

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-KSB contains forward-looking statements that relate to our plans, objectives, estimates, goals and future financial performance. Such statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and speak only of the date of this report. Words such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," and variations of such words and similar expressions, identify such forward-looking statements. Our business is subject to numerous risks and uncertainties, including our ability to register, commercialize or license our products successfully and to promote physician and patient acceptance of our products, our need to obtain substantial additional capital to fund our operations and product development, and our need to obtain governmental and regulatory approvals. These and other risks and uncertainties, many of which are addressed in the section entitled "Management's Discussion and Analysis or Plan of Operations," could cause our actual results, performance and developments to be materially different from those expressed or implied by any of these forward-looking statements.

ADDITIONAL INFORMATION

The Pilot Therapeutics name and logo, and the names Functional Liponomics(TM) and Airozin(TM), are our pending trademarks. This Annual Report on Form 10-KSB also includes trademarks of companies other than the registrant or its subsidiaries.

PILOT THERAPEUTICS HOLDINGS, INC.

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PART I

ITEM 1. BUSINESS

OVERVIEW

Pilot Therapeutics Holdings, Inc. (the "Parent") is a holding company for Pilot Therapeutics, Inc. ("Pilot", and together with the Parent, as "We", or the "Company"), a development stage specialty pharmaceutical company. Pilot is developing and commercializing its pipeline of novel over the counter ("OTC") medical food and pharmaceutical products that address what the Company believes to be large markets including asthma, triglyceride elevation, cystic acne and cancer. For over 50 years, certain fatty acids have been recognized as molecules that provide critical signals in organs and tissues. However when over-produced, these same molecules can cause human diseases. Pilot has expertise in understanding how dysfunctional fatty acid metabolism in the human body causes disease. Pilot utilizes a proprietary, state-of-the-art fatty acid and genomic profiling research platform, termed Functional Liponomics(TM), to discover and develop important pharmaceutical solutions for chronic human diseases.

Since inception on August 3, 1998, Pilot has been in the development stage and its activities have principally consisted of discovering and developing novel therapeutics, obtaining financing and recruiting personnel. Pilot is working on several long-term development projects that involve experimental technology and clinical trials that may require several years and substantial expenditures to complete. As expected, revenues to date have not resulted from Pilot's planned principal operations. Pilot's ability to meet its business plan objectives is dependent upon its ability to raise additional financing, substantiate its technology and, ultimately, to fund its operations from revenues.

CORPORATE HISTORY

The Parent, formerly Interallied Group, Inc. ("ILRG"), is incorporated under the laws of Delaware. Pilot is a North Carolina corporation incorporated on August 3, 1998. On August 24, 2001, pursuant to a Stock Exchange Agreement dated as of August 1, 2001, ILRG issued 7,726,217 shares of its common stock in exchange for all the issued and outstanding shares of Pilot's capital stock in a recapitalization transaction accounted for as a reverse acquisition. Prior to the recapitalization transaction, ILRG was a non-operating public shell corporation with no significant assets. ILRG was treated as the "acquired" company in the transaction, but remained a surviving legal entity with Pilot as its wholly owned subsidiary. Accordingly, the transaction was treated for accounting purposes as an issuance of stock by Pilot for the net monetary assets of ILRG, accompanied by a recapitalization. Since this transaction was in substance a recapitalization of ILRG and not a business combination, a valuation was not performed and no goodwill was recorded, as all assets and liabilities are stated at their historical costs. In connection with the transaction, all redeemable convertible preferred stock of Pilot Therapeutics, Inc. was converted into common stock of Pilot and then exchanged for common stock of ILRG.

Subsequent to the recapitalization transaction, on October 2, 2001, the shareholders of ILRG, a Nevada corporation, approved a proposal to reincorporate ILRG under the laws of Delaware by merger of ILRG into the Parent, then its wholly owned subsidiary, pursuant to an Agreement and Plan of Merger between ILRG and the Parent (the "Reincorporation"), in which each outstanding share of ILRG's common stock was converted into one share of the Parent's common stock. The Reincorporation became effective November 30, 2001, but did not result in any change in the business, assets or liabilities of ILRG, cause the corporate headquarters or other facilities to be moved, or result in any relocation of management or other employees. The Parent's stock, which was formerly traded on the OTC Bulletin Board under the symbol "ILRG", is now traded on the OTC Bulletin Board under the symbol "PLTT".

By virtue of the operation of Rule 12g-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), all shares of the Parent's common stock issued to the holders of issued and outstanding shares of ILRG common stock immediately prior to the effective time of the Reincorporation are deemed automatically registered under Section 12(g) of the Exchange Act; and the Parent continues to be subject to the reporting requirements of Section 13 of the Exchange Act in the same manner as ILRG had been subject to such requirements immediately prior to the Reincorporation.

As a result of the Reincorporation, Pilot is now a wholly-owned subsidiary of the Parent.

PILOT'S STRATEGY AND PRODUCT PIPELINE

As a foundation for growth, Pilot's strategic approach is to:

- discover and develop therapeutic OTC and pharmaceutical products utilizing its proprietary research platform and expertise in understanding how dysfunctional fatty acid metabolism causes human disease, referred to as Functional Liponomics(TM);
- take advantage of the potentially large opportunity in the OTC asthma market with the launch of AIROZIN(TM), believed to be the first OTC medical food for the dietary management of asthma;
- utilize near-term revenues from non-prescription OTC medical food products to help fund the development of long-term revenues from prescription pharmaceutical products;
- take advantage of regulatory changes governing the development of botanicals as drug products (Botanical Drug Guidance, August 2000) to rapidly move Pilot's botanical drug candidates into late-stage clinical trials leading to a New Drug Application ("NDA"); and,
- utilize relationships with key contract research organization ("CRO") and pharmaceutical partners to co-develop and support Pilot's lead drug candidates during late-stage clinical development.

Through years of research, Dr. Floyd H. Chilton (Pilot's founder and CEO) has developed Functional Liponomics(TM), a proprietary, state-of-the-art fatty acid and genomic profiling research platform. This discovery platform allows Pilot to identify critical points in fatty acid metabolism that lead to human diseases. More importantly, this platform also enables Pilot to design therapeutic strategies to control fatty acid signals which impact a wide range of human diseases, including asthma, stroke, heart disease and cancer. Functional Liponomics(TM), which explores causal relationships between specific genes and fatty acids and their effects on human diseases, was developed from research supported by the National Institutes of Health and major medical centers including Johns Hopkins and Wake Forest Universities.

Pilot is leveraging this core competency into its commercial product pipeline of novel pharmaceutical and OTC products. These products are specifically designed to safely and effectively address dysfunctional fatty acid metabolism in chronic human diseases.

Pilot's believes its lead OTC medical food product, AIROZIN(TM), is a revolutionary way to manage asthma. Over thirty years of research has shown that leukotrienes, a fatty acid derivative, causes inflammation leading to signs and symptoms of asthma. AIROZIN(TM) is an anti-inflammatory OTC medical food that Pilot-sponsored clinical trials have shown to reduce elevated leukotrienes associated with asthma. AIROZIN(TM) is a once a day formulation for the dietary management of asthma designed to avoid the side effects of other medications such as steroids. Specifically, we believe that AIROZIN(TM) is the first clinically proven product for the dietary management of asthma, a disease that afflicts approximately 17.3 million Americans, according to the Centers for Disease Control (1998).

Pilot is in the process of preparing for filing an Investigational New Drug Application ("IND") for AIROZIN(TM), to move into late phase clinical trials. Pilot is also in the process of preparing for filing an IND for its second product, PLT 732, a prescription pharmaceutical product for the treatment of high triglyceride levels associated with heart disease and stroke, to enable it to enter Phase II clinical trials.

AIROZIN(TM)

We believe that anti-inflammatory medications have proven to be the most important class of therapy for asthma patients. Anti-inflammatory medications such as steroids and leukotriene antagonists block the body's production of key inflammation-causing substances called leukotrienes and cytokines. Anti-inflammatory medications lead to fewer symptoms, better airflow, less sensitive airways, less airway damage, and fewer asthma attacks. These benefits are often observed within several weeks of medication.

Anti-inflammatory medications dominate the worldwide asthma market. According to the SG Cowen, Pharmaceutical Therapeutic Categories Outlook, October 2001, in 2000, sales of inhaled steroids and leukotriene antagonists exceeded \$3.3 billion and \$1 billion, respectively. In addition to treating asthma, steroids are used extensively for allergic rhinitis, commonly referred to as hay fever. Worldwide nasal steroid sales exceeded \$1.4 billion in 2000. Recent studies suggest leukotriene antagonists have good efficacy in allergic rhinitis, indicating positive potential sales growth in the leukotriene category.

In spite of their important contribution to asthma disease management, steroids are associated with a number of side effects because they affect more genes than those that regulate substances such as leukotrienes. While inhaled steroids have improved their safety profile, there are still major questions regarding the long-term use of steroids, especially in children. Thus, a major clinical endpoint for most new asthma therapeutics is the measure of their capacity to reduce a patient's reliance on steroids.

Pilot-sponsored clinical trials indicate that through dietary means AIROZIN(TM) blocks the production of leukotrienes, a fatty acid derivative, which cause inflammation leading to asthma. Specifically, AIROZIN(TM) has been the subject of the following clinical trials:

- A proof of principle study (n=67) in the National Institute of Health ("NIH") General Clinical Research Center at Wake Forest University School of Medicine
- An optimization of dose and active ingredients (n=30) in the NIH General Clinical Research Center at Wake Forest School of Medicine
- A trial to optimize the bioavailability of the active ingredients (n=45) at the Quintiles Transnational Corporation Phase I Clinical Trials Center in Lenexa, Kansas
- A Phase I/IIA safety and efficacy trial (n=45) in the Quintiles Transnational Phase I Clinical Trials Center in Lenexa, Kansas
- A Phase II efficacy trial (n=50) in asthmatics in the NIH General Clinical Research Center at Wake Forest School of Medicine
- A multicenter pediatric dosing trial (n=24) conducted by CompleWare Corporation, Iowa City, Iowa
- Five peer-reviewed and one submitted journal articles

Like steroids, AIROZIN(TM) blocks, through dietary means, leukotrienes, one family of critical asthma causing mediators. Based on the natural components' safe history of use and the results of clinical trials, we believe that AIROZIN(TM) may have a significant safety advantage when compared with other anti-inflammatory medications, such as steroids. We believe this is especially significant due to recent consumer trends toward self-medication and the fact that the only OTC products currently available to treat asthma are rescue products, unlike AIROZIN(TM), which is a maintenance product.

Pilot intends to launch AIROZIN(TM) in the marketplace in the second half of 2002. It is a once-a-day, oral OTC medical food that clinical trials have shown to be safe and effective for the dietary management of asthma. We believe that the launch of AIROZIN(TM) would represent the first OTC maintenance product to enter the asthma market place and the only novel OTC strategy to be launched for asthma in several years. The two existing OTC asthma medications, Primatene Mist(TM) and Bronkaid(TM), are rescue medications. They both contain the drug epinephrine, which works like a bronchodilator and relaxes the muscles around the airways. They work for about 20-30 minutes and therefore provide short-term relief of asthma symptoms. Primatene Mist(TM) and Bronkaid(TM) do not control asthma symptoms or prevent asthma attacks and are not recommended for people with high blood pressure, diabetes, thyroid disease, or heart disease. In contrast, we believe that AIROZIN(TM) may have a number of competitive advantages over these rescue products in that AIROZIN(TM) is a once a day, non-steroid, safe maintenance product for the dietary management of asthma. We believe that AIROZIN(TM) will be the first asthma medical food maintenance product sold over-the counter and has an opportunity to capture and secure a competitive advantage in a growing market.

PLT 732 for Triglyceride Elevations Associated with Coronary Heart Disease, Diabetes and Stroke

Designed to block triglyceride elevations in diseases such as cardiovascular disease ("CVD") and diabetes, our second botanical drug product candidate, PLT 732, has shown promising results in two proof-of-principle studies in hypertriglyceridemic patients. We believe that PLT 732 may have the opportunity to become first line therapy in the treatment of hypertriglyceridemia. Data from two Pilot-sponsored clinical trials (carried out in CROs) with this botanical show that PLT 732 reduced triglycerides in hypertriglyceridemia patients with no reported side effects in these limited studies.

Studies have identified high triglyceride levels as an independent risk factor for CVD. There are approximately 1.1 million heart attacks per year in the U.S. and approximately 12 million living survivors at risk for a second heart attack. A recent study in *Circulation* (vol. 104:2892, Dec. 2001) revealed that high triglyceride levels are a major risk factor associated with stroke in humans. We believe that PLT 732 has the potential to address these large markets.

We believe that the current products on the market for hypertiglyceridemia are not optimal. While effective in lowering cholesterol, the statin products often fail to control mixed hyperlipidemia. In addition statin-fibrate combination therapy has a risk of major side effects, such as myopathy. We believe that doctors do not currently have adequate tools to manage triglycerides, and must make difficult decisions to manage them.

We intend to capitalize upon FDA Botanical Guidance to move PLT 732 into Phase II clinical trials under an IND. PLT 732 will be developed as a botanical drug and marketed as a prescription product. Based on the Food and Drug Administration's ("FDA") Guidance for Botanical Drugs, we are preparing an IND documenting the safe history of botanical use, chemical composition, and data regarding PLT 732 from our safety and efficacy clinical trials.

Oral Retinoids for Cystic Acne and Cancer

We are also researching and developing pharmaceutical product candidates intended for the treatment of cancer and cystic acne via nuclear receptors. Studies over the last five years reveal that nuclear receptor, (which belong to the steroid superfamily of receptors) biology may hold the key to revolutionary treatments for complex human diseases such as cancer and cystic acne. Two of our products in development, PLT 99511, for cystic acne, and PLT 99257, for cancer have been identified using crucial points in nuclear receptor signaling that control human diseases. Both PLT 99511 and PLT 99257 are synthetic chemical entities and we plan to file INDs for these drug candidates to enable us to move into Phase I clinical trials in 2003.

PLT 99511 and PLT 99257 are selective agonists of the nuclear steroid retinoid receptor, RAR γ . The RAR γ receptor has been localized to selected tissues such as skin and transactivation of this receptor induces terminal differentiation of a number of cancers. We plan to move these products from late stage preclinical research to the Phase IIA, clinical proof-of-principle decision point.

Specifically, PLT 99511:

- is a RAR γ specific oral retinoid under investigation for severe acne.
- is an oral product that has been shown in early studies in a highly-predictive acne model to be 10-fold more potent than currently available medications in oral potency and superior in terms of maximal efficacy and time to onset of activity.
- due to its RAR γ specificity, does not affect serum triglycerides because the human liver does not contain the RAR γ receptor, which may provide a safety advantage over existing therapies.
- is currently projected to be ready for Phase I clinical trials in 2003.

PLT 99257 is a RAR γ specific oral retinoid under investigation for cancer. Pre-clinical, clinical and epidemiological data provide strong evidence that RAR γ agonists are potent chemotherapeutic and chemopreventative agents in cancer. For example, RAR γ agonists have shown efficacy in head and neck cancers, leukemias and cancers of the skin and cervix. PLT 99257 has shown potential efficiency in the several pre-clinical

models of cancer. Like PLT 99511, PLT 99257 does not appear to affect serum triglycerides, which may provide a safety advantage over existing therapies. PLT 99257 is projected to be ready for Phase I clinical trials in 2003.

STRATEGIC OUT-SOURCING

Raw Material Supply

Pilot is in the final stages of negotiating an agreement pursuant to which the supplier will supply Pilot with needed oils and provide certain chemical crop growing expertise to assist in the development of Airozin(TM) and Pilot's other pipeline products. In addition, this supplier currently develops plant-based sources and an agricultural system for many of Pilot's required bulk active ingredients.

Manufacturing

Pilot is in the final stages of negotiating a Research and Development Services Agreement with a manufacturer, pursuant to which the manufacturer would develop a formulation, flavoring, and manufacturing process for AIROZIN(TM). As part of this Agreement, the manufacturer would also manufacture test batches of AIROZIN(TM) suitable for consumer acceptability testing and may ultimately be engaged to manufacture the final product in their manufacturing facilities.

