and 2007, and the related consolidated statements of operations and changes in stockholders’ equity (deficit) and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits 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 consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements, referred to above, present fairly, in all material respects, the consolidated financial position of Cellegy Pharmaceuticals Inc. and its subsidiary as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and has negative working capital, liabilities that exceed its assets and significant recurring cash flow deficiencies. These factors raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans with regard to these matters are also described in Note 1. The 2008 and 2007 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Mayer Hoffman McCann P.C.

Plymouth Meeting, Pennsylvania  
May 12, 2009

**Cellegy Pharmaceuticals, Inc.**  
**Consolidated Balance Sheets**

	December 31,	
	2008	2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 129,124	\$ 1,826,614
Prepaid expenses and other current assets	34,304	267,478
Total assets	<u>\$ 163,428</u>	<u>\$ 2,094,092</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 71,804	\$ -
Accrued expenses and other current liabilities	184,805	397,277
Total current liabilities	<u>256,609</u>	<u>397,277</u>
Note payable	777,902	507,067
Total liabilities	<u>1,034,511</u>	<u>904,344</u>
Stockholders' equity (deficit):		
Preferred Stock, no par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2008 and 2007		
Common stock, par value \$.0001; 50,000,000 shares authorized; 29,834,796 shares issued and outstanding at December 31, 2008 and 2007	2,984	2,984
Additional paid-in capital	125,770,169	125,753,019
Accumulated deficit	(126,100,126)	(124,566,255)
Less: Note receivable, including \$44,110 of accrued interest	(544,110)	-
Total stockholders' equity (deficit)	<u>(871,083)</u>	<u>1,189,748</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 163,428</u>	<u>\$ 2,094,092</u>

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

**Cellegy Pharmaceuticals, Inc.**  
**Consolidated Statements of Operations**

	<b>Years Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Costs and expenses:		
Research and development	\$ -	\$ 23,022
Selling, general and administrative	1,322,124	1,798,626
Total costs and expenses	1,322,124	1,821,648
Operating loss	(1,322,124)	(1,821,648)
Other income (expenses):		
Interest and other income	59,088	92,832
Interest and other expense	(270,835)	(198,245)
Total other income (expenses)	(211,747)	(105,413)
Net loss applicable to common stockholders	<u>\$ (1,533,871)</u>	<u>\$ (1,927,061)</u>
Basic and diluted net loss per common share:	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>
Weighted average number of common shares used in per share calculations:		
Basic and diluted	<u>29,834,796</u>	<u>29,834,796</u>

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



**Cellegy Pharmaceuticals, Inc.**  
**Consolidated Statements of Changes in Stockholders' Equity (Deficit)**

	Common Stock		Additional	Accumulated	Note	Total
	Shares	Amount	Paid-in- Capital	Deficit	Receivable Due from Adamis Note 12	Stockholders' Equity (Deficit)
Balances at December 31, 2006	29,834,796	\$ 2,984	\$ 125,699,145	\$ (122,639,194)	\$ -	\$ 3,062,935
Noncash compensation expense related to stock options	-	-	53,874	-	-	53,874
Net loss	-	-	-	(1,927,061)	-	(1,927,061)
Balances at December 31, 2007	29,834,796	2,984	125,753,019	(124,566,255)	-	1,189,748
Noncash compensation expense related to stock options	-	-	17,150	-	-	17,150
Net loss	-	-	-	(1,533,871)	-	(1,533,871)
Note receivable due from Adamis' – Note 12	-	-	-	-	(544,110)	(544,110)
Balances at December 31, 2008	<u>29,834,796</u>	<u>\$ 2,984</u>	<u>\$ 125,770,169</u>	<u>\$ (126,100,126)</u>	<u>\$ (544,110)</u>	<u>\$ (871,083)</u>

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

**Cellegy Pharmaceuticals, Inc.**  
**Consolidated Statements of Cash Flows**

	<b>Years Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (1,533,871)	\$ (1,927,061)
<b>Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:</b>		
Equity compensation expense	17,150	53,874
Interest accretion on notes payable	270,835	184,942
Accrued interest on note receivable	(44,110)	-
Gain on settlement of debt obligation	-	(4,700)
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses and other current assets	233,174	11,262
Accounts receivable	-	62,605
Accounts payable	71,804	(174,839)
Accrued expenses and other current liabilities	(212,472)	(143,301)
Net cash used in operating activities	<u>(1,197,490)</u>	<u>(1,937,218)</u>
<b>Investing activities:</b>		
Issuance of note receivable	(500,000)	-
Net cash used in investing activities	<u>(500,000)</u>	<u>-</u>
<b>Financing activities:</b>		
Repayment of note payable	-	(40,000)
Net cash used in financing activities	<u>-</u>	<u>(40,000)</u>
Net decrease in cash and cash equivalents	(1,697,490)	(1,977,218)
Cash and cash equivalents, beginning of year	1,826,614	3,803,832
Cash and cash equivalents, end of year	<u>\$ 129,124</u>	<u>\$ 1,826,614</u>

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

**Cellegy Pharmaceuticals, Inc.**  
**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. (“Cellegy,” or the “Company”) and its wholly-owned subsidiary, Biosyn, Inc. (“Biosyn”). All intercompany balances and significant intercompany transactions have been eliminated.