Research and Development Collaboration Opportunities

Pilot has also entered into a research agreement with Wake Forest University ("WFU"), pursuant to which the clinical research, including dose tolerance and proof-of-principle studies, to support Pilot's evidence-based medical foods will be carried out in the WFU School of Medicine's General Clinical Research Center. Pilot believes that this collaboration is pivotal to develop discovery-stage bioactive lipid therapeutic products in a cost-effective manner. Pilot also seeks to leverage funding from the National Institutes of Health (NIH) and to utilize other laboratories at WFU as research collaborators and subcontractors in obtaining Small Business Administration (e.g. STTR / SBIR) funding. Pilot has received a Small Business Innovation Research (SBIR) Grant to fund research for the development of anti-cancer products.

Commercialization

On June 22, 2001, Pilot entered into an Investment and Royalty Agreement and a Loan Agreement with PharmaBio Development, Inc. ("PharmaBio") and a Commercialization Agreement with Innovex LP ("Innovex"). Innovex and PharmaBio are commonly controlled by Quintiles Transnational Corporation.

Under the Commercialization Agreement, Innovex will provide sales force services and certain marketing services on a fee-for-service basis to Pilot in connection with the development and promotion of certain proprietary technology specified in the Commercialization Agreement. Innovex will supply the sales force beginning on the date the sales force is launched, and continuing for five years. The Commercialization Agreement is non-cancelable by Pilot or Innovex during the five-year term, except for a material breach by or bankruptcy of either party, termination of the Investment and Royalty Agreement or if commercialization of the proprietary technology is no longer being pursued.

Under the Investment and Royalty agreement, PharmaBio will fund 50% of the estimated \$55,000,000 total commercialization cost under the Innovex Commercialization Agreement, during the five-year term following launch, provided that, without the approval of PharmaBio, such obligation will not exceed (i) \$6,000,000 for any single year, or (ii) \$30,000,000 in the aggregate. The funding will be structured so that 10% of the total estimated commitment amount will be paid upon launch of the Innovex sales force and the remaining amount will be paid in equal quarterly payments during the five-year term. Further, in exchange for PharmaBio's funding commitments, Pilot shall pay PharmaBio royalties on sales of a specified product covered by the Commercialization Agreement with such rates subject to adjustment as set forth in the Investment and Royalty Agreement to provide PharmaBio a minimum rate of return.

PATENTS/INTELLECTUAL PROPERTY

The Company's success is dependent in part on our ability to obtain and maintain patent protection for our products, obtain and maintain adequate licenses for the use of patents licensed or sublicensed from or to third parties, maintain trade secret protection, obtain and maintain protection of proprietary know-how, and operate without infringing the proprietary rights of others. Our policy is to aggressively protect our proprietary technology through patents, where appropriate, and through trade secrets or other types of intellectual property in other cases, or in addition to patent protection. Additionally, we rely on licenses of patent and other intellectual property rights from or to third parties. We, or our licensing partners, have obtained approximately 40 patents which will expire on various dates between 2015 and 2020. We have filed patent applications for additional patents covering our products, processes, and methodologies as appropriate, and currently have approximately 29 patents pending. Management intends to continue to file patents when needed to protect the Company's proprietary technologies, and intends to in-license or out-license selected patent rights where potentially beneficial to the Company.

The Company has 1) filed and in-licensed (from Wake Forest University) patent applications related to using Essential Fatty Acids (EFAs) for treating inflammatory diseases and patents and patent applications related to anti-cancer components and uses (co-owned by Glaxo-SmithKline); 2) filed patent applications related to using certain polyunsaturated fatty acids for treating various disease indications; and 3) in-licensed (from Bristol-Myers Squibb) a patent and patent application portfolio related to using receptor selective retinoids to treat acne and other disorders. A number of compounds that the Company intends to develop into over-the-counter medical food or prescription botanical or synthetic pharmaceutical products are covered by the patent portfolios described above, including (a) Airozin(TM) a proprietary medical food product for the dietary management of asthma; (b) PLT 99511, an in-licensed compound for the treatment of acne; (c) PLT 99257, an in-licensed compound for the treatment of cancer; and (d) PLT 732, a botanical drug compound for the treatment of hypertriglyceridemia. Each of the patents for these compounds will expire on various dates between 2015 and 2020 and certain patents are pending. Management expects to develop additional potential commercial compounds from its overall patent portfolio and Functional Liponomics(TM) research and development platform, and file additional patent applications relating to such compounds.

In December 1998, Pilot entered into a license agreement with Wake Forest University whereby it licensed certain patented or patent pending inventions from Wake Forest in exchange for common stock. Pilot is required to pay Wake Forest license fees and milestone payments based upon the achievement of certain product development events related to licensed products, as defined in the agreement. In addition, Pilot is obligated to pay royalties, ranging from 3% to 5%, to Wake Forest based on net sales of products related to the licenses obtained, with a minimum royalty of \$30,000 beginning in the year ended December 31, 2001. Pilot has the option to issue warrants to Wake Forest, in an amount determined by the terms of the agreement, to purchase common stock with an exercise price of \$1.00 per share in lieu of the cash payment of the minimum royalty up until net sales of licensed products exceed \$5 million in a calendar year.

In April 1999, Pilot entered into an exclusive license agreement with Johns Hopkins University for the rights to certain patented or patent pending inventions. The license agreement provides for Pilot to reimburse Johns Hopkins for the costs of maintaining the patent rights, pay a processing fee of \$5,000, and pay an annual maintenance fee beginning in 2001 of \$2,500. Pilot is required to pay royalties of 1.5% of net sales, with minimum payments until cumulative net sales reach a certain level. There are also milestone payments based upon the achievement of certain product development events, as defined in the agreement. In the event the license is sold there are payments due on the amount of the sale, ranging from 5% to 10%, as well as 5% of any additional amounts that may be received from any sublicense. The license agreement terminates concurrently with the expiration of the patents.

On October 3, 2001, Pilot and Bristol-Myers Squibb ("BMS") signed an agreement granting Pilot a worldwide exclusive license to develop and market a BMS patented class of oral retinoids. Pilot will pay license fees and royalties based upon certain milestones and net sales of products containing the patented compound, respectively.

The Company has several pending trademarks that it intends to use to uniquely identify and brand its products in the marketplace. The Company typically seeks to register these marks in the United States, but in the future may seek to register these marks in other parts of the world where the products are made, used or consumed. The primary pending trademarks owned by the Company are AIROZIN(TM) and Functional Liponomics(TM). In

addition, trademark applications for the AIROZIN design, AIROZIN – ITS FOR BREATHING, NATURALLY, and the Pilot Therapeutics name and logo are currently pending. This Annual Report on Form 10-KSB also includes trademarks of companies other than the Company.

GOVERNMENTAL REGULATIONS

The manufacture and sale of medical food products and botanical and synthetic drugs are subject to regulation principally by the FDA and state and local authorities in the United States, and by comparable agencies in certain foreign countries. The Federal Trade Commission ("FTC") and state and local authorities regulate the advertising of foods and OTC drugs. The Federal Food, Drug and Cosmetic Act ("FDC Act") and the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of the Company's products. In general, products falling within the FDA's definition of drugs, whether botanical or synthetic, require premarketing clearance by the FDA. Products falling within the definition of "medical foods" (a legal category recognized by Congress in 1988 in the Orphan Drug Amendments, 21 U.S.C. Section 360ee(b)(3), incorporated into the FDC Act by the Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353, 2357) do not require premarketing clearance. In addition to the requirement that a medical food be generally recognized as safe ("GRAS"), 21 U.S.C. Section 360ee(b)(3) states:

"The term medical food means a food which is formulated to be consumed or administered externally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

The FDA's regulations further interpret the definition of medical food, limiting it to a food in pertinent part "only if":

- It is a specially formulated and processed product as opposed to a naturally occurring foodstuff used in its natural state;
- It is intended for the dietary management of a patient who has special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
- It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
- It is intended to be used under medical supervision; and
- It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

The Company intends to market its lead medical food product, AIROZIN(TM) for the dietary management of asthma, as a medical food. Pilot is pursuing and believes it will obtain self-affirmed GRAS status for AIROZIN(TM) and, if obtained, believes that AIROZIN(TM) will be marketed as a medical food product that does not require FDA pre-marketing clearance.

The Company intends to develop and commercialize both botanical and synthetic drug products. In general, the steps required before a drug may be marketed in the United States include (i) preclinical laboratory and animal testing, (ii) submission to the FDA of an Investigational New Drug ("IND") application, which must become effective before clinical trials may commence, (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the drug, (iv) submission to the FDA of a New Drug Application ("NDA") and (v) FDA approval of the NDA prior to any commercial sale or shipment of the drug. In addition to obtaining FDA approval for each drug product, each drug manufacturing establishment must be registered with the FDA and must comply with good manufacturing practice requirements.

Preclinical testing is generally conducted in laboratory animals to evaluate the potential safety and the efficacy of a drug. The results of these studies are submitted to the FDA as a part of an IND application, which must be approved before clinical trials in humans can begin. Typically, clinical evaluation involves a time consuming and

costly three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the early safety profile, the pattern of drug distribution and metabolism. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large-scale, multi-center, controlled trials are conducted with patients afflicted with a target disease to provide sufficient data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical trials and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient.

In August 2000, the FDA published "Draft Guidance for Industry: Botanical Drug Products" ("Draft Guidance"), which provides, among other things, that botanical drug products that are generally recognized as safe (GRAS), currently legally marketed as dietary supplements or foods, or are demonstrated to have a safe history of use, may require less preclinical and toxicology information than synthetic new drugs, which could result in more rapid advancement from IND filing to late-stage (Phase II and Phase III) clinical trials than generally expected for synthetic or new chemical entities. Based on the fact that the Company's botanical ingredients have a history of safe use, and may have marketed as medical foods with GRAS ingredients, the Company believes its botanical drug products may obtain this more rapid advancement to late-stage clinical trials following the filing of INDs.

In addition, see the Section captioned "RISK FACTORS" in Item 6 herein.

RESEARCH AND DEVELOPMENT

Pilot entered into a research agreement with Wake Forest whereby Wake Forest will perform sponsored research. Beginning in July 1999, the agreement requires Pilot to request that Wake Forest perform sufficient research that Pilot shall pay Wake Forest a minimum of \$50,000 per year through the year ending December 31, 2002.

In connection with a research agreement with Wake Forest, Pilot entered into a sponsored research sub-agreement in March 2001. The term of this sub-agreement is from March 2001 to October 2001, with a final report due in 2002. In exchange for research assistance, Pilot will pay fees to Wake Forest in the aggregate of \$170,356 over the specified term of the agreement. Certain research milestones, the initiation of the project and the presentation of the final report trigger cash payments to be made by Pilot. The Company has expensed \$148,363 of the aggregate cost of the research project for the year ending December 31, 2001.

During the fiscal years ended December 31, 2001 and December 31, 2000, the Company incurred research and development expenses of \$1,724,384 and \$1,106,981, respectively.

EMPLOYEES

As of December 31, 2001, we had 13 full-time employees, three (3) who have Ph.D.s. Of these 13 employees, five (5) employees were engaged in research and development and contract related research and development activities, one (1) was engaged in production or production development related activities and seven (7) were in administrative, business development, or sales and marketing positions. We consider relations with our employees to be good. None of our employees are covered by a collective bargaining agreement.

DIRECTORS AND EXECUTIVE OFFICERS

The directors and executive officers of the Parent and their ages are as follows:

| Name | Age | Position |
|-------------------------|-----|--|
| Glenn J. Kline | 38 | Chairman of the Board of Directors |
| Floyd H. Chilton, Ph.D. | 44 | Founder, Director, President, Chief Executive Officer and Chief Scientific Officer |
| Santo J. Costa, J.D. | 56 | Director |
| James W. Johnston | 55 | Director |
| Bradley J. Udem, Ph.D. | 44 | Director |
| Margaret M. Urquhart | 52 | Director |
| Jack Voller | 55 | Vice President of Marketing, Pilot Therapeutics, Inc. |
| John Crain | 54 | Vice President of Sales, Pilot Therapeutics, Inc. |
| Beth Fordham-Meier | 36 | Vice President of Corporate Development, Pilot Therapeutics, Inc. |
| David J. Mills | 35 | Treasurer, Secretary and Controller |

Glenn J. Kline has been the Chairman of the Board of Directors since the Company's inception in August 1998. Since 1997, Mr. Kline has been Managing Partner of The Academy Funds ("Academy"), an early stage venture group. Academy actively participated in the formation of Pilot and continues to help guide our corporate strategy and raise necessary funding. In the five years prior to joining Academy, Mr. Kline worked at Del Monte Foods Co., a \$1.5 billion multinational corporation, where he was a member of the executive management team as Senior Director in charge of the Business Development and Strategic Planning Group. Prior to joining Del Monte Foods Co., Mr. Kline spent seven years at Ventana Growth Funds, a venture capital firm based in California. He currently serves on the board of directors for the University of North Carolina General Administration Partnership for Innovation, Silicon Wireless Corporation and Sharp Vista Technologies, Inc.

Floyd H. Chilton, Ph.D., Founder, Director, President, Chief Executive Officer and Chief Scientific Officer. Dr. Chilton has been a Director of the Company since inception in August 1998. Prior to joining the Company as President, CEO and CSO in December 2000, Dr. Chilton was Director of Molecular Medicine, Professor of Physiology and Pharmacology, Professor of Internal Medicine and Professor of Biochemistry at the Wake Forest University School of Medicine from 1991 to 2000 and an Assistant Professor at the Johns Hopkins School of Medicine from 1986 to 1991. Dr. Chilton holds 18 issued and 25 pending patents. He has authored or co-authored over 100 scientific articles and book chapters.

Santo J. Costa, J.D. Mr. Costa has been a Director of the Company since January 13, 2000. Since January 2002, he has been a consultant for Quintiles Transnational Corp., a premier contract pharmaceutical organization, where he was Vice Chairman from December 1999 to December 2001 and President from April 1994 to December 1999. He joined Quintiles as President and Chief Operating Officer in April 1994 at the time of its initial public offering (IPO). Prior to joining Quintiles, Mr. Costa spent 23 years in the pharmaceutical industry, most recently serving as Senior Vice President for Administration and General Counsel of Glaxo, Inc.

James W. Johnston. Mr. Johnston has been a Director of the Company since May 1999. He has been President and Chief Executive Officer of Stonemarket Enterprises, Inc. a consulting and investment company, since July 1996. He previously served as Vice Chairman of RJR Nabisco, Inc., a holding company, from 1995-1996. He also served as Chairman of R.J. Reynolds Tobacco Co. and was Chief Executive Officer. Mr. Johnston also serves on the Board of Directors of Sealy Corporation.

Bradley J. Udem, Ph.D. Mr. Udem has been a Professor of Medicine and Physiology at the Asthma and Allergy Center of The Johns Hopkins University School of Medicine since 1987. Mr. Udem has been a Director of the Company since 1999.

Margaret M. Urquhart. Ms. Urquhart has been a Director of the Company since April 2001. She was the President of Krispy Kreme Stores, North America, from December 1999 to December 2000, and the President of Lowes Foods, Inc from November 1995 to December 1999, where she had the distinction of being one of two women in the country to serve as president of a supermarket chain with more than 50 stores. Similarly, as Vice President and Officer of Hannaford Bros. Co. and President of its subsidiary, Wellby Super Drug Stores, she had the distinction of being the first woman to be President of an American retail drug store chain. Urquhart serves on the Boards of Trustees for Salem Academy and College and the North Carolina School of the Arts.

Jack Voller, Vice President of Marketing, Pilot Therapeutics, Inc. Mr. Voller has been the Vice President of Marketing, Pilot Therapeutics, Inc. since January 2002, and he served as the Vice President of Sales for Pilot from September 2001 to January 2002. Mr. Voller has over 24 years of marketing experience most recently as Senior Product Manager at Glaxo SmithKline from 1997 to September 2001. Previously, Mr. Voller spent 10 years with Warner-Lambert (now Pfizer) most recently as the Director of Professional Sales and Marketing and was with Bristol-Myers Squibb for the prior 12 years. Some of the products introduced and or marketed under Mr. Voller include major OTC brands such as Listerine(R) Mouthwash, Benadryl(R) Allergy Medication, and Lubriderm(R) Skin Care products. He also directed the launches of innovative products such as Benadryl(R) Dye Free and Cool Mint Listerine(R).

John Crain, Vice President of Sales, Pilot Therapeutics, Inc. Mr. Crain joined Pilot as Vice President of Sales in January 2002. Mr. Crain has over 30 years of experience in the over-the-counter market, most recently as Vice-President of Sales and Marketing at Dickinson Brands from 1997 to February 2001. In that position he was responsible for developing and directing sales and marketing efforts. Prior to that Mr. Crain served as Vice President of Sales for 7 years at Goody's Pharmaceuticals and then Block Drug where he directed all sales activities for Goody's Headache Powders(R). From 1979 to 1991, Mr. Crain worked for Warner Lambert (now Pfizer) where he held a variety of management positions including Regional Director of Sales as well as Director of Sales Operations. Mr. Crain has introduced and or marketed products such as Listerine(R), Efferdent(R), Lubriderm(R) and Benadryl(R).

Beth W. Fordham-Meier, Vice President Corporate Development, Pilot Therapeutics, Inc. Ms. Fordham-Meier has been the Vice President Corporate Development (formerly Business Development) of Pilot since June 1999. Ms. Fordham-Meier joined Pilot with over 15 years experience in biotechnology and pharmaceutical licensing, intellectual property management, and corporate development and planning. From September 1993 to May 1999, Ms. Fordham-Meier was with Wake Forest University most recently serving as Patent Administrator and Director of Technology Transfer and Industry Relations.

David Mills, Treasurer, Secretary and Controller. Mr. Mills joined the Company in October 2001. Prior to joining Pilot, Mr. Mills spent over 11 years with the accounting firm of Ernst & Young LLP, most recently as an audit senior manager in the North Carolina Entrepreneurial Services Practice. Mr. Mills is a Certified Public Accountant and a member of the American Institute of Certified Public Accountants. He received his B.S. in accounting from Virginia Tech.

Item 2. Properties

The Company's operations are located in approximately 5,000 square foot facility located at 101 North Chestnut Street, Winston-Salem, North Carolina. This facility is used as the Company's corporate headquarters, sales and marketing offices and a research and development laboratory. The lease is for a 5-year lease term expiring in 2004, and provides for annual rent payments of approximately \$70,000.

The Company's facilities and all of its operations are subject to the plant and laboratory safety requirements of various federal, state and local occupational safety and health laws. The Company believes it has complied in all material respects with regard to governmental regulations applicable to it.

The Company believes that its facilities are in good condition and are suitable and adequate for the Company's business. In addition, the Company believes that its facilities are adequately covered by insurance.

Item 3. Legal Proceedings

The Company is not presently involved in any material litigation nor, to our knowledge, is any material litigation threatened against the Company.

Item 4. Submission of Matters to a Vote of Security Holders

On October 2, 2001, the shareholders of the Parent, holding in excess of a majority of the issued and outstanding voting stock of the Company and acting by written consent in lieu of a shareholders' meeting, approved (1) the Reincorporation and (2) a proposal to approve the Parent's 2001 Stock Incentive Plan. The number of shares of the Parent's common stock held by the shareholders executing the consent was 5,483,594.

PART II

Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters

Market for the Registrant's Common Equity

The Parent's common stock is traded on the OTC Bulletin Board under the symbol "PLTT". Prior to December 1, 2001, the Parent's common stock had traded under the symbol "ILRG".

The table below shows the range of high and low per share closing prices for our common stock for the periods indicated, as quoted by the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

| Quarter ended | 2001 | | 2000 | |
|---------------|---------|---------|---------|---------|
| | High | Low | High | Low |
| March 31 | \$ 7.00 | \$ 5.75 | \$ 5.50 | \$ 5.00 |
| June 30 | 7.50 | 6.00 | 6.25 | 5.00 |
| September 30 | 7.00 | 6.25 | 6.75 | 5.25 |
| December 31 | 9.25 | 5.25 | 7.00 | 6.38 |

As of February 28, 2002, there were approximately 284 record holders of our common stock.

We have never declared or paid any cash dividends on shares of our common stock. We currently intend to retain all earnings for future growth and, therefore, do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

During the fourth quarter of 2001, the Parent issued the following securities that were not registered under the Securities Act of 1933:

- On December 1, 2001, the Parent issued 112 shares of common stock to a former employee in connection with the exercise of stock options at an exercise price of \$2.50 per share. The securities were issued pursuant to an exemption from registration under Rule 701 under the Securities Act of 1933.
- On December 1, 2001, the Parent issued 1,400 shares of common stock to a former employee in connection with the exercise of stock options at an exercise price of \$.385 per share. The securities were issued pursuant to an exemption from registration under Rule 701 under the Securities Act of 1933.
- On December 27, 2001, the Parent issued 22,390 shares of common stock to a former employee in connection with the exercise of stock options at an exercise price of \$.385 per share. The securities were issued pursuant to an exemption from registration under Rule 701 under the Securities Act of 1933.
- In addition, on January 9, 2002, the Parent issued 479,500 shares of common stock to accredited investors in a private placement of securities exempt from registration under Rule 506 under the Securities Act of 1933. These shares were sold at a purchase price of \$4.00 per share, for aggregate gross proceeds of \$1,918,000.

Item 6. Management's Discussion and Analysis of Financial Condition and Plan of Operations

Certain statements in this section and elsewhere in this Annual Report on Form 10-KSB are forward-looking in nature and relate to our plans, objectives, estimates and goals. Such statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and speak only as of the date of this report. The terms "expect," "anticipate," "believe," "intend," "estimate," "plan," and "project" and similar words or expressions are intended to identify forward-looking statements. The forward-looking statements are based on current expectations, are inherently uncertain, are subject to risks, and should be viewed with caution. Our business is subject to many risks and uncertainties, including our ability to register, commercialize or license our products successfully and to promote physician and patient acceptance of our products, our need to obtain substantial additional capital to fund our operations and the progress of product development, and the uncertain regulatory environment (and the resulting requirements and restrictions regarding pre-marketing approval and label and promotional claims) surrounding our lead product. These and other risks and uncertainties, many of which are described in more detail in this section of our Annual Report on Form 10-KSB under "Risk Factors," could cause actual results and experience to differ materially from those expressed or implied by any of these forward-looking statements.

OVERVIEW

Because we are a small business issuer in the development stage that has not yet had revenues from operations, the following discussion and analysis relates to our plan of operation for the next 12 months. However, we have also provided a comparative analysis of our financial condition and results of operations from the years ended December 31, 2001 and December 31, 2000, to the extent such analysis relates to our plan of operation.

The following discussion, analysis and plan of operation should be read in conjunction with the accompanying Consolidated Financial Statements and related notes of Pilot Therapeutics Holdings, Inc., formerly Interallied Group, Inc. ("ILRG"), and its wholly owned subsidiaries including Pilot Therapeutics, Inc. (together referred to as the "Company," "us" or "we").

The comparative results of operations for the years ended December 31, 2001 and 2000 include only the historical information of Pilot Therapeutics Holdings, Inc.'s wholly-owned subsidiary Pilot Therapeutics, Inc. and not the operations of ILRG. Prior to the recapitalization transaction with Pilot Therapeutics, Inc., ILRG was engaged in restaurant operations until the second quarter of 2000; when such operations were discontinued. Our current operations are the discovery and development of pharmaceutical products. Management believes that comparative presentation of the results of significantly unrelated operations could be misleading.

RESULTS OF OPERATIONS

As a development stage company, our operating activities have been limited primarily to research and product development (including preclinical and clinical development) and, accordingly, we have not yet generated any revenues from operations.

Research and Development Expenses

Since inception, we have been developing products that are created from our proprietary Functional Liponomics(TM) discovery platform. The Functional Liponomics(TM) discovery platform combines state-of-the-art lipid and genomic profiling to identify points where dysfunctional lipid metabolism impacts human disease. We expect that over the next 12 months, we will continue: (i) the development of our medical food product for asthma, AIROZIN(TM), that we currently expect to launch in the second half of 2002; (ii) the preparation and filing of an Investigational New Drug ("IND") application and continuation of clinical trials for our lead botanical drug candidates for coronary heart disease (PLT 732), and AIROZIN(TM), our OTC product for asthma.

Our research and development expenses in 2001 were \$1,724,000, as compared with \$1,107,000 in 2000, an increase of 56%. This increase in research and development expenses is primarily attributable to the intensification of clinical trials of pipeline products generated from our Functional Liponomics(TM) discovery platform, as we

prepare our lead products for introduction into the marketplace. Approximately 95% of these research and development expenses related to development and clinical trials related to products from Functional Liponomics(TM).

General and Administrative Expenses

General and administrative expenses have increased from \$516,000 in 2000 to \$5,205,000 in 2001. This increase is primarily a result of the beginning of the marketing and commercialization of AIROZIN(TM). Approximately 54% of these costs relate to commercialization and marketing relating of AIROZIN(TM) and approximately 27% relates to the non-cash amortization of deferred compensation on certain stock options issued to employees and consultants. We expect general and administrative costs to continue to increase as a result of the selling and marketing costs associated with the launch of AIROZIN(TM), including the hiring of additional personnel, over the next 12 months.

Net Loss

Due to the increased research and development and general and administrative expenses, and the lack of any revenues to offset expenses, we had a net loss of \$7,090,995 in 2001, as compared with a net loss of \$1,719,056 in 2000.

PLAN OF OPERATION

Since our inception in August 1998, we have raised sufficient funds from investors and other financing from strategic alliances to sustain our research and product development activities to date. At December 31, 2001, we had cash and cash equivalents totaling \$830,000, a decrease of \$218,000 compared to December 31, 2000. In addition, at December 31, 2001 we had \$1,281,000 in escrowed cash related to capital raised in a private placement of common stock. The private placement subsequently closed in January 2002, in which we raised capital totaling \$1,781,000, net of placement fees.

Net cash used in operating activities increased to \$4,553,000 for the year ending December 31, 2001, up from \$1,459,000 for the year ending December 31, 2000. This increase primarily resulted from the net losses of \$7,091,000 and \$1,719,000 for the years ended December 31, 2001 and 2000, respectively. In 2001 this loss was offset by non-cash charges of \$1,476,000, relating to the amortization of deferred compensation on certain stock options issued to employees and consultants of \$1,418,000 and depreciation of property and equipment of \$58,000. At December 31, 2001, we had working capital of \$271,000 compared with a working capital of \$623,000 at December 31, 2000.

We expect to incur additional losses for the foreseeable future as a result of our expenditures for research and product development, including costs associated with conducting preclinical testing and clinical trials, and charges associated with the purchase of technology, product launches and other necessary expenditures. We intend to invest significantly in our products prior to entering into possible collaborative arrangements. This will increase our need for capital and may result in substantial losses for several years. We expect the amount of losses will fluctuate significantly from quarter to quarter as a result of increases in our research and development expenses, the execution of clinical trials, the execution or termination of collaborative arrangements, the initiation, success or failure of clinical trials, or the success or failure of product marketing.

Based on the level of operating cash requirements expected for 2002, we will require significant additional funding to continue our operations beyond the second quarter of 2002. Therefore, we are currently seeking to raise approximately \$5.5 million to \$10 million of additional capital to fund: (i) the development, marketing and launch of AIROZIN(TM), our product for asthma, and (ii) the preparation and filing of an IND and clinical trials for our lead botanical drug candidates for coronary heart disease (PLT 732), and AIROZIN(TM), our OTC product for asthma.

We are aggressively pursuing possible sources of capital, including possible equity private placements, debt offerings and expanded strategic alliances or partnerships. We have previously been successful in raising additional capital and believe that we will be successful in the future. However, there can be no assurance that we will be able to raise sufficient additional financing. If we are unsuccessful in our efforts to obtain sufficient additional financing,

we may be required to reduce or delay research and development activities, as well as the development and marketing of the launch of AIROZIN(TM) until such time that additional financing is obtained, or to cease operations. We could also be required to enter into a strategic alliance or partnership or a possible business combination that could involve the merger or sale of the Company.

If we raise additional funds by issuing equity securities, substantial dilution to our existing stockholders may result. There can be no assurance that we will be successful in raising the necessary additional financing on acceptable terms, or at all.

Under our June 2001 Loan Agreement with PharmaBio (an affiliate of Quintiles), we have a \$6,000,000 line of credit (the "Loan"). The Loan is available to Pilot for general working capital purposes with \$4,000,000 outstanding at December 31, 2001. Under the Loan Agreement the final \$2,000,000 would have been available had the Company consummated a defined equity sale by December 31, 2001, which the Company did not complete. Since a defined equity sale was not consummated by December 31, 2001, the final \$2,000,000 will not become available to the Company. The Loan accrues interest at the greater of 10% or prime plus 2.5%. Interest on the Loan is payable quarterly and the principal will be due in a lump sum payment at the end of the 36-month term (June 2004). The Loan has a commitment fee in the amount of 1% of each increment outlined above that becomes available to Pilot, which is paid on the first anniversary of the date on which the increment becomes available. PharmaBio may at any time elect to convert the Loan, including the quarterly interest payments and the commitment fee, into shares of the Company's common stock based on a "conversion price" as defined in the Loan Agreement, which ranges from \$1.915 to \$2.50 per share. Additionally, PharmaBio may purchase additional shares of the Company's common stock at the conversion price up to an amount equal to the difference between the total credit availability under the Loan and the amount outstanding under the Loan.

Our future liquidity, capital requirements and our ability to achieve profitability will depend on many factors, including scientific progress in research and development programs, the size and complexity of our programs, the scope and results of preclinical studies and clinical trials, our ability to establish and retain corporate partnerships and collaborative arrangements, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the cost of establishing our manufacturing capabilities, commercialization activities and arrangements, the cost of manufacturing preclinical and clinical material and other factors not within our control. There can be no assurance that the additional financing necessary to meet our short and long-term capital requirements will be available on acceptable terms or at all.

In 2002, we currently expect to increase our total number of employees from 13 to approximately 20, subject to obtaining additional financing. Pursuant to the provisions of our operating and capital leases, our minimum lease payment commitment for 2002 is approximately \$165,000.

Contractual Obligations and Commercial Commitments

The following table summarizes the Company's future contractual cash obligations as of December 31, 2001:

| | 2002 | 2003 | 2004 |
|-----------------------------|-----------|-----------|-----------|
| Operating lease commitments | \$ 42,093 | \$ 41,448 | \$ 11,911 |
| Capital lease obligations | 35,357 | 32,530 | 1,431 |

The following table summarizes commercial commitments of the Company that could potentially require performance by the Company in the event of demands by third parties or contingent events:

| | 2002 | 2003 |
|--|-------------|-------------|
| Open raw material purchase commitments | \$1,600,000 | \$1,600,000 |

In connection with the manufacturing and distribution of our first product AIROZIN(TM), expected to launch in the second half of 2002, we have purchase commitments to suppliers totaling approximately \$3,200,000. These commitments are for the purchase of raw materials over the next 24 months.

Off-Balance Sheet Arrangements

The Company does not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Certain Trading Activities Accounted for at Fair Value

The Company does not engage in any commodity or derivative trading activities.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

General

The Company's discussion and analysis of its Plan of Operation is based upon the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to licensing agreements, purchase agreements, product returns, bad debts, inventories, intangible assets, income taxes, financing operations, and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Research and Development

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs and costs associated with sponsored research and development.

Patent Costs

Patent costs are expensed due to the uncertainties involved in realizing value in the future from specific patents.

Inventories

The Company writes down its inventory for obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.

Income Taxes

We currently have significant deferred tax assets, which are subject to periodic recoverability assessments. Realization of our deferred tax assets is principally dependent upon our achievement of projected future taxable income. Until such time, a valuation allowance will be recorded for the deferred tax asset to reduce the amount to a balance that is more likely than not to be realized.