Cellegy is a specialty pharmaceutical company. Cellegy’s wholly owned subsidiary, Biosyn, Inc., has intellectual property relating to a portfolio of proprietary product candidates known as microbicides. Biosyn’s product candidates, which include both contraceptive and non-contraceptive microbicides, are used intravaginally. Biosyn’s product candidates include Savvy®, which underwent Phase 3 clinical trials in Ghana and Nigeria for reduction in the transmission of Human Immunodeficiency Virus/Acquired Immunodeficiency Disease, or HIV/AIDS, both of which were suspended in 2005 and 2006 and terminated before completion, and is the subject to a Phase 3 contraception trial in the United States.

Our cash and cash equivalents were approximately \$129,000 and \$1,800,000 at December 31, 2008 and 2007, respectively.

We prepared the consolidated financial statements assuming that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. In preparing these consolidated financial statements, consideration was given to the Company’s future business alternatives as described below, which may preclude the Company from realizing the value of certain assets during their future course of business.

On February 12, 2008, Cellegy entered into a definitive merger agreement (the “Merger Agreement”) providing for the acquisition of Cellegy by Adamis Pharmaceuticals Corporation (“Adamis”). In connection with the signing of the Merger Agreement, Cellegy issued to Adamis an unsecured convertible promissory note pursuant to which Cellegy agreed to lend Adamis \$500,000 to provide funds to Adamis during the pendency of the merger transaction. Any principal outstanding under the promissory note accrues interest at 10% per annum. On April 1, 2009, Cellegy completed the merger transaction with Adamis. In connection with the closing of the merger transaction, the promissory note converted into shares of Adamis stock, and these shares were immediately cancelled.

Cellegy’s operations currently relate primarily to the intellectual property rights of its Biosyn subsidiary. While the Savvy Phase 3 contraception trial in the United States has been completed and the analysis of the results is expected to be completed by the end of 2009, Cellegy is not directly involved with the conduct and funding thereof, and the Company believes it is uncertain that it will commercialize Savvy or that the Company will ever realize revenues therefrom. The Company believes that its future cash flows will be derived primarily from the sale of Adamis’ products.

The Company has negative working capital, liabilities that exceed its assets and significant cash flow deficiencies. Additionally, Adamis will need significant funding for future operations and the expenditures that will be required to conduct the clinical and regulatory work to develop the merged company’s product candidates. Management is currently seeking additional funding to satisfy existing obligations, liabilities and future working capital needs, to build working capital reserves and to fund its research and development projects. There is no assurance that Adamis will be successful obtaining the necessary funding to meet its business objectives.

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

*Use of Estimates*

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

*Research and Development*

Research and development expenses include expenses associated with regulatory filings for ongoing clinical trials and are charged to expense as they are incurred.

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 expenses. 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 short term money market funds. The carrying value of cash and cash equivalents approximates fair value as of December 31, 2008 and 2007. As of December 31, 2008, the Company's cash and cash equivalents are maintained at two financial institutions in the United States. Deposits in these financial institutions may, from time to time, exceed federally insured limits.

*Concentration of Credit Risk*

As of December 31, 2008, the Company had its cash in demand deposits and in money market funds.

*Property and Equipment*

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

	<u><b>Estimated Useful Lives</b></u>
Furniture and fixtures	3 years
Office equipment	3 years

*Stock-based Compensation*

For the years ended December 31, 2008 and 2007, for stock options granted prior to the adoption of SFAS No. 123R, *Share-Based Payment* ("SFAS No. 123"), there is no difference between reported amounts and pro forma net loss and basic and diluted income per common share if compensation expense for the Company's various stock option plans had been determined based upon estimated fair values at the grant dates in accordance with SFAS No. 123.

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

Cellegy values its options on the date of grant using the Black-Scholes valuation model. The Company did not grant any stock options during 2008 and 2007.

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

*Accounting for Merger Related Costs*

For the year ended December 31, 2008, Cellegy incurred certain accounting, legal and other filing costs in conjunction with its pending merger with Adamis. These costs were expensed as incurred.

*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. The total number of shares that had their impact excluded were:

	<b>Pre-Reverse Split – Note 12</b>	
	<b>Years Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Options	1,341,227	1,349,741
Warrants	2,114,593	2,114,593
Total number of shares excluded	3,455,820	3,464,334

*Recent Accounting Pronouncements*

*SFAS No. 157, Fair Value Measurements*

SFAS No. 157, *Fair Value Measurements* (“SFAS 157”), has been issued by the Financial Accounting Standards Board (the “FASB”). This new standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value but does not expand the use of fair value in any new circumstances. Currently, over 40 accounting standards within GAAP require (or permit) entities to measure assets and liabilities at fair value. The standard clarifies that for items that are not actively traded, such as certain kinds of derivatives, fair value should reflect the price in a transaction with a market participant, including an adjustment for risk, not just the Company’s mark-to-model value. SFAS 157 also requires expanded disclosure of the effect on earnings for items measured using unobservable data. Under SFAS 157, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. In this standard, the FASB clarified the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, SFAS 157 establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, for example, the reporting entity’s own data. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy.

In February 2008, the FASB issued FSP SFAS No. 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Its Related Interpretive Accounting Pronouncements That Address Leasing Transactions* (“FSP SFAS No. 157-1”) and FSP SFAS No. 157-2, *Effective Date of FASB Statement No. 157* (“FSP SFAS No. 157-2”). FSP SFAS No. 157-1 removes leasing from the scope of SFAS No. 157. FSP SFAS No. 157-2 delays the effective date of SFAS No. 157 for the Company from its fiscal 2009 to its fiscal 2010 year for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The Company does not expect its adoption of the provisions of FSP SFAS No. 157-1 and FSP SFAS No. 157-2 will have a material effect on its financial condition, results of operations or cash flows.

In February 2007, FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (“SFAS No. 159”). Under SFAS No. 159, a company may elect to measure at fair value various eligible items that are not currently required to be so measured. Eligible items include, but are not limited to, accounts receivable, available-for-sale securities, equity method investments, accounts payable and firm commitments. SFAS No. 159 is effective in fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of its fiscal 2009 year. The Company does not expect its adoption of the provisions of SFAS No. 159 will have a material effect on its financial condition, results of operations or cash flows.

#### *SFAS No. 141 (Revised 2007), Business Combinations*

On December 4, 2007, the FASB issued SFAS No. 141 (Revised 2007), *Business Combinations* (“SFAS 141R”). Under SFAS 141R, an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition date fair value with limited exceptions. SFAS 141R will change the accounting treatment for certain specific items, including:

- acquisition costs will be generally expensed as incurred;
- non-controlling interests will be valued at fair value at the acquisition date;
- acquired contingent liabilities will be recorded at fair value at the acquisition date;
- in-process research and development will be recorded at fair value as an indefinite-lived intangible asset at the acquisition date until the completion or abandonment of the associated research and development efforts;
- restructuring costs associated with a business combination will be generally expensed subsequent to the acquisition date; and
- changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense.

SFAS 141R also includes a substantial number of new disclosure requirements. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Earlier adoption is prohibited.

#### *SFAS No. 160, “Non-controlling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51”*

On December 4, 2007, the FASB issued SFAS No. 160, *Non-controlling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51* (“SFAS 160”). SFAS 160 establishes new accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a non-controlling interest (minority interest) as equity in the consolidated financial statements and separate from the parent’s equity. The amount of net income attributable to the non-controlling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent’s ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the non-controlling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its non-controlling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (“EITF 07-10”). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development activities to be recorded as an asset and expensing the payments when the research and development activities are performed. EITF 07-3 applies prospectively for new contractual arrangements entered into in fiscal years beginning after December 15, 2007. The Company currently recognizes these non-refundable advanced payments as an asset upon payment, and expenses costs as goods are used and services are provided. There was no effect on the Company’s financial statement from the adoption of this pronouncement.

#### *FIN No. 48, “Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109”*

FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109* (“FIN 48”) was issued on July 13, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company’s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes* .. FIN 48 prescribes a recognition threshold and measurement attribute for the consolidated financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The new FASB standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

The provisions of FIN 48 are to be applied to all tax positions upon initial adoption of this standard. Only tax positions that meet the more-likely-than-not recognition threshold at the effective date may be recognized or continue to be recognized upon adoption of FIN 48. The cumulative effect of applying the provisions of FIN 48 should be reported as an adjustment to the opening balance of retained earnings (or other appropriate components of equity in the consolidated balance sheet) for that fiscal year. Cellegy adopted FIN 48 on January 1, 2007 and its implementation did not have a material impact on Cellegy’s financial position, results of operations or cash flows.

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

*Reclassifications*

Certain reclassifications have been made to 2007 amounts to conform with 2008 presentation.