License Fees

Upon execution and continuation of license agreements, license initiation and maintenance fees are evaluated as to whether the underlying licensed compound or drug candidate has alternative uses, and if none, have been recorded as an expense. License milestones criteria are continuously evaluated.

Financial Instruments

Many of our debt and equity transactions are complex transactions, which require significant judgments in the area of determining fair value. Critical assumptions such as the expected volatility of our stock and the expected life of the financial instrument are subject to judgment and may change in the future.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (the "FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 133, "Accounting for Derivative Investments and Hedging Activities." SFAS No. 133 established a new model for accounting for derivatives and hedging activities and supercedes several existing standards. The provisions of SFAS No. 133, as amended by Statements 137 and Statement 138, became effective for all fiscal quarters of fiscal years beginning after June 15, 2000. The adoption of Statement 133 did not have an impact on the Company's financial statements, as the Company has not entered into any hedging or derivative activities.

In June 2001, the FASB issued SFAS No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized, but will be subject to annual impairment tests. Other intangible assets will continue to be amortized for their useful lives. The amortization provisions of SFAS No. 142 apply to goodwill and intangible assets acquired after June 30, 2001. The adoption did not have an impact on our financial condition or our results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supersedes both SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion). SFAS No. 144 retains the fundamental provisions in SFAS No. 121 for recognizing and measuring impairment losses on long-lived assets held for use and long-lived assets to be disposed of by sale, while also resolving significant implementation issues associated with Statement 121. SFAS No. 144 retains the basic provisions of Opinion 30 on how to present discontinued operations in the income statement but broadens that presentation to include a component of an entity (rather than a segment of a business). Unlike SFAS No. 121, an impairment assessment under SFAS No. 144 will never result in a write-down of goodwill. Rather, goodwill is evaluated for impairment under SFAS No. 142, Goodwill and Other Intangible Assets. The Company is required to adopt SFAS No. 144 no later than the year beginning after December 15, 2001, and plans to adopt its provisions during the quarter ending March 31, 2002. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial statements.

RISK FACTORS

The Plan of Operation contains forward-looking statements concerning our business and operations and we desire to take advantage of the "safe harbor" provisions of the Private Securities Litigations Reform Act of 1995. The following risks and uncertainties could cause our actual results and experience to differ materially from the results expressed or implied by the forward-looking statements set forth above under "Plan of Operation" or elsewhere in this Annual Report on Form 10-KSB.

There is no assurance that the Company will be able to raise additional capital necessary to sustain its operations past the second-quarter of 2002.

Based on the current level of operating cash requirements expected for 2002 and in anticipation of the commercialization of AIROZIN(TM), we will require significant additional funding to continue our operations beyond the second quarter of 2002. Possible sources of funds include additional or expanded strategic alliances, additional equity or debt public offerings and/or private placements, and additional grants and contracts. While we have previously been successful in raising additional capital, there can be no assurance that we will be able to raise sufficient capital to continue our current level of operations beyond the second quarter of 2002. If we are unsuccessful in our efforts to obtain sufficient additional financing, we may be required to reduce or cease operations, delay or reduce research activities or enter into a business combination transaction that would involve the merger or sale of the Company.

In light of our financial condition and operating results, our independent accountants have included in their report on our consolidated financial statements as of and for the year ended December 31, 2001 an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

Since the Company's inception in 1998, it has had operating losses and does not currently have any products at-market or other activities generating revenues.

The Company's accumulated deficit as of December 31, 2001 was \$10,321,000, and the Company anticipates that its operating and capital expenditures will increase significantly into 2002 and in future years primarily due to its commitment to: (i) file an IND, complete clinical development, manufacture and market its lead OTC medical food product, AIROZIN(TM) for asthma; (ii) file an IND application, under the FDA's Botanical Drug Guidance, and continue clinical trials for PLT 732, for elevated triglycerides, (iii) file INDs for PLT 99511, for cystic acne, and PLT 99527, for cancer; (iv) identify and develop additional pharmaceutical products; and (v) support the marketing, sales, and distribution of pipeline pharmaceutical products, including hiring additional personnel and expanding office and laboratory space and / or entering into strategic alliances for cost-and-risk-sharing.

The Food and Drug Administration may object to the Company's desired language on the labels of its medical foods.

Regulations of the Food and Drug Administration (FDA) prescribe permissible claims that may, and required claims that must, be made on the labels of medical foods. In the case of AIROZIN(TM) or one or more of the Company's other medical food products, the FDA may not accept the Company's desired label language and may require the Company to support its label claims with additional data or to revise the label. Furthermore, FDA regulations pertaining to label claims for medical foods may change, or the FDA may take the position that the Company's medical foods should instead be classified as dietary supplements, non-medical foods, "drugs" or any other statutory category. As a consequence of any of these events, the Company may be required to change its desired label claims which could materially and adversely affect the Company's ability to market and sell its products, or may be required to support the claims by conducting clinical testing that could take several years, be expensive and yield unpredictable results, any of which could materially and adversely affect the Company's business, results of operations or financial condition.

The current regulatory framework governing medical foods could change or additional regulations could arise at any stage during the Company's product development.

The basic regulatory framework governing medical foods, including AIROZIN(TM), is provided in the Federal Food, Drug and Cosmetic Act ("FDC Act") and the Orphan Drug Amendments of 1988. Currently, the FDC Act and the Orphan Drug Amendments and associated sections of the Food, Drug and Cosmetic Act and FDA medical food regulations generally prohibit the FDA from regulating the active ingredients in dietary supplements or medical foods as "drugs" unless product claims are made or promotional activities are conducted that would trigger classification as a drug. Accordingly, the development time of medical foods is shorter than that required for pharmaceuticals; and the Company is seeking to leverage the reduced development time for its medical food products to reduce development costs and generate earlier revenues than generally expected for drugs. If the current regulations governing these products were to change or compliance with such regulations were to become more expensive or time-consuming, potential profit margins for the Company's medical food products would be materially reduced and the Company may opt to alter its development or marketing strategy or to abandon development or product launch, any of which may materially and adversely affect the Company's business, results of operations or financial condition.

The Company believes that its medical food products, as they are to be promoted and intended by the Company for use, will be considered by the FDA to be medical foods that are exempt from being considered drugs and therefore do not require pre-marketing clearance. However, there can be no assurance that the FDA will not take a contrary position. If the FDA were to do so, the Company may be required to seek FDA approval for such products, market such products as dietary supplement products or withdraw such products from the market. The Company believes that such products are subject to regulations governing product safety, use of ingredients, labeling, promotion and manufacturing methods.

In addition, the Company also will be subject to foreign regulatory authorities governing clinical trials and pharmaceutical sales if it seeks to market its products outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from country to country and the time required may be longer or shorter than that required for FDA approval. There can be no assurance that any foreign regulatory agency will approve any product submitted for review by the Company.

The Food and Drug Administration could consider the Company's botanical drug products to be "new chemical entities."

There can be no assurance that the FDA will not consider the Company's botanical drug products to be "new chemical entities." If the FDA were to do so, the Company may be required to conduct additional preclinical and clinical testing for such products, and even with additional testing may not obtain FDA approval to market such products nor obtain a period of exclusivity, which could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company's ability to market medical food products could be affected by the Company's ability to obtain generally recognized as safe ("GRAS") status.

There can be no assurance that Pilot will obtain GRAS status for AIROZIN(TM) as required to market the product as a medical food. A failure of the Company to obtain GRAS status for AIROZIN(TM) could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company's long-term success may depend on the acquisition, development and commercialization of new products, and the results of its research and development efforts for new products are unpredictable.

The Company's long-term viability and growth will depend on the successful acquisition, development and commercialization of new products from research activities and collaborations. The successful development and commercialization of new products is uncertain and dependent on numerous factors, many of which are beyond the Company's control. If the Company is unable to commercialize its pipeline products or to discover or acquire and

commercialize new products, the Company's business, operating results and financial condition would be materially and adversely affected.

The Company could experience difficulty in managing growth.

The Company currently has limited resources with which to manage rapid growth. The Company's ability to manage growth successfully will require the Company to continue to improve its operational, management and financial systems and controls and to expand its work force. There can be no assurance that the Company will be able to expand and adapt its infrastructure to manage growth on a timely basis, at a commercially reasonable cost, or at all. If the Company's management is unable to utilize and expand its operational, management, and financial systems and controls to manage growth effectively, the Company's business, operating results, and financial condition could be materially and adversely affected.

The Company is dependent on key management and qualified scientific personnel.

The Company is highly dependent on the efforts of its management. The loss of the services of one or more members of management could impede the achievement of the Company's business objectives. Due to the specialized scientific nature of the Company's business, the Company is also highly dependent upon its continuing ability to attract and retain qualified executives and scientific personnel. There is intense competition for qualified personnel for the Company's activities and there can be no assurance that the Company can presently, or will be able to continue to, attract and retain qualified personnel necessary for the development of its existing business and its expansion into areas and activities requiring additional expertise. The loss of, or failure to recruit additional, scientific, technical and executive personnel could have a material adverse effect on the business of the Company.

The Company is dependent on Quintiles Transnational Corporation and its other strategic partners.

The Company seeks to leverage its strategic partnerships to reduce costs, accelerate product development and commercialization and enhance shareholder value. In particular, the Company substantially relies, and for the foreseeable future will substantially rely, on Quintiles Transnational Corporation and its subsidiaries, Innovex L.P. and PharmaBio Development, Inc., to provide top level commercialization and financial resources. In addition, the Company relies on providers of raw material supplies for its first products, as well as manufacturing support. If any of the Company's strategic partners were to terminate its relationship with the Company or were to fail to provide the expected resources and services successfully and in a timely manner, the Company's business could be materially and adversely affected.

The Company has limited manufacturing capability.

The Company does not own sufficient large-scale manufacturing capacity to manufacture commercial quantities of its lead products or its pipeline products under development, including AIROZIN(TM). Accordingly, the Company is in the final stages of negotiating a Research and Development Services Agreement with a manufacturer pursuant to which the manufacturer would develop a formulation, flavoring, and manufacturing process for its products, both for commercial development testing and for commercial sale. In addition, the Company is in the final stages of negotiations for an agreement pursuant to which the supplier will supply Pilot with needed oils and provide certain chemical crop growing expertise to assist in the development of AIROZIN(TM) and Pilot's other pipeline products. If the Company is unsuccessful in securing a third party to manufacture commercial quantities of its products, the Company may need to invest substantial sums to purchase or construct facilities sufficient to meet long-term manufacturing requirements for AIROZIN(TM) and its other products.

The Company's lead product requires fatty acids from seeds of plants that must be grown.

An active fatty acid in the Company's lead product, AIROZIN(TM), gamma linolenic acid, is derived from the seed of borage plants. These seeds must be secured in order to manufacture AIROZIN(TM). While the Company has secured seed to manufacture AIROZIN(TM) for one year, there is no guarantee that a major crop failure would not impact the supply of borage seed or that the Company will be able to secure seeds at affordable cost in future years. If the Company were unable to secure sufficient and / or affordable seeds, the Company's business, results of operations and financial condition could be materially and adversely affected.

The Company cannot be certain that it is free to market its lead and pipeline products without infringing on the rights of others.

The Company, through its exclusive license from Wake Forest University, has obtained an issued U.S. Letters Patent relating to its lead product, AIROZIN(TM); and has in-licensed or filed additional pending and issued U.S. and foreign patents relating to AIROZIN(TM) and its pipeline products. The Company has also obtained opinions of counsel based upon prior art identified through patentability or freedom-to-operate searches applicable to its business or that was cited by patent examiners during patent prosecution. No search, however, is exhaustive or certain to identify all applicable art. There can be no assurance that a third party will not assert a claim to any art that may prevent the Company from having the freedom to market its lead and pipeline products, or that may enable such party to compete effectively with the Company.

The Company relies on patent and trademark protection, trade secrets, know-how, and continuing technological advancement to develop and maintain its competitive position.

The Company has both in-licensed and developed a substantial portfolio of patents and patent applications and has applied to register several trademarks that it believes will be important in distinguishing its business and providing barriers-to-entry for potential competitors. There can be no assurance, however, that the Company will not be precluded from commercialization, or delayed, by the proprietary rights of others, or by competing products or technologies, or that it will not be required to expend substantial resources to preserve or defend its rights, whether because the holders of its licensed patents fail to secure and protect their rights and the Company must assume control of patent prosecution, or otherwise. Furthermore, there can be no assurance that the Company's currently pending patent applications will be issued as patents, that its issued patents will not be challenged or invalidated, or that any patent protection will be sufficiently broad to enable the Company freedom-to-operate or provide a barrier-to-entry for potential competitors, or that the Company's currently pending trademark applications will be registered as trademarks.

Furthermore, there can be no assurance that others will not independently develop similar technologies or duplicate the technology owned by or licensed to or from the Company or design around the patented aspects of such technology. There can be no assurance that the products and technologies that the Company currently is developing and intending to market will not infringe patents or other rights owned by others. A claim or finding of infringement on any of the Company's products could have a material adverse effect on the Company's business, financial condition and results of operations.

Management believes that the laws governing the obtaining and enforcing of foreign patents are different than those for obtaining domestic patents. Therefore, the Company recognizes that its patent position, if any, may be different in the United States than in Europe, Asia, or elsewhere. In addition, the protection provided by foreign patents once they are obtained may be different or weaker than that provided by domestic patents.

The Company relies and expects to continue to rely upon unpatented proprietary know-how and continuing technological innovation in the development and manufacture of its principal products. The Company's policy is to require all its employees, consultants and advisors to enter into confidentiality and non competition agreements with the Company. There can be no assurance, however, that these agreements will provide meaningful protection for the Company's trade secrets or proprietary know-how in the event of any unauthorized use or disclosure of such information, nor can there be no assurance that others will not obtain access to or independently develop similar or equivalent trade secrets or know-how. In addition, there can be no assurance that the Company's former employees will not engage in competition with the Company, which could potentially require the Company to seek potentially costly legal remedy to cease competition. Any disclosure of confidential information including trade secrets or know-how of the Company, or any competition with the Company by its former employees could have a material adverse affect of the Company's business, financial condition and results of operations.

Clinical trials may not generate results that support the safety or efficacy of AIROZIN(TM), the Company's lead product.

Currently, the Company is sponsoring Phase II-like clinical trials for AIROZIN(TM) in adult asthmatics and has completed safety and efficacy trials in adults with no side effects reported. However, market research reveals that children will represent a large proportion of AIROZIN(TM)'s market. Based on previous trial results, the Company is or will be sponsoring dosing and safety clinical trials in children. These trials may not demonstrate that AIROZIN(TM) is safe or effective in children. As a result, the Company may be forced to delay the launch of AIROZIN(TM) to conduct further development activities and to conduct additional clinical trials, which would materially and adversely affect the Company's business, financial condition and results of operations.

The Company's pharmaceutical products are subject to governmental regulations and approvals, and required preclinical or clinical testing may be unsuccessful or expensive.

The FDA and similar governmental agencies in foreign countries impose substantial requirements on pharmaceutical products, like the Company's botanical and synthetic drug candidates, before permitting late-stage clinical development, manufacture, marketing and sales to the public. Thus, pharmaceutical development is costly and time-consuming, and dependent on a number of factors such as the type, complexity and novelty of the product and the ability to enroll patients in necessary clinical trials. There can be no assurance, however, that the Company will not encounter delays in current or future clinical trials, which may result in increased costs, program delays, or both. Furthermore, there can be no assurance that the FDA or other governmental agencies will approve all or some uses of the Company's products or will not require that its products undergo additional testing and surveillance programs.

The Company faces substantial competition.

The Company faces competition from a substantial number of companies that market dietary supplement products, potentially including from marketers of prescription leukotriene modifiers or other pharmaceutical products that are marketed for diseases that the Company intends to address with its products. The Company may not be or remain the only company intending to market or marketing a medical food for asthmatics and the Company may not be able to compete successfully with any competitor or potential competitor with substantial resources engaged or that may become engaged in the asthma market. Even if the Company's drug candidates products for the treatment of asthma, elevated triglycerides, severe acne, or cancer are brought to market, they may not be able to compete successfully with the current gold-standard treatments or with other competitors or potential competitors with substantial resources engaged or that may become engaged in the those markets.