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

At December 31, 2008 and 2007, prepaid expenses and other current assets include the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Prepaid insurance	\$ 34,304	\$ 134,248
Security deposits	-	8,100
Accrued retention compensation	-	120,130
Other	-	5,000
<b>Total prepaid expenses and other current assets</b>	<b>\$ 34,304</b>	<b>\$ 267,478</b>

Accrued retention compensation of approximately \$120,000 as of December 31, 2007 represents the unamortized portion of approximately \$139,000 in retention payments offered and accepted by employees in 2007. The retention payments were to be paid if the employee maintained his or her employment with the Company through the retention period indicated in the individual's retention agreement. The retention payment was in lieu of all other severance or similar payments that the Company may have been obligated to make under any other existing agreement, arrangement or understanding, but would be in addition to any accrued salary and vacation earned through the end of the respective retention period. As of December 31, 2008, the retention periods have been satisfied.

**3. Property and Equipment, Net**

At December 31, 2008 and 2007, property and equipment, net consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Furniture, fixtures and office equipment	\$ 19,855	\$ 19,855
Less: accumulated depreciation	(19,855)	(19,855)
<b>Total property and equipment, net</b>	<b>\$ -</b>	<b>\$ -</b>

Cellegy recorded no depreciation expense in 2008 and 2007.

**4. Accrued Expenses and Other Current Liabilities**

Cellegy accrues for services received but for which billings have not been received. Accrued expenses and other current liabilities at December 31, 2008 and 2007, were as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Accrued legal fees	\$ -	\$ 29,317
Accrued compensation	103,016	29,739
Accrued retention compensation	-	139,370
Accrued accounting and consulting fees	65,500	125,000
Accrued insurance	-	12,995
Other	16,289	60,856
<b>Total accrued expenses and other current liabilities</b>	<b>\$ 184,805</b>	<b>\$ 397,277</b>

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

**5. Notes Payable**

*Ben Franklin Note*

Biosyn issued a note to Ben Franklin Technology Center of Southeastern Pennsylvania ("Ben Franklin Note") in October 1992, in connection with funding the development of a compound to prevent the transmission of AIDS.

The Ben Franklin Note was recorded at its estimated fair value of \$205,000 and was assumed by Cellegy in connection with its acquisition of Biosyn in 2004. The repayment terms of the non-interest bearing obligation include the remittance of an annual fixed percentage of 3.0% applied to future revenues of Biosyn, if any, until the principal balance of \$777,902 (face amount) 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 nonprofit sources. Absent a material breach of contract by Cellegy, there is no obligation to repay the amounts in the absence of future Biosyn revenues. Cellegy accreted the discount of \$572,902 against earnings using the interest rate method (approximately 46%) over the discount period of five years, which was estimated in connection with the note's valuation at the time of the acquisition. At December 31, 2008 and 2007, the outstanding balance of the note was \$777,902 and \$507,067, respectively.

SFAS 157 emphasizes market-based measurement through the use of valuation techniques that maximize the use of observable or market-based inputs. The Ben Franklin Note's peculiar repayment terms outlined above affects the note's comparability with main stream market issues and also affects its transferability. The value of the note would also be impacted by the ability to estimate Biosyn's expected future revenues which in turn hinge largely upon the outcome of its ongoing Savvy contraception trial, the results of which are currently under review and which are not known by the Company. Given the above factors and therefore the lack of market comparability, the Ben Franklin Note would be classified under SFAS #157 as a Level 3 input. As such, the Company's management has therefore determined that the carrying value of the Ben Franklin Note as of December 31, 2008 approximates its fair market value.

*MPI Note*

In 2007, Cellegy settled its obligation to MPI, Inc. of \$44,700 for \$40,000 and recorded \$4,700 in other income.

**6. Commitments and Contingencies**

*Operating Leases*

Until May 31, 2008, the Company leased its facility a month-to-month basis and has no future minimum lease payments as of December 31, 2008. Operating lease expense is recorded on a straight-line basis over the term of the lease. Rent expense was approximately \$13,500 and \$32,400 for the years ended December 31, 2008 and 2007, respectively.

**7. License and Other Agreements**

*Biosyn*

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

In October 1996, Biosyn acquired the C31G Technology from its inventor, Edwin B. Michaels. As part of the agreement, Biosyn is required to make annual royalty payments equal to the sum of 1.0% of net product sales of up to \$100 million, 0.5% of the net product sales over \$100 million and 1% of any royalty payments received by Biosyn under license agreements. The term of the agreement lasts until December 31, 2011, or upon the expiration of the C31G Technology's patent protection, whichever is later. Biosyn's current C31G patents expire between 2011 and 2018.

In May 2001, Biosyn entered into an exclusive license agreement with Crompton, now Chemtura ("Chemtura"), 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 Chemtura a nonrefundable, upfront license fee that was expensed in research and development. Chemtura common stock warrants, which in connection with Cellegy's acquisition of Biosyn in 2004 were assumed and became warrants to purchase 39,050 (pre-reverse split) shares of Cellegy common stock, exercisable for a period of two years upon initiation of Phase 3 trials of UC-781. Chemtura 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.