The Company may be required to defend lawsuits or pay damages for product liability claims.

Product liability is a major risk in the testing and marketing of biotechnology, natural and pharmaceutical products. The Company faces substantial product liability exposure in human clinical trials and for products that may or may not receive regulatory approval for commercial sale. The Company currently maintains product liability insurance coverage based on its product portfolio, sales volumes and claims experience to date and intends to continue and expand such coverage as the Company, in consultation with the Company's insurance professionals, deems advisable. The Company has retained and utilizes product liability counsel to assist it in its efforts to reduce liability risk. However, there can be no assurance that the Company can avoid liability or that the Company's current or future insurance will provide adequate coverage against potential liabilities, either for clinical trials or commercial sales, or that its liability counsel will be successful in avoiding or prevailing against product liability claims or damages.

The Company may be required to pay damages for environmental accidents and to incur significant costs for environmental compliance.

The Company's research and development activities involve the controlled use of hazardous materials, chemicals, viruses and radioactive and teratogenic compounds which are subject to federal, state and local laws and regulations governing the in-use, manufacture, storage, handling and disposal. The Company cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident or injury, the

Company could be held liable for substantial damages. Furthermore, the Company may be required to incur significant costs to comply with environmental laws and regulations in the future.

The Company may not receive third party reimbursement for any of its OTC medical food products.

The Company's future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to contain or reduce the costs of health care through various means. The Company expects a number of federal, state and foreign proposals to control the cost of drugs through governmental regulation. The form that any health care reform legislation may take, and what actions federal, state, foreign, and private payors may take in response to the proposed reforms, are uncertain. The Company does not currently intend to seek reimbursement for the cost of its medical food products and related treatments from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. As a result, its ability to achieve market acceptance and its results of operations may be adversely affected.

There is a limited trading volume for the Company's common stock, and the Company expects to experience volatility in its common stock price.

The Company's common stock is listed on the OTC Bulletin Board, and is thinly traded. There can be no assurance that an active or liquid trading market in the Company's common stock will develop or be sustained. Furthermore, the market price of the Company's common stock is subject to significant fluctuations in response to variations in quarterly operating results, the failure of the Company to achieve operating results consistent with securities analysts' projections of the Company's performance, and other factors. The stock market has experienced extreme price and volume fluctuations and volatility that has particularly affected the market prices of many biotechnology, emerging growth and developmental stage companies. Factors such as announcements of the introduction of new products by the Company or its competitors, announcements of joint development efforts or corporate partnerships in the nutraceutical/pharmaceutical markets, market conditions in the nutraceutical, pharmaceutical, biotech and other emerging growth sectors, and rumors relating to the Company or its competitors may have a significant impact on the market price of the Company's common stock.

Shares eligible for future sale or registration could have a possible adverse effect on market price.

At December 31, 2001, the Company has 50,000,000 shares of common stock authorized with 9,748,873 shares outstanding. Of these shares, 8,345,935 million shares are restricted pursuant to Rule 144 but 1,402,938 shares are not restricted and are freely tradable. Sales of substantial amounts of these shares in the public market or the prospect of such sales could adversely affect the market price of the Company's common stock.

Item 7. Financial Statements

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

**PILOT THERAPEUTICS HOLDINGS, INC.
(a development stage company)**

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REPORT OF INDEPENDENT ACCOUNTANTS

To the Stockholders and Board of Directors of
Pilot Therapeutics Holdings, Inc.
(formerly Pilot Therapeutics, Inc.)

We have audited the accompanying consolidated balance sheets of Pilot Therapeutics Holdings, Inc. and subsidiaries (a development stage company) as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the each of the two years in the period ended December 31, 2001 and for the period from August 3, 1998 (inception) through December 31, 2001. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our 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 Pilot Therapeutics Holdings, Inc. (a development stage company) at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for the each of the two years in the period ended December 31, 2001 and for the period from August 3, 1998 (inception) through December 31, 2001, in conformity with accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared assuming that Pilot Therapeutics Holdings, Inc. will continue as a going concern. As more fully described in Note 1, the Company is in the development stage, and incurred recurring operating losses and has an accumulated deficit of \$10,320,703 at December 31, 2001. The Company does not have sufficient liquidity to meet its obligations and sustain its planned operations for the year ending December 31, 2002. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ERNST & YOUNG LLP

Greensboro, North Carolina
February 22, 2002

PILOT THERAPEUTICS HOLDINGS, INC.
(a development stage company)

Consolidated Balance Sheets

| | December 31 | |
|--|--------------|--------------|
| | 2001 | 2000 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 829,565 | \$ 1,047,206 |
| Restricted Cash | 1,281,500 | - |
| Accounts receivable | 244,014 | - |
| Inventories | 153,338 | - |
| Prepaid and other current assets | 243,188 | 33,922 |
| | 2,751,605 | 1,081,128 |
| Furniture and equipment, net | 155,209 | 184,194 |
| Other | 51,904 | 54,642 |
| | \$ 2,958,718 | \$ 1,319,964 |
| Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,326,647 | \$ - |
| Accrued expenses and other current liabilities | 721,611 | 400,939 |
| Current portion of capital lease obligation | 35,357 | 23,698 |
| | 2,083,615 | 424,637 |
| Total current liabilities | | |
| Long-term portion of capital lease obligation | 23,573 | 54,765 |
| Convertible debt, net of imputed value of beneficial conversion | 2,778,068 | 2,713,875 |
| | 4,885,256 | 3,193,277 |
| Total liabilities and redeemable convertible preferred stock | | |
| Commitment and contingencies | - | - |
| Redeemable convertible preferred stock, Series A and Series B | - | 750,000 |
| Stockholders' equity (deficit): | | |
| Common stock; \$.001 par value; 50,000,000 shares authorized; 9,748,873 shares issued and outstanding at December 31, 2001 | 9,749 | 2,011 |
| Capital in excess of stated value | 8,811,085 | 124,976 |
| Deferred compensation | (1,612,674) | - |
| Common stock subscriptions | 1,186,005 | - |
| Deficit accumulated during development stage | (10,320,703) | (2,750,300) |
| | (1,926,538) | (2,623,313) |
| Total stockholders deficit | | |
| | \$ 2,958,718 | \$ 1,319,964 |

See accompanying notes.

PILOT THERAPEUTICS HOLDINGS, INC.
(a development stage company)

Consolidated Statements of Operations

| | Year ended December 31 | | Cumulative from August 3, 1998 (inception) to December 31, 2001 |
|---|------------------------|-----------------------|--|
| | 2001 | 2000 | 2001 |
| Operating expenses: | | | |
| License fees | \$ - | \$ - | \$ 112,500 |
| Research and development | 1,724,384 | 1,106,981 | 3,306,710 |
| General and administrative | 5,204,944 | 516,134 | 6,178,990 |
| | | | |
| Loss from operations | (6,929,328) | (1,623,115) | (9,598,200) |
| Interest expense | (207,121) | (116,952) | (324,073) |
| Other income, net | 45,454 | 21,011 | 80,978 |
| | | | |
| Net loss | (7,090,995) | (1,719,056) | (9,841,295) |
| Accreted redemption value on Series A and B redeemable convertible preferred stock | (479,408) | - | (479,408) |
| | | | |
| Net loss to common | <u>\$ (7,570,403)</u> | <u>\$ (1,719,056)</u> | <u>\$ (10,320,703)</u> |
| | | | |
| Pro forma basic and diluted loss per common share | (0.73) | (0.19) | |
| Pro forma weighted Average common shares outstanding – basic & diluted | 9,725,287 | 9,244,248 | |

See accompanying notes.

PILOT THERAPEUTICS HOLDINGS, INC.
(a development stage company)

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
For the period August 3, 1998 (inception) to December 31, 2001

| | Redeemable Convertible Preferred Stock Series A & B | Common Stock | Capital in Excess of Stated Value | Deferred Compensation | Stock Subscription | Deficit Accumulated During the Development Stage | Total |
|--|---|--------------|-----------------------------------|-----------------------|--------------------|--|----------------|
| | Shares | Shares | Amount | Amount | Value | Amount | |
| Issuance of common stock at inception (August 3, 1998) | - | 1,350,000 | \$ 1,350 | \$ - | \$ - | \$ - | \$ 1,350 |
| Issuance of common stock in exchange for license fee | - | 562,500 | 563 | - | 111,937 | - | 112,500 |
| Issuance of Series A preferred stock, net of issuance cost | 500,000 | - | - | - | (15,652) | - | 484,348 |
| Net loss | - | - | - | - | - | (191,208) | (191,208) |
| Balance at December 31, 1998 | - | - | - | - | - | (191,208) | 406,990 |
| Issuance of common stock | - | 219,125 | 218 | - | 5,063 | - | - |
| Repurchase of common stock | - | (236,454) | (236) | - | - | - | - |
| Issuance of Series A preferred stock, net of issuance cost | 250,000 | - | - | - | (899) | - | - |
| Net loss | - | - | - | - | - | - | - |
| Balance at December 31, 1999 | 750,000 | 1,895,171 | 1,895 | - | 100,449 | (840,036) | 249,101 |
| Exercise of common stock options | - | 116,114 | 116 | - | 15,885 | - | (840,036) |
| Issuance of common stock warrants with convertible demand promissory notes | - | - | - | - | 8,642 | - | (178,900) |
| Net loss | - | - | - | - | - | - | 16,001 |
| Balance December 31, 2000 | 750,000 | 2,011,285 | 2,011 | - | 124,976 | (1,719,056) | 8,642 |
| Conversion of exchangeable demand promissory note | 738,179 | - | - | - | - | (2,750,300) | (1,873,313) |
| Issuance of Series B redeemable convertible preferred stock, net of issuance costs | 196,240 | - | - | - | (13,754) | - | 2,827,225 |
| Accreted redemption value on Series A and B redeemable convertible preferred stock | - | - | - | - | - | - | 737,846 |
| Exercise of common stock options | - | 31,402 | 31 | - | 9,483 | - | - |
| Imputed value of beneficial conversion on convertible debt | - | - | - | - | 1,221,932 | - | 9,514 |
| Deferred compensation related to the issuance of certain stock options | - | - | - | - | - | - | 1,221,932 |
| Amortization of deferred compensation and stock-based compensation | - | - | - | (3,030,608) | - | - | - |
| Common stock forfeitures | - | (20,031) | (20) | - | - | - | - |
| Common stock subscriptions received | - | - | - | - | 1,186,005 | - | 1,417,934 |
| Stock exchange with the Interallied Group, Inc., net | (1,684,419) | 7,726,217 | 7,727 | - | 4,437,820 | - | - |
| Net loss | - | - | - | - | - | (7,090,995) | - |
| Balance December 31, 2001 | - | 9,748,873 | \$9,749 | \$ (1,612,674) | \$ 1,186,005 | \$ (10,320,703) | \$ (1,926,538) |

See accompanying notes.

PILOT THERAPEUTICS HOLDINGS, INC.
(a development stage company)

Consolidated Statements of Cash Flows

| | For the year ended December 31 | | Cumulative from August 3, 1998 (inception) to December 31, 2001 |
|--|-----------------------------------|---------------|--|
| | 2001 | 2000 | 2001 |
| Operating activities: | | | |
| Net loss | \$(7,090,995) | \$(1,719,056) | \$(9,841,295) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Noncash license fee | - | - | 112,500 |
| Depreciation and amortization | 58,109 | 33,073 | 98,647 |
| Noncash promissory notes charges | - | 22,517 | 22,517 |
| Compensation related to issuance of certain stock options | 1,417,934 | - | 1,417,934 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (244,014) | - | (244,014) |
| Inventories | (153,338) | - | (153,338) |
| Prepaid expenses and other current assets | (209,266) | (15,420) | (243,188) |
| Other assets | 2,738 | - | (51,904) |
| Accounts payable and accrued expenses | 1,665,174 | 219,729 | 2,066,113 |
| Net cash used in operating activities | (4,553,658) | (1,459,157) | (6,816,028) |
| Investing activities: | | | |
| Purchases of furniture and equipment | (29,124) | (81,833) | (150,341) |
| Net cash used in investing activities | (29,124) | (81,833) | (150,341) |
| Financing activities: | | | |
| Proceeds from issuance of convertible debt | 4,000,000 | 2,450,000 | 6,800,000 |
| Payments on capital lease obligation | (19,533) | (15,552) | (44,585) |
| Proceeds from issuance of common stock | - | - | 6,395 |
| Proceeds from exercise of stock options | 9,514 | 16,001 | 25,515 |
| Stock Exchange with Interallied Group, Inc. | (362,686) | - | (362,686) |
| Net proceeds from issuance of Series A redeemable convertible preferred stock | - | - | 633,449 |
| Net proceeds from issuance of Series B redeemable convertible preferred stock | 737,846 | - | 737,846 |
| Net cash provided by financing activities | 4,365,141 | 2,450,449 | 7,795,934 |
| Net (decrease) increase in cash and cash equivalents | (217,641) | 909,459 | 829,565 |
| Cash and cash equivalents at beginning of period | 1,047,206 | 137,747 | - |
| Cash and cash equivalents at end of period | \$ 829,565 | \$ 1,047,206 | \$ 829,565 |

See accompanying notes.

PILOT THERAPEUTICS HOLDINGS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business

Pilot Therapeutics Holdings, Inc. with its wholly-owned subsidiary Pilot Therapeutics, Inc. (collectively the "Company") is a specialty pharmaceutical company. Through lipid profiling and metabolism, the Company has developed a proprietary, state-of-the-art lipid and genomic profiling research platform, termed Functional Liponomics(TM). Using Functional Liponomics(TM), the Company is developing novel, branded therapeutic pharmaceutical products that are specifically designed to safely and effectively address dysfunctional lipid metabolism in chronic human diseases such as asthma, coronary heart disease, cancer, cystic acne and rheumatoid arthritis.

Since its inception on August 3, 1998, the Company has devoted substantial effort towards conducting product discovery and development, raising capital, conducting clinical trials, recruiting personnel and supporting the sales and marketing organizations and infrastructure in anticipation of the commercial launch of the Company's first product for asthma, Airozin(TM) in the second half of 2002. In the course of such activities, the Company has sustained operating losses and expects such losses to continue for the next several years. The Company is working on several long-term development projects that involve experimental technology and may require several years and substantial expenditures to complete. The Company has not generated any significant revenues or product sales and has not achieved profitable operations or positive cash flow from operations. The Company's deficit accumulated during the development stage aggregated \$10,320,703 through December 31, 2001.

The Company's ability to meet its business plan objectives is dependent upon its ability to raise additional financing, substantiate its technology and, ultimately, to fund its operations from revenues. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. The Company plans to continue to finance its operations in 2002 with a combination of stock issuances, debt issuances, license payments, and payments from strategic research and development arrangements and, in the longer term, revenues from product sales. There are no assurances, however, that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its planned products.

The Company is considered a development stage company for financial statement disclosure purposes because the Company is devoting substantially all of its efforts to establishing new products.

2. Formation of Company and Basis of Presentation

Pilot Therapeutics Holdings, Inc., formerly Interallied Group, Inc. ("ILRG"), is incorporated under the laws of Delaware. On October 2, 2001, the shareholders of ILRG, a Nevada corporation, approved to reincorporate ILRG under the laws of Delaware pursuant to an Agreement and Plan of Merger between ILRG and Pilot Therapeutics Holdings, Inc. ("Reincorporation"). The Reincorporation became effective November 30, 2001, at which time ILRG's name changed to Pilot Therapeutics Holdings, Inc.

On August 24, 2001, pursuant to a Stock Exchange Agreement dated as of August 1, 2001, ILRG issued 7,726,217 shares of its common stock in exchange for all the issued and outstanding shares of capital stock of Pilot Therapeutics, Inc., a North Carolina corporation, in a recapitalization transaction accounted for as a reverse acquisition. Prior to August 24, 2001, ILRG was a non-operating public shell corporation with no significant assets and was treated as the "acquired" company in the transaction, but remains the surviving legal entity. Accordingly, the transaction was treated for accounting purposes as an issuance of stock by Pilot Therapeutics, Inc. for the net monetary assets of ILRG, accompanied by a recapitalization. Since this transaction is in substance a recapitalization of ILRG and not a business combination, a valuation was not performed and no goodwill was recorded, as all assets and liabilities are stated at their historical costs. In connection with the transaction all redeemable convertible preferred stock of Pilot Therapeutics, Inc. was converted into common stock.

2. Formation of Company and Basis of Presentation (continued)

As a result of the Reincorporation of ILRG into Pilot Therapeutics Holdings, Inc., Pilot Therapeutics, Inc. is now a wholly-owned subsidiary of Pilot Therapeutics Holdings, Inc.

The comparative results of operations for the year ended December 31, 2000 include only the historical information of Pilot Therapeutics Holdings, Inc.'s wholly-owned subsidiary Pilot Therapeutics, Inc. ("Pilot") and not the operations of ILRG, now Pilot Therapeutics Holdings, Inc. ILRG was engaged in restaurant operations until the second quarter of 2000 when such operations were discontinued, and the Company's current operations are the discovery and development of novel branded therapeutic pharmaceutical products. Management believes that comparative presentation of the results of significantly unrelated operations could be misleading. Given that Pilot is in the development stage, the consolidated financial statements include the historical comparative and cumulative results of operations and cash flows of Pilot from August 3, 1998, its date of inception.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Pilot Therapeutics Holdings, Inc. and its wholly owned subsidiaries, including Pilot Therapeutics, Inc. All inter-company transactions have been eliminated in consolidation.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity date of three months or less to be cash equivalents.

Restricted Cash

Restricted cash is cash received in connection with common stock subscription agreements and is held in escrow until the subscription period is closed.

Inventories

Inventories, consisting primarily of purchased raw materials, are stated at the lower of cost (first-in, first-out) or market.

Furniture and Equipment

Furniture and equipment are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets ranging from 3 to 7 years. Assets capitalized under capital leases are amortized over the shorter of the remaining term of the lease or the estimated useful life of the asset. Accumulated depreciation at December 31, 2001 and 2000 was approximately \$99,000 and \$41,000, respectively.

Research and Development

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs and costs associated with sponsored research and development and are expensed as incurred.

Patent Costs

Patent costs are expensed due to the uncertainties involved in realizing value in the future from specific patents.

3. Summary of Significant Accounting Policies (continued)

Impairment of Long-Lived Assets

The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. The Company also records the assets to be disposed of at the lower of their carrying amount or fair value less cost to sell. To date, the Company has not experienced any impairment losses on its long-lived assets used in operations. While the Company's current and historical operating and cash flow losses are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets and accordingly, the Company has not recognized any impairment losses at December 31, 2001.

Income Taxes

Income taxes are computed using the asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. In estimating future tax consequences, the Company generally considers all expected future events other than enactment of changes in tax law or rates. If it is "more likely than not" that some portion or all of a federal tax asset will not be realized, a valuation allowance is recorded.

License Fees

Upon execution and continuation of license agreements, license initiation and maintenance fees are evaluated as to whether the underlying licensed compound or drug candidate has alternative uses, and if none, have been recorded as an expense. License milestones criteria are continuously evaluated.

Stock Based Compensation

The Company accounts for stock-based compensation arrangements for employees in accordance with Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" (APB No. 25) and related interpretations, and complies with the disclosure provisions of Statement of Financial Accounting Standards (SFAS No. 123) "Accounting for Stock-Based Compensation" (SFAS No. 123). Under APB No. 25, compensation expense is recognized based on the excess, if any, of the fair value of the Company's stock over the exercise price of the option on the measurement date. Compensation expense is recognized over the respective vesting period. All stock based awards to non-employees are accounted for at their fair value in accordance with SFAS No. 123 and related interpretations.

Use of Estimates

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

Segment Information

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and does not have separately reportable segments as defined by SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information".

3. Summary of Significant Accounting Policies (continued)

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation.

Recent Accounting Pronouncements

In June 1998, The Financial Accounting Standards Board (the "FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 133, "Accounting for Derivative Investments and Hedging Activities." SFAS No. 133 established a new model for accounting for derivatives and hedging activities and supercedes several existing standards. The provisions of SFAS No. 133, as amended by Statements 137 and Statement 138, became effective for all fiscal quarters of fiscal years beginning after June 15, 2000. The adoption of Statement 133 did not have an impact on the Company's financial statements as the Company has not entered into any hedging or derivative activities.

In June 2001, the FASB issued SFAS No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subject to annual impairment tests. Other intangible assets will continue to be amortized for their useful lives. The amortization provisions of SFAS No. 142 apply to goodwill and intangible assets acquired after June 30, 2001. The adoption did not have an impact on our financial condition or our results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supersedes both SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion). SFAS No. 144 retains the fundamental provisions in SFAS No. 121 for recognizing and measuring impairment losses on long-lived assets held for use and long-lived assets to be disposed of by sale, while also resolving significant implementation issues associated with Statement 121. SFAS No. 144 retains the basic provisions of Opinion 30 on how to present discontinued operations in the income statement but broadens that presentation to include a component of an entity (rather than a segment of a business). Unlike SFAS No. 121, an impairment assessment under SFAS No. 144 will never result in a write-down of goodwill. Rather, goodwill is evaluated for impairment under SFAS No. 142, Goodwill and Other Intangible Assets. The Company is required to adopt SFAS No. 144 no later than the year beginning after December 15, 2001, and plans to adopt its provisions during the quarter ending March 31, 2002. Management does not expect the adoption of SFAS No. 144 to have a material impact on the Company's financial statements.

4. Loss per Share

The Company has excluded all outstanding stock options from the calculation of pro forma diluted loss per common share because they are anti-dilutive for all years presented. The pro forma weighted average number of shares outstanding at December 31, 2001 takes into account the stock exchange described in Note 1 and assumes the stock exchange was effective at January 1, 2000, with the shares outstanding at that time. Using the date of the share exchange the weighted average number of shares outstanding is 4,657,212 and 1,338,834 for the years ended December 31, 2001 and 2000, respectively. The loss per common share for basic and diluted is \$1.52 and \$1.28 for the years ended December 31, 2001 and 2000, respectively.

5. Convertible Debt

On June 22, 2001, Pilot entered into an Investment and Royalty Agreement and a Loan Agreement with PharmaBio Development, Inc. ("PharmaBio") and a Commercialization Agreement with Innovex LP ("Innovex"). See Note 10 for discussion of the terms of the Investment and Royalty, Loan and Commercialization Agreements. Innovex and PharmaBio are commonly controlled by Quintiles Transnational Corporation.

5. Convertible Debt (continued)

Under the Loan Agreement Pilot has a \$6,000,000 line of credit (the "Loan"). The Loan is available to Pilot for general working capital purposes with \$4,000,000 outstanding at December 31, 2001. Under the Loan Agreement the final \$2,000,000 would have been available had the Company consummated of a defined equity sale by December 31, 2001, which the Company did not complete. The Loan accrues interest at the greater of 10% or prime plus 2.5%. Interest on the Loan is payable quarterly and the principal will be due in a lump sum payment at the end of the 36-month term. The Loan has a commitment fee in the amount of 1% of each increment outlined above that becomes available to Pilot, which is paid on the first anniversary of the date on which the increment becomes available.

PharmaBio may at any time elect to convert the Loan, including the quarterly interest payments and the commitment fee, into shares of the Company's common stock based on a "conversion price" as defined in the Loan Agreement, of \$1.915 to \$2.50 per share. Additionally, PharmaBio may purchase additional shares of the Company's common stock at the conversion price up to an amount equal to the difference between the total credit availability under the Loan and the amounts outstanding under the Loan. In connection with the Loan the Company has recorded the imputed beneficial conversion at a value of \$1,221,932 as a result of the Company not completing a defined equity sale and finalizing the conversion price at \$1.915.

In 2000, Pilot Therapeutics, Inc. issued convertible demand promissory notes in the aggregate principal amount of \$2,713,875. The promissory notes accrued interest at 8.5%. In conjunction with the issuance of the convertible demand promissory notes warrants to purchase an aggregate of 83,477 shares of common stock at an exercise price of \$3.83. In February 2001, the unpaid principal and accrued interest on the promissory notes were converted into shares of Pilot Therapeutics, Inc. Series B Preferred Stock at a price of \$3.83 per share.

6. Leases

The Company leases certain lab equipment under capital lease obligations. The leases are payable in monthly installments of \$2,946 and have terms up to 4 years at effective interest rates of 16.5%. The leases are collateralized by all the leased property and a certificate of deposit equal to 55% of the value of the leased equipment at inception, or approximately \$50,000 at December 31, 2001. The cost and accumulated depreciation of the items under capital lease were \$103,515 and \$54,857, respectively, at December 31, 2001.

Additionally, the Company leases office space and certain office equipment under operating leases with remaining terms of between 2 and 3 years.

Future minimum payments at December 31, 2001 under non-cancelable operating and capital leases with initial or remaining terms of one year or more are as follows:

| | Operating Leases | Capital Leases | Total |
|------------------------------------|---------------------|-------------------|-------------------|
| 2002 | \$ 42,093 | \$ 35,357 | \$ 77,450 |
| 2003 | 41,448 | 32,530 | 73,978 |
| 2004 | 11,911 | 1,431 | 13,342 |
| Total | 95,452 | 69,318 | 164,770 |
| Less amounts representing Interest | - | (10,388) | (10,388) |
| | <u>\$ 95,452</u> | <u>\$ 58,930</u> | <u>\$ 154,382</u> |

Rent expense under operating leases was approximately \$56,000, \$37,000 and \$120,000 for the years ended December 31, 2001 and 2000 and for the period from August 3, 1998 (inception) to December 31, 2001, respectively.

7. Income Taxes

A benefit for federal and state income taxes has not been recorded as the Company has incurred net operating losses since inception.

A reconciliation of the differences between the statutory federal income tax rate of 34% and the effective tax rate for the years ended December 31, 2001 and 2000 is as follows:

| | 2001 | 2000 |
|------------------------------------|---------|---------|
| Federal statutory rate | (34.0)% | (34.0)% |
| Permanent differences and other | 0.5 | 0.3 |
| State taxes net of federal benefit | 4.9 | 4.9 |
| Change in valuation allowance | 28.6 | 28.8 |
| Total gross deferred tax assets | 0.0% | 0.0% |

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liability are as follows:

| | 2001 | 2000 |
|----------------------------------|--------------|--------------|
| Deferred tax assets: | | |
| Net operating loss carry forward | \$ 2,909,160 | \$ 1,039,696 |
| Deferred compensation | 505,961 | - |
| Patent and Trademark costs | 48,234 | 16,912 |
| Other | 7,992 | 235 |
| Total deferred tax assets | 3,471,347 | 1,056,843 |
| Deferred tax liabilities | (10,661) | (978) |
| Net deferred tax assets | 3,460,686 | 1,055,865 |
| Valuation allowance | (3,460,686) | (1,055,865) |
| Net deferred taxes | \$ - | \$ - |

At December 31, 2001, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$8,152,790, which are available to offset future federal taxable income, if any, in varying amounts from 2018 through 2021. However, the utilization of the net operating losses will be subject to certain limitations as prescribed by Section 382 of the Internal Revenue Code.

8. Stockholders' Equity

On October 2, 2001, the shareholders of the Company approved a proposal to reincorporate under the laws of Delaware by merger into Pilot Therapeutics Holdings, Inc., a Delaware corporation and wholly owned subsidiary of IIRG (the "Reincorporation"). The Reincorporation became effective November 30, 2001.

As a result of the Reincorporation, Pilot Therapeutics, Inc. (a North Carolina corporation) became a wholly owned subsidiary of Pilot Therapeutics Holdings, Inc. However, the Reincorporation did not result in any change in the business, assets or liabilities of the Company, will not cause the corporate headquarters or other facilities to be moved, and will not result in any relocation of management or other employees.

Private Placement of Common Stock

In addition, on January 9, 2002, the Company issued 479,500 shares of common stock to accredited investors in a private placement of securities exempt from registration under Rule 506 under the Securities Act of 1933. These shares were sold at a purchase price of \$4.00 per share, for aggregate gross proceeds of \$1,918,000 and net proceeds of \$1,784,000.

8. Stockholders' Equity (continued)

Redeemable Convertible Preferred Stock

Prior to the transaction with ILRG in August 2001, Pilot Therapeutics, Inc. had authorized 2,566,580 shares of redeemable convertible preferred stock ("Preferred Stock") with a par value of \$0.001. The Preferred Stock was designated as 750,000 shares of Series A and 1,566,580 as Series B with the remaining 250,000 shares undesignated. At December 31, 2000, 750,000 shares of the Series A Preferred Stock was outstanding, which was converted in August 2001 as part of the transaction with ILRG.

In 1998, Pilot Therapeutics, Inc. issued 500,000 shares of Series A Preferred Stock in exchange for net cash proceeds of \$348,348 and conversion of a note payable for \$100,000. In connection with the transaction, warrants to purchase 250,000 shares of common stock were issued. During 1999, 250,000 additional shares of Series A Preferred Stock was issued for net cash proceeds of \$249,101, with warrants for the purchase of 62,500 shares of common stock.

During 2001, Pilot Therapeutics, Inc. received \$751,600 and converted the outstanding convertible promissory notes in the aggregate principal and accrued interest amount of \$2,827,225, into shares of Series B Preferred Stock.

In connection with the Stock Exchange Agreement dated as of August 1, 2001, between Pilot Therapeutics, Inc. and ILRG, all redeemable convertible preferred stock and related common stock warrants of Pilot Therapeutics, Inc. were converted into common stock.

The holders of Preferred Stock had the following rights; 1) the holder is entitled to receive non-cumulative dividends when declared by the Board of Directors with no dividends payable to common shareholders unless an equivalent amount is declared on the Preferred Stock; 2) the holder of Preferred Stock had the right to convert the shares at anytime into shares of common stock one for one, subject to dilution issued as defined in the Amended Articles of Incorporation; 3) in the event of a liquidation the holders shall be entitled to received an amount equal to \$1.00 per share, as adjusted for stock splits or dividends, before payments to common stock holders; 4) after the seventh anniversary of the issue date, the holders of 50% of the outstanding shares voting together as a single group may request the Preferred Stock to be redeemed at the fair market value plus declared but unpaid dividends or the liquidation preference price.

There are no authorized or issued shares of Preferred Stock or common stock warrants outstanding at December 31, 2001.

Stock Option Plans

Pilot adopted a stock option plan in 1998 ("1998 Plan"), which was assumed by the Company on August 24, 2001, upon consummation of the stock exchange described in Note 1. The Company adopted a 2001 Stock Incentive Plan ("2001 Plan") on August 24, 2001. Under the 2001 Plan, options to purchase up to 1,200,000 shares of common stock may be granted to employees, directors, independent contractors, consultants and advisors. Awards may be made to participants in the form of incentive and non-qualified stock options, stock appreciation rights, restricted stock, performance awards and other stock grants or stock-based awards. At December 31, 2001, a total of 1,135,768 shares were available for future stock option grants.