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

In February 2003, Biosyn acquired exclusive worldwide rights from the National Institutes of Health (“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. There were no royalty payments incurred for the years ended December 31, 2008 and 2007. Due to cancellation of its license with the NIH in 2007, Biosyn forfeited the rights for the commercialization of CV-N but the existing agreements between Biosyn and research institutions related to CV-N remain in effect.

On January 31, 2006, Cellegy announced that it had entered into a nonexclusive, developing world licensing agreement with the Contraceptive Research and Development Organization (“CONRAD”) for the collaboration on the development of Cellegy’s entire microbicide pipeline. The agreement encompasses the licensing in the developing countries (as defined in the agreements) of Savvy, UC-781 and Cyanovirin-N. The agreement provided CONRAD with access to Biosyn’s current and past microbicidal research.

Under the terms of certain of its agreements, Biosyn has been granted the right to commercialize products 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 previously entered into various other collaborating research and technology agreements. Should any discoveries be made under such arrangements, Biosyn may be required to negotiate the licensing of the technology for the development of the respective discoveries. There are no significant funding commitments under any of these other agreements.

There were no royalty payments made under any of the aforementioned agreements for the years ended December 31, 2008 and 2007.

## **8. Stockholders’ Equity**

### *Preferred Stock*

The Company’s Restated Certificate of Incorporation in effect as of December 31, 2008 provides that the Company may issue up to 5,000,000 shares of preferred stock in one or more series. The Board of Directors is authorized to establish, from time to time, the number of shares to be included in, and the designation of, any such series and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon any wholly unissued series of preferred stock and to increase or decrease the number of shares of any such series without any further vote or action by the stockholders.

### *Stock Market Listing*

Cellegy’s common stock trades on the Over-the-Counter Bulletin Board (“OTCBB”) formerly under the symbol: CLGY.OB. In connection with its merger with Adamis, the Company’s common stock symbol was changed to ADMP in April, 2009.

### *Stock Option Plans*

#### *2005 Equity Incentive Plan*

The 2005 Equity Incentive Plan (the “2005 Plan”) replaced the 1995 Equity Incentive Plan (the “Prior Plan”) which had expired. The 2005 Plan is administered by the Company’s Compensation Committee. The Board of Directors may at any time amend, alter, suspend or discontinue the 2005 Plan without stockholders’ approval, except as required by applicable law. The 2005 Plan is not subject to ERISA and is not qualified under Section 401(a) of the Internal Revenue Code of 1986, as amended.

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

The 2005 Plan provides for the granting of options and other awards to employees, directors and consultants. Options granted under the 2005 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options may be granted only to employees. The Compensation Committee determines who will receive options or other awards under the 2005 Plan and their terms, including the exercise price, number of shares subject to the option or award, and the vesting and exercisability thereof. Options granted under the 2005 Plan generally have a term of ten years from the grant date, and exercise price typically is equal to the closing price of the common stock on the grant date. Options typically vest over a three-year or four-year period. Options granted under the 2005 Plan typically expire if not exercised within 90 days from the date on which the optionee is no longer an employee, director or consultant. The vesting and exercisability of options may also be accelerated upon certain change of control events. There were 16,000 options vested under the 2005 Plan during 2008. Activity under the 2005 Plan is summarized as follows:

	<b>Pre-Reverse Split – Note 12</b>	<b>Weighted</b>
	<b>Shares Under</b>	<b>Average</b>
	<b>Option</b>	<b>Exercise Price</b>
Balance at December 31, 2007	48,000	\$ 1.34
Granted	-	-
Canceled	-	-
Exercised	-	-
Balance at December 31, 2008	48,000	1.34

The following table summarizes those stock options outstanding related to the 2005 Plan at December 31, 2008:

<b>Pre-Reverse Split – Note 12</b>			
<b>Options Exercisable and Outstanding</b>			
<b>Weighted</b>	<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate</b>
<b>Average</b>	<b>Average</b>	<b>Average</b>	<b>Intrinsic</b>
<b>Number of</b>	<b>Remaining</b>	<b>Exercise</b>	<b>Value</b>
<b>Options</b>	<b>Contractual</b>	<b>Price</b>	<b>Value</b>
<b>Options</b>	<b>Life</b>	<b>Price</b>	<b>Value</b>
48,000	7.00 Years	\$ 1.34	\$ -

*Prior Plan*

The Prior Plan will continue to govern the stock options previously granted thereunder, however, no further stock options or other awards may be made pursuant to the Prior Plan. There were 38,958 options vested under the Prior Plan during 2008. Activity under the Prior Plan is summarized as follows:

	<b>Pre-Reverse Split – Note 12</b>	<b>Weighted</b>
	<b>Shares Under</b>	<b>Average</b>
	<b>Option</b>	<b>Exercise Price</b>
Balance at December 31, 2007	204,944	\$ 2.66
Granted	-	-
Canceled	-	-
Exercised	-	-
Balance at December 31, 2008	204,944	2.66

The following table summarizes those stock options outstanding and exercisable related to the Prior Plan at December 31, 2008:

<b>Pre-Reverse Split – Note 12</b>			
<b>Options Exercisable and Outstanding</b>			
<b>Weighted</b>	<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate</b>
<b>Average</b>	<b>Average</b>	<b>Average</b>	<b>Intrinsic</b>
<b>Number of</b>	<b>Remaining</b>	<b>Exercise</b>	<b>Value</b>
<b>Options</b>	<b>Contractual Life</b>	<b>Price</b>	<b>Value</b>
204,944	5.42 Years	\$ 2.66	\$ -

*1995 Directors' Stock Option Plan*

In 1995, Cellegy adopted the 1995 Directors' Stock Option Plan (the "Directors' Plan") to provide for the issuance of nonqualified stock options to eligible outside Directors. When the plan was established, Cellegy reserved 150,000 shares for issuance. From 1996 to 2005, a total of 350,000 shares were reserved for issuance under the Directors' Plan. The 2005 Plan replaced the Directors' Plan.

The Directors' Plan provides for the grant of initial and annual nonqualified 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.

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

Activity under the Directors' Plan is summarized as follows:

	<b>Pre-Reverse Split – Note 12</b>	<b>Weighted</b>
	<b>Shares Under</b>	<b>Average</b>
	<b>Option</b>	<b>Exercise Price</b>
Balance at December 31, 2007	92,000	\$ 4.45
Granted	-	-
Canceled	8,000	5.50
Exercised	-	-
Balance at December 31, 2008	<u>84,000</u>	<u>4.35</u>

The following table summarizes those stock options outstanding and exercisable related to the Directors' Plan at December 31, 2008:

<b>Pre-Reverse Split – Note 12</b>			
<b>Options Exercisable and Outstanding</b>			
<b>Weighted</b>	<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate</b>
<b>Average</b>	<b>Average</b>	<b>Average</b>	<b>Intrinsic</b>
<b>Number of</b>	<b>Remaining</b>	<b>Exercise</b>	<b>Value</b>
<b>Options</b>	<b>Contractual Life</b>	<b>Price</b>	<b>Value</b>
84,000	4.24 Years	\$ 4.35	\$ -

There are no options available for future grants under the Directors' Plan.

*Non-Plan Options*

In November 2003, the Company granted an option to Mr. Richard Williams, on his appointment to become Chairman of the Board, to purchase 1,000,000 shares of common stock (pre-reverse split – see Note 12). A total of 400,000 of the shares subject to the options have an exercise price of \$2.89 per share and a total 600,000 of the shares subject to the options have an exercise price of \$5.00 per share. The option was vested and exercisable in full on the grant date and, as of December 31, 2008, 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. Activity relating to Biosyn option grants is summarized as follows:

	<b>Pre-Reverse Split – Note 12</b>	<b>Weighted</b>
	<b>Shares Under</b>	<b>Average</b>
	<b>Option</b>	<b>Exercise Price</b>
Balance at December 31, 2007	4,797	\$ 0.29
Granted	-	-
Canceled	(514)	(0.29)
Exercised	-	-
Balance at December 31, 2008	<u>4,283</u>	<u>0.29</u>

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

The following table summarizes information about stock options outstanding and exercisable related to Biosyn option grants at December 31, 2008:

<b>Pre-Reverse Split – Note 12</b>			
<b>Options Exercisable and Outstanding</b>			
<b>Weighted Average Number of Options</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Aggregate Intrinsic Value</b>
4,283	5.05 Years	\$ 0.29	\$ -

*Shares Reserved*

As of December 31, 2008, the Company has reserved shares of common stock for future issuance as follows:

Biosyn options	4,283
Director's Plan	84,000
Warrants	2,114,593
Non-plan options	1,000,000
1995 Equity Incentive Plan	204,944
2005 Equity Incentive Plan	1,000,000
<b>Total shares reserved</b>	<b>4,407,820</b>

*Warrants*

The Company has the following warrants outstanding to purchase common stock as of December 31, 2008:

	<b>Warrant Shares</b>	<b>Exercise Price Per Share</b>	<b>Date Issued</b>	<b>Expiration Date</b>
June 2004 PIPE	604,000	\$ 4.62	July 27, 2004	July 27, 2009
Biosyn warrants	81,869	5.84-17.52	October 22, 2004	2013 - 2014
May 2005 PIPE				
Series A	714,362	2.25	May 13, 2005	May 13, 2010
Series B	714,362	2.50	May 13, 2005	May 13, 2010
<b>Total warrants</b>	<b>2,114,593</b>			

*Non Cash Compensation Expense Related to Stock Options*

For the years ended December 31, 2008 and 2007, the Company recorded non-cash compensation expense of \$17,150 and \$53,874, respectively, all of which was charged to selling, general and administrative expenses.

**9. Income Taxes**

At December 31, 2008, the Company had net operating loss carryforwards of approximately \$95.7 million and \$24.0 million for federal and state purposes, respectively. The federal net operating loss carryforwards expire through the year 2028. The state net operating loss carryforwards expire through the year 2018. At December 31, 2007, the Company also had state research and development credit carryforwards of approximately \$2.8 million and \$200,000 for federal and state purposes, respectively. The federal credits expire through the year 2027 and the state credits expire through the year 2019. The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes that could limit the Company's ability to utilize these carryforwards. The Company most likely has experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Cellegy's merger with Adamis as described in Footnote 1, may also impact the ability for the Company to utilize its current net operating loss carryforwards. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, the Company may not be able to take full advantage of these carryforwards for federal income tax purposes. The Company determined that the net operating loss carryforwards relating to Biosyn are limited due to its acquisition in 2004 and has reflected the estimated amount of usable net operating loss carryforwards in its deferred tax assets below.

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

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The amount of deferred tax assets in 2008 and 2007, not available to be recorded as a benefit due to the exercise of nonqualified employee stock options are approximately \$559,000.

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Deferred tax assets:</b>		
Net operating loss carryforward	\$ 33,000	\$ 32,100
Credit carryforward	2,900	2,900
Capitalized research and development	7,300	7,400
Depreciation and amortization	1,400	1,000
Other, net	300	300
<b>Total deferred tax assets</b>	<b>44,900</b>	<b>43,700</b>
Valuation allowance	(44,900)	(43,700)
<b>Net deferred tax assets</b>	<b>\$ -</b>	<b>\$ -</b>

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

	<b>Years Ended December 31,</b>			
	<b>2008</b>		<b>2007</b>	
<b>Net loss</b>	<b>\$ (1,534)</b>		<b>\$ (1,927)</b>	
Tax (benefit) at Federal statutory rate	\$ (522)	34.00%	\$ (655)	34.00%
Meals and entertainment	-	-	1	(0.05)
Stock compensation expense	6	(0.37)	24	(1.26)
Research credits	-	-	6	(0.31)
Deferred taxes not benefited	516	(33.63)	624	(32.38)
<b>Provision for taxes</b>	<b>\$ -</b>	<b>-%</b>	<b>\$ -</b>	<b>-%</b>

The valuation allowance for deferred tax assets for 2008 increased by approximately \$1.2 million and for 2007 decreased by approximately \$3.5 million.

On January 1, 2007, the Company adopted FIN 48 which clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. FIN 48 requires that Cellegy recognize in the financial statements the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The implementation of FIN 48 did not have a material impact on the Company's consolidated financial statements. At December 31, 2008, the Company had no unrecognized tax benefits and has not accrued any tax liabilities for unrecognized tax obligations.

The Company does not believe the total amount of unrecognized benefits or obligations as of December 31, 2008 will increase or decrease significantly in the next twelve months. The Company's Federal, California, and Pennsylvania tax returns subsequent to 2004 are subject to examination by the tax authorities.

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

**10. Related Party Transactions**

The Company pays fees to its board members in connection with services rendered to the board. In 2007, the Company began paying fees to its board members for their services rendered only as board members and not for services rendered in connection with the audit, nominating, and compensation committees. There were no fees paid to board members in 2008, nor were any such fees owed as of December 31, 2008. The total cash payments to board members made in connection with these services during the year ended December 31, 2007 was \$49,500.

**11. Note Receivable**

In connection with the signing of the Merger Agreement with Adamis on February 12, 2008, Cellegy issued to Adamis an unsecured convertible promissory note in the amount of \$500,000 (the "Promissory Note") to provide additional funds to Adamis during the pendency of the merger transaction. Principal outstanding under the Promissory Note accrues interest at 10% per annum. The Promissory Note becomes immediately due and payable in the event that the Merger Agreement is terminated by Adamis or Cellegy for certain specified reasons or on the later of (i) the sixteen month anniversary of the issue date of the Promissory Note or (ii) the date that is two business days following the first date on which certain other notes issued by Adamis to a third party have been repaid in full. If the Promissory Note is outstanding as of the closing of the merger transaction, the Promissory Note will not be repaid, but will convert into shares of Adamis stock, and these shares will be immediately cancelled. Cellegy will receive no additional shares. At December 31, 2008, the Company has included the Promissory Note and its related interest income accrual in stockholders' equity. See Note 12 "Subsequent Events".