8. Stockholders' Equity (continued)

A summary of the Company's stock option plans at December 31, 2001 and 2000 and changes during the periods then ended is presented in the table below:

| | 2001 | | 2000 | |
|--|------------------|---------------------------------|----------------|---------------------------------|
| | Shares | Weighted-Average Exercise Price | Shares | Weighted-Average Exercise Price |
| Shares under option: | | | | |
| Outstanding, beginning of year | 487,772 | \$ 0.101 | 580,000 | \$ 0.058 |
| Granted | 1,151,220 | \$ 1.949 | 140,000 | \$ 0.150 |
| Exercised | (31,402) | \$ 0.302 | (232,228) | \$ 0.024 |
| Forfeited | (77,738) | \$ 0.361 | - | - |
| Outstanding, end of year | <u>1,529,852</u> | \$ 1.460 | <u>487,772</u> | \$ 0.101 |
| Exercisable, end of year | <u>718,689</u> | \$ 0.465 | <u>212,470</u> | |
| Weighted average fair value of options granted | \$ 3.07 | | \$ 0.07 | |

For various price ranges, weighted average characteristics of outstanding stock options at December 31, 2001 were as follows:

| Range of Exercise Prices | Outstanding Options | | | Exercisable Options | |
|--------------------------|---------------------|---|---------------------------------|---------------------|---------------------------------|
| | Shares | Weighted-Average Remaining Life (years) | Weighted-Average Exercise Price | Shares | Weighted-Average Exercise Price |
| \$0.050 - \$0.150 | 451,772 | 7.76 | \$0.08 | 325,778 | \$0.07 |
| \$0.300 - \$0.425 | 674,800 | 9.29 | 0.37 | 322,360 | 0.36 |
| \$2.500 - \$3.500 | 196,180 | 9.59 | 2.54 | 64,956 | 2.61 |
| \$4.000 - \$6.500 | 94,500 | 9.95 | 4.32 | 5,595 | 4.45 |
| \$7.150 - \$9.900 | 112,600 | 6.21 | 9.23 | - | - |

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its Plans. Stock options issued to non-employees are accounted for in accordance with SFAS 123. Accordingly, the Company records deferred compensation for stock-based compensation grants based on the excess of the fair market value of the common stock on the measurement date over the exercise price. In addition, the Company records the fair value of option issued to non-employee consultants at the fair value per share, as computed using the Black-Scholes option-pricing model and variable plan accounting. Deferred compensation amounts are amortized over the vesting periods of each option.

During the year ended December 31, 2001, the Company recorded aggregate deferred compensation of \$3,030,608 related to the issuance of stock options, with related amortization of \$1,417,934 during 2001.

8. Stockholders' Equity (continued)

Had compensation cost to employees been determined based on the fair value at the grant dates for awards in 2001 and 2000 consistent with the provisions of SFAS No. 123, the Company's net loss would have been the pro forma amounts indicated below:

| | | |
|---|-----------------------|-----------------------|
| Net loss available for common stockholders | | |
| As reported | \$ (7,090,995) | \$ (1,719,056) |
| Pro forma | <u>\$ (7,594,917)</u> | <u>\$ (1,724,383)</u> |
| Pro forma basic and diluted loss per common share | | |
| As reported | \$ (0.73) | \$ (0.19) |
| Pro forma | <u>\$ (0.78)</u> | <u>\$ (0.19)</u> |
| Pro forma weighted average shares outstanding | 9,725,287 | 9,244,248 |

The fair value of options granted during the years ending 2001 and 2000 was estimated on the applicable grant dates using the Black-Scholes option pricing model. Significant weighted average assumptions used to estimate fair value for all years include: risk-free interest rates ranging from 3 percent to 4 percent; expected lives of ten years; no expected dividends; and a volatility factor of 61%.

In addition, the Company has options outstanding to an investment banking entity for the purchase of 10,000 shares of common stock at a price of one dollar. The options if not exercised, shall expire in March 2005.

9. License and Research Agreements

Wake Forest University

In December 1998, Pilot entered into a license agreement with Wake Forest University ("Wake Forest") whereby it licensed certain patented or patent pending inventions from Wake Forest in exchange for common stock. Pilot is required to pay Wake Forest license fees and milestone payments based upon the achievement of certain product development events related to licensed products, as defined in the agreement. In addition, Pilot is obligated to pay royalties, ranging from 3% to 5%, to Wake Forest based on net sales of products related to the licenses obtained, with a minimum royalty of \$30,000 beginning in the year ended December 31, 2001. Pilot has the option to issue warrants to Wake Forest, in an amount determined by the terms of the agreement, to purchase common stock with an exercise price of \$1.00 per share in lieu of the cash payment of the minimum royalty up until net sales of licensed products exceed \$5 million in a calendar year.

Pilot also entered into a research agreement with Wake Forest whereby Wake Forest will perform sponsored research. Beginning in July 1999, the agreement requires Pilot to request that Wake Forest perform sufficient research that Pilot shall pay Wake Forest a minimum of \$50,000 per year through the year ending December 31, 2002.

In connection with a research agreement with Wake Forest, Pilot entered into a sponsored research sub-agreement in March 2001. The term of this sub-agreement is from March 2001 to October 2001, with a final report due in 2002. In exchange for research assistance, Pilot will pay fees to Wake Forest in the aggregate of \$170,356 over the specified term of the agreement. Certain research milestones, the initiation of the project and the presentation of the final report trigger cash payments to be made by Pilot. The Company has expensed \$148,363 of the aggregate cost of the research project for the year ending December 31, 2001.

Johns Hopkins University

In April 1999, Pilot entered into an exclusive license agreement with Johns Hopkins University ("Johns Hopkins") for the rights to certain patented or patent pending inventions. The license agreement provides for Pilot to reimburse Johns Hopkins for the costs of maintaining the patent rights, pay a processing fee of \$5,000, and pay an annual maintenance fee beginning in 2001 of \$2,500.

9. License and Research Agreements (continued)

Pilot is required to pay royalties of 1.5% of net sales, with minimum payments until cumulative net sales reach a certain level. There are also milestone payments based upon the achievement of certain product development events, as defined in the agreement. In the event the license is sold there are payments due on the amount of the sale, ranging from 5% to 10%, as well as 5% of any additional amounts that may be received from any sublicense. The license agreement terminates concurrently with the expiration of the patents.

Bristol-Myers Squibb

On October 3, 2001, Pilot and Bristol-Myers Squibb ("BMS") signed an agreement granting Pilot a worldwide exclusive license to develop and market a BMS patented class of oral retinoids. Pilot will pay license fees and royalties based upon certain milestones and net sales of products containing the patented compound, respectively.

10. Quintiles Transnational Corporation Agreements

On June 22, 2001, Pilot entered into an Investment and Royalty Agreement and a Loan Agreement with PharmaBio Development, Inc. ("PharmaBio") and a Commercialization Agreement with Innovex LP ("Innovex"). Innovex and PharmaBio are commonly controlled by Quintiles Transnational Corporation.

Under the Commercialization Agreement, Innovex will provide sales force services and certain marketing services on a fee-for-service basis to Pilot in connection with the development and promotion of certain proprietary technology specified in the Commercialization Agreement. Innovex will supply a sales force beginning on the date the sales force is launched, and continuing for five years. The Commercialization Agreement is non-cancelable by Pilot or Innovex during the five-year term, except for a material breach by or bankruptcy of either party, termination of the Investment and Royalty Agreement or if commercialization of the proprietary technology is no longer being pursued.

Under the Investment and Royalty agreement, PharmaBio will fund 50% of the estimated \$55,000,000 total commercialization cost under the Innovex Commercialization Agreement, during the five-year term following launch, provided that, without the approval of PharmaBio, such obligation will not exceed (i) \$6,000,000 for any single year, or (ii) \$30,000,000 in the aggregate. The funding will be structured so that 10% of the total estimated commitment amount will be paid upon launch of the Innovex sales force and the remaining amount will be paid in equal quarterly payments during the five-year term. Further, in exchange for PharmaBio's funding commitments, Pilot shall pay PharmaBio royalties on sales of a specified product covered by the Commercialization Agreement with such rates subject to adjustment as set forth in the Investment and Royalty Agreement to provide PharmaBio a minimum rate of return.

11 Purchase Commitments

In connection with the manufacturing of the Company's first product the Company has purchase commitments from suppliers of approximately \$3,200,000. These commitments are for the purchases of raw materials over the next 24 months.

12 Supplemental Cash Flow Informatio

| | Year ended December 31 | | Cummulative from August 3, 1998 (inception) to December 31, 2001 |
|---|------------------------|------|--|
| | 2001 | 2000 | |
| Furniture and equipment obtained with capital leases | \$ - | \$ - | \$ 103,515 |
| Exchange of demand promissory note principle and interest for convertible demand promissory note | \$ - | \$ - | \$ 263,875 |
| Exchange of convertible demand promissory notes for Series B redeemable convertible demand promissory note | \$ 2,713,875 | \$ - | \$ 2,713,875 |
| Accrued interest on convertible demand promissory notes exchanged for Series B redeemable convertible preferred stock | \$ 113,350 | \$ - | \$ 113,350 |
| Costs associated with issuance of Series B redeemable convertible preferred stock | \$ 13,754 | \$ - | \$ 13,754 |

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable

PART III

Item 9. Executive Officers, Promoters and Control Persons, Compliance with Section 16(a) of the Exchange Act.

The required information with respect to the identification of directors and executive officers is contained herein under Item 1 – Business under the caption “Directors and Executive Officers”.

Section 16(a) of the Exchange Act requires the Company's directors, officers and persons beneficially owning more than 10% of the Company's outstanding Common Stock to file periodic reports of stock ownership and stock transactions with the Commission. Based solely on a review of copies of these reports furnished to the Company, the Company believes all of these reports were filled in a timely manner except that David Mills failed to timely file a Form 3 upon becoming an officer of the Company in December 2001.

Item 10. Executive Compensation

The following table sets forth certain information regarding compensation paid by the Company for the fiscal year ended December 31, 2001 to the Company's Chief Executive Officer (the "Named Officer").

Summary Compensation Table

| Name and Principal Position | Annual Compensation | | | Other Annual Compensation (\$) | Long-Term Compensation Awards | All Other Compensation (\$) |
|--|---------------------|-------------|------------|--------------------------------|-------------------------------|-----------------------------|
| | Year (1) | Salary (\$) | Bonus (\$) | | Shares Underlying Options (#) | |
| Floyd H. Chilton, III President, Chief Executive Officer and Chief Scientific Officer | 2001 | \$180,000 | \$ - | \$ - | 118,000 | \$ 570 (2) |

(1) Prior to 2001, the Company was not a reporting company pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended.

(2) Consists of life insurance premiums paid by the Company.

Option Grants

The following table sets forth information regarding grants of stock options to the Named Officer pursuant to the Company's stock incentive plans during fiscal 2001.

Option Grants in Last Fiscal Year

| Name | Number of Securities Underlying Options Granted(#) | % of Total Options Granted to Employees in Fiscal Year | Exercise Price Per Share(\$/Sh) | Expiration Date |
|------------------|--|---|------------------------------------|-----------------|
| | | | | |
| Floyd H. Chilton | 30,000(1) | 2.6% | \$0.425 | 04/09/11 |
| | 3,000(2) | 0.3% | \$2.75 | 08/18/06 |
| | 85,000(3) | 7.4% | \$9.90 | 12/27/06 |

- (1) This nonqualified option has a term of 10 years and vests in thirty six equal monthly installments beginning May 10, 2001.
- (2) This incentive option has a term of five years and vests in nine equal quarterly installments beginning August 9, 2001.
- (3) This incentive option has a term of five years. The option to purchase 14,170 shares vests on June 28, 2002, and the remainder of the option vests in 10 equal quarterly installments beginning on September 28, 2002.

The following table sets forth information with respect to (i) shares acquired upon exercise by the Named Officer in 2001 and (ii) unexercised stock options granted under the Company's stock incentive plans as of the end of fiscal 2001.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Values

| Name | Shares Acquired on Exercise(#) | Value Realized\$(1) | Number of Securities Underlying Unexercised Options Held at December 31, 2001(#) | | Value of Unexercised In-the- Money Options at December 31, 2001\$(2) | |
|--------------------------|-----------------------------------|------------------------|--|---------------|--|---------------|
| | | | Exercisable | Unexercisable | Exercisable | Unexercisable |
| Floyd H. Chilton, III | None | \$0.00 | 7,336 | 110,664 | \$63,187 | \$221,063 |

- (1) Calculated by determining the difference between the market value per share on the date of exercise and the exercise price for the respective options.
- (2) Calculated by determining the difference between the market value of \$9.25 per share for the Common Stock underlying the options at December 31, 2001 and the exercise prices of the Named Officer's options.

DIRECTOR COMPENSATION

The Company's Bylaws provide that the Board of Directors may by resolution from time to time fix the compensation of directors. In March 2001, Messrs. Costa, Johnston and Udem each received a nonqualified option to purchase 30,000 shares of Common Stock at a per share exercise price equal to the fair market value on the date of grant as determined by the Board of Directors. Ms. Urquhart received the same option in May 2001. All of such options vest quarterly over 36 months. In August 2001, each director also received a nonqualified option to purchase 6,000 shares at a per share exercise price equal to the fair market value on the date of grant as determined by the Board of Directors. These options vest monthly over 24 months. In addition, each director who is not also an employee of the Company is entitled to reimbursement from the Company for his or her reasonable expenses incurred in attending meetings of the Board of Directors.

Item 11. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding beneficial ownership of the Company's Common Stock as of March 31, 2002 by (i) each person known by the Company to own beneficially more than 5% of the Common Stock, (ii) each director of the Company, (iii) each director nominee, (iv) the Named Officer and (v) all executive officers and directors as a group.

| <u>Name and Address</u> | <u>Common Stock</u> | |
|--|--|-------------------------|
| | <u>Amount and Nature of Beneficial Ownership (1)</u> | <u>Percent of Class</u> |
| Centennial Venture Partners, LLC 920 Main Campus Drive, Suite 400 Raleigh, NC 27606 | 1,554,346 | 14.7% |
| Wake Forest University Wake Forest School of Medicine Medical Center Boulevard Winston-Salem, NC 27517 | 1,125,000 | 10.7% |
| Academy Venture Fund, LLC 11540 North Community House Road, Suite 150 Charlotte, NC 28227 | 916,748 | 8.7% |
| Quintiles Transnational Corp. 4709 Creekstone Drive, Suite 200 Durham, NC 27703 | 2,088,773 (2) | 16.5% |
| Dr. Floyd H. Chilton, III c/o Pilot Therapeutics Holdings, Inc. 101 North Chestnut Street Winston-Salem, NC 27101 | 1,963,004 (3) | 18.6% |
| Glenn J. Kline c/o Centennial Venture Partners, LLC 920 Main Campus Drive, Suite 400 Raleigh, NC 27606 | 2,471,094 (4) | 23.4% |
| James W. Johnston c/o Stonemarker Enterprises, Inc. 380 Knollwood Street, Suite 570 Winston-Salem, NC 27103 | 105,220 (5) | 1.0% |
| Santo J. Costa 108 Martinique Place Cary, NC 27511 | 40,064 (6) | [*] |
| Bradley J. Udem c/o Johns Hopkins University School of Medicine Bayview Medical Center Department of Medicine JHAAC 3A.44 3400 North Charles Street Baltimore, MD 21218 | 46,260 (7) | [*] |
| Margaret Urquhart c/o Pilot Therapeutics Holdings, Inc. 101 North Chestnut Street Winston-Salem, NC 27101 | 23,782 (8) | [*] |
| All directors and executive officers as a group (10 persons) | 4,855,975 (9) | 44.5% |

* Less than 1%.

- (1) Beneficial ownership is determined in accordance with the rules of the Commission and is based upon filings made by such persons with the Commission and upon information provided to the Company. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of Common Stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of the record date are deemed outstanding. These shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. Except as indicated in the footnotes to this table and as provided pursuant to applicable community property laws, the stockholders named in the table have sole voting and investment power with respect to the shares set forth opposite each stockholder's name.
- (2) Based on a Schedule 13G filed jointly by Quintiles Transnational Corp. ("Quintiles") and PharmaBio Development Inc. ("PharmaBio") on December 21, 2001. Pursuant to an Agreement between PharmaBio, a subsidiary of Quintiles; and Pilot Therapeutics, Inc. ("PTI"), a subsidiary of Pilot, PharmaBio has made loans to PTI in the aggregate amount of \$4,000,000. Such amount is convertible by PharmaBio into Pilot's Common Stock based on the "conversion price" as defined in such agreement, which is subject to adjustment in accordance with such agreement. Based on an assumed conversion price of \$1.915 per share and the current outstanding loan amount of \$4,000,000, PharmaBio has the right to acquire 2,088,773 shares of Pilot's Common Stock. See "Certain Transactions," below.
- (3) Includes 1,527,500 shares that Dr. Chilton owns directly, 422,500 shares that Dr. Chilton may be deemed to indirectly beneficially own as a result of family holdings and 13,004 shares that Dr. Chilton has the right to acquire within 60 days pursuant to the exercise of certain options.
- (4) The reporting person is the Senior Managing Director of Centennial Venture Partners, LLC and Academy Venture Fund, LLC which own the reported securities. The reporting person disclaims beneficial ownership of the reported securities except to the extent of his pecuniary interest therein.
- (5) Includes 67,292 shares that Mr. Johnston owns directly and 37,928 shares that may be acquired pursuant to options exercisable within 60 days.
- (6) Represents shares that may be acquired pursuant to options exercisable within 60 days.
- (7) Represents shares that may be acquired pursuant to options exercisable within 60 days.
- (8) Includes 12,500 shares that Ms. Urquhart owns directly and 11,282 shares that may be acquired pursuant to options exercisable within 60 days.
- (9) Includes an aggregate of 206,551 shares that may be acquired pursuant to options exercisable within 60 days and that are held by executive officers of the Company who are not also directors.