**12. Subsequent Events**

The stockholders of Cellegy and Adamis approved the merger transaction and related matters at an annual meeting of Cellegy's stockholders and at a special meeting of Adamis stockholders each held on March 23, 2009. On April 1, 2009, Cellegy completed the merger transaction with Adamis. In connection with the closing of the merger transaction, the promissory note converted into shares of Adamis stock, and these shares were immediately cancelled.

In connection with the consummation of the merger and pursuant to the terms of the Merger Agreement, the Company changed its name from Cellegy Pharmaceuticals, Inc. to Adamis Pharmaceuticals Corporation, and Adamis changed its corporate name to Adamis Corporation.

Pursuant to the terms of the Merger Agreement, immediately before the consummation of the merger Cellegy effected a reverse stock split of its common stock. Pursuant to this reverse stock split, each 9.929060333 shares of common stock of Cellegy that were issued and outstanding immediately before the effective time of the merger was converted into one share of common stock and any remaining fractional shares held by a stockholder (after the aggregating fractional shares) were rounded up to the nearest whole share (the "Reverse Split").

As a result, the total number of shares of Cellegy that were outstanding immediately before the effective time of the merger were converted into approximately 3,000,000 shares of post-Reverse Split shares of common stock of the Company. Pursuant to the terms of the Merger Agreement, at the effective time of the merger, each share of Adamis common stock that was issued and outstanding immediately before the effective time of the merger ceased to be outstanding and was converted into the right to receive one share of common stock of the Company. As a result, the Company expects to issue approximately 42,978,067 post-reverse split shares of common stock to the holders of the outstanding shares of common stock of Adamis before the effective time of the merger.

During 2008, the Company's common stock traded on the OTCBB under the symbol "CLGY.OB." In April, 2009, and following its merger with Adamis and the change of Cellegy's corporate name, the trading symbol for the common stock changed to "ADMP".

Also in connection with the closing of the merger, Cellegy amended its certificate of incorporation to increase the authorized number of shares of common stock from 50,000,000 to 175,000,000 and the authorized number of shares of preferred stock from 5,000,000 to 10,000,000.

Cellegy's stockholders also approved a new 2009 Equity Incentive Plan (the "2009 Plan"), which became effective upon the closing of the merger. The 2009 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards, and other forms of equity compensation (collectively "stock awards"). In addition, the 2009 Plan provides for the grant of performance cash awards. The aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the 2009 Plan is 7,000,000 shares. The number of shares reserved of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2010 through and including January 1, 2019, by the lesser of (a) 5.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year or (b) a lesser number of shares of common stock determined by the Company's board of directors before the start of a calendar year for which an increase applies.

EXHIBIT 21.1

SUBSIDIARIES OF ADAMIS PHARMACEUTICALS CORPORATION.

Name	State of Incorporation
Biosyn, Inc.	Pennsylvania
Cellegy Holdings, Inc	Delaware
Adamis Corporation	Delaware
Adamis Laboratories, Inc.	Delaware
Adamis Viral Therapeutics, Inc.	Delaware

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***CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM***

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 33-96384, 333-06065, 333-60343, 333-42840, 333-91588, 333-114229 and 333-121838) of Cellegy Pharmaceuticals, Inc. of our report dated May 12, 2009 relating to the 2008 and 2007 consolidated financial statements of Cellegy Pharmaceuticals, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2008.

/s/ MAYER HOFFMAN McCANN P.C.

Plymouth Meeting, Pennsylvania  
May 12, 2009



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

I, Dennis J. Carlo, certify that:

1. I have reviewed this annual report on Form 10-K of Adamis Pharmaceuticals Corporation;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 annual report is being prepared; and
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting disclosure to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
  - c) 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
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
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: May 12, 2009

By: /s/ Dennis J. Carlo  
Chief Executive Officer

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

I, Robert O. Hopkins, certify that:

1. I have reviewed this annual report on Form 10-K of Adamis Pharmaceuticals Corporation;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 annual report is being prepared; and
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting disclosure to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
  - c) 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
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
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: May 12, 2009

By: /s/ Robert O. Hopkins  
Vice President, Finance and Chief Financial Officer

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER****PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT**

The undersigned, Dennis J. Carlo, the Chief Executive Officer of Adamis Pharmaceuticals Corporation (the “Company”), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company’s Annual Report on Form 10-K for the year ended December 31, 2008 (the “Report”) fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DENNIS J. CARLO

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Dennis J. Carlo  
*Chief Executive Officer*

Dated: May 12, 2009

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.

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## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

## PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Robert O. Hopkins, as Vice President, Finance and Chief Financial Officer of Adamis Pharmaceuticals, Corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Annual Report on Form 10-K for the year ended December 31, 2008 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ ROBERT O. HOPKINS

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Robert O. Hopkins  
*Vice President and Chief Financial Officer*

Dated: May 12, 2009

This certification is being furnished to the SEC with this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.

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