Item 12. Certain Relationships and Related Transactions

Transactions with Wake Forest University

In December 1998, Pilot entered into a license agreement with Wake Forest University ("Wake Forest") whereby it licensed certain patented or patent pending inventions from Wake Forest in exchange for common stock. Pilot is required to pay Wake Forest license fees and milestone payments based upon the achievement of certain product development events related to licensed products, as defined in the agreement. In addition, Pilot is obligated to pay royalties, ranging from 3% to 5%, to Wake Forest based on net sales of products related to the licenses obtained, with a minimum royalty of \$30,000 beginning in the year ended December 31, 2001. Pilot has the option to issue warrants to Wake Forest, in an amount determined by the terms of the agreement, to purchase common stock with an exercise price of \$1.00 per share in lieu of the cash payment of the minimum royalty up until net sales of licensed products exceed \$5 million in a calendar year.

Pilot also entered into a research agreement with Wake Forest whereby Wake Forest will perform sponsored research. Beginning in July 1999, the agreement requires Pilot to pay Wake Forest a minimum of \$50,000 per year for research through the year ending December 31, 2002.

In connection with a research agreement with Wake Forest, Pilot entered into a sponsored research sub-agreement in March 2001. The term of this sub-agreement was extended from March 2001 to October 2001, with a final report due no later than November 7, 2001. In exchange for research assistance, Pilot is to pay fees to Wake Forest in the aggregate of \$170,356 over the specified term of the agreement. Certain research milestones, the initiation of the project and the presentation of the final report trigger the cash payments to be made by Pilot. During 2001, the Company paid an aggregate of 43,000 to Wake Forest under the terms of the research sub-agreement.

Transactions with Affiliates of Quintiles Transnational Corporation

On June 22, 2001, Pilot entered into an Investment and Royalty Agreement and Loan Agreement with PharmaBio Development, Inc. ("PharmaBio") and a Commercialization Agreement with Innovex LP ("Innovex"). Innovex and PharmaBio are commonly controlled by Quintiles Transnational Corporation ("Quintiles"), which is the beneficial owner of approximately 16.5% of the Company's common stock. Santo J. Costa, a Director of the Company, is the former President and Vice Chairman of Quintiles, and is currently a consultant to Quintiles.

Under the Commercialization Agreement, Innovex will provide sales force services and certain marketing services on a fee-for-service basis to Pilot in connection with the development and promotion of certain proprietary technology specified in the Commercialization Agreement. Innovex will supply a sales force beginning on the date the sales force is launched, and continuing for five years. The Commercialization Agreement is non-cancelable by Pilot or Innovex during the five-year term, except for a material breach by or bankruptcy of either party, termination of the Investment and Royalty Agreement or if commercialization of the proprietary technology is no longer being pursued.

Under the Investment and Royalty agreement, PharmaBio will fund 50% of the estimated \$55,000,000 total commercialization cost under the Innovex Commercialization Agreement, during the five-year term following launch, provided that, without the approval of PharmaBio, such obligation will not exceed (i) \$6,000,000 for any single year, or (ii) \$30,000,000 in the aggregate. The funding will be structured so that 10% of the total estimated commitment amount will be paid upon launch of the Innovex sales force and the remaining amount will be paid in equal quarterly payments during the five-year term. Further, in exchange for PharmaBio's funding commitments, Pilot shall pay PharmaBio royalties on sales of a specified product covered by the Commercialization Agreement with such rates subject to adjustment as set forth in the Investment and Royalty Agreement to provide PharmaBio a minimum rate of return.

Under the Loan Agreement, Pilot has a \$6,000,000 line of credit (the "Loan"). The Loan is available to Pilot for general working capital purposes with \$4,000,000 outstanding at December 31, 2001. Under the Loan Agreement, the final \$2,000,000 would have been available had the Company consummated a defined equity sale by December 31, 2001, which the Company did not complete. Since a defined equity sale was not consummated by December 31, 2001, the final \$2,000,000 will not become available. The Loan accrues interest at the greater of 10% or prime plus 2.5%. Interest on the Loan is payable quarterly, and the principal will be due in a lump sum payment

at the end of the 36-month term. The Loan has a commitment fee in the amount of 1% of each increment outlined above that becomes available to Pilot, which is paid on the first anniversary of the date on which the increment becomes available.

PharmaBio may at any time elect to convert the Loan, including the quarterly interest payments and the commitment fee, into shares of the Company's Common Stock based on a "conversion price" as defined in the Loan Agreement, which ranges from \$1.915 to \$2.50 per share. Additionally, on or before the maturity date, PharmaBio may purchase additional shares of the Company's Common Stock at the conversion price up to an amount equal to the difference between the total credit availability under the Loan and the amounts outstanding under the Loan.

Financing Transactions with Centennial Venture Fund, LLC and Academy Venture Fund, LLC

On December 11, 1998, Centennial Venture Fund, LLC, a limited liability company managed by an entity of which Glenn J. Kline, Chairman of the Company's Board of Directors, is Managing Partner ("Centennial"), purchased 500,000 shares of Pilot's Series A Preferred Stock for an aggregate purchase price of \$500,000 in Pilot. In connection with the purchase, Pilot issued to Centennial a warrant to purchase 250,000 shares of its Common Stock. On November 1, 1999, Centennial made a bridge loan to Pilot in the amount of \$250,000, in exchange for a convertible promissory note. Effective June 6, 2000, in accordance with the terms of the convertible note, the accrued interest was capitalized and such note was exchanged for a new convertible promissory note in the amount of \$263,875 and a warrant to purchase 65,969 shares of Pilot's Common Stock.

On February 21, 2000, Academy Venture Fund, LLC, a limited liability company managed by an entity of which Mr. Kline is Managing Partner ("Academy"), acquired 100,000 shares of Pilot's Series A Preferred Stock, as well as the related warrant to purchase 25,000 shares of Pilot's Common Stock, from the original purchaser for an aggregate purchase price of \$100,000. On March 6, 2000, Academy made a bridge loan to Pilot in the amount of \$250,000 in exchange for a convertible promissory note and a warrant to purchase 62,500 shares of Pilot's Common Stock. On November 27, 2000, Academy made an additional bridge loan to Pilot in the amount of \$500,000 in exchange for a convertible promissory note.

On February 28, 2001, Academy purchased 130,548 shares of Pilot's Series B Preferred Stock for an aggregate purchase price of \$500,000. In addition, on February 28, 2001, Centennial's convertible promissory note in the original principal amount of \$263,875 was converted into 73,143 shares of Pilot's Series B Preferred Stock, and Academy's convertible promissory notes in the original principal amounts of \$250,000 and \$500,000 were converted into an aggregate of 204,007 shares of Pilot's Series B Preferred Stock.

On August 24, 2001, all of Pilot's Series A and Series B Common Stock converted into shares of Pilot's Common Stock, and each share of Pilot's Common Stock was exchanged for two shares of Common Stock of ILRG in the recapitalization transaction described herein in Item 1-Business in the section captioned "Corporate History" (the "Recapitalization"). Subsequent to the Recapitalization, effective November 30, 2001, ILRG reincorporated in Delaware in a transaction in which ILRG merged with and into the Company, and each share of ILRG's Common Stock was converted into one share of the Company's Common Stock.

On April 4, 2002, Academy purchased 25,000 shares of the Company's Common Stock in a private transaction for an aggregate purchase price of \$100,000. In addition, Academy has proposed to invest an additional \$475,000 in the Company as part of the additional financing the Company is currently seeking.

Additional Director and Officer Financing Transactions

On April 28, 2000, James W. Johnston, a Director of the Company, made a bridge loan to Pilot in the amount of \$100,000, in exchange for a convertible promissory note and a warrant for 25,000 shares of Pilot's Common Stock. On February 28, 2001, this promissory note was converted into 27,953 shares of Pilot's Series B Preferred Stock, which shares were later converted into shares of Common Stock of ILRG in the Recapitalization.

On April 28, 2000, Sara Brooks Strassle, then the Chief Executive Officer and a Director of Pilot, made a bridge loan to Pilot in the amount of \$50,000, in exchange for a convertible promissory note and a warrant for 12,500 shares of Pilot's Common Stock. On February 28, 2001, this promissory note was converted into 13,977 shares of Pilot's Series B Preferred Stock, which shares were later converted into shares of Common Stock of ILRG in the Recapitalization.

On November 27, 2000, Russell Armistead, then the interim Chief Financial Officer and a Director of Pilot, made a bridge loan to the Company in the amount of \$25,000, in exchange for a convertible promissory note. On February 28, 2001, this promissory note was converted into 6,666 shares of Pilot's Series B Preferred Stock, which shares were later converted into shares of Common Stock of ILRG in the Recapitalization.

In addition, on January 9, 2002, the Company issued 479,500 shares of common stock to accredited investors in a private placement of securities exempt from registration under Rule 506 under the Securities Act of 1933. These shares were sold at a purchase price of \$4.00 per share, for aggregate gross proceeds of \$1,918,000. Margaret Urquhart, a Director of the Company, purchased 12,500 shares of the Company's Common Stock in the private placement for an aggregate purchase price of \$50,000.

PART IV

Item 13. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) Exhibits. The following documents are filed as part of this report:

(1) Consolidated Financial Statements of the Company are included in Part II, Item 7:

Reports of Independent Accountants
Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statements of Changes in Stockholders' Equity
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

(2) Exhibits

See the Exhibit Index following the Signature Page, which is incorporated herein by reference.

(b) Reports on Form 8-K

The Company filed the following reports on Form 8-K during the fourth quarter of the year ended December 31, 2001.

1. A Current Report on Form 8-K/A, filed on October 3, 2001, to report change in registrant's certifying accountants.
2. A Current Report on Form 8-K/A, filed on December 14, 2001, to report, pursuant to Item 5, registrant's reincorporation in Delaware.
3. A Current Report on Form 8-K/A, filed on December 21, 2001, to report, pursuant to Item 5, amendment of Loan Agreement with PharmaBio Development, Inc.

SIGNATURES

Pursuant to the requirement of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PILOT THERAPEUTICS HOLDINGS, INC.

By: /s/ Floyd H. Chilton III
President and Chief Executive Officer

Date: April 15, 2002

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

| Signature | Title | Date |
|---|---|----------------|
| <u>/s/ Glenn Kline</u> Glenn Kline | Chairman of the Board of Directors | April 15, 2002 |
| <u>/s/ Floyd H. Chilton III</u> Floyd H. Chilton III | President, Chief Executive Officer, Chief Scientific Officer and Director (Principal Executive Officer) | April 15, 2002 |
| <u>/s/ David J. Mills</u> David J. Mills | Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer) | April 15, 2002 |
| <u>/s/ Santo J. Costa</u> Santo J. Costa | Director | April 15, 2002 |
| <u>/s/ James W. Johnston</u> James W. Johnston | Director | April 15, 2002 |
| <u>/s/ Bradley J. Udem</u> Bradley J. Udem | Director | April 15, 2002 |
| <u>/s/ Margaret M. Urquhart</u> Margaret M. Urquhart | Director | April 15, 2002 |

EXHIBITS

| Exhibit No. | Description of Exhibit |
|-------------|---|
| 2.1 | Stock Exchange Agreement dated August 1, 2001 among Interallied Group, Inc. and the shareholders of Pilot Therapeutics, Inc., incorporated by reference to Exhibit 2.1 to the Company's Form 8-K filed August 28, 2001. |
| 2.2 | Agreement and Plan of Merger dated October 10, 2001 by and between ILRG and Pilot Therapeutics Holdings, Inc. incorporated by reference to Exhibit 99.1 to the Company's Form 8-K filed December 14, 2001. |
| 4.1 | Promissory Note of Pilot Therapeutics, Inc. dated June 22, 2001 payable to PharmaBio Development, Inc., incorporated by reference to Exhibit 4.1 to the Company's Form 10-QSB filed November 14, 2001. |
| 4.2 | Loan Agreement dated June 22, 2001 by and between Pilot Therapeutics, Inc. and PharmaBio Development, Inc., incorporated by reference to Exhibit 4.2 to the Company's Form 10-QSB filed November 14, 2001. |
| 4.3 | Security Agreement dated June 22, 2001 by and between Pilot Therapeutics, Inc. and PharmaBio Development, Inc., incorporated by reference to Exhibit 4.3 to the Company's Form 10-QSB filed November 14, 2001. |
| 4.4 | Amendment to Loan Agreement dated December 21, 2001 by and between Pilot Therapeutics, Inc. and PharmaBio Development, Inc., incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed December 21, 2001. |
| 10.1 | Interallied Group, Inc. Stock Option Plan, incorporated by reference to Exhibit 10.1 to the Company's Form 10-QSB filed November 14, 2001. |
| 10.2 | Interallied Group, Inc. 2001 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 to the Company's Form 10-QSB filed November 14, 2001. |
| 10.3 | License Agreement dated December 11, 1998 by and between Pilot Therapeutics, Inc. (formerly known as Pilot Biotechnologies, Inc.) and Wake Forest University, incorporated by reference to Exhibit 10.3 to the Company's Form 10-QSB filed November 14, 2001. |
| 10.4 | Research Agreement dated December 11, 1998 by and between Pilot Therapeutics, Inc. (formerly known as Pilot Biotechnologies, Inc.) and Wake Forest University School of Medicine, incorporated by reference to Exhibit 10.4 to the Company's Form 10-QSB filed November 14, 2001. |

- 10.5 Investment and Royalty Agreement dated June 22, 2001 by and between Pilot Therapeutics, Inc. and PharmaBio Development, Inc., incorporated by reference to Exhibit 10.5 to the Company's Form 10-QSB filed November 14, 2001.
- 10.6 Commercialization Agreement dated June 22, 2001 by and between Pilot Therapeutics, Inc. and Innovex LP, incorporated by reference to Exhibit 10.5 to the Company's Form 10-QSB filed November 14, 2001.
- 10.7 License Agreement dated October 3, 2001 by and between Pilot Therapeutics, Inc. Bristol-Myers Squibb Company, incorporated by reference to Exhibit 10.6 to the Company's Form 10-QSB filed November 14, 2001.
- 10.8 Letter agreement dated June 2, 1999 between the Company and Beth Fordham-Meier (filed herewith).
- 21 Subsidiaries of the Registrant
- 23 Consent of Ernst & Young LLP

Exhibit 21

Subsidiaries

Pilot Therapeutics, Inc. (North Carolina corporation)

Pilot Pharmaceuticals Corporation (North Carolina corporation wholly-owned by Pilot Therapeutics, Inc.)

Pilot Nutraceuticals Corporation (North Carolina corporation wholly-owned by Pilot Therapeutics, Inc.)

Exhibit 23

Consent of Independent Accountants

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-76478) pertaining to the Stock Option Plan of Pilot Therapeutics Holdings, Inc. of our report dated February 22, 2002, with respect to the consolidated financial statements of Pilot Therapeutics Holdings, Inc. included in this Annual Report (Form 10-KSB) for the year ended December 31, 2001.

/s/ERNST & YOUNG LLP

Greensboro, North Carolina
April 11, 2002

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